BS EN ISO 13606-1:2012

BSI Standards Publication

Health informatics — Electronic health record communication

Part 1: Reference model (ISO 13606-1:2008)

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National foreword

This British Standard is the UK implementation of EN ISO 13606-1:2012. It is identical to ISO 13606-1:2008. It supersedes BS EN 13606-1:2007, which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee IST/35, Health informatics.

A list of organizations represented on this committee can be obtained on request to its secretary.

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Medizinische Informatik - Kommunikation von Patientendaten in elektronischer Form - Teil 1: Referenzmodell (ISO 13606-1:2008)

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Foreword

The text of ISO 13606-1:2008 has been prepared by Technical Committee ISO/TC 215 “Health informatics” of the International Organization for Standardization (ISO) and has been taken over as EN ISO 13606-1:2012 by Technical Committee CEN/TC 251 “Health informatics” the secretariat of which is held by NEN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by April 2013, and conflicting national standards shall be withdrawn at the latest by April 2013.

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

This document supersedes EN 13606-1:2007.

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

Endorsement notice

The text of ISO 13606-1:2008 has been approved by CEN as a EN ISO 13606-1:2012 without any modification.

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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ISO 13606-1 was prepared by Technical Committee ISO/TC 215, *Health informatics*.

ISO 13606 consists of the following parts, under the general title *Health informatics — Electronic health record communication*:

— *Part 1: Reference model*

— *Part 2: Archetype interchange specification*

— *Part 3: Reference archetypes and term lists*

— *Part 5: Interface specification*

0 Introduction

0.1 Preface

The overall goal of ISO 13606 is to define a rigorous and stable information architecture for communicating part or all of the Electronic Health Record (EHR) of a single subject of care (patient). This is to support the interoperability of systems and components that need to communicate (access, transfer, add or modify) EHR data via electronic messages or as distributed objects:

— preserving the original clinical meaning intended by the author;

— reflecting the confidentiality of that data as intended by the author and patient.

ISO 13606 is not intended to specify the internal architecture or database design of EHR systems or components. Nor is it intended to prescribe the kinds of clinical application that might require or contribute EHR data in particular settings, domains or specialities. For this reason, the information model proposed here is called the EHR Extract, and might be used to define a message, an XML document or schema, or an object interface. The information model in this part of ISO 13606 is an ISO Reference Model for Open Distributed Processing (RM-ODP) RM-ODP Information Viewpoint of the EHR Extract.

ISO 13606 considers the EHR to be the persistent longitudinal and potentially multi-enterprise or multi-national record of health and care provision relating to a single subject of care (the patient), created and stored in one or more physical systems in order to inform the subject's future healthcare and to provide a medico-legal record of care that has been provided. Whilst an EHR service or system will need to interact with many other services or systems providing terminology, medical knowledge, guidelines, workflow, security, persons registries, billing etc., ISO 13606 has only touched on those areas if some persistent trace of such interactions is required in the EHR itself, and requires specific features in the reference model to allow their communication.

ISO 13606 may offer a practical and useful contribution to the design of EHR systems but will primarily be realised as a common set of external interfaces or messages built on otherwise heterogeneous clinical systems.

This part of ISO 13606 is the first part to be published of a five-part series. In this part of ISO 13606 dependency upon one of the other parts of this series is explicitly stated where it applies.

0.2 Technical approach

ISO 13606 has drawn on the practical experience that has been gained in implementing a European precursor prestandard, ENV 13606, other EHR-related standards and specifications, commercial systems and demonstrator pilots in the communication of whole or part of patients' EHRs, and on fifteen years of research findings in the field. ISO 13606 builds on ENV 13606, in order to provide a more rigorous and complete specification, to accommodate new requirements identified, to incorporate a robust means of applying the generic models to individual clinical domains, and to enable communication using HL7 version 3 messages. A mapping from the European prestandard is also provided to support implementers of systems that conformed to it. The technical approach to producing ISO 13606 has taken into account several contemporary areas of requirement.

a) In addition to a traditional message-based communication between isolated clinical systems, the Electronic Health Record will in some cases be implemented as a middleware component (a record server) using distributed object technology and/or web services.

b) "Customers" of such record services will be not only other electronic health record systems but also other middleware services such as security components, workflow systems, alerting and decision support services and other medical knowledge agents.

c) There is wide international interest in this work, and this part of ISO 13606 has been drafted jointly through CEN and ISO with significant input from many member countries.

d) Mapping to HL7 version 3 has been considered an important goal, to enable conformance to this part of ISO 13606 within an HL7 version 3 environment.

e) The research and development (R & D) inputs on which ENV 13606 was based have moved forward since 1999 and important new contributions to the field have been taken into account. The *open* EHR foundation, integrating threads of R & D in Europe and Australia, is one such example.

Given the diversity of deployed EHR systems, ISO 13606 has made most features of EHR communication optional rather than mandatory. However, some degree of prescription is required to make EHR Extracts safely processable by an EHR recipient system, which is reflected through mandatory properties within the models in Parts 1, 2, and 4, and through normative term lists (defined in Part 3).

ISO 13606 will, in practice, usually be adopted alongside other health informatics standards that define particular aspects of health data representation. Annex B explains how ISO 13606 can be used alongside key complementary standards, including the HL7 Version 3 Reference Information Model (RIM), EN 14822-1, EN 14822-2, EN 14822-3, CEN/TS 14822-4 (GPIC), prEN 12967 (HISA) and prEN13940 (CONTSYS).

0.3 The Dual Model approach

The challenge for EHR interoperability is to devise a generalized approach to representing every conceivable kind of health record data structure *in a consistent way*. This needs to cater for records arising from any profession, speciality or service, whilst recognising that the clinical data sets, value sets, templates, etc. required by different healthcare domains will be diverse, complex and will change frequently as clinical practice and medical knowledge advance. This requirement is part of the widely acknowledged health informatics challenge of *semantic interoperability*.

The approach adopted by ISO 13606 distinguishes a reference model, defined in this part of ISO 13606 and used to represent the generic properties of health record information, and archetypes (conforming to an archetype model, defined in Part 2), which are meta-data used to define patterns for the specific characteristics of the clinical data that represent the requirements of each particular profession, speciality or service.

The Reference Model represents the global characteristics of health record components, how they are aggregated, and the context information required to meet ethical, legal and provenance requirements. This model defines the set of classes that form the generic building blocks of the EHR. It reflects the stable characteristics of an electronic health record, and would be embedded in a distributed (federated) EHR environment as specific messages or interfaces (as specified in Part 5).

This generic information model needs to be complemented by a formal method of communicating and sharing the organizational structure of predefined classes of EHR fragment corresponding to sets of record components made in particular clinical situations. These are effectively precoordinated combinations of named RECORD_COMPONENT hierarchies that are agreed within a community in order to ensure interoperability, data consistency and data quality.

An Archetype is the formal definition of prescribed combinations of the building-block classes defined in the Reference Model for particular clinical domains or organizations. An archetype is a formal expression of a distinct, *domain-level concept*, expressed in the form of constraints on data whose instances conform to the *reference model.* For an EHR_Extract, as defined in this part of ISO 13606, an archetype instance specifies (and effectively constrains) a particular hierarchy of RECORD_COMPONENT sub-classes, defining or constraining their names and other relevant attribute values, optionality and multiplicity at any point in the hierarchy, the data types and value ranges that ELEMENT data values may take, and other constraints.

This part of ISO 13606 recognises that archetypes might be used to support communication between some EHR systems in the future, or might be used as a knowledge specification by some EHR system external interfaces when mapping parts of an EHR to an EHR_EXTRACT, or might not be used at all between some EHR systems. The use of archetypes is therefore supported, but not made mandatory, by this part of ISO 13606. A specification for communicating archetypes is defined by Part 2.

0.4 Requirements basis for this part of ISO 13606

From the early 1990s it was recognised that a generic representation is required for the communication of arbitrary health record information between systems, and in Europe this has resulted in a succession of EU sponsored R & D projects and two generations of CEN health informatics standards prior to this International Standard. These projects and standards have sought to define the generic characteristics of EHR information and to embody these in information models and message models that could provide a standard interface between clinical systems. The vision of such work has been to enable diverse and specialist clinical systems to exchange whole or parts of a person's EHR in a standardized way that can rigorously and generically represent the data values and contextual organization of the information in any originating system. A complementary goal has been to accommodate the evolving nature of medical knowledge and the inherent diversity of clinical practice.

Many investigations of user and enterprise requirements for the EHR have taken place over this period, which have sought to span the information needs of diverse specialties across primary, secondary and tertiary care, between professions and across countries. These requirements have been distilled and analysed by expert groups, mainly within Europe, in order to identify the basic information that needs to be accommodated within an EHR information architecture to:

— capture faithfully the original meaning intended by the author of a record entry or set of entries;

— provide a framework appropriate to the needs of professionals and enterprises to analyse and interpret EHRs on an individual or population basis;

— incorporate the necessary medico-legal constructs to support the safe and relevant communication of EHR entries between professionals working on the same or different sites.

This work includes the GEHR [41, 48, 57], EHCR-SupA [36-38], Synapses [42, 43], I4C and Nora projects and work by the Swedish Institute for Health Services Development (SPRI). These key requirement publications are listed in the Bibliography [51]. These requirements have recently been consolidated on the international stage within an ISO Technical Specification, ISO/TS 18308[9].

In this reference model the key EHR contextual requirements for such faithfulness are related to a set of logical building block classes, with suitable attributes proposed for each level in the EHR extract hierarchy. ISO/TS 18308 has been adopted as the reference set of requirements to underpin the features within this EHR communications reference model, and a mapping of these requirements statements to the constructs in the reference model is given in Annex D.

0.5 Overview of the EHR extract record hierarchy

The information in a health record is inherently hierarchical. Clinical observations, reasoning and intentions can have a simple or a more complex structure. They are generally organized under headings, and contained in "documents" such as consultation notes, letters and reports. These documents are usually filed in folders, and a patient may have more than one folder within a healthcare enterprise (e.g. medical, nursing, obstetric).

The EHR extract reference model needs to reflect this hierarchical structure and organization, meeting published requirements in order to be faithful to the original clinical context and to ensure meaning is preserved when records are communicated between heterogeneous clinical systems. To do this, the model formally sub-divides the EHR hierarchy into parts that have been found to provide a consistent mapping to the ways which individual EHRs are organized within heterogeneous EHR systems.

These parts are summarised in Table 1.

Table 1 — Main hierarchy components of the EHR Extract Reference Model

EHR hierarchy component	Description	Examples
EHR_EXTRACT	The top-level container of part or all of the EHR of a single subject of care, for communication between an EHR provider system and an EHR recipient.	Not applicable
FOLDER	The high level organization within an EHR, dividing it into compartments relating to care provided for a single condition, by a clinical team or institution, or over a fixed time period such as an episode of care.	Diabetes care, schizophrenia, cholecystectomy, paediatrics, St Mungo's Hospital, GP folder, Episodes 2000-2001, Italy
COMPOSITION	The set of information committed to one EHR by one agent, as a result of a single clinical encounter or record documentation session.	Progress note, laboratory test result form, radiology report, referral letter, clinic visit, clinic letter, discharge summary, functional health assessment, diabetes review
SECTION	EHR data within a COMPOSITION that belongs under one clinical heading, usually reflecting the flow of information gathering during a clinical encounter, or structured for the benefit of future human readership.	Reason for encounter, past history, family history, allergy information, subjective symptoms, objective findings, analysis, plan, treatment, diet, posture, abdominal examination, retinal examination
ENTRY	The information recorded in an EHR as a result of one clinical action, one observation, one clinical interpretation, or an intention. This is also known as a clinical statement.	A symptom, an observation, one test result, a prescribed drug, an allergy reaction, a diagnosis, a differential diagnosis, a differential white cell count, blood pressure measurement
CLUSTER	The means of organizing nested multi-part data structures such as time series, and to represent the columns of a table.	Audiogram results, electro-encephalogram interpretation, weighted differential diagnoses
ELEMENT	The leaf node of the EHR hierarchy, containing a single data value.	Systolic blood pressure, heart rate, drug name, symptom, body weight

An EHR_EXTRACT contains EHR data as COMPOSITIONs, optionally organized by a FOLDER hierarchy.

COMPOSITIONs contain ENTRYs, optionally contained within a SECTION hierarchy.

ENTRYs contain ELEMENTS, optionally contained within a CLUSTER hierarchy.

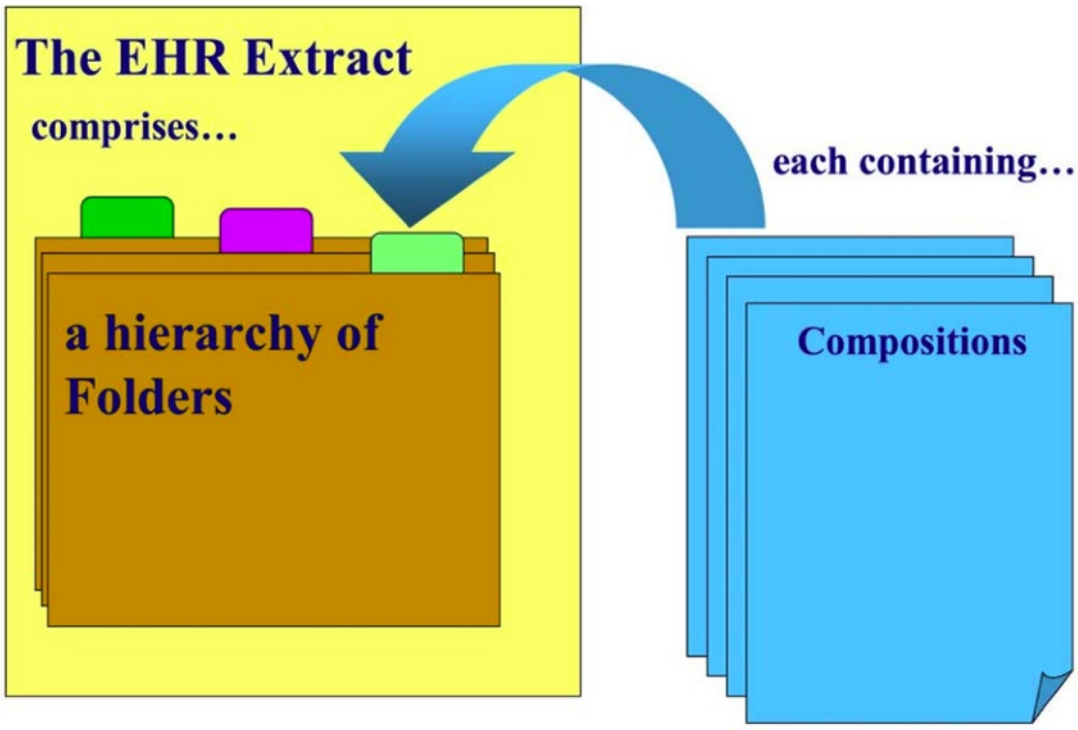


Figure 1 — Diagram of the EHR Extract hierarchy (Part 1)

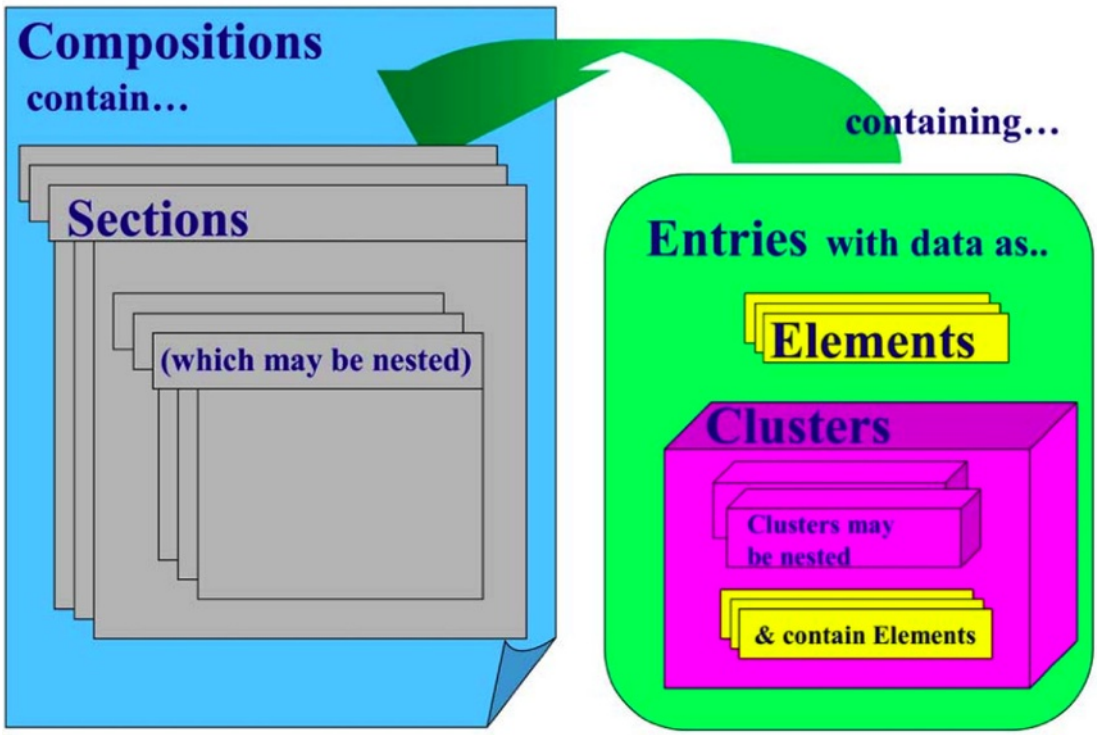


Figure 2 — Diagram of the EHR Extract hierarchy (Part 2)

0.6 Description of the main Reference Model classes

EHR_EXTRACT

The EHR_EXTRACT is used to represent part or all of the health record information extracted from an EHR provider system for the purposes of communication to an EHR recipient (which might be another EHR system, a clinical data repository, a client application or a middleware service such as an electronic guideline component) and supporting the faithful inclusion of the communicated data in the receiving system.

The EHR_EXTRACT class contains attributes to identify the subject of care whose record this is, the EHR Provider system from which it has been derived and the identifier of that subject's EHR in that system, and optionally the agent responsible for creating it.

The EHR_EXTRACT contains the EHR data, in three parts:

1) a set of COMPOSITIONs;

2) optionally, a directory of FOLDERs that provide a high-level grouping and organizing of the COMPOSITIONs;

3) optionally, a set of demographic descriptors for each of the persons, organizations, devices or software components that are identified within (1) and (2) above. This approach allows such entities to be referenced uniquely via an identifier within the body of the EHR, without repetition of the descriptive details each time, and also ensures that any EHR_EXTRACT can be interpreted in isolation if the recipient system does not have access to the services needed to decode the entity identifiers used by the EHR Provider.

A formal mechanism is defined in Part 4 of ISO 13606 for including access policy information within the EHR_EXTRACT. This is intended to inform the EHR recipient about the wishes of the subject of care and of healthcare providers for how future access requests for the data should be managed.

The EHR_EXTRACT also contains a summary of the filter or selection criteria by which this EHR_EXTRACT was created. This may or may not correspond directly to the criteria in the EHR request, and provides a record of the kind of subset this EHR_EXTRACT is of the overall EHR held by the EHR provider. This might be of importance if the EHR_EXTRACT is retained intact by the EHR provider or EHR recipient, and subsequently accessed by agents who do not have access to the original EHR request. For example, this class can specify if this EHR_EXTRACT is limited to the most recent version of each COMPOSITION (as required for most clinical care purposes) or if it includes all historic versions (which might be required for legal purposes). It might specify the maximum level of sensitivity of the data (implying that data that is more sensitive than this level may exist and have been filtered out), or that multi-media objects have been excluded to limit its total size. If the EHR_EXTRACT was created by selecting particular categories of clinical data (e.g., only laboratory data) then this may be indicated through a list of the archetypes that were included in the selection criteria. An option exists to include additional criteria (expressed as strings); this may be used to provide additional human readable information about this EHR_EXTRACT or may be used for locally-agreed computer-interpretable constraint information.

RECORD_COMPONENT

The main building block classes that are used to construct the EHR data hierarchy within an EHR_EXTRACT are kinds of RECORD_COMPONENT. This is an abstract class, the super-class of all of the concrete nodes in the EHR hierarchy: FOLDER, COMPOSITION, SECTION, ENTRY, CLUSTER, ELEMENT, and also the super-class for two other abstract class nodes: CONTENT and ITEM.

RECORD_COMPONENT defines the information properties that are common to all of these building blocks, including:

— the unique identifier that was issued to this EHR node by the EHR system in which it was first committed (its originating EHR system); other holders of this RECORD_COMPONENT need to retain this attribute value to ensure that any subsequent extracts are always consistently identified;

— the clinical name, used in its originating EHR system to label this part of the EHR data;

— optionally, a standardized coded concept to which the name has been mapped to support the semantic interoperability of equivalent EHR instances even if these have been given different clinical names by different EHR systems;

— the identifier of the archetype node to which this RECORD_COMPONENT conforms, to be used by archetype enabled-EHR systems or if archetypes have been used when mapping the data into the EHR_EXTRACT format;

— a sensitivity code and references to access control policies that should be used by the EHR recipient to govern future access to the data;

— support for links between any record components.

When generating an EHR_EXTRACT conformant to this part of ISO 13606 the EHR provider system might, in some situations, need to introduce a RECORD_COMPONENT into the hierarchy that does not have a direct correspondence with any original data in the EHR system. The synthesised attribute of RECORD_COMPONENT permits the exporting EHR provider system to indicate that a RECORD_COMPONENT has been created within the EHR_EXTRACT for this purpose.

Health record entries often refer to other pre-existing entries, and include them as “copies”. A common example of this is a discharge summary, which might include copies of several parts of an inpatient stay record such as the admission circumstances, the main diagnoses, principal interventions and treatments. In most cases the EHR_EXTRACT needs to contain these referenced RECORD_COMPONENTS explicitly by value, so that each COMPOSITION can be interpreted by the EHR Recipient. However, it is also important, medico-legally, to communicate that these entries are copies, and that they originate from a different part of that subject’s EHR. The optional attribute original_parent_ref may be used to represent the rc_id of the original parent RECORD_COMPONENT if the data are a copy.

Any RECORD_COMPONENT may include audit data about when and by whom it was committed in its originating EHR system. Each revised version of a RECORD_COMPONENT may document the version status, the reason for the revision and the identifier of the preceding version. However, for data protection reasons it is usually advised that previous (erroneous) versions of an EHR are not communicated as part of normal clinical shared care, but only in circumstances where an EHR transfer is being made for legal reasons.

It is important that each RECORD_COMPONENT be uniquely and consistently identified across multiple EHR_EXTRACTS, so that references to or between them remain valid. Examples of such references are semantic links, revision and attestation. The rc_id attribute is of data type *Instance Identifier (II)*, which incorporates an ISO OID; II is currently considered internationally to be the most appropriate data type for persistent identifiers that are required to be globally unique. It is unlikely that contemporary EHR systems will have existing primary keys or internal identifiers that correspond directly to globally-unique II instances. However, an EHR provider system that has been issued with an organizational OID might use its internal references to construct unique *local extensions* to that OID and thereby construct globally-unique rc_id values. Alternatively, it might create completely new rc_ids and retain a record of the mapping of these to each internal identifier, so that any future EHR_EXTRACTS it generates will use consistent rc_id values. It is also unlikely that an EHR recipient system will be able to use received rc_id values as its internal primary keys for the data, since every database uses a slightly different approach to generating and using such keys. The EHR recipient might therefore also need to keep a record of the mapping of imported rc_id values to its primary keys, so that future references to those RECORD_COMPONENTS can be appropriately matched, and it can create EHR_EXTRACTs that reapply those rc_id values to the exported data. An alternative approach is for EHR systems to explicitly store the rc_id values along with the clinical data, and treat this as part of the “payload” data and not attempt to use these also as primary keys. It should also be noted that the rc_id does not function as a primary key equivalent within an EHR_EXTRACT i.e. duplicate values of rc_id are permitted if each instance does indeed refer to the same piece of clinical data within the EHR provider system.

FOLDER

This class is used to represent the highest-level organizations of EHR data within the EHR_EXTRACT, e.g., to group COMPOSITIONs by episode, care team, clinical speciality, clinical condition or time interval. Internationally, this kind of organizing structure is used variably: in some enterprises and systems the folder concept is treated as an informal compartmentalization of the overall health record; in others it might represent a significant legal portion of the EHR relating to the services provided by an enterprise or team.

In the EHR_EXTRACT, FOLDERs are an optional hierarchy. FOLDERs may contain other FOLDERs to form a complete directory system, and may include any pertinent information about their committal or revision within the EHR Provider system. FOLDERs reference COMPOSITIONs via a list of unique identifiers, rather than by physically containing them. This permits any COMPOSITION to appear within more than one FOLDER, which is a requirement that some vendors and jurisdictions have indicated.

In some situations FOLDERs might be created specifically to organize the EHR_EXTRACT, or contain only a selected subset of the data in the corresponding folder in the EHR provider system. In such circumstances the FOLDERs within the EHR_EXTRACT will not have a direct correspondence with those in the contributing EHR provider system, i.e. they will have been synthesised.

A FOLDER may be used to group a set of COMPOSITIONS comprising the individual records made of members of a multi-professional team during a single clinical encounter. In situations like this where a FOLDER represents a finite interval of care, it may be attested. This approach should be used to communicate that the FOLDER's contents are a complete record of that interval of care. This also provides an indication to the EHR recipient that additional COMPOSITIONS ought not to be added to this FOLDER.

Since folder systems are used variably within EHR systems, this International Standard cannot prescribe how they should be handled within the EHR recipient's system: i.e. it does not require that the EHR recipient explicitly use these within its EHR system. However, if a FOLDER has been attested, an intact copy of this information shall be retained for future reference and possible onward communication.

COMPOSITION

The COMPOSITION represents the set of RECORD_COMPONENTS composed (authored) during one user's clinical session or record documentation session, for committal within one EHR. Common examples of this include a consultation note, a progress note, a report or a letter, an investigation report, a prescription form and a set of bedside nursing observations. The COMPOSITION documents the date and time or interval of the clinical encounter, and the legal jurisdiction in which the records were composed.

The composer is the agent (party, device or software) responsible for creating, synthesising or organizing information that is committed to an EHR. This agent takes responsibility for its inclusion in that EHR, even if not the originator of it and even if not the committer of it. The content of the COMPOSITION is primarily attributed to this person. Whether or not the composer is changed when a revision is made is optional. Applications will generally use the composer's name to label COMPOSITION data when used for clinical care. There may be occasions when there is no single main composer (e.g. a multi-professional tele-consultation, or a case conference); in such cases the composer role might not be formally specified even though each participant and clinical role is declared. The composer is therefore optional.

Provision is made for a COMPOSITION to include the details and locations of any other participants involved in the clinical encounter or record documentation session. Some of these might have participated from different locations (for example on the telephone, or via a video-consultation).

The COMPOSITION is the main container class for EHR data within the extract itself, to ensure that a consistent containment hierarchy is used within all Extracts: the EHR_EXTRACT contains a set of COMPOSITIONs together with audit data about the committal of each within the EHR Provider's system. A COMPOSITION is always used to communicate version updates between EHR systems, even if the actual updates refer to parts of that COMPOSITION. If multiple versions of EHR data are to be communicated within one EHR_EXTRACT, this will be as a set of distinct COMPOSITIONs, each referencing the preceding version and collectively referencing a version set identifier.

Each COMPOSITION also optionally documents any attestations (e.g. digital signatures) that pertain to it or to any of its contents.

Contribution The Contribution is the set of COMPOSITIONs committed by one user at one point in time in the EHR of one subject of care. Some clinical applications include complex screens capable of presenting multiple parts of an EHR simultaneously (for example through tabbed panes). On saving the screen, a user might actually be committing data to more than one part of the patient's EHR (e.g. the addition of a new consultation note and the revision of a medication entry stored elsewhere in the EHR). The Contribution refers to all of the changes and updates committed to that EHR during that committer's session. All of the COMPOSITIONs comprising one Contribution can be collectively identified by providing a common value for the contribution_id attribute.

SECTION

The record entries relating to a single clinical session are usually grouped under headings that represent phases or sub-topics within the clinical encounter, or assist with layout and navigation. Clinical headings usually reflect the clinical workflow during a care session, and might also reflect the main author's reasoning processes. Much research has demonstrated that headings are used differently by different professional groups and specialties, and that headings are not used consistently enough to support safe automatic processing of the EHR. They are therefore treated in this part of ISO 13606 as an optional (informal) containment for human navigation, filtering and readability.

SECTIONs may be used to represent the containment hierarchy of clinical headings used within the EHR provider system to group and organize entries within a COMPOSITION. Each SECTION may contain additional SECTIONs and/or ENTRYs.

ENTRY

The ENTRY is the container class for the ITEM data structure that represents the information acquired and recorded for a single observation or observation-set (battery or time series), a single clinical statement such as a portion of the patient's history or an inference or assertion, or a single action that might be intended or has actually been performed. The ENTRY class associates this ITEM structure with a set of context attributes to facilitate safe interpretation:

— information in an ENTRY may be about someone other than the patient (e.g. a relative): ENTRY defines the subject of the information;

— information in an ENTRY may have been provided by or is attributed to a particular individual: ENTRY defines the information provider;

— other participants might need to be associated with a particular ENTRY;

— the ENTRY may represent the evolving status of a clinical act (e.g. requested, performed, reported, cancelled) and may optionally carry an identifier that links it with a workflow system;

— the ENTRY may use a flag to advise the EHR recipient that the data structure includes some indication of uncertain findings or opinions, and that care needs to be taken when using the data for automated processing.

The ENTRY contains a data structure represented using CLUSTERS and ELEMENTS. It is important to note that ENTRY cannot contain further ENTRYs. The set of contexts defined at the ENTRY level (e.g. the subject of information) apply to the whole data structure and cannot be overridden.

ITEM, CLUSTER and ELEMENT

The ITEM may represent both the actual data describing the observation, inference, or action, and optionally the details describing the examination method, the patient's physical state or details supporting the clinical reasoning process such as a reference to an electronic guideline, decision support system or other knowledge reference. The item_category attribute provides an optional means of distinguishing these different parts of a

data structure, as an aid to the automated analysis or filtering of the ITEMS in an ENTRY. The codeset for this attribute is defined in ISO 13606-3.

Information in an ITEM (CLUSTER or ELEMENT) might have originated at a date/time different from the care activity or its recording. The obs_time attribute permits representation of a single date or time or an interval, to any level of granularity. This would permit, for example, an operation to be dated only by the year, the onset of a symptom to a month and year, a period of employment to be a precise date range or an interval in years, the precise time-stamping of an arrhythmia, or an angiogram to be organized as a time series of images.

Information in an ITEM might be emphasised by the author as being exceptional or noteworthy. This part of ISO 13606 does not define a code set for this attribute; any agreed terminology may be used to specify the degree of emphasis or to specify the kind of exception.

The CLUSTER supports the representation of complex data structures needed to represent the actual data values within a multi-part (nested) observation, clinical statement or instruction. These may need to be represented as a table, a tree or a time series. Specific examples include an ECG tracing, a full blood count, ankle reflex examination, the prescription of an intravenous drug infusion.

The ELEMENT class represents the leaf node within the EHR hierarchy. Each instance of this class will have a single data value. (A ratio, an interval or a co-ordinated term are considered here to be examples of single data values). Examples of ELEMENT might include reason for encounter, body weight, pulse. An ELEMENT may have a null data value, for example if a value is not known.

Data values

Each ELEMENT contains one data value, to represent the actual instance values. This is one of the CEN Data Types (CEN/TS 14796) for:

— text and coded terms;

— quantities including ratios, intervals and durations;

— dates and time;

— graphical and other MIME type (e.g. image, signal).

It is recognised that, at the time of producing this part of ISO 13606, a new set of health informatic data types is being developed by ISO/TC 215. Once this is published, CEN is expected to deprecate CEN/TS 14796 in favour of this new standard. In doing so, it will need to provide a mapping correspondence to the new data type standard, and this mapping will also need to be used in order to adopt the new data types alongside this part of ISO 13606.

In order to support the adoption of this part of ISO 13606 more widely internationally than the jurisdiction of CEN/TS 14967, the set of attribute data types actually used within this reference model (other than the data value of ELEMENT) are explicitly included in this part of ISO 13606 in a support package. These should also be deprecated in favour of ISO data types once published.

NOTE Primitive data types such as Boolean, Integer are assumed to follow ISO/IEC 11404 and are not further defined here.

0.7 Description of the other principal classes of the reference model

AUDIT_INFO

It is a medico-legal requirement to document and to communicate when and by whom EHR data were entered into an EHR system. It is also important to track changes to EHR data if modifications are made, and to communicate this within an EHR_EXTRACT. The AUDIT_INFO class is used to represent these audit data:

a) for any RECORD_COMPONENT, as a permanent record of its commitment in its originating EHR system;

b) for any COMPOSITION, as a record of its commitment within the EHR provider system that has generated this EHR_EXTRACT.

A COMPOSITION might therefore have up to two audit data sets, one relating to its originating EHR system (called “feeder_audit”) and one to its subsequent commitment within the EHR provider’s system (called “committal”), if these are different. This part of ISO 13606 does not, however, require or support the communication of an indefinite accumulation of audit data sets for every system into which a COMPOSITION is committed. This is because a cumulative set of audit data sets without the actual clinical data to show the details of what was changed each time is not considered to be of clinical value. If a full change history is required to be communicated, each version of the COMPOSITION needs to be included in the EHR_EXTRACT.

For committal, the AUDIT_INFO class represents the timestamp of committal, it identifies the committer, and the EHR system into which the data were committed. The timestamp reflects when this RECORD_COMPONENT was persisted with in an EHR system and therefore became part of the EHR of the subject of care. The committer is responsible for including this RECORD_COMPONENT within the EHR, but might not be responsible for deciding upon the clinical content being committed.

The committer and time committed attributes are optional, to allow for the possibility that some data will have been imported from simple legacy systems in which the clinical data originated but for which these values are not known. However, for the committal AUDIT_INFO association these attributes are required to have non-null values, since they represent the time and party responsible for authorizing the clinical data to be included within an EHR system conforming to this part of ISO 13606.

For revision, the AUDIT_INFO class represents the version status, an optional reason for revision, the identity of the immediately previous version that was the basis of this revision, and an identifier that is common to all versions so that non-sequential versions made on different EHR systems can still be related to each other. An optional version status attribute indicates if the present version was, at the time of its committal, a draft (i.e. intended to be replaced in the near future), an update to a previous draft version, a correction of an erroneous former version, or an empty COMPOSITION or ENTRY that is the logical deletion of its predecessor (e.g. if the predecessor was saved in the wrong EHR). If no status is given, it is assumed that this is the definitive (first) version.

EHR systems vary in the granularity of EHR data at which committal and revision are permitted, and it is quite likely that all of the RECORD_COMPONENTs within a part of an EHR hierarchy (e.g. within one COMPOSITION) will share the same audit data. The standard therefore only requires the representation of this information if it is different from that of the parent RECORD_COMPONENT.

FUNCTIONAL_ROLE

This class is used to represent the details of who and where an individual agent has contributed to the healthcare or health record of a subject of care. This class identifies:

— the function that was performed in the situation being documented;

— the identity of the agent performing the function;

— the mode in which participation was made (e.g. in person, by telephone);

— the healthcare facility at which the agent was present;

— the kind of service location, department or setting in which the agent performed that role.

Some of this information may be omitted if the performer was not acting within a healthcare facility, e.g. a subject of care entering data from home.

ATTESTATION_INFO

Attestation is the process of certifying and recording legal responsibility for a particular unit of information. The attestation of part of an EHR is a mechanism whereby the attester can provide his or her authority that those contents are, in his or her opinion, correct. This means that he or she is satisfied that the contents are a fair and faithful reflection of the processes they document, and do not deliberately misrepresent the truth. Attesting a part of an EHR will not have modified its content or interpretation, other than by adding weight to its authenticity. (Anything which added an opinion, a new viewpoint or perspective would have been either a revision or a new set of entries with a link to this one.)

Clearly any modification to a part of an EHR through revision cannot automatically carry forward any previous attestations; if necessary the original attester would have been invited to re-attest that he or she remains happy now it has been modified or the reviser attested the new version or both or neither.

There has been much debate over many years about what information needs to be retained within electronic systems:

a) to verify the authorization of the attester (ranging from a simple flag to indicate that he had been authenticated in that system's normal way, to a complex hash of the user's digital key, date and time and part or all of the document being signed and optionally sent to a trusted third party notary service);

b) as a permanent legal record of what was attested (ranging from no specific addition to the raw database record that is being signed, to XML output files with a stylesheet as a proxy to show how it was presented, to bitmaps of each screen as it was actually presented for signature).

Attestation may be carried out by more than one person, at different times from the committal, and might not always be required in some healthcare services. The attester will sometimes also be the committer, but might not be, for example, if a medical secretary is typing in the data.

This part of ISO 13606 acknowledges that in some situations it will be appropriate to communicate the detailed evidence of an attestation, and in others to simply confirm that the data were attested in the EHR provider’s system and to only communicate the name of the signatory and date of the attestation.

The ATTESTATION_INFO class represents the following data about an attestation:

— the date and time at which it occurred;

— the person who made this attestation, as a reference to the FUNCTIONAL_ROLE class described above;

— the list of RECORD_COMPONENTS that were attested;

— optionally the reason for, or legal significance of, this attestation;

— optionally the electronic signature (as encapsulated data, or as reference to it) that verifies the attestation;

— optionally the encapsulated data, or a reference to it, that represents the visual image that was actually viewed by the attester; it is now required in some EU countries that this is retained within the EHR in addition to the data in its processable form.

Attestations relating to a FOLDER are contained by that FOLDER; it is anticipated that this will be rare. More commonly, whole COMPOSITIONS or individual ENTRYs within a COMPOSITION will be attested; all attestations pertaining to a COMPOSITION or any of its contents are contained by the COMPOSITION.

RELATED_PARTY

It is occasionally the case that EHR data describe the health or a healthcare event about someone other than the subject of care. The commonest example of this is family history, but information about the subject of care's friend, life partner, sexual partner, employer, child, etc might sometimes be recorded in an EHR and this needs to be unambiguously distinguished from the majority of EHR information which is about the subject of care. The ENTRY includes an attribute "subject_of_information", which uses the RELATED_PARTY class to represent an information subject who is not the subject of care.

This class may be used:

a) to identify a person in terms of his or her relationship to the subject of care, as a coded term or textual description;

b) optionally to identify the person through an identifier, and to provide a demographic description set for that person within the demographics package of the EHR_EXTRACT.

It is recognised that, for data protection reasons, it is not common to actually link the EHR of one data subject to that of another (e.g. if a family member is also a patient at the same enterprise), but that this will occasionally occur within clinics providing genetic or family therapies, and sometimes in primary care. This part of ISO 13606 does not formally support a linkage between the EHRs of different subjects of care, although this class may be used to provide identifiers that are the actual identifiers by which another person is known within the EHR Provider's system, if such use is permitted.

LINK

A user may wish to create *ad hoc* semantic links between any arbitrary points in an EHR, for example to indicate the evolution of a condition, the likely historic cause of a problem, or a response to a previous request, to indicate cause and effect, to track the evolution of orders from request to completion, or to form linkage networks for clinical problems or episodes. In these situations a mechanism is required for a composer to point from any node in their current screen form or electronic document to any previous component in the EHR, and to label the link with an appropriate clinical term. Sometimes one location in the EHR may act as a kind of linkage hub, for example the formal statement of a clinical condition might be used as an anchor point for all historic and subsequent entries relating to that condition (e.g. in a problem oriented record).

Such links might be created by the user as a pointer from a new record entry to a pre-existing one, or might be created as a new statement of a clinical relationship between two or more pre-existing entries (by pointing to each of them from a current entry justifying the relationship). A wide range of end user interfaces can be envisaged for such functionality, but the task of this International Standard is to provide a generic and safe means for communicating the existence of such links to diverse EHR systems. This might at times require the communication of the link target as well at the link source, because a composer felt that any future recipient needs to be aware of the content of both entries, for example if a procedure or a drug prescription had catastrophic complications.

The LINK class that is associated with RECORD_COMPONENT permits any number of labelled links to be represented from a source component to any number of targets (by referencing their unique identifiers).

Two attributes are available to label each LINK:

a) a coarse-grained link category, which needs to be one of several values defined in Part 3;

b) an optional fine-grained label; an informative list of terms for this is given in Part 3, but other terminologies may be used.

A further and important feature is the follow_link Boolean attribute which, if true, indicates that the composer intended that any EHR_EXTRACT that includes the COMPOSITION containing the source shall also include the COMPOSITION containing the target and vice versa. The receiving system will need to indicate the existence of this additional information to users accessing data that are at one end of such a LINK.

0.8 Discussion of particular representation topics

Representing roles and responsibilities within the EHR _EXTRACT

Performing a care act in a modern health service can involve a large number of actors, with different roles and responsibilities, each of whom might need to be represented in a patient's EHR. The approach taken in most generic EHR architectures, including this part of ISO 13606, is to differentiate these into three broad categories.

Actors playing a role in the actual healthcare process

This set will usually include a core party who is the key person relating to the patient during that act (e.g. during a forceps delivery in an industrialized country it will normally be an obstetrician) and a series of related parties who may be providing or supporting parts of the care (e.g. midwives) are involved in making decisions (e.g. an anaesthetist) are observers (e.g. medical students) or are present to support or co-represent the patient (e.g. the patient's husband). These actors might not all be present: for example, the policies of a consultant in charge of care may be followed because the patient is under his team, even if he is himself not with the patient on that occasion. Sometimes actors might be documenting a case review or a care planning negotiation involving one or more professionals but where the patient is not present.

Actors contributing to the process of documenting care within the EHR

This will usually be a subset of those involved in care (and most commonly, the key actor), but might include people who were not part of delivering the care (e.g. a secretary or a transcriptionist) and may (more so in the future) include the person who is the subject of their care. It is important to recognise that the different actors will often complete different records of events and may also attest them independently.

Actors confirming the validity of the EHR documentation

The paper analogy of this is the signing of a letter or report. Most commonly the act of signing a document combines two intentions: to confirm that the document is correct (e.g. free of typos and omissions) and for the signator to confirm that he agrees to the content (e.g. to validate a prescription). In most of these situations the status or seniority of the signator is important. Some of the actors described in a care act will not themselves sign the entries describing their contribution to care: much of healthcare works through delegation. For example, the medical record documentation made by a junior doctor on a ward round is rarely reviewed by the consultant and almost never countersigned. Most observations on an observation monitoring chart are not individually signed. With electronic systems this practice might change, but some level of delegation and trust will probably always exist within care teams.

Clearly there is a wide range of potential roles and responsibilities that might need to be represented in an EHR, and as patterns of health service evolve these might change in the future. The goal of the EHR_EXTRACT architecture is to permit any number of actors and roles to be defined within a COMPOSITION: either for the whole COMPOSITION or more narrowly for individual ENTRYs.

The approach taken in this part of ISO 13606 (as in other EHR architectures such as ENV 13606 and HL7 CDA), is:

— to specify a small number of roles that need to be unambiguously communicated to ensure safe interpretation of EHR_EXTRACTs by a receiving system, and which are likely to arise frequently;

— to permit other *ad hoc* participations to be defined by health services, systems or in individual EHR instances at the COMPOSITION or ENTRY level;

— to permit any number of attestations to be added to the EHR, to sign FOLDERs or COMPOSITIONs or to permit attestation only of parts of COMPOSITIONs.

Some specific roles that have been defined in this reference model are discussed below.

Subject of care

It is assumed that each EHR, and therefore any EHR_EXTRACT, will be about the health and healthcare of one person, who is also, in data protection terms, the data subject. This does have important implications for data contained in that EHR that might relate to a different data subject (as in the case of family history); this is discussed below under subject of information.

Several “special case” exceptions are often cited to the norm that each EHR is about one data subject.

Pregnancy: here it is usual practice for the mother’s record to contain the full pregnancy care record including that of her baby or babies until after birth, when any relevant information is copied into the new records of those babies.

In utero interventions: in some situations a new record is created well before a baby is born, perhaps if significant healthcare is required. In such situations the new record is being created for the foetus as a convenience to permit a separation of data from the mother’s record, and in anticipation of a new legal record for the baby. Depending upon the age of the foetus, and the laws pertaining to each country, either the baby or the mother will be the legal data subject, but in any case there is still a single identifiable subject of care for each record.

Multiple pregnancy with each foetus having its own record: this is often cited as a situation in which health actions might really “belong” to two or more subjects of care. In these situations it would seem logical that each baby's EHR_EXTRACT contains a copy of the relevant COMPOSITIONs, rather than attempting a complex join between two or more records to reference a single COMPOSITION held in one of these records. (Of course, more complex cross-linkage arrangements might be made within local EHR systems, permitting users to enter the data once and have it logically added to both records).

“Siamese” twins: yes, there has been discussion on such rare cases! Again in this case it seems logical and safe for each twin to have a copy of the relevant COMPOSITIONs, whenever separate EHRs are created, rather than inter-linked record extracts that might not be safely managed by receiving systems.

Donated organs: Some test results relating to the donor of an organ may be appropriate to store in the EHR of the person receiving the donated organ – such as the viral status of the donor and in future the genetic record of the donor – as the person will from this time on be a genetic mosaic. For this reason, the subject of the information or some information in the EHR may be “donor”.

The subject of care identifier in the EHR_EXTRACT will reference a snapshot of demographic information as held by the EHR Provider, to enable the patient to be matched to the demographics repository of the EHR Recipient, and/or for the EHR_EXTRACT to be referenced to the individual subject of care even if external demographics services are not available. Subject of care is defined at the root of the model, in the EHR_EXTRACT class.

Composer

This actor is the person who has actually composed the words, terms, figures and values, etc. that are represented in the COMPOSITION. The composer will almost always have played a key role in the information gathering, thinking or enacting aspects of the healthcare being documented. Sometimes, though, he or she might be a junior team member writing up the notes on behalf of a team. Even so, it will be the composer's words or phrases that shape the documentation.

The composer attribute therefore represents the party who composed the data in a COMPOSITION, irrespective of who committed it or who attested it. The COMPOSITION will be seen as being primarily attributed to this person. Whether or not the composer is changed when a revision is made is optional, as it will depend upon the extent of the change made and if the revising party is willing and in a position to assume primary responsibility for the revised COMPOSITION as its composer. Applications may use the composer's name to label COMPOSITION data for display purposes. (The role of team members other than the composer can be added as other participations, either for the whole COMPOSITION or for individual ENTRYs.)

Committer

In many situations the person who composes the words is not the one who keys them in. A common example is dictated letters and reports, which may be typed up by a secretary or transcriptionist. A junior clinical team member might also describe himself as the committer if he is really only acting as the scribe for another (composing) senior team colleague. In some transcription scenarios the typed text is checked by the composer who then commits it to the patient's EHR himself. In some scenarios several clinical team members are working in collaboration to deliver a care service; each of these might be able to document (and attest) their own portions of this care in the patient's record.

Other situations might arise in which the committer is not responsible for data entry, for example when a measurement device is directly feeding a clinical application. In these situations the information_provider or other_participations attributes of ENTRY can be used to supplement the set of defined actors.

Subject of information

This attribute is needed to identify the person about whom the information in an ENTRY relates if not the subject of care e.g. if the information is about a family member, such as the patient's father or mother. This is regarded as an important "safety" attribute to supplement any meaning implied by a component name or archetype, particularly if records are communicated across countries and languages.

In some contexts parties might only be specified precisely if they are registered within the local demographics service AND they have given their consent to be identified in this patient's EHR. This will increasingly arise in clinical fields like cancer genetics that manage patients within their family context. The more common situation is where the patient is describing the health of others.

The subject_of_information association from ENTRY refers to the class RELATED_PARTY, permitting the relationship of that subject to the patient to be defined as a coded term, and optionally also through a party identifier (probably linking to the demographics service within the EHR system).

This approach will allow archetypes to be re-used with different subjects of care, and the unambiguous processing of EHR ENTRYs to distinguish data about the patient from data about other parties.

Information provider

Most of the information documented in an EHR will originate from the patient or one of the other participants in the care act. However at times ENTRYs may be added whose data values have originated from some other party, for example a relative or carer who might be with the patient or seeing the patient's doctor alone confidentially. Other clinical parties might provide information indirectly (e.g. by telephone) to the composer.

The info_provider association from ENTRY refers to the class FUNCTIONAL_ROLE, permitting their function and mode of contribution (by telephone, in person, etc.) to be represented. As with the subject of information, the party might or might not be formally identified, depending on consent and if they are registered in the local demographic service. The formal identification of information providers provides one way for a composer to attribute some ENTRYs in that COMPOSITION to other clinicians or to devices (the other_participations attribute in another way).

Demographics

An electronic health record may refer to a wide range of specific entity instances, such as the subject of care, the various healthcare and other agents who have played roles in the delivery of healthcare, devices that have measured body parameters or delivered treatments, and organizations that have assumed responsibilities for care. Many of these referenced entities multiply within any given EHR, and in any enterprise might be defined within a demographics server.

In this reference model an equivalent approach has been taken: specific entities are defined once within a demographic extract package, and referenced as necessary throughout the rest of the EHR_EXTRACT by a dedicated instance identifier. The instance identifier used within the EHR_EXTRACT might be, but need not be, one of the actual identifiers by which each entity is known in the EHR Provider system.

The goal of this part of the model is to provide a necessary and sufficient description of each entity to support human interpretation of the EHR, and demographic matching to enable the EHR recipient to identify the corresponding entities within its own demographic server. If a more detailed exchange of demographic information is required, it is recommended that an appropriate alternative standard be used, such as CEN/TS 14796.

The whole DEMOGRAPHIC_EXTRACT package is optional, and the demographic details of each entity need not be communicated if it is known that both EHR Provider and EHR Recipient share or can access a common demographic service – for example within one enterprise, region or health service.

Revision

Revision is an important and potentially complicated area. In addition to the well-known medico-legal requirements for tracking and attributing revisions, the following functional requirements have underpinned the approach taken:

1) the vast majority of requests for parts of or whole EHRs will warrant the generation of an EHR_EXTRACT that contains the most up-to-date versions of the contained RECORD_COMPONENTs;

2) even in such situations, it may be important to know that the communicated RECORD_COMPONENTs have been the subject of a correction;

3) there will be an infrequent need to transfer serial versions of RECORD_COMPONENTs for clinical care purposes, for example to explain an error;

4) there is a need to be able to transfer a whole EHR, including all versions of revised components, for example when care is legally being transferred between enterprises;

5) the COMPOSITION should anchor the communication of committal and revision within the EHR_EXTRACT, even though the changes made through a revision might only affect a few of its contained components;

6) the evolution of FOLDERs over time may also need to be similarly revision-managed, although this will usually be within EHR systems and a FOLDER audit log will probably only occasionally be included within an EHR_EXTRACT;

7) in many cases it might not be legal to communicate errors that have been corrected; revised components should therefore not “contain” the original data that have been corrected, even if marked as logically deleted. For example, erroneous data corrected at the request of a patient need not be communicated according to EU Directives and most national data protection legislation;

8) in some cases, for example if determined by a court of law, data might be physically deleted from an EHR system; in such cases it might sometimes be appropriate to retain an empty place-holder RECORD-COMPONENT at the same point in the hierarchy, to indicate when and why the deletion took place.

A variety of techniques exists for version-tracking of modifications within databases, any of which might be used within individual EHR systems. The approach taken for this part of ISO 13606 is to specify a structured way in which the necessary clinical and medico-legal requirements can be met within an EHR_EXTRACT, without prescribing any particular versioning methodology to be used inside these EHR systems.

The AUDIT_INFO class contains a set of attributes that define the EHR system, committer and time committed that define the origin of any RECORD_COMPONENT within the EHR system in which it was first created. This data set needs to be included within the EHR_EXTRACT whenever this RECORD_COMPONENT is communicated. If the RECORD_COMPONENT is a revision of a former version, an additional set of descriptions and references to previous versions needs also to be provided. It is therefore always possible to know if a RECORD_COMPONENT has been revised, when, why, by whom and in which EHR system. The identity of the previous version is known, but it is only possible to access this previous version if the EHR recipient has the necessary privileges and the EHR provider is prepared to release it.

Communicating EHR queries

Users frequently require views of certain types of entry or of higher level groupings, which can be derived computationally by filtering the longitudinal EHR for certain classes of information (in future this could be by archetype). Certain attribute or data values might be used to sort the resulting filtrate into a suitable user view, for example by date, alphabetically or by descending size of the value.

There are no specific features required of the underlying EHR entries to support this, and the logic for deriving each view will usually reside within a clinical application, not within each individual EHR. The result of performing the query is not normally itself stored in the EHR or communicated, so the EHR communications reference model does not need to represent it. Examples might be a graph of blood pressures over time or a list of medication prescribed within the past 30 d.

Some views or filtrations might be derived by a "custom" query that has been specifically composed for use within a particular subject of care's EHR. In such cases it may be desirable to store the query parameters within the patient's EHR for the benefit of future clinicians. The extent to which this is useful to share between enterprises and systems depends on how interoperable that query specification is. Given that the language for specifying archetype definitions and constraints (Archetype Definition Language – ADL) has now been standardized (in Part 2), and the guidelines community is also progressing towards interoperable specifications, it seems likely that a generic EHR query specification will emerge.

There is, as yet, no standardized convention for specifying an EHR-related query, but it is likely that these specifications will be a data set of string values or name value pairs. Such a specification can be represented within the ITEM sub-classes CLUSTER and ELEMENT, with data values of type STRING. ENTRY archetypes can therefore be used to define the representation of any EHR queries that need to be communicated. This has the advantage that more than one such query specification can be defined for use within healthcare systems, and refined over time, without requiring any modification to this part of ISO 13606. An illustrative example is given below.

ENTRY Blood Pressure Graph Query

CLUSTER: Query Specification

ELEMENT: Query Syntax: <EHR_OQLv1>

ELEMENT: Query String: "Select….

where Cluster.meaning = <Blood Pressure>

and containing.Entry.subject_of_information = <Patient>

and containing.Composition.Clinical_Session.session_time.start

> (now>-365days)"

ELEMENT: Datetime first authored: 20 February 2003

NOTE The actual syntax of the query string in the example above is for illustration only, and does not conform to any known syntax. In the case of such a real query stored in the record the syntax would have to follow whatever scheme is identified in the query syntax ELEMENT.

Communicating presentation information

It is not generally regarded as appropriate to include details within an EHR communication of how the clinical data were originally presented on screen at the time of data capture, for several reasons:

1) data capture screens do not often correspond directly to data presentation screens, even within one clinical application, so it is not of much clinical use for another healthcare professional to be informed about how the screen looked just before it was saved;

2) clinical data can often be displayed in more than one way (e.g. on summary screens, detail screens), and different users might find different presentations of more or less use to their situation;

3) the EHR recipient system might not be able to precisely display the screen layouts supported by the EHR provider's system;

4) the EHR recipient's healthcare professionals are likely to have their own applications through which they wish to view both imported and locally-created data consistently.

However, there are two scenarios in which precise presentation information might be important to communicate along with the EHR data:

a) if there is a need to capture the appearance of the screen and the way the data were organized for medico-legal purposes (e.g., to show what data a clinician actually saw when signing the data);

b) if a particular presentation of the data conveys unique insight into its interpretation, such as a diagram or chart.

In both cases, the attested_view attribute of ATTESTATION_INFO can be used to include an encapsulated data representation for any level of granularity of EHR data. This attribute may be used, for example, to include the rendered view of an HL7 version 3 CDA Release 1 or Release 2 document.

Rather than presentation, clinical requirements investigations have shown the more frequent need to highlight a particular part of the data as being noteworthy, abnormal or unexpected. In such situations the requirement is usually to indicate that the data should be emphasised appropriately to the end user rather than dictate if it needs to be shown in bold or in red font. The ITEM emphasis attribute permits this to be communicated as a coded value.

Communicating multimedia data

The requirement to include and communicate multimedia data within EHRs, for example the results of diagnostic imaging studies, is without question. Health professionals from all disciplines and specialities wish to be fully informed when making care decisions, and patients themselves increasingly wish to be able to see and understand their own health problems, including visual formats such as images. Downstream users of multimedia reports might include those offering supplementary specialist opinions on a study and advising on subsequent care planning, or those needing to review former studies when interpreting a new one (potentially at another site or in another country).

Within an EHR, data of a wide range of media types may be included as the specific data value of an ELEMENT. More complex multimedia data structures can therefore be represented by combinations of ELEMENT classes optionally contained by CLUSTERs, as tables, lists or trees. Particular data structures or multimedia reports can be represented as specific ENTRYs or COMPOSITIONs, and can be archetyped.

The data type option for encapsulated data (short code ED), as defined by CEN/TS 14796, permits any MIME data type to be represented.

0.9 Comparison between ISO 13606-1 and EN 13606-1

In February 2007, CEN published EN 13606-1, which is the European version of this part of ISO 13606 and which applies jurisdictionally to European Member Bodies. This International Standard, ISO 13606-1, is materially identical to its European equivalent. There are several areas of minor difference between the two documents, which will not affect its adoption, implementation or conformance, but which are summarised here for the benefit of those readers in possession of both documents.

ISO 13606-1 differs from EN 13606-1 in the following normative provisions:

— the wording of Clause 1 **Scope** has been modified (extended) to include the following phrase at the end of the second paragraph: "or as the representation of EHR data within a distributed (federated) record system.";

— Subclause 5.2 Member State Conformance has been reworded to be more appropriate to the ISO context, and been re-titled **Member Country Conformance**;

— the value of the attribute rm_id within the class EHR_EXTRACT has been changed from “EN 13606-1” to “ISO 13606-1”.

This Introduction has been edited to clarify (but not to alter) the receiver responsibilities in respect of FOLDERs and LINKs, and the circumstances in which the identity of the composer of a revised COMPOSITION might be changed if it is revised.

The following editorial changes have been made:

— references to a European Standard have been changed to International Standard throughout;

— references to EN 13606 have been changed to ISO 13606 throughout;

— general wording that refers to Europe or to European prestandards has been modified where appropriate for an International Standard readership;

— a few definitions for terms that did not confirm to ISO regulations have been editorially rephrased but not materially reworded – i.e. their technical interpretation is unchanged;

— a few outstanding minor typographical errors and inconsistencies of terms used within the document have been tidied.

This section of the Introduction does not have a corresponding counterpart in EN 13606-1, as the exact content of this ISO 13606-1 was not known when EN 13606-1 was published.

INTERNATIONAL STANDARD **ISO 13606-1:2008(E)**

Health informatics — Electronic health record communication —

Part 1: Reference model

1 Scope

This part of ISO 13606 specifies the communication of part or all of the electronic health record (EHR) of a single identified subject of care between EHR systems, or between EHR systems and a centralized EHR data repository.

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

This part of ISO 13606 will predominantly be used to support the direct care given to identifiable individuals, or to support population monitoring systems such as disease registries and public health surveillance. Uses of health records for other purposes such as teaching, clinical audit, administration and reporting, service management, research and epidemiology, which often require anonymization or aggregation of individual records, are not the focus of this part of ISO 13606 but such secondary uses might also find this document useful.

This part of the multipart series, ISO 13606, is an information viewpoint specification as defined in ISO/IEC 10746-1[13]. This part of ISO 13606 is not intended to specify the internal architecture or database design of EHR systems.

2 Normative references

The following referenced documents are indispensable for the application 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.

CEN/TS 14796:2004, *Health Informatics — Data Types*

3 Terms and definitions

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

3.1
abstract class
virtual common parent to two or more classes which cannot itself be instantiated

3.2
access control
means of ensuring that the resources of a data processing system can be accessed only by authorized entities in authorized ways

[ISO/IEC 2382-8:1998, definition 08.04.01]

3.3
accountability
property that ensures that the actions of an entity may be traced uniquely to that entity

[ISO/IEC 2382-8:1998, definition 08.01.10]

3.4
archetype instance
metadata class instance of an archetype model, specifying the clinical concept and the value constraints that apply to one class of record component instances in an electronic health record extract

3.5
archetype model
information model of the metadata to represent the domain-specific characteristics of electronic health record entries by specifying values or value constraints for classes and attributes in the electronic health record reference model

3.6
archetype repository
persistent repository of archetype definitions, accessed by a client authoring tool or by a run-time component within an electronic health record service

3.7
attester
party (person) who certifies and records legal responsibility for a particular unit of information

3.8
attestation
process of certifying and recording legal responsibility for a particular unit of information

3.9
audit trail
chronological record of activities of information system users which enables prior states of the information to be faithfully reconstructed

3.10
authentication
process of reliably identifying security subjects by securely associating an identifier and its authenticator

3.11
authorization
granting of rights

3.12
client application
healthcare application that is behaving at that moment as a requester of health record data from a shareable electronic health record

3.13
clinical information
information about a person, relevant to his or her health or healthcare

3.14
committed
information that has been persisted within an electronic health record system and which constitutes part of the electronic health record of a subject of care

3.15
committer
agent (party, device or software) whose direct actions have resulted in data being committed to an electronic health record

3.16
composer
agent (party, device or software) responsible for creating, synthesising or organizing information that is committed to an electronic health record

NOTE This agent takes responsibility for its inclusion in that electronic health record, even if not the originator of it and even if not the committer of it.

3.17
confidentiality
property that information is not made available or disclosed to unauthorized individuals, entities or processes

[ISO 7498-2:1989]

3.18
contribution
set of record components committed by one user at one point in time in the electronic health record of one subject of care

3.19
digital signature
data appended to, or a cryptographic transformation of, a data unit that allows a recipient of the data unit to prove the source and integrity of the unit and protect against forgery e.g. by the recipient

[ISO 7498-2:1989, definition 3.3.16]

3.20
distributed processing
information processing in which discrete components may be located in different places, or where communication between components may suffer delay or may fail

3.21
electronic health record extract
part or all of the electronic health record of a subject of care, communicated in compliance with this part of ISO 13606

3.22
electronic health record information architecture
ODP information viewpoint specification of an electronic health record

3.23
electronic health record provider
entity in legitimate possession of electronic health record data and in a position to communicate it to another appropriate entity

3.24
electronic health record recipient
entity to whom electronic health record data is communicated by an electronic health record provider

3.25
electronic health record requester
entity initiating a request for electronic health record communication to take place between an electronic health record provider and an electronic health record recipient

3.26
electronic health record system
system for recording, retrieving and manipulating information in electronic health records

3.27
entries
health record data in general (clinical observations, statements, reasoning, intentions, plans or actions) without particular specification of their formal representation, hierarchical organization or of the particular record component class(es) that might be used to represent them

3.28
federated health record
virtual view of a patient's health record that can be obtained from all electronic health record entries about that patient that are held by different systems in communication using standard electronic health record extracts

3.29
feeder system
repository (for health record data) that may be queried within a federation of electronic health record systems in order to contribute to a federated health record

3.30
generic
applicable to requirements or information models across healthcare professions, domains and countries

3.31
healthcare agent
person, device, or software that performs a role in a healthcare activity

[EN 13940-1:2005]

3.32
healthcare device
device or equipment involved in the direct or indirect provision of healthcare services to an individual or to a population

3.33
healthcare organization
organization involved in the direct or indirect provision of healthcare services to an individual or to a population

3.34
healthcare party
person involved in the direct or indirect provision of healthcare services to an individual or to a population

3.35
healthcare service
service provided with the intention of directly or indirectly improving the health of the person or populations to whom it is provided

3.36
legacy data
data that were collected and maintained using a “previous” system, but are now preserved on a “current” system

3.37
metadata
data that define object class and property for the information collected

3.38
non-repudiation
service providing proof of the integrity and origin of data (both in an unforgeable relationship), which can be verified by any party

[ISO/TS 17090-1:2002, definition 3.2.21]

3.39
patient
synonym for a subject of care

3.40
persistent data
data which are stored on a permanent basis

3.41
personal health record
health record for which the subject of care or a legal representative of the subject of care is the data controller

3.42
privacy
freedom from intrusion into the private life or affairs of an individual when that intrusion results from undue or illegal gathering and use of data about that individual

[ISO/IEC 2382-8:1998, definition 08.01.23]

3.43
record component
part of the electronic health record extract of a single subject of care, represented as a node within a hierarchical data structure conforming to this part of ISO 13606

3.44
role
set of behaviours that is associated with a task

[ISO/TS 17090-1:2002, definition 3.2.24]

3.45
semantic interoperability
ability for data shared by systems to be understood at the level of fully defined domain concepts

[ISO/TS 18308:2004, definition 3.38]

3.46
shareable electronic health record
electronic health record with a standardized information model which is independent of electronic health record systems and accessible by multiple authorized users

[adapted from ISO/TR 20514:2005, definition 2.33]

3.47
standard
document, established by consensus and approved by a recognised body, which provides, for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context

[ISO/IEC Guide 2:2004, definition 3.2]

3.48
state
〈of a process〉 condition or situation during the lifecycle of an object during which it satisfies some condition, performs some activity or waits for some event

[ISO/TS 18308:2004, definition 3.39]

3.49
subject of care
person scheduled to receive, receiving, or having received healthcare

3.50
view
alternate presentation of data for a different user or purpose

4 Abbreviations

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

— **CEN**: Comité Européen de Normalisation (European Committee for Standardization) a federation of 28 national standards bodies that are also ISO member bodies

— **CEN/TC 251**: CEN Technical Committee 251 (develops standards within health informatics)

— **CMET**: Common Message Element Type (a formalism defined by HL7)

— **EHCR**: Electronic Healthcare Record

— **EHR**: Electronic Health Record

— **EU**: European Union

— **GEHR**: Good European Health Record (a research project, 1992-5)

— **GP**: General Practitioner

— **HISA**: Health Informatics Service Architecture (acronym used for EN 12967[17])

— **HL7**: Health Level Seven

— **IANA**: Internet Assigned Numbers Authority

— **IETF**: Internet Engineering Task Force

— **ISO**: International Organization for Standardization

— **ODP**: Open Distributed Processing (ISO/IEC 10746-1[13], used for describing distributed systems)

— **OID**: Object Identifier
— **R&D**: Research and Development
— **RFC**: Request For Comments
— **UML**: Unified Modelling Language
— **W3C**: World Wide Web Consortium
— **XML**: Extensible Mark-up Language

5 Conformance

5.1 EHR System conformance

5.1.1 A system for communication of EHR information is conformant with this part of ISO 13606 if all information that is exchanged which is within the scope of this part of ISO 13606 can be expressed in a form where there is a direct correspondence between the communicated data structure and the information model of an EHR_EXTRACT defined in Clause 6 herein using UML. ISO 13606-5 specifies different exchange models.

5.1.2 Some conformant EHR systems will use only a subset of the many optional classes, attributes and data types defined in this part of ISO 13606, according to the intended uses. For a sending system this will be determined by the EHR data that can be stored in that system. An EHR receiving system that is fully conformant needs either to be able to handle all possible information that can be expressed using this part of ISO 13606 or to declare its limitations of scope. Also, when all information classes and attributes are implemented, it is necessary to declare the limitations of the semantic interoperability of an EHR system conformant to this part of ISO 13606 in relation to the use of terminology systems and e.g. various encapsulated objects.

5.1.3 It is recommended that a conformance declaration be made where the following items may serve as a guide for what this shall contain:

a) identification of the product/system;

b) intended use or uses of the system (e.g. if this is a special purpose EHR, a primary care or hospital, or limited to a particular clinical domain);

c) if it is capable of sending or receiving EHR_EXTRACTS, or both;

d) declaration of a subset of classes from the standard that is used;

e) declaration of the use of Data Types;

f) declaration of the associated terminology systems that are used;

g) specification of the syntax or syntaxes supported for the expression of the EHR_EXRACT (this may, for instance, specify specific XML schemata).

5.2 Member country conformance

5.2.2 If national legislation is in conflict with any provision of Clause 6 of this part of ISO 13606, then conformance to nominated parts of the model and text in Clause 6 may be waived. The specification of these changes will be called a national profile and is specific for a member country.

5.2.3 This national profile shall be used for conformance testing in that member country.

5.2.4 For the purpose of complying with this conformance statement, national standards bodies shall notify ISO/TC 215 when a national profile is needed and used for conformance testing in their jurisdictions.

5.2.5 The notification in English shall contain all the relevant parts of the national legislation, the resulting requirements, all needed and applied changes to the model and text of Clause 6 of this part of ISO 13606 plus the date of acceptance of this national profile by the national standards bodies of that member country.

5.2.6 ISO/TC 215 shall publish the notification of this national profile.

6 Reference model

6.1 Index to packages

NOTE This index is provided as a clickable resource for those reading this document electronically. The order within packages is alphabetic to aid navigation. The tabular specification details that follow are in diagram order.

6.2 Package: EXTRACT package

6.2.1 General

Inner elements	
Name	**Type**
ATTESTATION_INFO	Class
AUDIT_INFO	Class
CLUSTER	Class
COMPOSITION	Class
CONTENT	Class
EHR_EXTRACT	Class
ELEMENT	Class
ENTRY	Class
EXTRACT_CRITERIA	Class
FOLDER	Class
FUNCTIONAL_ROLE	Class
ITEM	Class
LINK	Class
RECORD_COMPONENT	Class
RELATED_PARTY	Class
SECTION	Class

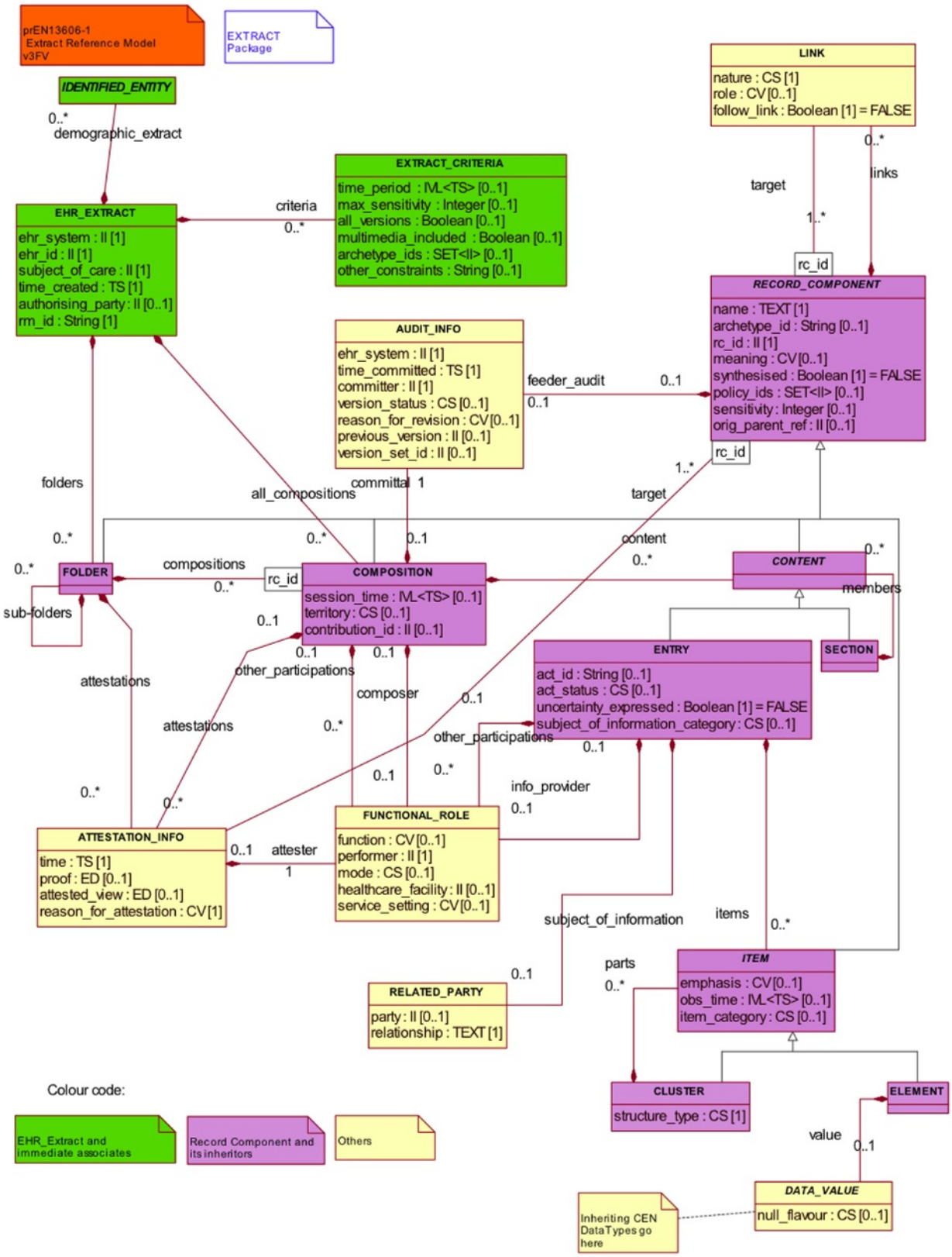


Figure 3 — UML class diagram of extract package

Package: EXTRACT Package

6.2.2 Class EHR_EXTRACT

This class represents the root node of an EHR Extract: part or all of the health record information extracted from an EHR Provider system for the purposes of communication to an EHR Recipient (which might be another repository, a client application or a middleware service such as an electronic guideline component).

Attributes			
Signature	**Optionality**	**Multiplicity**	**Documentation**
authorizing_party:II	0..1	N/A	Agent authorizing the EHR Extract to be created and communicated. This attribute is optional since some extracts might be created automatically between (authorized) interacting computing services.
ehr_id:II	1	N/A	The identity of the EHR from which this EHR Extract has been created. It shall be unique for that EHR Provider system for this subject of care.
ehr_system:II	1	N/A	The identity of the EHR Provider system from which this EHR Extract has been created.
rm_id:String	1	N/A	The identity and version of the reference model standard under which this EHR_EXTRACT was made. For an EHR Extract conforming to this part of ISO 13606 the attribute will have the string value “ISO 13606”.
subject_of_care:II	1	N/A	Unique identifier of the subject of care from whose EHR this EHR Extract was created, as defined by the EHR Provider system.
time_created:TS	1	N/A	The date and time at which data from this subject of care’s EHR was queried or exported in order to create this EHR Extract.

Attributes from associations			
Signature	**Optionality**	**Multiplicity**	**Documentation**
all_compositions:Set<COMPOSITION>	0..1	0..*	All COMPOSITIONS included in this EHR_EXTRACT are included by value through this association.
criteria:Set<EXTRACT_CRITERIA>	0..1	0..*	The set of criteria by which the EHR of the subject of care was queried or filtered in order to generate this EHR_EXTRACT. These might not correspond directly to the criteria supplied in an EHR_EXTRACT Request.
folders:Set<FOLDER>	0..1	0..*	The FOLDER hierarchy contained within the EHR_EXTRACT; each FOLDER may contain a set of rc_ids that reference COMPOSITIONs and/or other FOLDERs.
demographic_extract: Set<IDENTIFIED_ENTITY>	0..1	0..*	An optional set of demographic descriptors corresponding to relevant identifiers used within other parts of this EHR_EXTRACT to reference persons, organizations, devices or software.

Package: EXTRACT Package

6.2.3 Class EXTRACT_CRITERIA

The attributes of this class list the constraints or restrictions that were placed on the query or filter process that created this EHR_EXTRACT. The EHR Recipient is only required to retain this information after receipt of this EHR_EXTRACT if it might subsequently be communicated again with the same content.

Attributes			
Signature	**Optionality**	**Multiplicity**	**Documentation**
all_versions:Boolean	0..1	N/A	This attribute indicates if this EHR_EXTRACT is limited to the most recent version of each COMPOSITION or if it includes all historic versions.
archetype_ids:SET<II>	0..1	N/A	This attribute identifies a set of archetypes if these were used as a basis for selecting data to include in this EHR_EXTRACT.
max_sensitivity :Integer	0..1	N/A	This attribute specifies the maximum permitted sensitivity level (extent of authorization) that was used to extract the data from the EHR provider system.
multimedia_included :Boolean	0..1	N/A	This attribute indicates if multimedia data have deliberately been excluded from this EHR_EXTRACT.
other_constraints:String	0..1	N/A	This attribute may be used to represent additional criteria that were used; it is primarily intended for human readership, but might be used for locally-agreed structured criteria.
time_period :IVL<TS>	0..1	N/A	This attribute specifies a date or time interval to which this EHR_EXTRACT is limited.

Package: EXTRACT Package

6.2.4 Class RECORD_COMPONENT{Abstract}

Direct Subclassifiers:
CONTENT, COMPOSITION, ITEM, FOLDER

This abstract class is the super-class of all of the concrete nodes in the EHR hierarchy: FOLDER, COMPOSITION, SECTION, ENTRY, CLUSTER, ELEMENT, and of two abstract class nodes: CONTENT and ITEM.

Attributes			
Signature	**Optionality**	**Multiplicity**	**Documentation**
archetype_id: String	0..1	N/A	The unique identifier of the archetype node to which this RECORD_COMPONENT corresponds, either in the EHR Provider system or as a mapping produced when this EHR_EXTRACT was created. The syntax for populating this attribute value is defined in ISO 13606-2.
meaning:CV	0..1	N/A	The standardized clinical or administrative concept to which the name attribute has been mapped. In archetyped systems it will correspond to the archetype node name. In non-archetyped systems it might be a coded term from an appropriate terminology system.
name:TEXT	1	N/A	The name, expressed as a coded value or as plain text, specifies the clinical or administrative concept to which this EHR node corresponds, as labelled in the EHR system in which it was first committed.
orig_parent_ref:II	0..1	N/A	The identity of the RECORD_COMPONENT that is the original parent (context) for this RECORD_COMPONENT, to be present if this information has been copied from another part of the EHR of this subject of care.
policy_ids:SET<II>	0..1	N/A	This attribute identifies one or more access control policies that specifically pertain to this RECORD_COMPONENT and which need to be communicated to the EHR Recipient to govern future access to it. The identifiers may refer to policy information included in this EHR_EXTRACT as defined in ISO 13606-4, or to policies held in external policy servers to which the EHR Recipient has access.
rc_id:II	1	N/A	The globally-unique identifier by which this node in the EHR hierarchy is referenced in the EHR system to which the data were first committed. This identifier shall be retained by the EHR Recipient and re-used whenever this RECORD_COMPONENT is subsequently included in another EHR_EXTRACT.
sensitivity:Integer	0..1	N/A	The sensitivity of this RECORD_COMPONENT, represented using the code set for this attribute defined in ISO 13606-4.
synthesised:Boolean	1	N/A	This attribute value shall be TRUE if this RECORD_COMPONENT has been created in order to comply with this part of ISO 13606, but this point in the EHR hierarchy has no corresponding node in the EHR from which it was extracted.

Attributes from associations				
Signature		**Optionality**	**Multiplicity**	**Documentation**
	links:Set<LINK>	0..1	0..*	Any RECORD_COMPONENT may have zero or more semantic links to other RECORD_COMPONENTs.
feeder_audit:AUDIT_INFO		0..1	N/A	This association represents the committal and revision information specifically for this RECORD_COMPONENT in the EHR system in which it was originally committed. This association may be omitted if this RECORD_COMPONENT shares the same committal information as its parent RECORD_COMPONENT. In the case of a COMPOSITION, this association may also be omitted if the EHR Provider system is its originating system (since the data will be identical to that represented via the committal association).

Package: EXTRACT Package

6.2.5 Class FOLDER

RECORD_COMPONENT
|
+--**FOLDER**

The FOLDER class may be used to organize and group COMPOSITIONs within an EHR_EXTRACT. This hierarchy might correspond to or resemble the high-level organization of the EHR within the EHR Provider system, or have been created specifically for this EHR_EXTRACT.

Attributes from associations			
Signature	**Optionality**	**Multiplicity**	**Documentation**
sub-folders:Set<FOLDER>	0..1	0..*	This association permits the representation of a FOLDER hierarchy.
attestations:Set<ATTESTATION_INFO>	0..1	0..*	This association permits a FOLDER to contain any number of attestations that pertain to it or to its contents.
compositions:Set<COMPOSITION>	0..1	0..*	This association qualifier references a set of logically-contained COMPOSITIONS via their rc_ids.

Package: EXTRACT Package

6.2.6 Class COMPOSITION

RECORD_COMPONENT
|
+--**COMPOSITION**

A COMPOSITION represents the set of RECORD_COMPONENTS composed (authored) during one clinical encounter or documentation session, and committed within one EHR.

Attributes			
Signature	**Optionality**	**Multiplicity**	**Documentation**
contribution_id:II	0..1	N/A	This optional identifier may be used to logically group the set of COMPOSITIONs committed by one user at one point in time in the EHR of one subject of care, if an EHR system has permitted data to be committed simultaneously into multiple COMPOSITIONs.
session_time:IVL<TS>	0..1	N/A	The date and time or interval during which the clinical encounter or documentation session occurred.
territory:CS	0..1	N/A	Code for the territory in which this COMPOSITION was created, identified by ISO 3166. This will indicate the country under whose laws this COMPOSITION was created.

Attributes from associations			
Signature	**Optionality**	**Multiplicity**	**Documentation**
attestations:Set<ATTESTATION_INFO>	0..1	0..*	This association permits a COMPOSITION to contain any number of attestations that pertain to it or to its contents.
other_participations:Set<FUNCTIONAL_ROLE>	0..1	0..*	This association permits the representation of any other agents who have contributed to this clinical encounter or documentation session.
committal:AUDIT_INFO	1	N/A	This mandatory association contains the committal (and optionally revision) information for this COMPOSITION in the EHR Provider's system.
content:Set<CONTENT>	0..1	0..*	This association contains the set of SECTIONs and ENTRYs that are part of this COMPOSITION. A COMPOSITION may have no content if it is a revision of a COMPOSITION previously recorded in error.
composer:FUNCTIONAL_ROLE	0..1	N/A	Agent (person, device or software) responsible for creating, synthesising or organizing information that is committed to an EHR. This agent takes responsibility for its inclusion in that EHR, even if not the originator of it and even if not the committer of it. The content of the COMPOSITION is primarily attributed to this person. Whether or not the composer is changed when a revision is made is optional, usually depending upon the extent of the changes made.

Constraints		
Name	**Expression**	**Documentation**
TERRITORY	inv: territory.coding_scheme_name = "ISO 3166"	(none)

Package: EXTRACT Package

6.2.7 Class CONTENT{Abstract}

RECORD_COMPONENT
|
+--**CONTENT**

Direct Subclassifiers:
ENTRY, SECTION

This class is the abstract parent of SECTION and ENTRY, which constitute the EHR data content of a COMPOSITION.

Package: EXTRACT Package

6.2.8 Class SECTION

CONTENT
|
+--**SECTION**

SECTION contains the set of ENTRYs and optionally further SECTIONs that are grouped under one clinical heading.

Attributes from associations			
Signature	**Optionality**	**Multiplicity**	**Documentation**
members:Set<CONTENT>	0..1	0..*	This association permits a SECTION to contain other SECTIONs and/or ENTRYs.

Package: EXTRACT Package

6.2.9 Class ENTRY

CONTENT
|
+--**ENTRY**

The ENTRY class contains (as ITEMs) the information acquired and recorded for a single observation or observation-set (battery or time series), a single clinical statement such as a portion of the patient's history or an inference or assertion, or a single action that is intended or has actually been performed. An ENTRY may have zero ITEMs if it is a revision of an ENTRY previously recorded in error.

Attributes			
Signature	**Optionality**	**Multiplicity**	**Documentation**
act_id:String	0..1	N/A	The identifier value of this attribute relates this ENTRY, if it documents an activity, to an act management or workflow system.
act_status:CS	0..1	N/A	This attribute represents the action state of the ENTRY if it is an activity being managed by an act management or workflow system. The code set for this attribute is defined in ISO 13606-3.
subject_of_information_category:CS	0..1	N/A	The relationship category of person or object about whom the information in this ENTRY relates to the subject of care. The code set for this attribute is defined in ISO 13606-3. An ENTRY about more than one information subject shall be duplicated per subject within the EHR_EXTRACT.
uncertainty_expressed:Boolean	1	N/A	This attribute is set to TRUE to advise the EHR Recipient that this ENTRY contains data that indicates some degree of uncertainty, and that care should be taken when using these data within automated processes and systems.

Attributes from associations			
Signature	**Optionality**	**Multiplicity**	**Documentation**
items:Set<ITEM>	0..1	0..*	This association contains the data structure and values of the ENTRY.
info_provider:FUNCTIONAL_ROLE	0..1	N/A	Person, software or device that has provided the information documented in this ENTRY. The agent need not be specified if the information source is implicit from the clinical context or the participants identified for the COMPOSITION.
other_participations:Set<FUNCTIONAL_ROLE>	0..1	0..*	This association represents any other agents who have contributed to the health or healthcare processes documented within this ENTRY.
subject_of_information:RELATED_PARTY	0..1	N/A	The relationship to the subject of care, and optionally the identifier, of the person or object about whom the information in this ENTRY relates.

Constraints		
Name	**Expression**	**Documentation**
ACT_STATUS	inv: act_status.coding_scheme_name = 'CEN/TC251/EN13606-3:ACT_STATUS'	(none)
SUBJECT_CATEGORY	inv: subject_of_information_category.coding_scheme_name = 'CEN/TC251/EN13606-3:SUBJECT_CATEGORY'	(none)

Package: EXTRACT Package

6.2.10 Class ITEM{Abstract}

RECORD_COMPONENT
|
+--**ITEM**

Direct subclassifiers:
ELEMENT, CLUSTER

This class is the abstract parent of CLUSTER and ELEMENT, which represent the data structure and values contained by an ENTRY.

Attributes			
Signature	**Optionality**	**Multiplicity**	**Documentation**
emphasis:CV	0..1	N/A	A way of denoting that the composer wished to mark this ITEM as being of particular note (an unusual measurement value, an unexpected outcome, anything that might be considered necessary to highlight to a future reader).
item_category:CS	0..1	N/A	This attribute value may be used to classify or logically group sub-components of the ITEM data structure, to distinguish core values from the method of investigation, the patient state etc. The code set for this attribute is defined in ISO 13606-3.
obs_time:IVL<TS>	0..1	N/A	The date and time, or interval, at which the ITEM actually occurred or was true, if different from the session time of the COMPOSITION.

Constraints		
Name	**Expression**	**Documentation**
ITEM_CATEGORY	inv:item_category.coding_scheme_name = 'CEN/TC251/EN13606-3:ITEM_CATEGORY'	(none)

Package: EXTRACT Package

6.2.11 Class CLUSTER

ITEM
|
+--**CLUSTER**

This class represents the hierarchical organization of the data structure of each ITEM within an ENTRY, to permit the nesting or grouping of ELEMENTs with the same obs_time, or of one item_category or to organize rows of tabular data.

Attributes			
Signature	**Optionality**	**Multiplicity**	**Documentation**
structure_type:CS	1	N/A	This will indicate the time and/or spatial organization of the data within this CLUSTER. The code set for this attribute is defined in ISO 13606-3.

Attributes from associations			
Signature	**Optionality**	**Multiplicity**	**Documentation**
parts:Set<ITEM>	0..1	0..*	This association permits a CLUSTER to contain other CLUSTERs and/or ELEMENTs.

Constraints		
Name	**Expression**	**Documentation**
STRUCTURE_TYPE	inv: structure_type.coding_scheme_name = 'CEN/TC251/EN13606-3:STRUCTURE_TYPE'	(none)

Package: EXTRACT Package

6.2.12 Class ELEMENT

ITEM
|
+--**ELEMENT**

This class represents the leaf nodes within the EHR hierarchy. Each instance of this class will have a single data value, which is one of a defined set of data types.

Attributes from associations			
Signature	**Optionality**	**Multiplicity**	**Documentation**
value:DATA_VALUE	0..1	N/A	An ELEMENT has a single DATA_VALUE containing the value, unless this is indicated as absent by a null_flavour attribute.

Package: EXTRACT Package

6.2.13 Class AUDIT_INFO

This class represents the committal and revision data about a RECORD_COMPONENT. Through the committal association from COMPOSITION this class represents the committal and revision data about this COMPOSITION in the EHR Provider system. Through the feeder_audit association from RECORD_COMPONENT this class represents the committal and revision data about this RECORD_COMPONENT in the original EHR system in which it was first committed.

Attributes			
Signature	**Optionality**	**Multiplicity**	**Documentation**
committer:II	1	N/A	The party responsible for committing this RECORD_COMPONENT within the EHR of this subject of care.
ehr_system:II	1	N/A	This attribute identifies the EHR system in which this RECORD_COMPONENT was committed.
previous_version:II	0..1	N/A	This attribute is the rc_id of the RECORD_COMPONENT of which the current RECORD_COMPONENT is a revision. If this attribute is null, there is no previous version (i.e. it is the very first version).
reason_for_revision:CV	0..1	N/A	A code for the reason for assigning the current version status.
time_committed:TS	1	N/A	Date and time at which this RECORD_COMPONENT was committed within the identified EHR system and therefore became part of that EHR of the subject of care.
version_set_id:II	0..1	N/A	This attribute value is the rc_id of the very first version of this RECORD_COMPONENT. This attribute may be null if this RECORD_COMPONENT is the very first version.
version_status:CS	0..1	N/A	The medico-legal status of this version of the RECORD_COMPONENT. The code set for this attribute is defined in ISO 13606-3.

Constraints		
Name	**Expression**	**Documentation**
VERSION_STATUS	inv:attribute_version_status.coding_scheme_name = 'CEN/TC251/EN13606-3:VERSION_STATUS'	(none)

Package: EXTRACT Package

6.2.14 ATTESTATION_INFO

This class documents the details of any attestations that pertain to the RECORD_COMPONENTS within a FOLDER or COMPOSITION.

Attributes			
Signature	**Optionality**	**Multiplicity**	**Documentation**
attested_view:ED	0..1	N/A	The encapsulated data, or a reference to it, that represents the reproducible rendering (image or presentation specification) that was actually viewed by the attester.
proof:ED	0..1	N/A	The electronic signature (as encapsulated data, or as reference to it) that verifies the attestation. This is optional as it may not always be required when communicating EHR_EXTRACTS, particularly within a single health service.
reason_for_attestation:CV	1	N/A	A coded value giving the reason for this attestation, to define its specific purpose or the legal requirement it meets.
time:TS	1	N/A	The date and time at which this attestation occurred.

Attributes from associations			
Signature	**Optionality**	**Multiplicity**	**Documentation**
target:Set<RECORD_COMPONENT>	1	1..*	The rc_id(s) of the RECORD_COMPONENT(s) that was/were attested.
attester:FUNCTIONAL_ROLE	1	N/A	The identification and role of the person making the attestation.

Package: EXTRACT Package

6.2.15 Class FUNCTIONAL_ROLE

This class is used to document the participation of a person, device or software component in some activity recorded in the EHR.

Attributes			
Signature	**Optionality**	**Multiplicity**	**Documentation**
function:CV	0..1	N/A	A coded representation of the function or role that was performed.
healthcare_facility:II	0..1	N/A	The organization at which the role was performed.
mode:CS	0..1	N/A	The mechanism by which that participation was made. The code set for this attribute is defined in ISO 13606-3.
performer:II	1	N/A	The identity of the agent performing that the function or role.
service_setting:CV	0..1	N/A	The type of service location at which the role was performed.

Constraints		
Name	**Expression**	**Documentation**
FUNCTIONAL_ROLE_MODE	inv:mode.coding_scheme_name = 'CEN/TC251/EN13606-3:FUNCTIONAL_ROLE'	(none)

Package: EXTRACT Package

6.2.16 Class RELATED_PARTY

This class is provided, for ENTRY.subject_of_information, to identify a person in terms of his or her relationship to the subject_of_care.

Attributes			
Signature	**Optionality**	**Multiplicity**	**Documentation**
party:II	0..1	N/A	The optional personal identification of the related party.
relationship:TEXT	1	N/A	The relationship of the Related_Party to the subject of care.

Package: EXTRACT Package

6.2.17 Class LINK

The LINK class defines the semantics of a non-containment relationship between two RECORD_COMPONENTs. A source RECORD_COMPONENT may have links to any number of target RECORD_COMPONENTs.

Attributes			
Signature	**Optionality**	**Multiplicity**	**Documentation**
follow_link:Boolean	1	N/A	If this attribute is TRUE then the COMPOSITION that contains the target RECORD_COMPONENT shall be included in this EHR_EXTRACT.
nature:CS	1	N/A	The general semantic category of the link that is being declared between two RECORD_COMPONENTS. The code set for this attribute is defined in ISO 13606-3.
role:CV	0..1	N/A	The detailed semantic description of the relationship of the target RECORD_COMPONENT to the source RECORD_COMPONENT. An optional code set for this attribute is defined in ISO 13606-3.

Attributes from associations			
Signature	**Optionality**	**Multiplicity**	**Documentation**
target:Set<RECORD_COMPONENT>	1	1..*	The rc_id of the RECORD_COMPONENT that is the target of the link.

6.3 Package: DEMOGRAPHICS package

6.3.1 General

Inner Elements	
Name	**Type**
_self - S.276.1107.04.24ENTITY_NAME	Class
_self - S.276.1107.04.27ENTITY_NAME_PART	Class
_self - S.276.1107.04.56HEALTHCARE_PROFESSIONAL_ROLE	Class
_self - S.276.1107.04.7IDENTIFIED_ENTITY	Class
_self - S.276.1107.04.38IDENTIFIED_HEALTHCARE_PROFESSIONAL	Class
_self - S.276.1107.04.62ORGANIZATION	Class
_self - S.276.1107.04.69PERSON	Class
_self - S.276.1107.04.31POSTAL_ADDRESS	Class
_self - S.276.1107.04.35POSTAL_ADDRESS_PART	Class
_self - S.276.1107.04.52SOFTWARE_OR_DEVICE	Class
_self - S.276.1107.04.12SUBJECT_OF_CARE_PERSON_IDENTIFICATION	Class
_self - S.276.1107.04.65TELECOM	Class

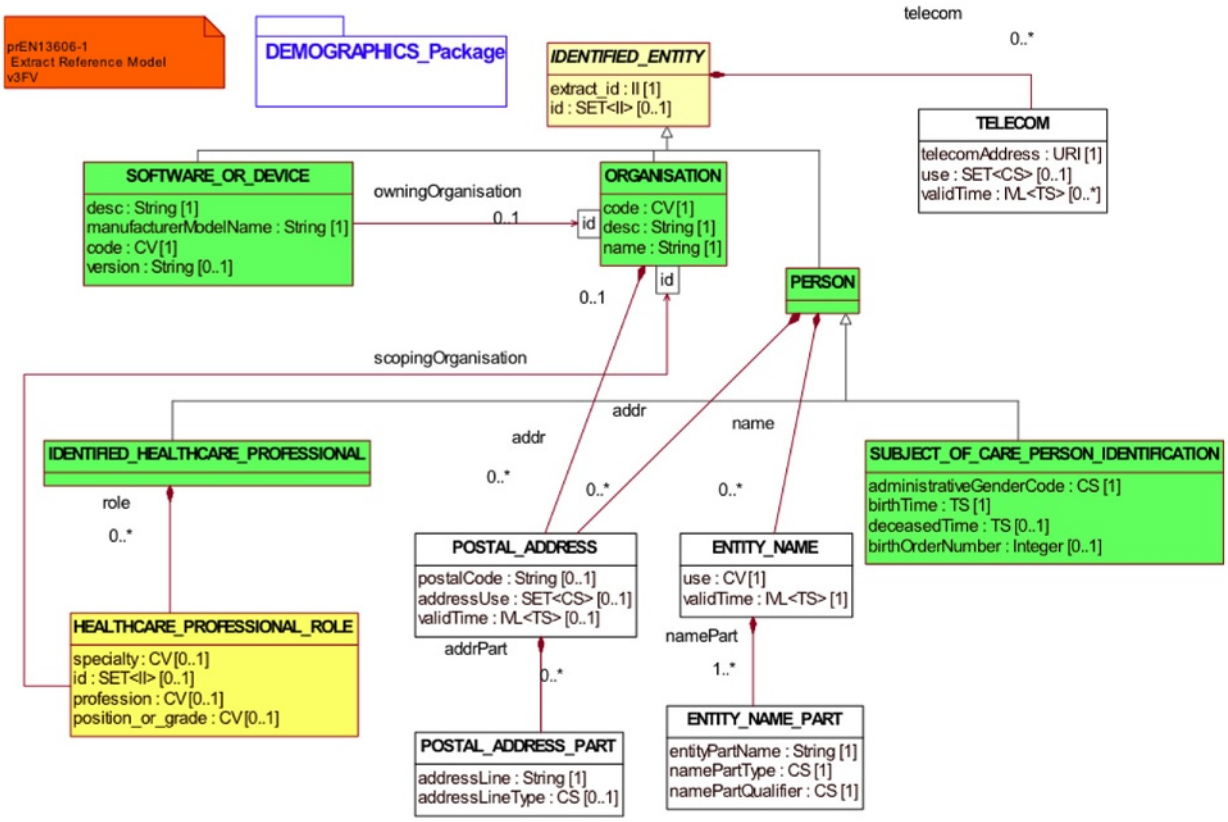


Figure 4 — UML class diagram of the demographics package

Package: DEMOGRAPHICS Package

6.3.2 Class IDENTIFIED_ENTITY{Abstract}

Direct subclassifiers:

SOFTWARE_OR_DEVICE, ORGANIZATION, PERSON

Any identified party, which may be an organization, person, or device or software.

Attributes			
Signature	**Optionality**	**Multiplicity**	**Documentation**
extract_id:II	1	N/A	The unique identifier used consistently within the extract package of this EHR_EXTRACT to represent the IDENTIFIED_ENTITY referred to in this demographics package.
id:	0..1	N/A	An optional set of identifiers by which this IDENTIFIED_ENTITY may be referenced within EHR systems, by health services, professional bodies etc., to support demographic matching of this IDENTIFIED_ENTITY by the EHR recipient.

Attributes from Associations			
Signature	**Optionality**	**Multiplicity**	**Documentation**
telecom:Set<TELECOM>	0..1	0..*	A set of communications descriptors by which this IDENTIFIED_ENTITY may be contacted or connected to.

Package: DEMOGRAPHICS Package

6.3.3 Class SOFTWARE_OR_DEVICE

```
IDENTIFIED_ENTITY
|
+--SOFTWARE_OR_DEVICE
```

Description of a piece of equipment or device. (Corresponds to GPIC 2.055)

Attributes			
Signature	**Optionality**	**Multiplicity**	**Documentation**
code:CV	1	N/A	Code used to describe the type of device/equipment.
desc:String	1	N/A	String used to provide details of the device type or additional information to support the coded device type information.
manufacturerModelName:String	1	N/A	Name of the model and possibly its version as designated by the manufacturer.
version:String	0..1	N/A	(none)

Attributes from associations			
Signature	**Optionality**	**Multiplicity**	**Documentation**
owningOrganization:ORGANIZATION	0..1	N/A	The name and identity of the organization owning this instance of the device or software; this is usually the organization in which it was used.

Package: DEMOGRAPHICS Package

6.3.4 Class ORGANIZATION

```
IDENTIFIED_ENTITY
|
+--ORGANIZATION
```

Information about an organization. (Corresponds to GPIC 2008)

Attributes			
Signature	**Optionality**	**Multiplicity**	**Documentation**
code:CV	1	N/A	Nature of business or specialty of the organization EXAMPLES nursing home, pathology department.
desc:String	1	N/A	Free text description of the organization.
name:String	1	N/A	A name that is commonly used as a descriptor or label for the organization.

Attributes from associations			
Signature	**Optionality**	**Multiplicity**	**Documentation**
addr:Set<POSTAL_ADDRESS>	0..1	0..*	This association permits the representation of any number of addresses for this organization.

Package: DEMOGRAPHICS Package

6.3.5 Class PERSON

IDENTIFIED_ENTITY
|
+--**PERSON**

Direct subclassifiers:
IDENTIFIED_HEALTHCARE_PROFESSIONAL, SUBJECT_OF_CARE_PERSON_IDENTIFICATION

General demographic information about a person. (Corresponds to GPIC 2.006.)

Attributes from associations			
Signature	**Optionality**	**Multiplicity**	**Documentation**
name:Set<ENTITY_NAME>	0..1	0..*	This association represents the name(s) by which this person is known.
addr:Set<POSTAL_ADDRESS>	0..1	0..*	This association permits the representation of any number of addresses for this person.

Package: DEMOGRAPHICS Package

6.3.6 Class IDENTIFIED_HEALTHCARE_PROFESSIONAL

PERSON
|
+--**IDENTIFIED_HEALTHCARE_PROFESSIONAL**

Provides a means of referencing an identified healthcare professional. (Based on GPIC 2.034 but with a more detailed role association.)

Attributes from associations			
Signature	**Optionality**	**Multiplicity**	**Documentation**
role:Set<HEALTHCARE_PROFESSIONAL_ROLE>	0..1	0..*	This association permits an IDENTIFIED_HEALTHCARE_PROFESSIONAL to be associated with any number of roles, which may be scoped (authorized) by one or more organizations.

Package: DEMOGRAPHICS Package

6.3.7 Class HEALTHCARE_PROFESSIONAL_ROLE

Describes the role played by the person as a healthcare professional. (Based on the GPICS class of the same name but with the added association to IdentifiedOrganization.)

Attributes			
Signature	**Optionality**	**Multiplicity**	**Documentation**
id:SET<II>	0..1	N/A	One or more identifiers for the person acting in this particular role as a healthcare professional. NOTE A healthcare professional may be associated with different identifiers when operating in different environments. For example, the identifier for Dr Schmidt may be different when she is in her GP surgery than when she is working in an antenatal clinic.
position_or_grade:CV	0..1	N/A	Job title for the healthcare professional EXAMPLES chief nurse, junior house officer.
profession:CV	0..1	N/A	The position or nature of the job carried out by the healthcare professional. EXAMPLES nurse, surgeon, general practitioner.
specialty:CV	0..1	N/A	Code representing the specialty within which the healthcare professional is operating. EXAMPLES dermatology, general medicine.

Attributes from associations			
Signature	**Optionality**	**Multiplicity**	**Documentation**
scopingOrganization:ORGANIZATION	0..1	N/A	The organization in which this role may be fulfilled, and which might also have authorized this role.

Package: DEMOGRAPHICS Package

6.3.8 Class SUBJECT_OF_CARE_PERSON_IDENTIFICATION

PERSON
|
+--**SUBJECT_OF_CARE_PERSON_IDENTIFICATION**

Information about a person that may be used for identification purposes. (Corresponds to GPIC 2.015.)

Attributes			
Signature	**Optionality**	**Multiplicity**	**Documentation**
administrativeGenderCode:CS	1	N/A	Gender of the patient, for administrative purposes (not necessarily for clinical purposes). VALUES: 0 = male 1 = female 2 = intersex 9 = unknown.
birthOrderNumber:Integer	0..1	N/A	For newborn patients in a multiple birth, the order in which this patient was born.
birthTime:TS	1	N/A	Date and time of birth. NOTE The birth time may be expressed as a time, date or just a year.
deceasedTime:TS	0..1	N/A	Date and time of death.

Package: DEMOGRAPHICS Package

6.3.9 Class TELECOM

(Corresponds to GPIC Common Access Group.) Locator for some resource (information or services) mediated by telecommunication equipment. The responder of a telecom address may be an automatic service that can respond with information (e.g. FTP or HTTP services). In such cases a telecom address is a reference to that information accessible through that address. A given telecom address value may have limited validity through time and may be tagged by a use code to indicate under what circumstances a specific telecommunication address may be preferred among a set of alternatives. The telecommunication address is an extension of the universal resource locator (URL) that is specified as an internet standard RFC 1738[23].

Attributes			
Signature	**Optionality**	**Multiplicity**	**Documentation**
telecomAddress:URI	1	N/A	The address is a character string whose format is entirely defined by the URI scheme.
use:SET<CS>	0..1	N/A	VALUES: HT = home telephone WT = work telephone AS = answering service EC = emergency contact MC = mobile contact PG = pager FX = fax.
validTime:IVL<TS>	0..*	N/A	One or more time range when this telecommunication type is appropriate (e.g. after 18:00).

Package: DEMOGRAPHICS Package

6.3.10 Class POSTAL_ADDRESS

Used to represent the mailing, home or business address. (Corresponds to GPIC Common Access Group.)

Attributes			
Signature	**Optionality**	**Multiplicity**	**Documentation**
addressUse:SET<CS>	0..1	N/A	One or more codes advising a system or user which address in a set of like addresses to select for a given purpose VALUES: - BIR (birthplace) - H (home) - HP (primary home) - HV (vacation address) - WP (work place).
postalCode:String	0..1	N/A	The postal or zip code.
validTime:IVL<TS>	0..1	N/A	Interval of time associated with the address. Note: The valid time may provide a: - start date/time or - an end date/time or – both.

Attributes from associations			
Signature	**Optionality**	**Multiplicity**	**Documentation**
addrPart:Set<POSTAL_ADDRESS_PART>	0..1	0..*	This association represents the parts of an address data structure.

Package: DEMOGRAPHICS Package

6.3.11 Class POSTAL_ADDRESS_PART

An address line. (Corresponds to GPIC Common Access Group.)

Attributes			
Signature	**Optionality**	**Multiplicity**	**Documentation**
addressLine:String	1	N/A	The address part represented as a string.
addressLineType:CS	0..1	N/A	VALUES: BNM = boat name CNT = country CPA = county or parish CTY = city/town FNM = flat number HNR = house number HNM = house name POB = post box SAL = street address line STA = state or province STR = street name.

Package: DEMOGRAPHICS Package

6.3.12 Class ENTITY_NAME

Specifies a name of a person, organization, place or thing.

EXAMPLES "Leonardo da Vinci", "United Nations Organization", "Eiffel Tower", etc.

An entity name may be as simple as a character string or may consist of several entity name parts. The entity name data type is essentially a sequence of entity name part values.

Attributes			
Signature	**Optionality**	**Multiplicity**	**Documentation**
use:CV	1	N/A	Code representing the purpose/primary use of the name.
validTime:IVL<TS>	1	N/A	Interval of time associated with the entity name. NOTE The valid time may provide a: start date/time or an end date/time or both.

Attributes from associations			
Signature	**Optionality**	**Multiplicity**	**Documentation**
namePart:Set<ENTITY_NAME_PART>	1	1..*	An Entity Name can comprise any number of parts.

Package: DEMOGRAPHICS Package

6.3.13 Class ENTITY_NAME_PART

Specifies a part of the name of a person, organization, place or thing.

Attributes			
Signature	**Optionality**	**Multiplicity**	**Documentation**
entityPartName:String	1	N/A	The name part represented as a string.
namePartQualifier:CS	1	N/A	VALUES: AC = academic NB = nobility PR = professional W = prefix (voorvoegsel) BR = birth CL = preferred name IN = initial.
namePartType:CS	1	N/A	VALUES: FAM = family GIV = given PFX = prefix SFX = suffix.

6.4 Package: SUPPORT package

6.4.1 General

This package is the subset of the data types defined in CEN/TS 14796 that are used as attribute types in the EHR_EXTRACT and DEMOGRAPHICS packages. For further documentation of these data types, including permitted specializations of the classes defined in this package, the reader shall refer to that CEN Technical Specification.

Inner Elements	
Name	**Type**
self - S.276.1107.04.234CS	Class
self - S.276.1107.04.244CV	Class
self - S.276.1107.04.2DATA_VALUE	Class
self - S.276.1107.04.191ED	Class
self - S.276.1107.04.187II	Class
self - S.276.1107.04.209IVL	Class
self - S.276.1107.04.209OID	Class
self - S.276.1107.04.226TEXT	Class
self - S.276.1107.04.269TS	Class
self - S.276.1107.04.211URI	Class

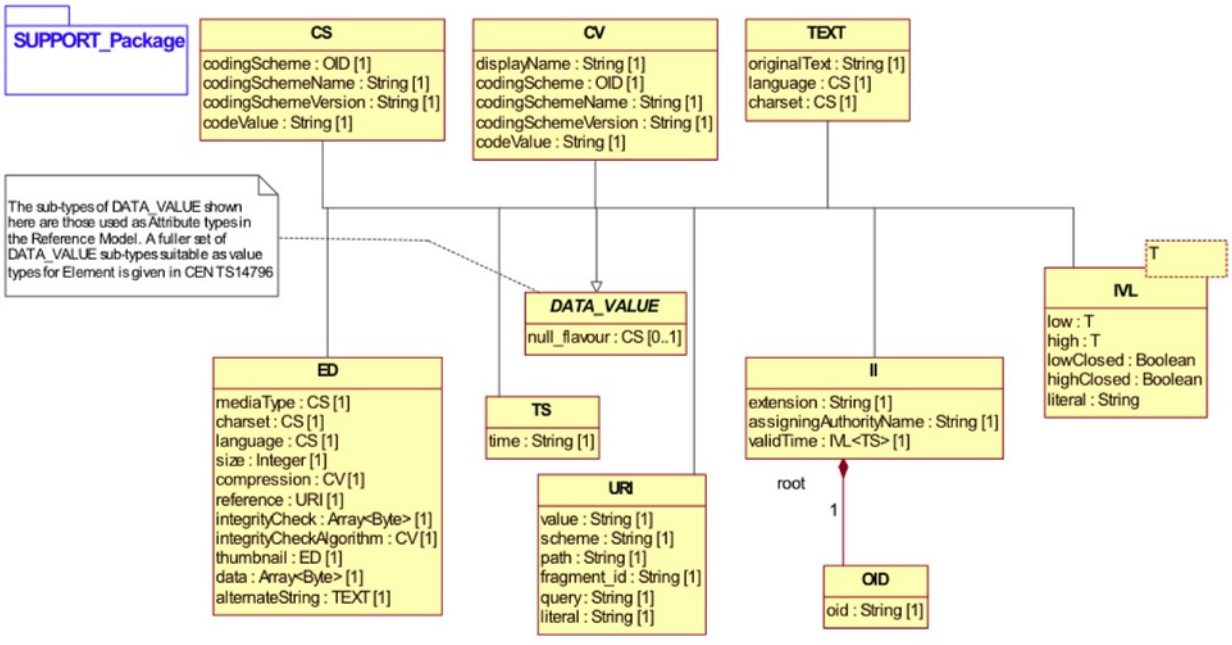


Figure 5 — UML class diagram of support package

Package: SUPPORT Package

6.4.2 Class DATA_VALUE{Abstract}

Direct Subclassifiers:
II, ED, CV, TEXT, CS, TS, URI, IVL

Each ELEMENT contains one data value, to represent the actual instance value being recorded. DATA_VALUE is an abstract class representing the value of this ELEMENT. It is instantiated as one of the CEN Data Types for coded terms, measurements with units, etc.

Attributes			
Signature	**Optionality**	**Multiplicity**	**Documentation**
null_flavour:CS	0..1	N/A	If no data value is available, this attribute can carry a code to give a reason for there being no value.

Constraints		
Name	**Expression**	**Documentation**
NULL_FLAVOUR	inv: null_flavour.coding_scheme_name = 'BS ISO 21090/A.2/Null flavour values'	(none)

Package: SUPPORT Package

6.4.3 Class CS

DATA_VALUE
|
+--**CS**

Coded Simple type for which the applicable code set is specified (by constraint) in this part of ISO 13606.

Attributes			
Signature	**Optionality**	**Multiplicity**	**Documentation**
codeValue:String	1	N/A	String containing the value of the code.
codingScheme:OID	1	N/A	An Object Identifier (OID) according to ISO/IEC 8824-1 that uniquely identifies the coding scheme to which the concept and code value belong. EXAMPLE “106.75.314.67.89.24,” may identify the WHO classification of diseases.
codingSchemeName:String	1	N/A	A string containing a name of the coding scheme (e.g. “SNOMED CT”).
codingSchemeVersion:String	1	N/A	A string giving the version of the coding scheme.

Package: SUPPORT Package

6.4.4 Class CV

DATA_VALUE
|
+--**CV**

Coded Value. This is similar to CS but the applicable code set is not constrained by this part of ISO 13606.

Attributes			
Signature	**Optionality**	**Multiplicity**	**Documentation**
codeValue:String	1	N/A	String containing the value of the code.
codingScheme:OID	1	N/A	An Object Identifier (OID) according to ISO/IEC 8824-1 that uniquely identifies the coding scheme to which the concept and code value belong. EXAMPLE "106.75.314.67.89.24," may identify the WHO classification of diseases.
codingSchemeName:String	1	N/A	A string containing a name of the coding scheme (e.g. "SNOMED CT").
codingSchemeVersion:String	1	N/A	A string giving the version of the coding scheme.
displayName:String	1	N/A	String containing a short, human-readable description of the concept that may be abbreviated for display purposes.

Package: SUPPORT Package

6.4.5 Class TEXT

DATA_VALUE
|
+--**TEXT**

Plain text expressed in a defined language using a defined character set.

Attributes			
Signature	**Optionality**	**Multiplicity**	**Documentation**
charset:CS	1	N/A	Specifies the character set and character encoding used.
language:CS	1	N/A	Specifies the language of text data. Code set defined by ISO 639[2].
originalText:String	1	N/A	A string of indeterminate length.

Package: SUPPORT Package

6.4.6 Class ED

DATA_VALUE
|
+--**ED**

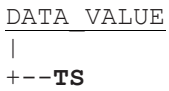
Indicates whether the raw byte data are compressed, and what compression algorithm was used.

Attributes			
Signature	**Optionality**	**Multiplicity**	**Documentation**
alternateString:TEXT	1	N/A	Text to display in lieu of multimedia display/replay.
charset:CS	1	N/A	Where applicable, specifies the character set and character encoding used.
compression:CV	1	N/A	Indicates whether the raw byte data are compressed, and what compression algorithm was used.
data:Array<Byte>	1	N/A	The actual data if supplied inline.
integrityCheck:Array<Byte>	1	N/A	A short binary value representing a cryptographically strong checksum over the binary data.
integrityCheckAlgorithm:CV	1	N/A	Specifies the algorithm used to compute the integrityCheck value.
language:CS	1	N/A	For character based information the language property specifies the human language of the text using ISO 639[2].
mediaType:CS	1	N/A	Identifies the type of the encapsulated data and identifies a method to interpret or render the data.
reference:URI	1	N/A	URI reference to electronic information stored outside the record as a file, database entry etc., if supplied as a reference.
size:Integer	1	N/A	The size of the data in bytes.
thumbnail:ED	1	N/A	An abbreviated rendition of the full data.

Constraints		
Name	**Expression**	**Documentation**
MEDIA_TYPE	inv: media_type.coding_scheme_name = 'in BS ISO 21090:2005, Annex D'[16]	The IANA defined domain of media types is established by the Internet standard RFC 2045[24] [http://www.ietf.org/rfc/rfc2045.txt] and 2046[25] [http://www.ietf.org/rfc/rfc2046.txt]. RFC 2046 defines the media type to consist of two parts: a) top level media type and b) media subtype. However, this part of ISO 13606 treats the entire media type as one atomic code symbol in the form defined by IANA, i.e., top level type followed by a slash "/" followed by media subtype. Currently defined media types are registered in a database [http://www.iana.org/assignments/media-types/index.html] maintained by IANA.
CHARSET	inv: charset.coding_scheme_name = 'in BS ISO 21090 Annex C'	The charset shall be identified by an Internet Assigned Numbers Authority (IANA) Charset Registration [http://www.iana.org/assignments/character-sets] in accordance with RFC 2978[28] [http://www.ietf.org/rfc/rfc2978.txt].
LANGUAGE	inv: language.coding_scheme_name = "ISO 639"	(none)

Package: SUPPORT Package

6.4.7 Class TS



An instant in the lapse of time regarded as dimensionless. Time-points are determined by specifying their position (i.e. their 'distance' in time from the zero-point) in a time-oriented reference system.

NOTE 1 This data type is described more fully in ISO 8601[7].

NOTE 2 TimePoint is a family of data types whose values are points in time to various common resolutions: year, month, day, hour, minute, second and fractions thereof.

Attributes			
Signature	**Optionality**	**Multiplicity**	**Documentation**
time:String	1	N/A	A complete representation of calendar date and time, conforming to ISO 8601.

Package: SUPPORT Package

6.4.8 Class URI

DATA_VALUE
|
+--**URI**

Purpose is a reference to an object which conforms to the universal resource identifier (URI) standard, as defined by W3C RFC 2936[27]. See *Universal Resource Identifiers in WWW* by Tim Berners-Lee at http://www.ietf.org/rfc/rfc2396.txt. This is a World-Wide Web RFC for global identification of resources. See http://www.w3.org/Addressing for a starting point on URIs. See http://www.ietf.org/rfc/rfc2806.txt for new URI types like telephone, fax and modem numbers.

Attributes			
Signature	**Optionality**	**Multiplicity**	**Documentation**
fragment_id:String	1	N/A	A part of, a fragment or a sub-function within an object. Allows references to sub-parts of objects, such as a certain line and character position in a text object. The syntax and semantics are defined by the application responsible for the object.
literal:String	1	N/A	A literal expression may be used in circumstances when the normal data type for some reason cannot be provided.
path:String	1	N/A	A string whose format is a function of the scheme. Identifies the location in <scheme>- space of an information entity. Typical values include hierarchical directory paths for any machine. EXAMPLE with scheme = “ftp”, path might be /pub/images/image_01. The strings“.” and “..” are reserved for use in the path. Paths may include internet/intranet location identifiers of the form: sub_domain...domain, e.g. “info.cern.ch”.
query:String	1	N/A	Query string to send to application implied by scheme and path Enables queries to applications, including databases to be included in the URI any query meaningful to the server, including SQL.
scheme:String	1	N/A	A distributed information “space” in which information objects existing. The scheme simultaneously specifies an information space and a mechanism for accessing objects in that space. EXAMPLE if scheme = “ftp”, it identifies the information space in which all ftp-able objects exist, and also the application - ftp - which can be used to access them.
value:String	1	N/A	The telecommunication address as specified in Internet standard RFC 1738.

Package: SUPPORT Package

6.4.9 Class II

DATA_VALUE
|
+--**II**

The globally unique identity of some object.

Attributes			
Signature	**Optionality**	**Multiplicity**	**Documentation**
assigningAuthorityName:String	1	N/A	A human readable name or mnemonic for the assigning authority. This name is provided solely for the convenience of unaided humans interpreting an II value. NOTE No automated processing needs to depend on the assigning authority name to be present in any form.
extension:String	1	N/A	The value of the identifier, unique within its assigning authority's namespace.
validTime:IVL<TS>	1	N/A	If applicable, specifies during what time the identifier is valid. By default, the identifier is valid indefinitely. Any specific interval may be undefined on either side indicating unknown effective or expiry time. NOTE Identifiers for information objects in computer systems should not have restricted valid times, but should be globally unique at all times. The identifier valid time is provided mainly for real-world identifiers, whose maintenance policy may include expiry (e.g. credit card numbers).

Attributes from associations			
Signature	**Optionality**	**Multiplicity**	**Documentation**
root:OID	1	N/A	A unique identifier that guarantees the global uniqueness of the instance identifier. The root alone may be the entire instance identifier, an extension value is not always required.

Package: SUPPORT Package

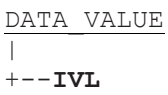
6.4.10 Class OID

A unique identifier that guarantees the global uniqueness of the instance identifier. The root alone may be the entire instance identifier; an extension value is not needed.

Attributes			
Signature	**Optionality**	**Multiplicity**	**Documentation**
oid:String	1	N/A	A globally unique string identifier consisting of numbers and dots.

Package: SUPPORT Package

6.4.11 Class IVL<T>



A set of consecutive values of an ordered base data type.

Any ordered type can be the basis of an interval; it does not matter whether the type is discrete or continuous. If the data type is only partially ordered, all elements of the interval should be elements of a totally ordered subset of always intervals.

Attributes			
Signature	**Optionality**	**Multiplicity**	**Documentation**
low:T	0..1	—	The lower boundary of the interval.
high:T	0..1	—	The upper boundary of the interval.
lowClosed:Boolean	0..1	—	A Boolean, indicating whether the interval is closed or open at the low boundary. Unspecified or infinite boundaries are always open.
highClosed:Boolean	0..1	—	A Boolean, indicating whether the interval is closed or open at the high boundary.
literal:String	0..1	—	The literal form of the interval data type.

Template Parameters		
Name	**Type**	**Default Value**
T	(none)	(none)

6.5 Primitive data types

The following primitive types are assumed to be available on any platform implementation this part of ISO 13606, and are not further defined here:

— Boolean

— Byte

— Character

— Double

— Integer

— Real

— String

— Set <T>

— Array<T>

— Set<T>

— List<T>

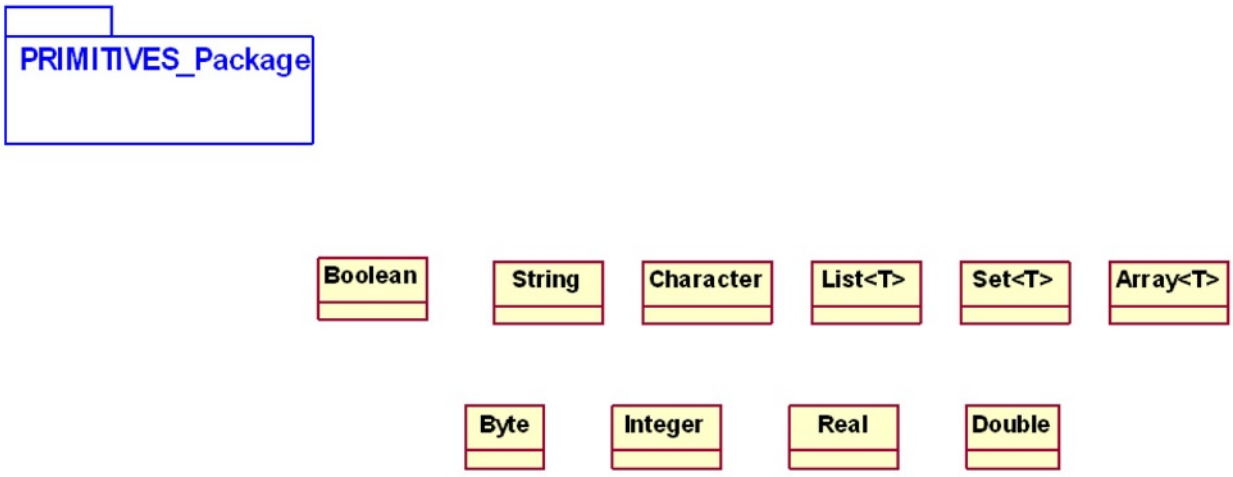


Figure 6 — UML class diagram of primitives package

Annex A
(informative)

UML profile

A.1 Introduction

The model is presented using a constrained form of UML diagrams, described below in a UML Profile. The detailed documentation of the features of the model is derived automatically using a formal UML modelling tool and is described below.

A.2 General

The classes of the model together with their associations and inheritances are grouped into packages, and these are shown in a number of separate diagrams. Package boundaries are shown as blue lines with the name of the package, also shown in blue, in the top left box of the package outline.

Class boxes usually have three compartments as described below.

The top compartment contains the name of the class in upper case, and may also show the owning class in parentheses when the class belongs to a package other than the package that is the subject of the diagram. Some diagrams also show class constraints in the top compartment.

The second compartment, if present, contains attributes, showing attribute name, attribute type and multiplicity. Multiplicity may also be further qualified by the 'ordered' marker. Attribute names are shown in lower case. Attribute types are shown in title case if the type is one of the basic types and in upper case if the type is another class.

The third compartment, if present, contains operations, showing operation name, return type and parameters passed. Operation names and types follow the same casing rules as attributes.

A class box with only two compartments has class name and attributes: a class box with only one compartment has just a name.

Colour itself has no significance, but is used to enhance readability. Inheritance lines are shown in black, and association lines in maroon. Colour fills of class boxes are sometimes used to highlight particular groupings of Classes. Grey class boxes are used to indicate that the class details are shown on another diagram.

Associations between classes are always 'single ended' with the association name and multiplicity placed at the far end of the line. If a double-ended association is required, it is shown as two single-ended associations, one in each direction, between the two classes. This restriction has been applied to make it possible to document each association automatically in a pure O-O way, as though it were an attribute of the near-end class. Navigation arrows are not used.

Multiplicities at the near end of an association are to be assumed to be 1 if not shown.

Filled diamonds signify containment by value, while unfilled diamonds signify containment by reference.

Associations to parameterized classes have a box attached to the target class containing the name of the attribute in the target class that is the parameter used to reference that class.

A.3 Detailed documentation of the model

Detailed documentation of the model has been generated automatically from a UML modelling tool, which has been constrained as follows.

In the printed form of this part of ISO 13606, only some internal hyperlinks are possible, but in the electronic version, a fully hyperlinked document is available. Links to and from the diagrams are also provided in the electronic form.

The order of documentation is by package and, within package, by class.

Each class has a starting section showing the owning package, any inheritance, inner elements, and any internal model documentation, and is followed by up to four tabular sections for:

— attributes;

— attributes derived from associations;

— operations;

— constraints.

The associations themselves are shown in the diagrams using UML notation, but are documented in O-O form as derived associations using the following transformations:

Association far end name	becomes	Attribute name
Association far end class	becomes	Attribute type

Association multiplicity	**generates**	**Container type**	**and**	**Attribute optionality**	**Original multiplicity**
0..*		Set<far end CLASS>		0..1	0..*
0..* {ordered}		List<far end CLASS>		0..1	0..* {ordered}
1..*		Set<far end CLASS>		1	1..*
1..* {ordered}		List<far end CLASS>		1	1..* {ordered}
*		Set<far end CLASS>		0..1	*
0..1		Not a container		0..1	N/A
1		Not a container		1	N/A

Annex B
(informative)

Relationship to other standards

B.1 Relationship to HL7 version 3

A number of countries have so far indicated the intention of adopting an HL7 version 3 communications environment (messages, service interfaces and web services) as part of a national e-health infrastructure programme. However, the challenge of connecting a large number of healthcare enterprises, legacy systems, and of establishing some of the necessary foundation components (such as a national demographic service for patients and for healthcare staff) means that this infrastructure will take many years to realise. (Other countries might remain a deliberately mixed economy of message formalisms for some years to come, which HL7 is also looking to support.)

The approach taken in this International Standard to HL7 version 3 interoperability is to recognise this as an important (non-exclusive) option by which EHR data will be logically communicated, and to ensure that it is possible to represent the constructs of the logical model defined in Clause 6 of this part of ISO 13606 as classes and attributes of the HL7 Reference Information Model.

The development of this part of ISO 13606 has been reflected in the HL7 standards development process since 2002, and valuable cross-harmonization has taken place.

The position taken on this part of ISO 13606 from an HL7 perspective is:

1) to recognise the value of the work that has been undertaken to produce this part of ISO 13606, and to seek to ballot a conformant HL7 static model to underpin EHR communications within HL7 version 3;

2) to receive the normative model of Clause 6 as a domain analysis model within the terms of the HL7 Development Framework (HDF); this advocates the development of a domain model faithful to the information requirements of each user domain, followed by a mapping of that model to either the RIM or to an appropriate HL7 refined message information model (RMIM);

3) to nominate the HL7 Clinical Statement Pattern (a domain message information model) to be the most appropriate mapping target for all generic clinical representations, including the EHR communications model.

As a consequence, an ISO 13606-1 static model (RMIM) has been produced that is derived from the HL7 clinical statement and also logically conforms to the model in Clause 6 of this part of ISO 13606. It therefore conforms to this part of ISO 13606. An HL7 13606 Implementation Guide is also being developed.

B.2 Relationship to EN 13940 (CONTSYS standard)

The CONTSYS standard defines a system of concepts to support continuity of care across care teams and healthcare enterprises. Much of CONTSYS would therefore be implemented by clinical workflow systems, such as care planning or guideline systems, and in act (lifecycle) management systems. The forthcoming CEN HISA standard is therefore closely harmonised with CONTSYS.

Some parts of the CONTSYS standard refer directly to clinical information and some other parts, although implemented via workflow systems, might result in entries in an EHR that capture the consequences of a shared care interaction.

This part of ISO 13606 defines the EHR_EXTRACT in very generic terms, and ISO 13606-2 defines a means of communicating knowledge structures (archetypes) that are likely to reflect contemporary evidence-based care guidelines. Most of the CONTSYS constructs that relate to clinical information will be represented as specific archetypes rather than as classes and attributes in the ISO 13606 reference model. However, some fundamental CONTSYS concepts do have correspondence with the reference model. These are listed below, to indicate how an EHR system developer should map CONTSYS concepts within an EHR_EXTRACT.

Table B.1 — Mapping of CONTSYS to ISO 13606-1

CONTSYS concept	13606-1 mapping correspondence
Contact clinical encounter record management	Class COMPOSITION No specific distinction is made between these two sub-types of contact element: different archetypes will be used for each of these sub-types.
Health issue	A health issue definition or statement may be represented as a specific (optionally archetyped) ENTRY within a COMPOSITION.
Contact element	The set of SECTIONs and/or ENTRYs within one COMPOSITION that contain LINKs to only one health issue.
Health issue thread	The chronological evolution of a health issue may be represented as a series of ENTRYs that each use LINK to refer to the health issue definition. The Link nature attribute shall have the value “LINK-C0” as defined in ISO 13606-3, which means “is related to the same problem or health issue”. A fine grained label may be applied to the LINK via the role attribute.
Episode of care	This would be derived as a query within an EHR system, as the interval between the earliest and latest instances of COMPOSITION that contain a LINK to a given health issue definition.
Cumulative episode of care	This would be derived as a query across multiple EHR systems, as the interval between the earliest and latest instances of COMPOSITION that contain a LINK to a given health issue definition.
Healthcare goal	A healthcare goal definition or statement may be represented as a specific (optionally archetyped) ENTRY within a COMPOSITION.
Health approach	This is the set of COMPOSITIONs and/or ENTRYs that contain a LINK to a specified healthcare goal.
Guideline	A clinical guideline is rarely represented explicitly within the EHR of a single subject of care: it is normally referenced as an external knowledge resource. Specific (optionally archetyped) ENTRYs might be used for such a reference, or alternatively the ITEM_CATEGORY may be used to distinguish an ELEMENT that contains the reference to an external guideline.
Protocol	(As for guideline above)
Programme of care	A programme of care might de documented wholly or in part explicitly within an individual EHR, optionally with references to a specific protocol. A specific (optionally archetyped) COMPOSITION should be used for this purpose.

Table B.1 (*continued*)

CONTSYS concept	13606-1 mapping correspondence
Healthcare objective	Each healthcare objective definition or statement is likely to be represented as an ENTRY within a programme of care COMPOSITION.
Healthcare goal	Each healthcare goal definition or statement is likely to be represented as an ENTRY within a programme of care COMPOSITION. It may have a LINK to a healthcare objective.
Care plan	A care plan might be represented as a COMPOSITION and/ or a set of ENTRYs, with a LINK to a programme of care COMPOSITION.
Activities bundle	This will be the set of COMPOSITIONs and/or ENTRYs within an EHR that have a LINK to a particular care plan.
Mandate for care	A specific set of (optionally archetyped) COMPOSITIONs should be used to document mandates for care.
Period of service	Interval bounded by earliest and latest COMPOSITIONs linked to one mandate for care.

B.3 Relationship to prEN 12967 HISA standard

prEN 12967 defines a generic Health Informatics Service Architecture, as a logical design for information systems serving the needs of large or small healthcare enterprises. Its Information Viewpoint specification (Part 2 of this series) defines the major classes of information that need to be managed within a healthcare enterprise, and potentially need to be shared with other computational resources. One package within this International Standard defines a generic representation of clinical information. A set of generic classes common to all of the HISA Information Viewpoint are also defined.

Most of the clinical information held within an HISA conformant system that relates to an identified subject of care (as opposed to terminology, or other knowledge resources) will need to be mapped to an EHR_EXTRACT in order to be communicated via this International Standard. However, some of the generic HISA classes include attributes that are needed to manage the integrity of a physical data repository but which do not need to be communicated to another EHR repository. The table below lists the main HISA classes that relate to communicable EHR data, and indicates which data values correspond to the classes and attributes of the ISO 13606-1 Reference Model. Because some of the HISA classes are even more generic than those in ISO 13606, in some cases a range of options is indicated; the exact mapping choice will depend upon the clinical concepts represented by the data. Those HISA classes and attributes that do not need to be included in an EHR communication have been omitted.

Table B.2 — Mapping of HISA to ISO 13606-1

EN 12967class and attribute	ISO 13606 class and attribute
GenericHISAClass	RECORD_COMPONENT
SystemAttributes displayName and userCode updateTime updateAgent updateUnit authorization isDeleted NOTE Supplementary access policy information might be represented as Business Rules associated with an instance of this class.	RECORD_COMPONENT and AUDIT_INFO name time_committed committer ehr_system policy_ids version_status
ExtendedAttributes	Represented using the ED data type of CEN/TS 14796
VersionAttributes	This information needs to be mapped as a reference to the ID attribute value of the previous version of ClinicalInformation or ClinicalInformationComplex
ClinicalInformation and ClinicalInformationComplex id values unitMeasure status SubjectOfCare Agent Activity NOTE The HISA class StateChanges may provide additional status information that maps to the ISO 13606-1 AUDIT_INFO class.	These classes will be mapped to the RECORD_COMPONENT hierarchy depending upon the level of granularity of each node. rc_id data_value of an ELEMENT PQ data type defined by CEN/TS 14796 AUDIT_INFO.version_status EHR_EXTRACT.subject_of_care FUNCTIONAL_ROLE via a LINK to other RECORD_COMPONENTs
Subclasses of ClinicalInformation: HealthIssue, ClinicalObservationAndResult, EvaluationAndOthers, Clinical Objective, Demand for care	These would be represented as specific (optionally archetyped) COMPOSITIONS and/or ENTRYs.
TypeOfClinicalInformation	RECORD_COMPONENT.meaning and RECORD_COMPONENT.archetype_id
ActivityClinicalInformationAssociation and ReasonForAssociationOfTypesOfClinicalInformation	LINK.nature and LINK.role NOTE In cases of revision, the reason for revision might also be represented by ReasonForAssociationOfTypesOfClinicalInformation, to be mapped to AUDIT_INFO.reason_for_revision.
RoleOfAgentInClinicalInformationLifeCycle	FUNCTIONAL_ROLE

B.4 Relationship to EN 14822-1 to EN 14822-3 and CEN/TS 14822-4 GPIC standard

EN 14822-1 to EN 14822-3 and CEN/TS 14822-4 define a set of general purpose information components, which are UML model fragments to represent distinct health informatics business objects that are frequently required within healthcare messages. These models are each constrained sub-sets of HL7 version 3 RIM classes and attributes, to support the future development of CEN messages that also conform to HL7 version 3. EN 14822 defines sets of clinical and non-clinical GPICs.

The non-clinical GPICs will largely be used to construct specific messages, rather than to exchange large quantities of clinical data. The exception to this is several demographics GPICs, which overlap in scope with the demographics package of this part of ISO 13606. For each of the classes in the demographics package documented in Clause 6, if applicable, the reference number of the GPIC to which it most closely corresponds is indicated in the class main documentation.

Data that have been communicated via clinical GPICs might subsequently persist within an EHR system and be included within an EHR_EXTRACT. Archetypes can be used to represent those clinical data structures, if appropriate.

B.5 Relationship to the IHE XDS specification

The cross document sharing (XDS) specification, developed by the integrating healthcare enterprise organization (IHE) defines an information architecture and service interfaces for a shareable repository of clinical documents. This is widely regarded as a stepping stone towards realising interoperable EHRs, albeit limited to the exchange of whole documents without necessarily being able to analyse their contents. In order to facilitate the use of XDS as a migration strategy towards the use of ISO 13606, the XDS specification has been harmonized with ISO 13606 to enable an EHR_EXTRACT to be stored within an XDS repository, with some limitations, namely:

a) only one hierarchical level of FOLDER is presently supported by the XDS;

b) whole COMPOSITIONs can be stored in the XDS, but without any ability to search within a COMPOSITION.

Tables B.3 to B.5 list the key attributes of the XDS document registry and their correspondence to classes and attributes of the ISO 13606 reference model. This table of correspondence may be used when importing an EHR_EXTRACT into an XDS repository, or when communicating one or more XDS documents as an EHR_EXTRACT. The XDS registry specification uses ebXML as its persistence mechanism, and some additional mapping and data transformations may be required to ensure that the attribute values are of the correct data type for that registry.

Table B.3 — Mapping of XDS document entry to ISO 13606-1

Attribute of XDS document entry	ISO 13606-1 mapping
AvailabilityStatus	Class AUDIT_INFO attribute: revision_status NOTE If a document is replaced, the ebXML specification of XDS requires a reference to the previous version, which may be obtained from the previous_version attribute of AUDIT_INFO.
PatientId	Class: EHR_EXTRACT attribute: subject_of_care
UniqueId	Class RECORD_COMPONENT attribute: rc_id
ClassCode	Class COMPOSITION Attribute: name
EventCode	Class RECORD_COMPONENT attribute: meaning
TypeCode	(Mapped to XDS registry codes, from COMPOSITION.meaning)
CreationTime	Class AUDIT_INFO attribute: time_committed
ServiceStartTime and ServiceStopTime	Class: COMPOSITION attribute: session_time
AuthorInstitution	Class: COMPOSITION association: composer.FUNCTIONAL_ROLE.healthcare_facility
AuthorDepartment	Class: COMPOSITION association: composer.FUNCTIONAL_ROLE.service_setting
AuthorPerson	Class: COMPOSITION association: composer.FUNCTIONAL_ROLE.performer
HealthcareFacilityTypeCode	(Mapped from composer.FUNCTIONAL_ROLE.healthcare_facility)
LegalAuthenticator	Class FUNCTIONAL_ROLE (association from class ATTESTATION) attribute: performer
FormatCode	Class EHR_EXTRACT attribute: rm_id

Table B.4 — Mapping of XDS Submission Set to ISO 13606-1

Attribute of XDS submission set	ISO 13606-1 mapping
UniqueId	This may be added in the message wrapper containing the EHR_EXTRACT, by the EHR provider system.
AuthorInstitution	Class EHR_EXTRACT attribute: ehr_system
SubmissionTime	Class EHR_EXTRACT attribute: time_created
AuthorPerson	Class EHR_EXTRACT attribute: authorizing_party

Table B.5 — Mapping of XDS folder to ISO 13606-1

Attribute of XDS folder	ISO 13606-1 mapping
UniqueId	Class FOLDER attribute: rc_id
LastUpdateTime	Managed by the XDS service
CodeList	Class FOLDER attribute: meaning

B.6 Relationship to the former ENV 13606

This clause provides a mapping guide between this part of ISO 13606 and ENV 13606-1 in order to enable implementers familiar with that European prestandard to identify the areas of correspondence, and ease the process of designing migration interfaces. Please note that mappings for the attributes and associations of the sub-classes of ENV 13606-1 Record Component have not been repeated if they are the same as those of ENV 13606-1 Record Component itself.

Table B.6 — Mapping of ENV 13606-1 to ISO 13606-1

ENV 13606 class	ENV 13606 attribute	Comment on the ENV 13606 specification	ISO 13606 class	ISO 13606 attribute	Mapping comments
Root architectural component			EHR_EXTRACT		
	Attestation information			—	Attestation is considered to apply to particular components of the EHR, not to the EHR_EXTRACT as a whole. The root folder of the EHR directory can be attested, as it is a kind of RECORD_COMPONENT
	Presentation information			—	Presentation is considered to apply to particular components of the EHR, not to the EHR_EXTRACT as a whole
	Component unique identifier			ehr_system AND ehr_id	
	Originating healthcare agent			authorizing_party	
	Originating date and time			time_created	
	Related healthcare agent			—	Other parties can be specified for particular components in the EHR hierarchy, not for the EHR_EXTRACT as a whole. However, they can be defined in the root folder of the EHR directory, as it is a kind of RECORD_COMPONENT
	Related date and time			—	Other dates and times can be specified for particular components in the EHR hierarchy, not for the EHR_EXTRACT as a whole. However, they can be defined in the root folder of the EHR directory, as it is a kind of RECORD_COMPONENT
	Component name structure			—	The EHR_EXTRACT class does not include a name attribute, but the root FOLDER of the EHR directory can, as it is a kind of RECORD_COMPONENT

Table B.6 (*continued*)

ENV 13606 class	ENV 13606 attribute	Comment on the ENV 13606 specification	ISO 13606 class	ISO 13606 attribute	Mapping comments
	Subject of care identifier			subject_of_care	
	Component status information	Set to “Current” at the time of creation		—	For communication purposes, any EHR_EXTRACT is deemed current at the time of creation, given by the time_created attribute above
	Distribution rule reference			Not applicable	The approach to access control is defined in ISO 13606-4
	Language			—	Language is considered pertinent to individual terms or text values within the EHR data, not to the EHR_EXTRACT as a whole
Record component			RECORD_COMPONENT		
	Attestation information			ATTESTATION_INFO	
	Presentation information	ENV 13606 only provided for a presentation reference, but did not otherwise formalise the representation of presentation information		—	Archetypes will be used to represent the specific presentation characteristics required for individual kinds of EHR data
	Revision information			AUDIT_INFO	
	Component unique identifier			rc_id	
	Originating healthcare agent			AUDIT_INFO.committer	
	Originating date and time			AUDIT_INFO.time_committed	

Table B.6 (*continued*)

ENV 13606 class	ENV 13606 attribute	Comment on the ENV 13606 specification	ISO 13606 class	ISO 13606 attribute	Mapping comments
	Related healthcare agent	No interoperable specification was provided for the kinds of "related" agents that might be represented			These are provided for as associations from COMPOSITION and ENTRY
	Related date and time	No interoperable specification was provided for the kinds of "related" dates and times that might be represented			Provision is made through specific associations from COMPOSITION (session_time) and ITEM (obs_time)
	Component name structure			Name	This attribute may be represented as a code or plain text; in either case the language used may be included within the data type for string
	Subject of care identifier				This attribute value is defined in the EHR_EXTRACT, and is not repeated at every node throughout the EHR hierarchy
	Component status information			AUDIT_INFO.revision_ status	
	Distribution rule reference			sensitivity policy_ids	The approach to access control is specified in ISO 13606-4: some revision to this reference
	Language				Language can be defined for the individual terms or text values used for attribute values or for data values within the EHR
Folder OCC			FOLDER		
	OCC type	default value = "Folder OCC"		(Class name)	This is given by the class name and need not be repeated as an attribute value
Composition OCC			COMPOSITION		

Table B.6 (*continued*)

ENV 13606 class	ENV 13606 attribute	Comment on the ENV 13606 specification	ISO 13606 class	ISO 13606 attribute	Mapping comments
	Originating healthcare agent			AUDIT_INFO.committer	Since the COMPOSITION is the main container of EHR data within the EHR_EXTRACT, provision is made to represent the committer of the original data in its initial system and the committer of the COMPOSITION in the EHR provider system
	Originating date and time			AUDIT_INFO.time_ committed	Since the COMPOSITION is the main container of EHR data within the EHR_EXTRACT, provision is made to represent the committal time of the original data in its initial system and the committer of the COMPOSITION in the EHR provider system
	Related healthcare agent	No interoperable specification was provided for the kinds of “related” agents that might be represented		composer other_participations	
	Related date and time	No interoperable specification was provided for the kinds of “related” dates and times that might be represented		session_time	
	Component name category			archetype_id AND meaning	
	OCC type	default value = “Composition OCC”			This is given by the class name and need not be repeated as an attribute value
Headed Section OCC			SECTION		
	Component name category			archetype_id AND meaning	

Table B.6 (*continued*)

ENV 13606 class	ENV 13606 attribute	Comment on the ENV 13606 specification	ISO 13606 class	ISO 13606 attribute	Mapping comments
	OCC type	Default value = headed section OCC"			This is given by the class name and need not be repeated as an attribute value
Cluster OCC			ENTRY, CLUSTER		Please refer to the descriptions of these classes given in Clause 5
	Presentation information	ENV 13606 only provided for a presentation reference, but did not otherwise formalise the representation of presentation information	CLUSTER, ELEMENT	Emphasis	
	Related healthcare agent	No interoperable specification was provided for the kinds of “related” agents that might be represented	ENTRY	info_provider AND other _participations	
	Related date and time	No interoperable specification was provided for the kinds of “related” dates and times that might be represented	CLUSTER	obs_time	
	Annotation identifier		ENTRY	uncertainty_expressed	The annotations defined in ENV 13606-2 have not been retained, as they have been considered to overlap too much with the semantics of RECORD_COMPONENT names and terms used for data values
	OCC type	default value = “Cluster OCC”		-	
Data Item			CLUSTER, ELEMENT		Please refer to the descriptions of these classes given in Annex B
	Attestation information			ATTESTATION_INFO	

Table B.6 (*continued*)

ENV 13606 class	ENV 13606 attribute	Comment on the ENV 13606 specification	ISO 13606 class	ISO 13606 attribute	Mapping comments
	Presentation information	ENV 13606 only provided for a presentation reference, but did not otherwise formalise the representation of presentation information	CLUSTER, ELEMENT	Emphasis	
	Related date and time	No interoperable specification was provided for the kinds of “related” dates and times that might be represented	CLUSTER, ELEMENT	obs_time	
	Data item type reference	EN/TS 13606-4 defined several types of data item, including a community-defined one. This meant that the data item might either behave as a leaf node or as a kind of cluster.		archetype_id AND meaning	In ISO 13606, the ELEMENT class is always a leaf node. Compound ENV 13606 data items therefore map to CLUSTER, whilst single-values data items map to ELEMENT.
	Data item content			DATA_VALUE	The data types are now defined by the CEN data types standard and are not therefore defined in this part of ISO 13606
SCC			RECORD_COMPONENT	orig_parent_ref	Please refer to Clause 5 for a description of the ways in which views and selection criteria are now accommodated within this part of ISO 13606
			LINK	Target	
Link item			LINK		
Attestation information			ATTESTATION_INFO		

Table B.6 (*continued*)

ENV 13606 class	ENV 13606 attribute	Comment on the ENV 13606 specification	ISO 13606 class	ISO 13606 attribute	Mapping comments
	Attesting agent			FUNCTIONAL_ROLE.performer	
	Date and time of attestation			time	
	Reason for attestation			FUNCTIONAL_ROLE.function	
	Digital signature			proof	
Revision information			AUDIT_INFO		
	Revised version reference			previous_version	
	Reason for revision			reason_for_revision	
	Reason for revision comments				Reason for revision comments may be mapped to the original text attribute within the CV data type
Data types					These are now represented using the CEN data types. Please refer to EN 13606 for any required mapping information
Healthcare agent subsystem			DEMOGRAPHICS PACKAGE		

Annex C
(informative)

Clinical example

This annex shows how a simple part-record of an ante-natal check up can be represented using classes and attributes of the reference model. This is shown below as a spreadsheet, showing each class in bold and the list of its attributes directly below it. Containment is shown through indentation to the right. For each attribute, a "dot" notation has been used to indicate which attribute of the relevant data type has been used for each actual value. Some of the optional attributes available in the reference model have not been used, in order to limit the size of this example.

28-week check performed on 12/7/96 at 13:42 by Dr. D. Kalra

Gestation 27 weeks

Symptoms: "I feel lousy all the time"

Severe heartburn (link to previous antenatal check where this was noted to be mild)

Abdomen:

Cephalic presentation

Foetal heart 140/min, regular (using sonicaid)

Blood pressure: 100/60

To add complexity to this example, the blood pressure shown above is a corrected entry committed the day after this clinical encounter – the original blood pressure committed on the day was erroneously entered as 100/160. To send both versions, the EHR_EXTRACT example below sends the data as two complete COMPOSITIONS with references between them.

EHR_EXTRACT											
ehr_system.extension = Whittington											
ehr_system.assigningAuthorityName = NHS											
ehr_system.valid_time = 1/1/1990 - 1/1/3000											
ehr_system.root.oid = 9876543211											
ehr_id.extension = WH.1234											
ehr_id.assigningAuthorityName = NHS											
ehr_id.valid_time = 1/1/1990 - 1/1/3000											
ehr_id.root.oid = 9876543211											
subject_of_care.extension = 9876543											
subject_of_care.assigningAuthorityName = NHS											
subject_of_care.valid_time = 1/1/1990 - 1/1/3000											
subject_of_care.root.oid = 9876543211											
time_created.time = 16/07/2004 17:32											
rm_id = EN13606-1.0											
	FOLDER										
	rc_id.extension = 0001										
	rc_id.assigningAuthorityName = NLONDON-NHS										
	rc_id.valid_time = 1/1/1990 - 1/1/3000										
	rc_id.root.oid = 9876543213										
	name = Obstetrics										
	meaning.codingScheme = 1234567890										
	meaning.codingSchemeName = CEN										
	meaning.codingSchemeVersion = 1.1										
	meaning.codeValue = CENarch-asdyz										
	meaning.displayName = Obstetric care										
	synthesised = FALSE										
		COMPOSITION									
		rc_id.extension = 0113									
		rc_id.assigningAuthorityName = NLONDON-NHS									
		rc_id.valid_time = 1/1/1990 - 1/1/3000									
		rc_id.root.oid = 9876543213									
		name = 28-week check									
		meaning.codingScheme = 1234567890									
		meaning.codingSchemeName = CEN									
		meaning.codingSchemeVersion = 1.1									
		meaning.codeValue = CENarch-xvwyz									
		meaning.displayName = Antenatal review at 28 weeks gestation									
		synthesised = FALSE									
		sensitivity = 3									
		composer.performer.extension = KALRA194									
		composer.performer.assigningAuthorityName = NHS									
		committal.ehr_system.extension = Whittington									
		committal.ehr_system.assigningAuthorityName = NHS									
		committal.ehr_system.valid_time = 1/1/1990 - 1/1/3000									
		committal.ehr_system.root.oid = 9876543211									
		committal.time_committed = 12.07.1996 13:42									
		committal.committer.extension = KALRA194									
		committal.committer.assigningAuthorityName = NHS									
		committal.committer.valid_time = 1/1/1990 - 1/1/3000									
		committal.committer.root.oid = 9876543211									
		ENTRY									
		rc_id.extension = 0114									
		rc_id.assigningAuthorityName = NLONDON-NHS									
		rc_id.valid_time = 1/1/1990 - 1/1/3000									
		rc_id.root.oid = 9876543213									
		name = Gestation									
		meaning.codingScheme = 1234567890									
		meaning.codingSchemeName = CEN									
		meaning.codingSchemeVersion = 1.1									
		meaning.codeValue = CENarch-xvwyzA									

			meaning.displayName = Gestation of pregnancy									
			synthesised = FALSE									
			subject_of_information_category.codingScheme = 987654333									
			subject_of_information_category.codingSchemeName = EN13606-3 SUBJECT_CATEGORY									
			subject_of_information_category.codingSchemeVersion = 1.0									
			subject_of_information_category.codeValue = DS0									
			uncertainty_expressed = FALSE									
			ELEMENT									
			rc_id.extension = 0115									
			rc_id.assigningAuthorityName = NLONDON-NHS									
			rc_id.valid_time = 1/1/1990 - 1/1/3000									
			rc_id.root.oid = 9876543213									
			name = Gestational assessment									
			meaning.codingScheme = 1234567890									
			meaning.codingSchemeName = CEN									
			meaning.codingSchemeVersion = 1.1									
			meaning.codeValue = CENarch-xvwyzAA									
			meaning.displayName = Gestation assessment in weeks									
			item_category.codingScheme = 987654334									
			item_category.codingSchemeName = EN13606-3 ITEM_CATEGORY									
			item_category.codingSchemeVersion = 1.0									
			item_category.codeValue = IC01									
			synthesised = FALSE									
			value.PQ.value = 27									
			value.PQ.units = Weeks									
			value.PQ.property = time									
			ENTRY									
			rc_id.extension = 0116									
			rc_id.assigningAuthorityName = NLONDON-NHS									
			rc_id.valid_time = 1/1/1990 - 1/1/3000									
			rc_id.root.oid = 9876543213									
			name = Presenting symptoms									
			meaning.codingScheme = 1234567890									
			meaning.codingSchemeName = CEN									
			meaning.codingSchemeVersion = 1.1									
			meaning.codeValue = CENarch-xvwyzB									
			meaning.displayName = Symptoms within pregnancy									
			synthesised = FALSE									
			subject_of_information_category.codingScheme = 987654333									
			subject_of_information_category.codingSchemeName = EN13606-3 SUBJECT_CATEGORY									
			subject_of_information_category.codingSchemeVersion = 1.0									
			subject_of_information_category.codeValue = DS0									
			uncertainty_expressed = FALSE									
			ELEMENT									
			rc_id.extension = 0117									
			rc_id.assigningAuthorityName = NLONDON-NHS									
			rc_id.valid_time = 1/1/1990 - 1/1/3000									
			rc_id.root.oid = 9876543213									
			name = Symptom									
			meaning.codingScheme = 1234567890									
			meaning.codingSchemeName = CEN									
			meaning.codingSchemeVersion = 1.1									
			meaning.codeValue = CENarch-xvwabcA									
			meaning.displayName = Symptom description									
			item_category = IC01									
			synthesised = FALSE									
			value.TEXT.displayName = I feel lousy all the time									

				ELEMENT							
				rc_id.extension = 0118							
				rc_id.assigningAuthorityName = NLONDON-NHS							
				rc_id.valid_time = 1/1/1990 - 1/1/3000							
				rc_id.root.oid = 9876543213							
				name = Symptom							
				meaning.codingScheme = 1234567890							
				meaning.RC_UID = 0012							
				meaning.codingSchemeVersion = 1.1							
				meaning.codeValue = CENarch-xvwabcA							
				meaning.displayName = Symptom description							
				item_category.codingScheme = 987654334							
				item_category.codingSchemeName = EN13606-3 ITEM_CATEGORY							
				item_category.codingSchemeVersion = 1.0							
				item_category.codeValue = IC01							
				synthesised = FALSE							
				value.CODED_TEXT.codingScheme = ICD-12							
				value.CODED_TEXT.codingSchemeName = Int. Class. Diseases							
				value.CODED_TEXT.codingSchemeVersion = 12							
				value.CODED_TEXT.codeValue = D1234							
				value.CODED_TEXT.displayName = Reflux oesophagitis, severe							
				value.CODED_TEXT.originalText = Severe heartburn							
				links.nature = LINK-C0							
				links.role = LINK-C9							
				links.follow_link = FALSE							
				links.target.rc_id.extension = 0008							
				links.target.rc_id.assigningAuthorityName = NLONDON-NHS							
				links.target.rc_id.valid_time = 1/1/1990 - 1/1/3000							
				links.target.rc_id.root.oid = 9876543213							
			SECTION								
			rc_id.extension = 0120								
			rc_id.assigningAuthorityName = NLONDON-NHS								
			rc_id.valid_time = 1/1/1990 - 1/1/3000								
			rc_id.root.oid = 9876543213								
			name = Abdominal examination								
			synthesised = FALSE								
				ENTRY							
				rc_id.extension = 0121							
				rc_id.assigningAuthorityName = NLONDON-NHS							
				rc_id.valid_time = 1/1/1990 - 1/1/3000							
				rc_id.root.oid = 9876543213							
				name = Presentation							
				meaning.codingScheme = 1234567890							
				meaning.codingSchemeName = CEN							
				meaning.codingSchemeVersion = 1.1							
				meaning.codeValue = CENarch-xvwyzF							
				meaning.displayName = Foetal position							
				synthesised = FALSE							
				subject_of_information_category.codingScheme = 987654333							
				subject_of_information_category.codingSchemeName = EN13606-3 SUBJECT_CATEGORY							
				subject_of_information_category.codingSchemeVersion = 1.0							
				subject_of_information_category.codeValue = DS00							
				uncertainty_expressed = FALSE							
					ELEMENT						
					rc_id.extension = 0122						
					rc_id.assigningAuthorityName = NLONDON-NHS						
					rc_id.valid_time = 1/1/1990 - 1/1/3000						
					rc_id.root.oid = 9876543213						
					name = Lie						
					meaning.codingScheme = 1234567890						
					meaning.codingSchemeName = CEN						

					meaning.codingSchemeVersion = 1.1					
					meaning.codeValue = CENarch-xvwyzF1					
					meaning.displayName = Foetal orientation					
					item_category.codingScheme = 987654334					
					item_category.codingSchemeName = EN13606-3 ITEM_CATEGORY					
					item_category.codingSchemeVersion = 1.0					
					item_category.codeValue = IC01					
					synthesised = FALSE					
					value.CV.codingScheme = CTV3					
					value.CV.codingSchemeName = NHS Clin. Terms					
					value.CV.codingSchemeVersion = 1.0					
					value.CV.codeValue = 635284					
					value.CV.displayName = Longitudinal					
					ELEMENT					
					rc_id.extension = 0123					
					rc_id.assigningAuthorityName = NLONDON-NHS					
					rc_id.valid_time = 1/1/1990 - 1/1/3000					
					rc_id.root.oid = 9876543213					
					name = Presentation					
					meaning.codingScheme = 1234567890					
					meaning.codingSchemeName = CEN					
					meaning.codingSchemeVersion = 1.1					
					meaning.codeValue = CENarch-xvwyzF2					
					meaning.displayName = Foetal presentation					
					item_category.codingScheme = 987654334					
					item_category.codingSchemeName = EN13606-3 ITEM_CATEGORY					
					item_category.codingSchemeVersion = 1.0					
					item_category.codeValue = IC01					
					synthesised = FALSE					
					value.CV.codingScheme = CTV3					
					value.CV.codingSchemeName = NHS Clin. Terms					
					value.CV.codingSchemeVersion = 1.0					
					value.CV.codeValue = 635288					
					value.CV.displayName = Cephalic					
				ENTRY						
				rc_id.extension = 0131						
				rc_id.assigningAuthorityName = NLONDON-NHS						
				rc_id.valid_time = 1/1/1990 - 1/1/3000						
				rc_id.root.oid = 9876543213						
				name = Heart rate						
				meaning.codingScheme = 1234567890						
				meaning.codingSchemeName = CEN						
				meaning.codingSchemeVersion = 1.1						
				meaning.codeValue = CENarch-xvwyzH						
				meaning.displayName = Foetal cardiac assessment						
				synthesised = FALSE						
				subject_of_information_category = DS02						
				uncertainty_expressed = FALSE						
				subject_of_information_category.codingScheme = 987654333						
				subject_of_information_category.codingSchemeName = EN13606-3 SUBJECT_CATEGORY						
				subject_of_information_category.codingSchemeVersion = 1.0						
				subject_of_information_category.codeValue = DS002						
				subject_of_information.relationship.codeValue = "Foetus"						
					ELEMENT					
					rc_id.extension = 0133					
					rc_id.assigningAuthorityName = NLONDON-NHS					
					rc_id.valid_time = 1/1/1990 - 1/1/3000					
					rc_id.root.oid = 9876543213					
					name = FH					
					meaning.codingScheme = 1234567890					
					meaning.codingSchemeName = CEN					

					meaning.codingSchemeVersion = 1.1				
					meaning.codeValue = CENarch-xvwyzHA				
					meaning.displayName = Measurement of foetal cardiac rate per minute				
					item_category.codingScheme = 987654334				
					item_category.codingSchemeName = EN13606-3 ITEM_CATEGORY				
					item_category.codingSchemeVersion = 1.0				
					item_category.codeValue = IC01				
					synthesised = FALSE				
					value.PQ.value = 140				
					value.PQ.units = beats per minute				
					value.PQ.property = frequency				
					ELEMENT				
					rc_id.extension = 0135				
					rc_id.assigningAuthorityName = NLONDON-NHS				
					rc_id.valid_time = 1/1/1990 - 1/1/3000				
					rc_id.root.oid = 9876543213				
					name = Device				
					meaning.codingScheme = 1234567890				
					meaning.codingSchemeName = CEN				
					meaning.codingSchemeVersion = 1.1				
					meaning.codeValue = CENarch-xvwyzHD				
					meaning.displayName = Measurement device for foetal cardiac rate				
					item_category.codingScheme = 987654334				
					item_category.codingSchemeName = EN13606-3 ITEM_CATEGORY				
					item_category.codingSchemeVersion = 1.0				
					item_category.codeValue = IC04				
					synthesised = FALSE				
					value.CV.codingScheme = CEN DEV REG				
					value.CV.codingSchemeName = CEN device registry				
					value.CV.codingSchemeVersion = 6.8				
					value.CV.codeValue = 5621				
					value.CV.displayName = Sonicaid doppler deluxe				
					ELEMENT				
					rc_id.extension = 0136				
					rc_id.assigningAuthorityName = NLONDON-NHS				
					rc_id.valid_time = 1/1/1990 - 1/1/3000				
					rc_id.root.oid = 9876543213				
					name = FH rhythm				
					meaning.codingScheme = 1234567890				
					meaning.codingSchemeName = CEN				
					meaning.codingSchemeVersion = 1.1				
					meaning.codeValue = CENarch-xvwyzHR				
					meaning.displayName = Description of foetal cardiac rhythm				
					item_category.codingScheme = 987654334				
					item_category.codingSchemeName = EN13606-3 ITEM_CATEGORY				
					item_category.codingSchemeVersion = 1.0				
					item_category.codeValue = IC01				
					synthesised = FALSE				
					value.CV.codingScheme = CTV3				
					value.CV.codingSchemeName = NHS Clin. Terms				
					value.CV.codingSchemeVersion = 1.0				
					value.CV.codeValue = 635700				
					value.CV.displayName = Regular				
			ENTRY						
			rc_id.extension = 0151						
			rc_id.assigningAuthorityName = NLONDON-NHS						
			rc_id.valid_time = 1/1/1990 - 1/1/3000						
			rc_id.root.oid = 9876543213						
			name = BP						
			meaning.codingScheme = 1234567890						
			meaning.codingSchemeName = CEN						

			meaning.codingSchemeVersion = 1.1							
			meaning.codeValue = CENarch-xvbnh							
			meaning.displayName = Blood Pressure							
			synthesised = FALSE							
			subject_of_information_category.codingScheme = 987654333							
			subject_of_information_category.codingSchemeName = EN13606-3 SUBJECT_CATEGORY							
			subject_of_information_category.codingSchemeVersion = 1.0							
			subject_of_information_category.codeValue = DS00							
			uncertainty_expressed = FALSE							
			ELEMENT							
			rc_id.extension = 0155							
			rc_id.assigningAuthorityName = NLONDON-NHS							
			rc_id.valid_time = 1/1/1990 - 1/1/3000							
			rc_id.root.oid = 9876543213							
			name = Systolic							
			meaning.codingScheme = 1234567890							
			meaning.codingSchemeName = CEN							
			meaning.codingSchemeVersion = 1.1							
			meaning.codeValue = CENarch-xvbnhS							
			meaning.displayName = Measurement of systolic blood pressure							
			item_category.codingScheme = 987654334							
			item_category.codingSchemeName = EN13606-3 ITEM_CATEGORY							
			item_category.codingSchemeVersion = 1.0							
			item_category.codeValue = IC01							
			synthesised = FALSE							
			value.PQ.value = 100							
			value.PQ.units = mmHg							
			value.PQ.property = pressure							
			ELEMENT							
			rc_id.extension = 0158							
			rc_id.assigningAuthorityName = NLONDON-NHS							
			rc_id.valid_time = 1/1/1990 - 1/1/3000							
			rc_id.root.oid = 9876543213							
			name = Diastolic							
			meaning.codingScheme = 1234567890							
			meaning.codingSchemeName = CEN							
			meaning.codingSchemeVersion = 1.1							
			meaning.codeValue = CENarch-xvbnhD							
			meaning.displayName = Measurement of diastolic blood pressure							
			item_category.codingScheme = 987654334							
			item_category.codingSchemeName = EN13606-3 ITEM_CATEGORY							
			item_category.codingSchemeVersion = 1.0							
			item_category.codeValue = IC01							
			synthesised = FALSE							
			value.PQ.value = 160							
			value.PQ.units = mmHg							
			value.PQ.property = pressure							
		COMPOSITION								
		rc_id.extension = 0213								
		rc_id.assigningAuthorityName = NLONDON-NHS								
		rc_id.valid_time = 1/1/1990 - 1/1/3000								
		rc_id.root.oid = 9876543213								
		name = 28-week check								
		meaning.codingScheme = 1234567890								
		meaning.codingSchemeName = CEN								
		meaning.codingSchemeVersion = 1.1								
		meaning.codeValue = CENarch-xvwyz								
		meaning.displayName = Antenatal review at 28 weeks gestation								
		synthesised = FALSE								
		sensitivity = 3								
		composer.performer.extension = KALRA194								

		composer.performer.assigningAuthorityName = NHS										
		committal.ehr_system.extension = Whittington										
		committal.ehr_system.assigningAuthorityName = NHS										
		committal.ehr_system.valid_time = 1/1/1990 - 1/1/3000										
		committal.ehr_system.root.oid = 9876543211										
		committal.time_committed = 13.07.1996 09:11										
		committal.committer.extension = LLOYD345										
		committal.committer.assigningAuthorityName = NHS										
		committal.committer.valid_time = 1/1/1990 - 1/1/3000										
		committal.committer.root.oid = 9876543211										
		committal.version_status.codingScheme = 987654338										
		committal.version_status.codingSchemeName = EN13606-3 VERSION_STATUS										
		committal.version_status.codingSchemeVersion = 1.0										
		committal.version_status.codeValue = VER03										
		committal.previous_version.rc_id.extension = 0113										
		committal.previous_version.rc_id.assigningAuthorityName = NLONDON-NHS										
		committal.previous_version.rc_id.valid_time = 1/1/1990 - 1/1/3000										
		committal.previous_version.rc_id.root.oid = 9876543213										
		committal.version_set_id.rc_id.extension = 0113										
		committal.version_set_id.rc_id.assigningAuthorityName = NLONDON-NHS										
		committal.version_set_id.rc_id.valid_time = 1/1/1990 - 1/1/3000										
		committal.version_set_id.rc_id.root.oid = 9876543213										
			ENTRY									
			rc_id.extension = 0114									
			rc_id.assigningAuthorityName = NLONDON-NHS									
			rc_id.valid_time = 1/1/1990 - 1/1/3000									
			rc_id.root.oid = 9876543213									
			name = Gestation									
			meaning.codingScheme = 1234567890									
			meaning.codingSchemeName = CEN									
			meaning.codingSchemeVersion = 1.1									
			meaning.codeValue = CENarch-xvwyzA									
			meaning.displayName = Gestation of pregnancy									
			synthesised = FALSE									
			subject_of_information_category.codingScheme = 987654333									
			subject_of_information_category.codingSchemeName = EN13606-3 SUBJECT_CATEGORY									
			subject_of_information_category.codingSchemeVersion = 1.0									
			subject_of_information_category.codeValue = DS00									
			uncertainty_expressed = FALSE									
			original_parent_ref.rc_id.extension = 0113									
			original_parent_ref.rc_id.assigningAuthorityName = NLONDON-NHS									
			original_parent_ref.rc_id.valid_time = 1/1/1990 - 1/1/3000									
			original_parent_ref.rc_id.root.oid = 9876543213									
				ELEMENT								
				rc_id.extension = 0115								
				rc_id.assigningAuthorityName = NLONDON-NHS								
				rc_id.valid_time = 1/1/1990 - 1/1/3000								
				rc_id.root.oid = 9876543213								
				name = Gestational assessment								
				meaning.codingScheme = 1234567890								
				meaning.codingSchemeName = CEN								
				meaning.codingSchemeVersion = 1.1								
				meaning.codeValue = CENarch-xvwyzAA								
				meaning.displayName = Gestation assessment in weeks								
				item_category.codingScheme = 987654334								
				item_category.codingSchemeName = EN13606-3 ITEM_CATEGORY								
				item_category.codingSchemeVersion = 1.0								
				item_category.codeValue = IC01								
				synthesised = FALSE								
				value.PQ.value = 27								
				value.PQ.units = Weeks								
				value.PQ.property = time								

			ENTRY									
			rc_id.extension = 0116									
			rc_id.assigningAuthorityName = NLONDON-NHS									
			rc_id.valid_time = 1/1/1990 - 1/1/3000									
			rc_id.root.oid = 9876543213									
			name = Presenting symptoms									
			meaning.codingScheme = 1234567890									
			meaning.codingSchemeName = CEN									
			meaning.codingSchemeVersion = 1.1									
			meaning.codeValue = CENarch-xvwyzB									
			meaning.displayName = Symptoms within pregnancy									
			synthesised = FALSE									
			subject_of_information_category.codingScheme = 987654333									
			subject_of_information_category.codingSchemeName = EN13606-3 SUBJECT_CATEGORY									
			subject_of_information_category.codingSchemeVersion = 1.0									
			subject_of_information_category.codeValue = DS00									
			uncertainty_expressed = FALSE									
			original_parent_ref.rc_id.extension = 0113									
			original_parent_ref.rc_id.assigningAuthorityName = NLONDON-NHS									
			original_parent_ref.rc_id.valid_time = 1/1/1990 - 1/1/3000									
			original_parent_ref.rc_id.root.oid = 9876543213									
				ELEMENT								
				rc_id.extension = 0117								
				rc_id.assigningAuthorityName = NLONDON-NHS								
				rc_id.valid_time = 1/1/1990 - 1/1/3000								
				rc_id.root.oid = 9876543213								
				name = Symptom								
				meaning.codingScheme = 1234567890								
				meaning.codingSchemeName = CEN								
				meaning.codingSchemeVersion = 1.1								
				meaning.codeValue = CENarch-xvwabcA								
				meaning.displayName = Symptom description								
				item_category = IC01								
				synthesised = FALSE								
				value.TEXT.displayName = I feel lousy all the time								
				ELEMENT								
				rc_id.extension = 0118								
				rc_id.assigningAuthorityName = NLONDON-NHS								
				rc_id.valid_time = 1/1/1990 - 1/1/3000								
				rc_id.root.oid = 9876543213								
				name = Symptom								
				meaning.codingScheme = 1234567890								
				meaning.RC_UID = 0012								
				meaning.codingSchemeVersion = 1.1								
				meaning.codeValue = CENarch-xvwabcA								
				meaning.displayName = Symptom description								
				item_category.codingScheme = 987654334								
				item_category.codingSchemeName = EN13606-3 ITEM_CATEGORY								
				item_category.codingSchemeVersion = 1.0								
				item_category.codeValue = IC01								
				synthesised = FALSE								
				value.CODED_TEXT.codingScheme = ICD-12								
				value.CODED_TEXT.codingSchemeName = Int. Class. Diseases								
				value.CODED_TEXT.codingSchemeVersion = 12								
				value.CODED_TEXT.codeValue = D1234								
				value.CODED_TEXT.displayName = Reflux oesophagitis, severe								
				value.CODED_TEXT.originalText = Severe heartburn								
				links.nature = LINK-C0								
				links.role = LINK-C9								
				links.follow_link = FALSE								
				links.target.rc_id.extension = 0008								

				links.target.rc_id.assigningAuthorityName = NLONDON-NHS								
				links.target.rc_id.valid_time = 1/1/1990 - 1/1/3000								
				links.target.rc_id.root.oid = 9876543213								
			SECTION									
			rc_id.extension = 0120									
			rc_id.assigningAuthorityName = NLONDON-NHS									
			rc_id.valid_time = 1/1/1990 - 1/1/3000									
			rc_id.root.oid = 9876543213									
			name = Abdominal examination									
			synthesised = FALSE									
			original_parent_ref.rc_id.extension = 0113									
			original_parent_ref.rc_id.assigningAuthorityName = NLONDON-NHS									
			original_parent_ref.rc_id.valid_time = 1/1/1990 - 1/1/3000									
			original_parent_ref.rc_id.root.oid = 9876543213									
			ENTRY									
			rc_id.extension = 0121									
			rc_id.assigningAuthorityName = NLONDON-NHS									
			rc_id.valid_time = 1/1/1990 - 1/1/3000									
			rc_id.root.oid = 9876543213									
			name = Presentation									
			meaning.codingScheme = 1234567890									
			meaning.codingSchemeName = CEN									
			meaning.codingSchemeVersion = 1.1									
			meaning.codeValue = CENarch-xvwyzF									
			meaning.displayName = Foetal position									
			synthesised = FALSE									
			subject_of_information_category.codingScheme = 987654333									
			subject_of_information_category.codingSchemeName = EN13606-3 SUBJECT_CATEGORY									
			subject_of_information_category.codingSchemeVersion = 1.0									
			subject_of_information_category.codeValue = DS00									
			uncertainty_expressed = FALSE									
				ELEMENT								
				rc_id.extension = 0122								
				rc_id.assigningAuthorityName = NLONDON-NHS								
				rc_id.valid_time = 1/1/1990 - 1/1/3000								
				rc_id.root.oid = 9876543213								
				name = Lie								
				meaning.codingScheme = 1234567890								
				meaning.codingSchemeName = CEN								
				meaning.codingSchemeVersion = 1.1								
				meaning.codeValue = CENarch-xvwyzF1								
				meaning.displayName = Foetal orientation								
				item_category.codingScheme = 987654334								
				item_category.codingSchemeName = EN13606-3 ITEM_CATEGORY								
				item_category.codingSchemeVersion = 1.0								
				item_category.codeValue = IC01								
				synthesised = FALSE								
				value.CV.codingScheme = CTV3								
				value.CV.codingSchemeName = NHS Clin. Terms								
				value.CV.codingSchemeVersion = 1.0								
				value.CV.codeValue = 635284								
				value.CV.displayName = Longitudinal								
				ELEMENT								
				rc_id.extension = 0123								
				rc_id.assigningAuthorityName = NLONDON-NHS								
				rc_id.valid_time = 1/1/1990 - 1/1/3000								
				rc_id.root.oid = 9876543213								
				name = Presentation								
				meaning.codingScheme = 1234567890								
				meaning.codingSchemeName = CEN								

					meaning.codingSchemeVersion = 1.1					
					meaning.codeValue = CENarch-xvwyzF2					
					meaning.displayName = Foetal presentation					
					item_category.codingScheme = 987654334					
					item_category.codingSchemeName = EN13606-3 ITEM_CATEGORY					
					item_category.codingSchemeVersion = 1.0					
					item_category.codeValue = IC01					
					synthesised = FALSE					
					value.CV.codingScheme = CTV3					
					value.CV.codingSchemeName = NHS Clin. Terms					
					value.CV.codingSchemeVersion = 1.0					
					value.CV.codeValue = 635288					
					value.CV.displayName = Cephalic					
				ENTRY						
				rc_id.extension = 0131						
				rc_id.assigningAuthorityName = NLONDON-NHS						
				rc_id.valid_time = 1/1/1990 - 1/1/3000						
				rc_id.root.oid = 9876543213						
				name = Heart rate						
				meaning.codingScheme = 1234567890						
				meaning.codingSchemeName = CEN						
				meaning.codingSchemeVersion = 1.1						
				meaning.codeValue = CENarch-xvwyzH						
				meaning.displayName = Foetal cardiac assessment						
				synthesised = FALSE						
				subject_of_information_category = DS02						
				uncertainty_expressed = FALSE						
				subject_of_information_category.codingScheme = 987654333						
				subject_of_information_category.codingSchemeName = EN13606-3 SUBJECT_CATEGORY						
				subject_of_information_category.codingSchemeVersion = 1.0						
				subject_of_information_category.codeValue = DS002						
				subject_of_information.relationship.codeValue = "Foetus"						
					ELEMENT					
					rc_id.extension = 0133					
					rc_id.assigningAuthorityName = NLONDON-NHS					
					rc_id.valid_time = 1/1/1990 - 1/1/3000					
					rc_id.root.oid = 9876543213					
					name = FH					
					meaning.codingScheme = 1234567890					
					meaning.codingSchemeName = CEN					
					meaning.codingSchemeVersion = 1.1					
					meaning.codeValue = CENarch-xvwyzHA					
					meaning.displayName = Measurement of foetal cardiac rate per minute					
					item_category.codingScheme = 987654334					
					item_category.codingSchemeName = EN13606-3 ITEM_CATEGORY					
					item_category.codingSchemeVersion = 1.0					
					item_category.codeValue = IC01					
					synthesised = FALSE					
					value.PQ.value = 140					
					value.PQ.units = beats per minute					
					value.PQ.property = frequency					
					ELEMENT					
					rc_id.extension = 0135					
					rc_id.assigningAuthorityName = NLONDON-NHS					
					rc_id.valid_time = 1/1/1990 - 1/1/3000					
					rc_id.root.oid = 9876543213					
					name = Device					
					meaning.codingScheme = 1234567890					
					meaning.codingSchemeName = CEN					
					meaning.codingSchemeVersion = 1.1					
					meaning.codeValue = CENarch-xvwyzHD					

					meaning.displayName = Measurement device for foetal cardiac rate
					item_category.codingScheme = 987654334
					item_category.codingSchemeName = EN13606-3 ITEM_CATEGORY
					item_category.codingSchemeVersion = 1.0
					item_category.codeValue = IC04
					synthesised = FALSE
					value.CV.codingScheme = CEN DEV REG
					value.CV.codingSchemeName = CEN device registry
					value.CV.codingSchemeVersion = 6.8
					value.CV.codeValue = 5621
					value.CV.displayName = Sonicaid doppler deluxe
					ELEMENT
					rc_id.extension = 0136
					rc_id.assigningAuthorityName = NLONDON-NHS
					rc_id.valid_time = 1/1/1990 - 1/1/3000
					rc_id.root.oid = 9876543213
					name = FH rhythm
					meaning.codingScheme = 1234567890
					meaning.codingSchemeName = CEN
					meaning.codingSchemeVersion = 1.1
					meaning.codeValue = CENarch-xvwyzHR
					meaning.displayName = Description of foetal cardiac rhythm
					item_category.codingScheme = 987654334
					item_category.codingSchemeName = EN13606-3 ITEM_CATEGORY
					item_category.codingSchemeVersion = 1.0
					item_category.codeValue = IC01
					synthesised = FALSE
					value.CV.codingScheme = CTV3
					value.CV.codingSchemeName = NHS Clin. Terms
					value.CV.codingSchemeVersion = 1.0
					value.CV.codeValue = 635700
					value.CV.displayName = Regular
			ENTRY		
			rc_id.extension = 0251		
			rc_id.assigningAuthorityName = NLONDON-NHS		
			rc_id.valid_time = 1/1/1990 - 1/1/3000		
			rc_id.root.oid = 9876543213		
			name = BP		
			meaning.codingScheme = 1234567890		
			meaning.codingSchemeName = CEN		
			meaning.codingSchemeVersion = 1.1		
			meaning.codeValue = CENarch-xvbnh		
			meaning.displayName = Blood Pressure		
			synthesised = FALSE		
			subject_of_information_category.codingScheme = 987654333		
			subject_of_information_category.codingSchemeName = EN13606-3 SUBJECT_CATEGORY		
			subject_of_information_category.codingSchemeVersion = 1.0		
			subject_of_information_category.codeValue = DS00		
			uncertainty_expressed = FALSE		
			committal.ehr_system.extension = Whittington		
			committal.ehr_system.assigningAuthorityName = NHS		
			committal.ehr_system.valid_time = 1/1/1990 - 1/1/3000		
			committal.ehr_system.root.oid = 9876543211		
			committal.time_committed = 13.07.1996 09:11		
			committal.committer.extension = LLOYD345		
			committal.committer.assigningAuthorityName = NHS		
			committal.committer.valid_time = 1/1/1990 - 1/1/3000		
			committal.committer.root.oid = 9876543211		
			committal.version_status.codingScheme = 987654338		
			committal.version_status.codingSchemeName = EN13606-3 VERSION_STATUS		
			committal.version_status.codingSchemeVersion = 1.0		
			committal.version_status.codeValue = VER03		

			committal.previous_version.rc_id.extension = 0151								
			committal.previous_version.rc_id.assigningAuthorityName = NLONDON-NHS								
			committal.previous_version.rc_id.valid_time = 1/1/1990 - 1/1/3000								
			committal.previous_version.rc_id.root.oid = 9876543213								
			committal.version_set_id.rc_id.extension = 0151								
			committal.version_set_id.rc_id.assigningAuthorityName = NLONDON-NHS								
			committal.version_set_id.rc_id.valid_time = 1/1/1990 - 1/1/3000								
			committal.version_set_id.rc_id.root.oid = 9876543213								
				ELEMENT							
				rc_id.extension = 0155							
				rc_id.assigningAuthorityName = NLONDON-NHS							
				rc_id.valid_time = 1/1/1990 - 1/1/3000							
				rc_id.root.oid = 9876543213							
				name = Systolic							
				meaning.codingScheme = 1234567890							
				meaning.codingSchemeName = CEN							
				meaning.codingSchemeVersion = 1.1							
				meaning.codeValue = CENarch-xvbnhS							
				meaning.displayName = Measurement of systolic blood pressure							
				item_category.codingScheme = 987654334							
				item_category.codingSchemeName = EN13606-3 ITEM_CATEGORY							
				item_category.codingSchemeVersion = 1.0							
				item_category.codeValue = IC01							
				synthesised = FALSE							
				original_parent_ref.rc_id.extension = 0151							
				original_parent_ref.rc_id.assigningAuthorityName = NLONDON-NHS							
				original_parent_ref.rc_id.valid_time = 1/1/1990 - 1/1/3000							
				original_parent_ref.rc_id.root.oid = 9876543213							
				value.PQ.value = 100							
				value.PQ.units = mmHg							
				value.PQ.property = pressure							
				ELEMENT							
				rc_id.extension = 0258							
				rc_id.assigningAuthorityName = NLONDON-NHS							
				rc_id.valid_time = 1/1/1990 - 1/1/3000							
				rc_id.root.oid = 9876543213							
				name = Diastolic							
				meaning.codingScheme = 1234567890							
				meaning.codingSchemeName = CEN							
				meaning.codingSchemeVersion = 1.1							
				meaning.codeValue = CENarch-xvbnhD							
				meaning.displayName = Measurement of diastolic blood pressure							
				item_category.codingScheme = 987654334							
				item_category.codingSchemeName = EN13606-3 ITEM_CATEGORY							
				item_category.codingSchemeVersion = 1.0							
				item_category.codeValue = IC01							
				synthesised = FALSE							
				value.PQ.value = 60							
				value.PQ.units = mmHg							
				value.PQ.property = pressure							

Annex D
(informative)

Mapping to statements of requirement

As indicated in the Introduction, ISO/TS 18308 has been adopted as the requirements basis for this International Standard. A mapping of these statements to key constructs in the Reference Model is included here. Inevitably these mappings are not one-to-one. It is hoped that this table provides a further level of insight into the rationale behind elements of the approach taken in designing this Reference Model.

Code	Statement of requirement	Correspondence in ISO 13606-1
COC1.1	The EHRA shall support the production of a consumer oriented view. (9.1)	Handled through access control measures — defined in ISO 13606-4.
COC1.2	The EHRA shall support consumers' right of access to all EHR information subject to jurisdictional constraints. (9.1)	Handled through access control measures — defined in ISO 13606-4.
COC1.3	The EHRA shall support consumers being able to incorporate self-care information, their point of view on personal healthcare issues, levels of satisfaction, expectations and comments they wish to record in EHRs. (9.1)	Handled through access control measures — defined in ISO 13606-4. This part of ISO 13606 can represent any potential composer or committer of the data, including a patient or his/her representative.
COM2.1	The EHRA shall allow for the exchange of a complete EHRA or a part of an EHR (an extract) between EHRA compliant systems. (4.4)	EHR_EXTRACT
COM2.3	The EHRA shall define the semantics of merging data from an EHR extract with the EHR resident in the receiving system. (4.7)	EHR_EXTRACT
COM2.4	The EHRA shall provide an audit trail of exchange processes, including authentication, to enable identification of points of EHR extract transmittal and receipt. This needs to account for merging processes. (4.3)	Audit trail communication — defined in ISO 13606-4
COM2.6	The EHRA shall enable semantic interoperability of clinical concepts between EHR systems to support automatic processing of data at the receiving system. (3.3.4)	Semantics primarily represented by RECORD_COMPONENT.meaning, through the use of archetypes, and the use of coded value data types.
MEL1.1	The EHRA shall support measures to ensure an accurate reflection of the chronology of clinical events and information availability in the EHR. (6.3)	Information availability: RECORD_COMPONENT.committal.time_committed RECORD_COMPONENT.feeder_audit.time_committed Chronology of clinical events: COMPOSITION.session_time ITEM.obs_time

Code	Statement of requirement	Correspondence in ISO 13606-1
MEL1.2	The EHRA shall enable the viewing of an accurate representation of the EHR at any particular date and time since its creation. (6.4)	As for MEL1.1
MEL2.1	The EHRA shall cater for the subject of care of the EHR to be one or more persons. (6.1.1)	This requirement is not met by ISO 13606, which limits EHR communication to the EHR of a single subject of care. Data about more than one data subject may be included, if appropriate.
MEL2.2	The EHRA shall cater for the recording of appropriate patient identification attributes and clinically relevant patient attributes such as date of birth, sex, ethnicity, etc. (6.1.2)	This is represented through the demographics package, but only a minimal description set is included to facilitate demographic matching between EHR systems.
MEL2.3	The EHRA shall ensure that users who attest and commit any particular information to the record are uniquely and reliably identified. (6.1.3)	AUDIT_INFO.committer ATTESTATION_INFO.attester.performer
MEL2.4	The EHRA shall support the on-going ability to identify users, even if they change their name, profession, sex, or address. (6.1.3)	This is handled by using a single identifier throughout the EHR data, and referencing this to a demographic instance in the demographics package.
MEL2.5	The EHRA shall support measures to ensure that all clinical parties referred to in the EHR are uniquely identified. (6.1.4)	As MEL 2.4
MEL2.7	The EHRA shall support measures which ensure that every record entry is dated, and its author identified. (6.1.6)	AUDIT_INFO.time_committed COMPOSITION.composer.performer (optional)
MEL2.8	The EHRA shall support measures to ensure that there be an absolute requirement that each contribution to the record is attributed to a responsible healthcare party whether in the role of author or not. (6.1.5)	This may be via COMPOSITION.committal.committer or COMPOSITION.feeder_audit.committer and/or COMPOSITION.composer.performer
MEL2.9	The EHRA shall support measures which ensure that every contribution to the record is attested by a responsible person. (6.1.6)	FOLDER and COMPOSITION may each contain instances of ATTESTATION_INFO, which in turn may reference any number of RECORD_COMPONENTS. However, in this part of ISO 13606 the inclusion of attestation information is optional, as many EHR instances are never attested.
MEL3.1	The EHRA shall support the demonstration of clinical competence and accountability of clinicians. (6.2)	This is a generic requirement, that is hopefully met by many parts of the reference model.
MEL5.1	Where plain text or coded terms in the EHR have been translated or mapped, the original text or rubric in the original language shall be retained. (6.5.2)	These are properties of the TEXT and CV classes.
MEL7.1	The EHRA shall support versioning at the granularity at which information is attested. (6.8)	A whole set of committed entries shall be re-attested if parts of content are revised. Attestations point to data within a single COMPOSITION version, and are not automatically redirected to a revised one.

Code	Statement of requirement	Correspondence in ISO 13606-1
PRO1.1	The EHRA shall support the recording of any type of clinical event, encounter, or episode relevant to the care of a patient. (3.1)	These can be represented through archetypes.
PRO1.13	The EHRA shall support care planning, including the management of process states (e.g. planned, ordered, scheduled, in progress, on hold, pending, completed, amended, verified, cancelled), within the care planning process. (3.2.4)	ENTRY.act_id and ENTRY.act_status can be used to define a workflow (lifecycle) state and to reference a workflow management system. Optionally the LINK class to reference clinical indications and consequences of the activity.
PRO1.14	The EHRA shall support the recording and tracking of clinical orders and requests such as prescriptions and other treatment orders, investigation requests, and referrals. (3.3.6)	ENTRY.act_id and ENTRY.act_status can be used to define a workflow (lifecycle) state and to reference a workflow management system.
PRO1.15	The EHRA shall support the linking of orders with the observations that arise as a result (e.g. the results of an investigation or administration of a medication with the order for these interventions).	As PRO1.13
PRO1.16	The EHRA shall support integrated patient care including continuing collaborative multi-disciplinary care and case management across different healthcare sectors and settings (e.g. primary care, acute hospitals, allied health, home-based care). (3.2.3).	The reference model supports the representation of various participants, and of formalised clinical data structures via archetypes. Specific ITEMs may be marked as being a reference to an external guideline or care pathway via the item_category attribute.
PRO1.2	The EHRA shall support the creation, instantiation, and maintenance of clinical processes that support the activities of its users. (3.3.5).	ENTRY.act_id and ENTRY.act_status can be used to define a workflow (lifecycle) state and to reference a workflow management system. (This part of ISO 13606 does not directly deal with the creation or maintenance of clinical data or of clinical processes, but to the communication of data about them.)
PRO1.3	The EHRA shall support the continuity of a clinical process, the ability to query the status of a process, modify an existing process, and verify that a process has been completed. (3.3.5)	ENTRY.act_id and ENTRY.act_status can be used to define a workflow (lifecycle) state and to reference a workflow management system. Optionally the LINK class to reference clinical indications and consequences of the activity.
PRO1.4	The EHRA shall be able to accommodate partial completion of a clinical process. (3.3.5)	ENTRY.act_status can be used to represent and communicate that a clinical activity has not yet been completed.
PRO1.5	The EHRA shall support the recording and presentation of holistic health status, functional status, problems, conditions, environmental circumstances and issues. (3.2.1)	These kinds of data can be represented by RECORD_COMPONENT.meaning and through the use of archetypes.
PRO1.8	The EHRA shall support the recording of the clinical reasoning including by automated processes, for all diagnoses, conclusions, and actions regarding the care of a patient. (3.2.2)	Specific ITEMs may be marked as being about a clinical reasoning or justification via the item_category attribute

Code	Statement of requirement	Correspondence in ISO 13606-1
PRO1.9	The EHRA shall support the automatic presentation of warnings, alerts and reminders such as patient infective status, allergies and other therapeutic precautions, outstanding interventions, and urgent results. (3.2.1)	These kinds of data can be represented by RECORD_COMPONENT.meaning, through the use of archetypes, and the use of coded value data types. Specific ITEMs can be marked as being of particular note through the emphasis attribute.
PRO2.1	The EHRA shall support clear and consistent rules for entry, amendment, verification, transmittal, receipt, translation, and obsoleting/superceding of data. This requirement does not imply that it is necessary for a given implementation to allow deletion of EHR content. Local data retention rules will apply. (3.3.1)	This information is represented via the AUDIT_INFO class.
PRS1.2	The EHRA shall support the labelling of the whole and/or sections of the EHR as restricted to authorized users and/or purposes. This should include restrictions at the level of reading, writing, amendment, verification, and transmission/disclosure of data and records. (5.2)	Handled through access control measures — defined in ISO 13606-4.
PRS1.3	The EHRA shall support privacy and confidentiality restrictions at the level of both data sets and discrete data attributes.	Handled through access control measures — defined in ISO 13606-4.
PRS2.2	The EHRA shall support obtaining, recording and tracking the status of informed consent to access the whole and/or sections of the EHR, for defined purposes. (5.3)	Handled through access control measures — defined in ISO 13606-4.
PRS2.4	The EHRA shall support recording of the time frames attached to each consent. (5.3)	Handled through access control measures — defined in ISO 13606-4.
PRS3.1	The EHRA shall support measures to define, attach, modify and remove access rights to the whole and/or sections of the EHR. (5.1.1)	Handled through access control measures — defined in ISO 13606-4.
PRS3.3	The EHRA shall support measures to enable and restrict access to the whole and/or sections of the EHR in accordance with prevailing consent and access rules. (5.1.1)	Handled through access control measures — defined in ISO 13606-4.
PRS3.4	The EHRA shall support measures to separately control authorities to add to and/or modify the EHR from authorities to access the EHR. (5.1.1)	Handled through access control measures — defined in ISO 13606-4.
PRS5.1	The EHRA shall support recording of an audit trail of access to and modifications of data within the whole or sections of the EHR. (5.5)	Audit trail communication — defined in ISO 13606-4.
PRS5.2	The EHRA shall support recording of the nature of each access and/or modification. (5.5)	Audit trail communication — defined in ISO 13606-4.
STR1.1	The EHRA shall enable information in the EHR to be organized in different sections allowing navigation by users and views of sections to be returned as the result of queries. (1.1)	Class SECTION

Code	Statement of requirement	Correspondence in ISO 13606-1
STR1.3	The EHRA shall support an EHR which is moveable and mergeable between individuals and institutions independent of hardware, software (application programmes, operating systems, programming languages), databases, networks, coding systems, and natural languages. (2.6)	General objectives of this reference model
STR2.1	The EHRA shall enable storage of data as lists such that the order of the data is preserved when the data is displayed. (1.2.1)	CLUSTER.structure_type
STR2.10	The EHRA shall allow for comprehensive information storage and retrieval regarding patient care. The EHRA shall at a minimum allow for the recording of all structured and unstructured data on: patient history; physical examination; psychological, social, environmental, family and self-care information; allergies and other therapeutic precautions; preventative and well-being measures such as vaccinations and lifestyle interventions; diagnostic tests and therapeutic interventions such as medication and procedures; clinical observations, interpretations, decisions and clinical reasoning; requests/orders for further investigation, treatments or discharge; problems, diagnoses, issues, conditions, preferences and expectations; healthcare plans, health and functional status, and health summaries; disclosures and consents; suppliers, model and manufacturer of devices (e.g. implants or prostheses).	These kinds of data can be represented by RECORD_COMPONENT.meaning and through the use of archetypes.
STR2.11	The EHRA shall support the recording (and classifying for identification purposes) of patient identification, location, demographic, contact, employment and other administrative data. (1.3.3)	The patient is represented through the demographics package, but only a minimal description set is included to facilitate demographic matching between EHR systems.
STR2.12	The EHRA shall support standards for information which enable the unambiguous identification of the subject of care, the clinicians involved in care (including their role and context of care), the location of care, the date/time and duration of care, and third parties such as next of kin and non-clinical contacts. (1.3.3)	The class FUNCTIONAL_ROLE is associated with particular RECORD_COMPONENTs to define the parties responsible for fulfilling such roles.

Code	Statement of requirement	Correspondence in ISO 13606-1
STR2.13	The EHRA shall support the administration of healthcare processes and episodes of care as well as the organization of visit and encounter data. (1.3.3)	(General objectives of the reference model)
STR2.13	The EHRA shall support the administration of healthcare processes and episodes of care as well as the organization of visit and encounter data. (1.3.3)	These kinds of data might be represented through the use of archetypes, if relevant to the EHR.
STR2.14	The EHRA shall support the recording of financial and other commercial information such as health plan enrolment, eligibility and coverage information, guarantor, costs, charges, and utilization. (1.3.3)	These kinds of data might be represented through the use of archetypes, if relevant to the EHR.
STR2.15	The EHRA shall support the recording of legal status and consents relevant to the patient's healthcare (e.g. legal status of guardianship order, consents for operations and other procedures).	Consents for clinical actions: these kinds of data can be represented through the use of archetypes. Consents for information disclosure: defined in ISO 13606-4.
STR2.2	The EHRA shall enable storage of data in tables such that the relationships of the data with the row and column headings are preserved. (1.2.1)	CLUSTER.structure_type
STR2.3	The EHRA shall enable storage of data in hierarchies such that the relationship between the node parents and children are preserved. (1.2.1)	The overall RECORD_COMPONENT hierarchy
STR2.4	The EHRA shall enable storage of data such that simple name/value pairing is preserved. (1.2.1)	RECORD_COMPONENT attributes name, meaning and archetype_id
STR2.5	The EHRA shall enable the storage of multiple values of the same measurement taken at closely proximate times at the same contact, or at different contacts and at different locations. The context of these measurements shall be preserved – such as who took the measurement, what method was used, etc. These values should be able to be returned in a query and ordered in different ways. (1.1)	ITEM.obs_time, which is of type interval permitting date and time specifications to varying granularity, plus optionally archetyped date/time ELEMENTs for time series in which time is part of the data.
STR2.6	The EHRA shall support the inclusion of narrative free text. (1.2.2.1)	This is supported by the TEXT class.
STR2.8	The EHRA shall support the inclusion of comments within the data stored – enabling the clinician to qualify structured information appropriately. Comments shall be able to be linked to specific data attributes. (1.2.2.2)	ITEM.item_category permits the identification of clinical reasoning information.
STR2.9	The EHRA shall provide a means for different levels of emphasis to be associated with comments and other entries – this may alter the way they are displayed or their returning in a query. (1.2.2.2)	ITEM.emphasis plus any additional presentation attributes included within specific archetypes.

Code	Statement of requirement	Correspondence in ISO 13606-1
STR3.14	The EHRA shall support the recording of contextual data associated with the date/time the event occurred.	COMPOSITION.session_time
STR3.15	The EHRA shall support the recording of contextual data associated with the date/time the event was committed to the record.	AUDIT_INFO.time_committed
STR3.16	The EHRA shall support the recording of contextual data associated with the subject.	EHR_EXTRACT.subject_of_care and optionally ENTRY.subject_of_information
STR3.19	The EHRA shall support the recording of contextual data associated with the location where the event was recorded.	FUNCTIONAL_ROLE.healthcare_facility and FUNCTIONAL_ROLE.service_setting
STR3.2	The EHRA shall support the definition of the logical structure of numeric and quantifiable data, including the handling of units. (1.3.4.2)	The ITEM hierarchy can represent a data structure of any complexity; the CEN data type PQ can be used to represent individual numeric values or quantities.
STR3.20	The EHRA shall support the recording of contextual data associated with the reason for recording the information associated with the event.	ITEM.item_category permits the identification of clinical reasoning information.
STR3.21	The EHRA shall support the recording of contextual data associated with the protocol associated with the information recorded.	ITEM.item_category permits the identification of a protocol or guideline reference or description.
STR3.22	The EHRA shall define the semantic representation of links between different information in the EHR. (1.3.7)	Class LINK, and term sets of nature and role defined in ISO 13606-3.
STR3.23	The EHRA shall support links to ‘externally referenced data’ which are not able to be stored within the EHR, providing patient safety is not compromised. (1.3.7)	This can be represented using the CEN data type ED.
STR3.5	Quantity ranges.	This can be represented using the CEN data type PQ.
STR3.6	Quantity ratios.	This can be represented using the CEN data type PQ.
STR4.2	At the data attribute level, the EHRA shall support the capture of the code, the coding scheme (e.g., coding/classification system), version, original language and original rubric.	This can be represented using the data type CV.
STR4.3	The EHRA shall enable storage of data from terminologies and preserve the information about the terminology set from which it was chosen. (1.2.1)	This can be represented using the data type CV.
STR4.4	Where information is not represented uniquely in only one place and one way, the EHRA shall support explicit rules to avoid ambiguity (e.g. it needs to be clear what [not] [pedal pulses absent] means).	It has been agreed, after much consultation, that this should be handled by terminology systems and not by the record architecture.

Code	Statement of requirement	Correspondence in ISO 13606-1
STR4.6	The original textual representation as entered by the clinician shall be retained in the EHR when information is translated from one natural language to another or when terms are mapped from one coding/classification system to another.	This can be represented using the data types TEXT and CV.

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