



# SLOVENSKI STANDARD

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Health informatics - Electronic health record communication - Part 1: Reference model

Medizinische Informatik - Kommunikation von Patientendaten in elektronischer Form -  
Teil 1: Referenzmodell.

Informatique de santé - Dossier de santé informatisé et communication - Partie 1:  
Modele de référence

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**ICS:**

35.240.80	Uporabniške rešitve IT v zdravstveni tehniki	IT applications in health care technology
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English Version

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Informatique de santé - Dossier de santé informatisé et  
communication - Partie 1: Modèle de référence

Medizinische Informatik - Kommunikation von  
Patientendaten in elektronischer Form - Teil 1:  
Referenzmodell

This European Standard was approved by CEN on 15 December 2006.

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## Foreword

This document (EN 13606-1:2007) has been prepared by Technical Committee CEN/TC251 "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of an identical text or by endorsement, at the latest by August 2007, and conflicting national standards shall be withdrawn at the latest by August 2007.

This document supersedes ENV 13606-1:2000.

This multipart standard under the general heading *Health informatics – Electronic health record communication* consists of the following parts:

*Part 1: Reference model*

*Part 2: Archetypes interchange specification*

*Part 3: Reference archetypes and term lists*

*Part 4: Security*

*Part 5: Messages for exchange*

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

## Introduction

The overall goal of this European Standard 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.

This European Standard 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 applications that might request 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 European Standard is an ISO RM-ODP Information Viewpoint of the EHR Extract.

This European Standard 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 health care 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. this European Standard 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.

This European Standard 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.

## Technical approach

This European Standard has drawn on the practical experience that has been gained in implementing its European predecessor, 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. This European Standard builds on ENV 13606, updating it in order to make it more rigorous and complete, 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 existing prestandard is also provided to support implementers of existing conformant systems. The technical approach to producing this European Standard has taken into account several contemporary areas of requirement.

- 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.
- "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.
- There is wide international interest in this work, and this European Standard 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 European Standard within an HL7 version 3 environment.

e. The 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 *openEHR* foundation, integrating threads of R&D in Europe and Australia, is one such example.

Given the diversity of deployed EHR systems, this European Standard 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 of this series, and through normative term lists (defined in Part 3 of this series).

This European Standard will, in practice, usually be adopted alongside other health informatics standards that define particular aspects of health data representation. Annex B explains how this European Standard 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).

## The Dual Model approach

The challenge for EHR interoperability is to devise a generalised 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 health care 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 this European Standard distinguishes a Reference Model, defined in this European Standard and used to represent the generic properties of health record information, and Archetypes (conforming to an Archetype Model, defined in Part 2 of this series), which are meta-data used to define patterns for the specific characteristics of the clinical data that represents 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 of this series).

This generic information model needs to be complemented by a formal method of communicating and sharing the organisational structure of predefined classes of EHR fragment corresponding to sets of record components made in particular clinical situations. These are effectively pre-coordinated 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 organisations. 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 European Standard, 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 European Standard 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 European Standard. A specification for communicating archetypes is defined by Part 2 of this series.

## Requirements basis for this European Standard

From the early 1990's 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 one. 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 standardised way that can rigorously and generically represent the data values and contextual organisation 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, EHCRA-Supa, Synapses, I4C and Nora projects and work by SPRI. These key requirements publications are listed in the Bibliography. These requirements have recently been consolidated on the international stage within an ISO Technical Specification, ISO/TS 18308.

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.

## 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 organised 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 organisation, 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 in which individual EHRs are organised within heterogeneous EHR systems.

These parts are summarised in Table 1 below.

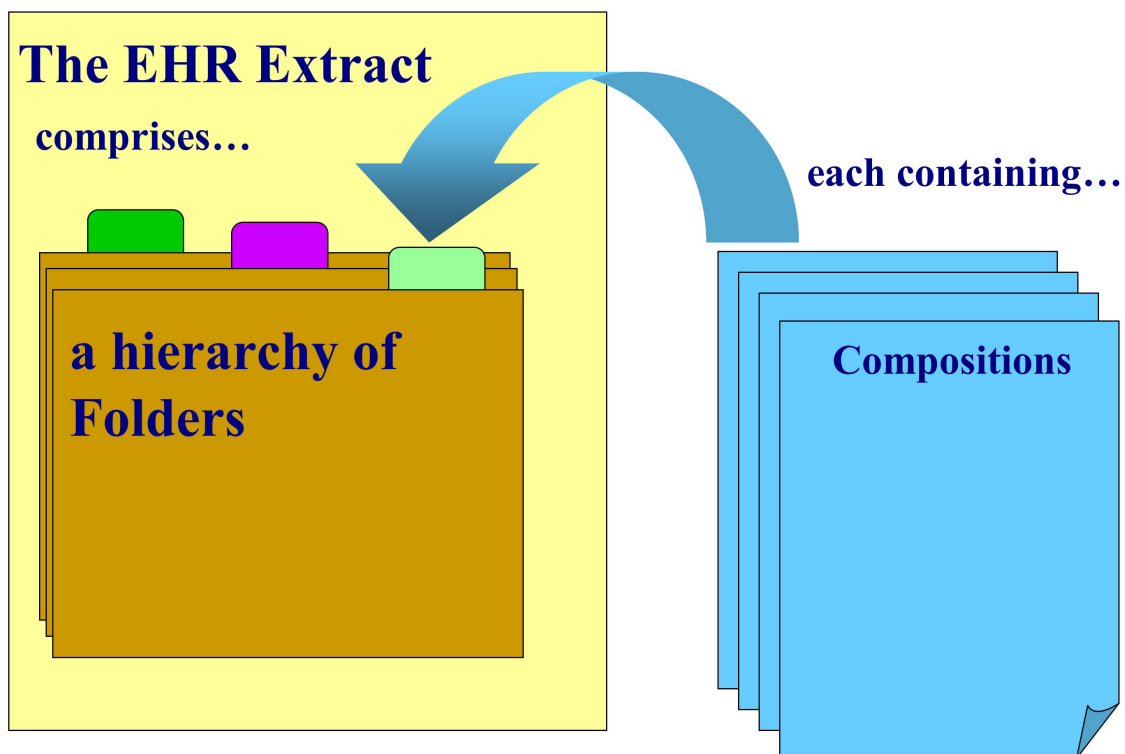
Table 1 — Main hierarchy components of the EHR Extract Reference Model

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 organisation 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 organising 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 organised by a FOLDER hierarchy.

COMPOSITIONs contain ENTRYs, optionally contained within a SECTION hierarchy.

ENTRYs contain ELEMENTs, optionally contained within a CLUSTER hierarchy.



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

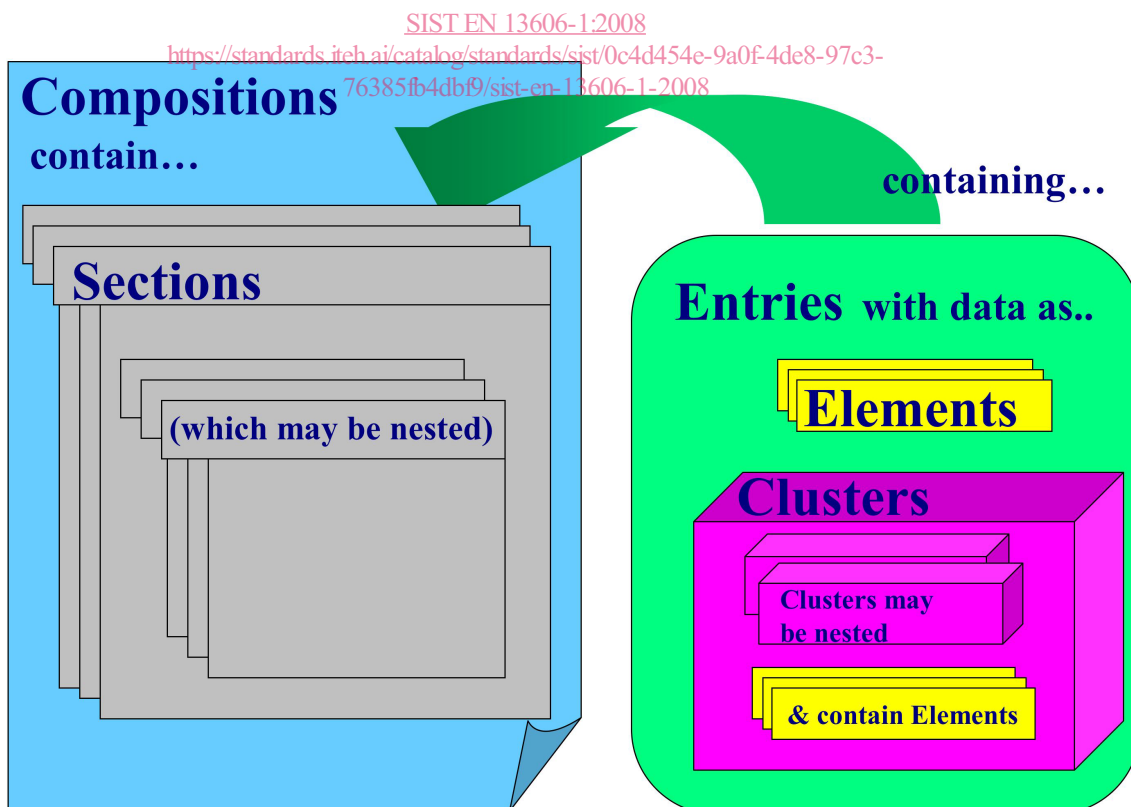


Figure 2 — Diagram of the EHR Extract hierarchy (part 2)

## 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 organising of the COMPOSITIONs;
- 3) optionally, a set of demographic descriptors for each of the persons, organisations, 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 this series 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 that 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 (for example, 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 standardised 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 European Standard 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 important medico-legally also 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 is 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 remaining 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; It 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 organisational 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 organisations 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 organising structure is used variably: in some enterprises and systems the folder concept is treated as an informal compartmentalisation 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 organise 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 European 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 uses these within its EHR system. However, if a FOLDER has been attested an intact copy of this information should 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 organising 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 European Standard 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 organise entries within a COMPOSITION. Each SECTION may contain additional SECTIONS and/or ENTRIES.

## 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;