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Health informatics — Service architecture (HISA) —

Part 2: Information viewpoint

Informatique de santé — Architecture de service —

Partie 2: Point de vue de l'information

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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.

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

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

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

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

This document was prepared by Technical Committee ISO/TC 215, *Health informatics*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 251, *Health informatics*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This second edition cancels and replaces the first edition (ISO 12967-2:2009), which has been technically revised. The main changes compared to the previous edition are as follows:

— use of terms, definitions and concepts from ISO 13940:2015 (Contsys), with textual alignment throughout the document including figures, to the extent possible and beneficial;

— reference to further standards, such HL7®;

— updates to the Bibliography.

A list of all parts in the ISO 12967 series can be found on the ISO website.

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

Introduction

The ISO 12967 series provides guidance for the description, planning and development of new systems as well as for the integration of existing information systems, both within one enterprise and across different healthcare organizations through an architecture integrating the common data and business logic into a specific architectural layer (i.e. the service architecture), distinct from individual applications and accessible throughout the whole information system through information services, as shown in Figure 1.

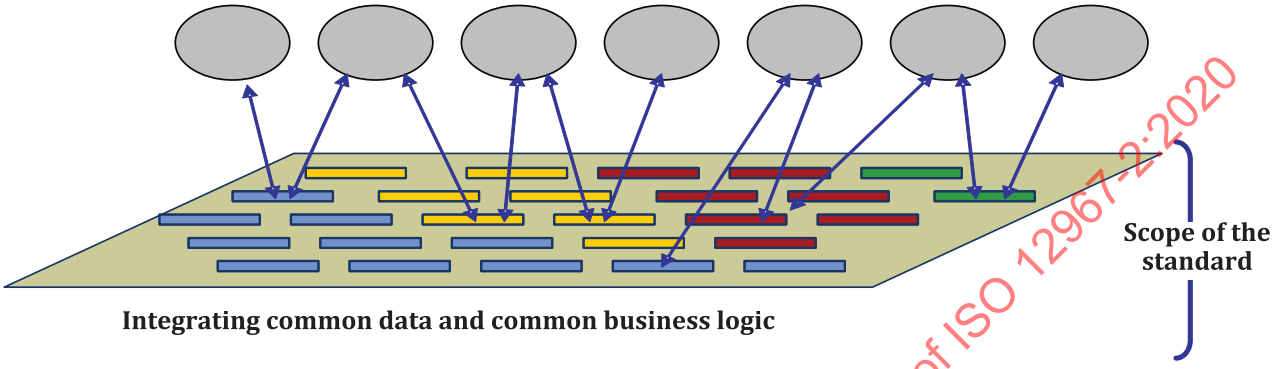

Figure 1 — Scope of the ISO 12967 series

The overall architecture is formalized according to ISO/IEC 10746 (all parts) and is therefore structured through the following three viewpoints.

a) Enterprise viewpoint: specifies a set of fundamental common requirements at enterprise level with respect to the organizational purposes, scopes and policies that should be supported by the information and functionality of the service architecture. It also provides guidance on how one individual enterprise (e.g. a regional healthcare authority, a large hospital or any other organization where this model is applicable) can specify and document additional specific business requirements, with a view to achieving a complete specification, adequate for the characteristics of that enterprise.

   Enterprise viewpoint is specified in ISO 12967-1.

b) Information viewpoint: specifies the fundamental semantics of the information model to be implemented by the service architecture to integrate the enterprise's common data and to support the enterprise requirements formalized in ISO 12967-1. It also provides guidance on how one individual enterprise can extend the standard model with additional concepts needed to support local requirements in terms of information to be put in common.

   Information viewpoint is specified in this document.

c) Computational viewpoint: specifies the scope and characteristics of the information services that should be provided by the service architecture for allowing access to the common data as well as for the execution of the business logic supporting the enterprise processes identified in the information viewpoint and in ISO 12967-1. It also provides guidance on how one individual enterprise can specify additional information services needed to support local specific requirements in terms of common business logic to be implemented.

   Computational viewpoint is specified in ISO 12967-3.

ISO 12967-1:2020, Annex C includes an explanation of ISO 23903:—[1)] and its relevance in regard to the ISO 12967 series, for integration with other International Standards such as ISO 13940.

1) Under preparation. Stage at the time of publication: ISO/DIS 23903:2020.

Health informatics — Service architecture (HISA) —

Part 2: Information viewpoint

1 Scope

This document specifies the fundamental characteristics of the information model implemented by a specific architectural layer (i.e. the service architecture) of the information system to provide a comprehensive and integrated storage of the common enterprise data and to support the fundamental business processes of the healthcare organization, as defined in ISO 12967-1.

The information model is specified in this document without any explicit or implicit assumption on the physical technologies, tools or solutions to adopt for its physical implementation in the various target scenarios. The specification is nevertheless formal, complete and non-ambiguous enough to allow implementers to derive an efficient design of the system in the specific technological environment that will be selected for the physical implementation.

This document does not aim at representing a fixed, complete, specification of all possible data that can be necessary for any requirement of any healthcare enterprise. It specifies only a set of characteristics, in terms of overall organization and individual information objects, identified as fundamental and common to all healthcare organizations, and that is satisfied by the information model implemented by the service architecture.

Preserving consistency with the provisions of this document, physical implementations are allowed extensions to the standard information model in order to support additional and local requirements. Extensions include both the definition of additional attributes in the objects of the standard model, and the implementation of entirely new objects.

Also, this document specification is extensible over time according to the evolution of the applicable standardization initiatives.

The specification of extensions is carried out according to the methodology defined in ISO 12967-1:2020, Clause 7.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

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

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

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

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

3.1
information object
information held by the system about entities of the real world

Note 1 to entry: Entities including the ODP system itself can be represented in an information specification in terms of information objects, their relationships and behaviour.

3.2
package
cluster of *information objects* (3.1)

3.3
middleware
enabling technology of *enterprise application integration* (3.4) describing a piece of software that connects two or more software applications so that they can exchange data

3.4
enterprise application integration
EAI
use of software and computer systems architectural principles to integrate a set of enterprise computer applications

3.5
subject of care
patient
subject of healthcare
healthcare actor with a person role; who seeks to receive, is receiving, or has received healthcare

[SOURCE: ISO 13940:2015, 5.2.1, modified — Note and Examples omitted.]

4 Abbreviated terms

ODP	Open Distributed Processing
HISA	Health Informatics Service Architecture
UML	Unified Modeling Language

5 Methodological principles

5.1 Language and notation adopted for the specification of the model

The objective of the information viewpoint specification is to describe the information relevant for the enterprise to be handled by the service architecture. It consists of a formal information model detailing the semantic and syntactic aspects of all data to be managed.

The specification is based on an object model, derived from the enterprise viewpoint by properly structuring and aggregating the information that has been identified as relevant in the specification of the business processes, tasks and activities.

The general approach of the ODP standard [i.e. ISO/IEC 10746 (all parts)] is also used in ISO 12967-1, the modeling language used in this document is UML.

The information viewpoint is concerned with information modeling (i.e. the kinds of information handled by the system). It focuses on the semantics of information and information processing in the system. It is fundamental that the individual components of a distributed system share a common understanding of the information they communicate when they interact, or the system will not behave as expected. Some of these items of information are handled, in one way or another, by many of the objects in the system. To ensure that the interpretation of these items is consistent, the information

language defines concepts for the specification of the meaning of information stored within, and manipulated by, an ODP system, independently of the way the information processing functions themselves are to be implemented.

Thus, information held by the ODP system about entities in the real world, including the ODP system itself, is represented in an information specification in terms of information objects, and their associations and behaviour. Atomic information objects represent basic information elements. More complex information is represented as composite information objects, each expressing associations over a set of constituent information objects.

Some elements visible from the enterprise viewpoint will be visible from the information viewpoint and vice versa. For example, an activity seen from the enterprise viewpoint will be in the information viewpoint as the specification of some processing which causes a state transition of an information entity.

Different notations for information specifications model the properties of information in different ways. It is possible to place emphasis on classification and reclassification of information types, or on the states and behaviour of information objects. In some specification languages, atomic information objects are represented as values. The approach to be taken will depend on the modeling technique and notation being used.

Assessment of conformance to the information specification of a system involves relating the requirements expressed in the specification to sets of observations of the behaviour of the system at conformance points identified in the engineering and technology specification, and assessing the degree of consistency between the requirements and the observations.

5.2 UML class diagram notation guidelines and profile

For each cluster of objects identified in the enterprise viewpoint, the information objects will be illustrated according to the following rationale.

— Information objects (i.e. classes) grouped in the packages will be not be coloured.

— Classes not expressly grouped in the package will also be represented if there are associations from classes belonging to the package to these classes. These classes, however, will be coloured in yellow.

— The names of classes will be meaningful and start with a capital letter (e.g. Person). If the name is composed of more than one word the blank spaces between the words present in the diagrams will be instead omitted in the section of the tables containing the class identifiers (e.g. “subject of care will have as class identifier “SubjectOfCare”). Blank spaces are left in the class names and diagrams also with the scope of supporting readability.

— Associations will be labelled when the label adds value to the diagram.

— Association labels indicate a property, or a verb phrase; in the latter case, an arrow is added to the association label to avoid ambiguity.

— Labels are always in lower case and, if a label is a verb phrase (with arrow), it will have one blank space in between words.

— Navigability is not relevant when using UML for an information specification and will not be represented.

— In general, in order to support readability, the classes should only contain the name of the class. Properties should be described in the tables; however, if properties are displayed in the diagrams, the following two points hold.

  — Notation for visibility of properties is not used, as it is not pertinent for the conceptual models used in the information viewpoint. Although visibility symbols could be used to indicate access control, this is not done as all healthcare-related information should be accessed through careful authorization.

  - Data types of the properties should be displayed in the class in the diagram.

- For some classes, associations to other classes could be modelled (in the UML diagrams) as attributes to the class. This reflects that the association has value rather than reference semantics, in addition to the resulting simplification of the model. In other cases, the same method might be used in the UML diagrams even though the association has reference semantics. This is done just to simplify the models. In the related class descriptions, these instances of simplified modeling are described as associations rather than attributes.
- Properties (attributes) of classes start with a lower-case letter (e.g. name). If the property is composed of more than one word, the blank spaces in between words are omitted (e.g. familyName, birthDate).
- Current ISO and low-level data types will preferably be used. These will allow mapping to CEN or ISO (in the future) when possible.
- Many-to-many binary associations named "related to" may be implemented as a set of specific associations or association classes of specific multiplicities.
- Cardinalities of properties are used in case of associations, especially to distinguish between optional and mandatory properties.
- Cardinality '*' is never used, as the reader might be confused as to whether a 0..* or 1..* was intended.
- When the composition symbol is used, the non-displayed cardinality will always be '1'.

5.3 Clusters of objects in the information model

The information specification is built by considering the elements of the enterprise viewpoint specification. ODP does not impose any methodology for the definition and use of the viewpoints. Thus, the enterprise specification has been used here for building the UML specification. This approach greatly facilitates the definition of the correspondences between the related entities that appear in the different viewpoints, also allowing the treatment of the consistency among the viewpoints.

In particular, this information specification incorporates the information handled by the system as described in ISO 12967-1:2020, 6.2 to 6.4.

According to the methodology identified in the enterprise viewpoint, seven clusters of objects have been identified, each of which is responsible for organizing and storing the information necessary for supporting the users' activities identified in the related areas of ISO 12967-1, as follows.

a) Classification objects

   These objects handle the information necessary for supporting the users' activities related to the management of classifications, coding criteria and dictionaries.

b) Subject of care objects

   These objects handle the information necessary for supporting the users' activities that are identified in the "subject of care workflow".

c) Activity management objects

   These objects handle the information necessary for supporting the users' activities identified in the "activity management workflow".

d) Healthcare information objects

   These objects handle the information necessary for supporting the users' activities identified in the "healthcare information workflow".

e) Resources objects

These objects handle the information necessary for supporting the users' activities related to the management of resources.

f) Users and authorization objects

These objects handle the information necessary for supporting the users' activities related to the management of users and authorizations.

g) Messaging objects

These objects handle the information necessary for supporting the structuring of data and the communications with other systems through messaging mechanisms.

These clusters of objects are specified in Clause 7 by means of UML models.

The HISA information models in this document are not a one-to-one unfolding of the concepts described in ISO 12967-1, but addressing key elements hereof such as Healthcare Information, with a viewpoint of the information constructs needed from a system perspective.

HISA is mainly about the IT domain. HISA defines models with classes and services related hereto, in the sense of what should be supported in the enterprise domain at an overall level, not at all detailed concepts and relations in the business domain.

HISA focuses on the information services, through which information is created, read, updated and deleted in connection with and as a result of many healthcare activities. The management of information through the services are key, but not as much the information itself. The high-level information models of HISA refer, for example, to only a fraction of the concepts and terms in ISO 13940 (Contsys).

Further general information on mapping between different domains and models with different purpose, levels and scopes is provided in ISO 12967-1:2020 Annex C.

NOTE In the following representative UML models, several terms and descriptions of the HISA classes have been updated to reflect current state of art regarding terminology. However, the original HISA class identifiers have not changed. These are unique to HISA and for this reason maintain their previous class identifier, thus supporting also backward compatibility.

5.4 Operational and descriptive information: classifications, knowledge and its instantiation

From the textual descriptions in the enterprise viewpoint, the service architecture shall be able to manage not only the daily operational information directly related to the various business processes, but also a knowledge base, allowing managing the descriptive concepts, vocabulary items, and rules required to instantiate particular properties of the operational information. Such "concept descriptive information" is the basic knowledge base required for the actual instantiation of the operational information in the healthcare enterprise.

NOTE The topic is also explained in in ISO 12967-1:2020, 11.9.

HISA information objects in each package shall thus be classified as:

— Operational, usually representing the actual (clinical, organizational, etc.) objects that are continuously generated during (and for) the daily activities. These include the personal and healthcare treatment information on patients, the individual resources used for carrying out the actual activities, etc.

  — The operational information objects model the entities involved in the daily activities of the healthcare enterprise in the treatment of subjects of care and in the functioning of the enterprise itself.

— Descriptive, usually enterprise or organization-related, specifying the criteria according to which the organization works and is structured. It includes general classifications of clinical concepts, rules

according to which the activities are performed, and more (e.g. the types of activities which are carried out in the radiology department, the diagnostic classification in use in the clinical setting, etc.).

— The descriptive information objects model the entities required for the overall knowledge base that is required by the healthcare enterprises to carry out daily activities related to the treatment of subjects of care and in the functioning of the enterprise itself.

For each "operational" information object, therefore, the model foresees one "descriptive" information object, containing the main classification data, the properties, the rules and the default values that are necessary for the management of the live data instantiated in the "operational" object, as exemplified in Figure 2.

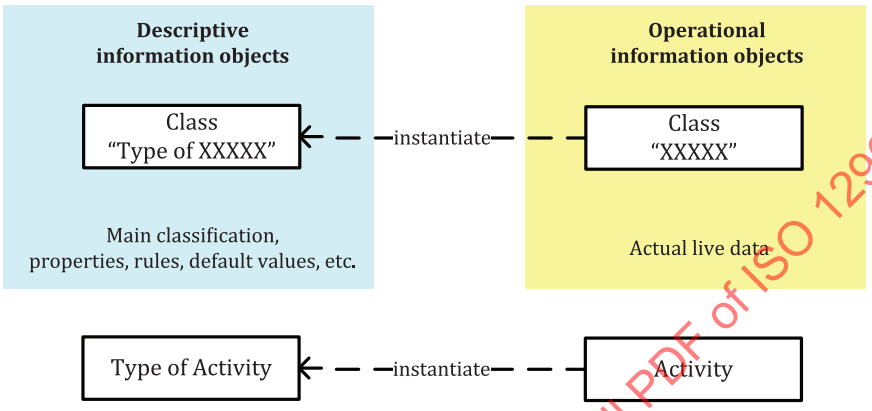

Figure 2 — Knowledge base implemented through the descriptive information objects

In addition to the properties and to the classification provided by the related "descriptive" class, each class and each attribute of each class can be classified according to different, multiple, multi-language classifications for different (clinical, epidemiological, statistic, etc.) purposes. To support this requirement, the HISA model provides the package of "Concept Information Objects", capable of organizing multiple classifications, terminologies and other concepts. See Figure 3.

Each individual information element (entire instance of one class or individual attribute of one class) can be related to the concept class to allow specifying as many classifications as necessary. In this case also, the principle of implementing a knowledge base is implemented by the HISA model that provides the following.

— **"Descriptive"** information objects, allowing the specification of the concepts according to which each class and each attribute of the class can be classified.

— **"Operational"** information objects (natively present in each HISA class, as described in the "Generic HISA class"), allowing the classification of each individual instance and each individual attribute according to multiple concepts.

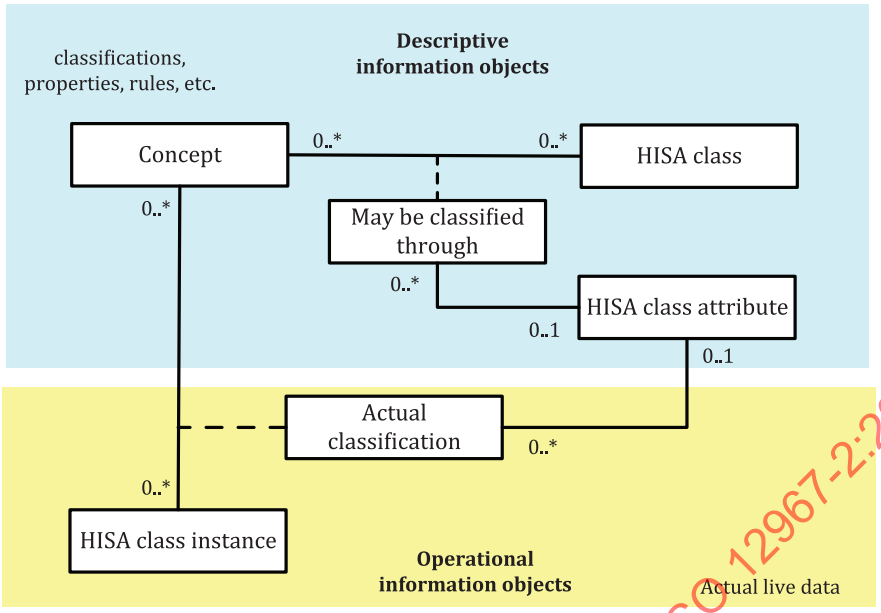

Figure 3 — Further classification criteria for each HISA class

5.5 Data types

The primitive data types given in Table 1 are used in this specification, as illustrated in Table 2.

Table 1 — Primitive data types

Data type	Semantics
String	Series of characters, as defined in ISO/IEC 11404:2007
Boolean	Boolean value, as defined in ISO/IEC 11404:2007
Integer	Integer, 32 bit two's complement
Double	Double precision floating point (64-bit Biblio entry)
Octet	8-bit code, as defined in ISO/IEC 11404:2007

Table 2 — Usage of primitive data types

HISA data type	Primitive data type	Semantics
Byte	Octet	Synonym of octet
ObjectIdentifier	String	Unchangeable string allowing the permanent and non-ambiguous identification of one instance of one information object. The syntax and the structure of the string shall be defined locally by the individual implementations, according to criteria capable of ensuring the uniqueness of the value also across different models and distributed, multiple physical environments.
Identifier	String	Short, human-readable string allowing the non-ambiguous identification of one instance of one information object.
InternalTimestamp	Array of bytes	Internal system representation of date and time at least up to the level of the millisecond. DateTime representations are specified in ISO 8601-1:2019 and ISO 8601-2:2019.

Table 2 *(continued)*

HISA data type	Primitive data type	Semantics
DateTime	String	DateTime representation are specified in ISO 8601-1:2019 and ISO 8601-2:2019. Representation of date and time shall be at least up to the level of the second.
Ordinal	Integer	A number which defines a position in an ordered series.
Unit	String	Unit of measure, expressed according to codes defined in the "Unified Code for Units of Measures" (https://unitsofmeasure.org).
URI	String	Uniform Resource Identifier NOTE First defined in Request for Comments (RFC) 2396 and finalized in RFC 3986.
SET<DataType>		Value that contains multiple values of the data type specified as its elements.

5.6 General characteristics of the model

The specification of the overall information model is structured through the following sections:

— Formalization of the general criteria and of the properties common to all classes identified in the model.

— One schema for each business process identified in the enterprise view, showing the sole classes relevant for that business process.

NOTE Due to the integration of the whole model, in each schema there are some classes that are related to objects relevant for other business processes and therefore described in other sections; for readability reasons these classes are highlighted with a brown colour.

— Specification of the identified objects, with the definition of the related properties and of the relations among them.

— Clause 5.2 summarizes essential guidelines on the UML notation adopted for the specification of the schemas.

6 General characteristics of the model

6.1 Common structure of each information object: the GenericHisaClass

Each object of the information model shall conform to a common structure (i.e. the "GenericHISAClass") comprising the following:

— set of attributes (named "specific attributes"), describing the semantic aspects specific to the class itself (e.g. Person's name, gender, etc.);

NOTE 1 These attributes are the ones that are illustrated in the property list of all classes in Clause 7.

— set of attributes (named "system attributes"), common to all objects, supporting general requirements in terms of accountability, auditing, legal/clinical requirements, etc. (e.g. the date time of registration/updating of the instance);

— indefinite number of multi-media properties (named "extended attributes"), which may be added dynamically at run-time and that allow to record further information on the objects; these properties shall comprise, among others, the following attributes:

  — actual datum (i.e. the value, for example a Person's photo, the colour of his/her eyes, etc.);

  - characteristics describing the properties of the actual datum (e.g. type [=IMAGE], size, etc.; these shall be described, where possible, through the CEN data types);
  - "system attributes", common to all instances of the object;
- indefinite number of textual properties (named "business rules"), which may be added dynamically at run-time and that allow to record specific (e.g. legal, clinical, organizational, operational) rules and criteria that are applicable when operating with the instance in certain contexts; these properties shall comprise, among other, the following attributes:
  - actual text of the rule;
  - scope of applicability of the rule;
  - "system attributes", common to all instances of the business rule object;

NOTE 2 The formalization of the semantics and of the syntax of such rules is under the responsibility of the specific implementation scenario and is outside the scope of this document, which prescribes the capability of each object to allow the recording and management of such type of information.

- indefinite number of properties (named "state changes"), which shall be added dynamically at run-time automatically by the class itself, and that shall record the changes that occurred in the "specific attributes" of the class, in order to keep track of the life cycle of the instance during the time; these properties shall comprise, among others, the following attributes:
  - value of the "system attributes" prior to the change;
  - identification of the system attributes that have been changed;
  - new values assigned to the system attributes that have been changed;
  - date, time of the change;
  - identification of the agent (i.e. individual or system process) that has effected the change;
- set of attributes (named "versioning attributes"), common to all objects, supporting the definition and management of multiple versions of the instance of the object, each of them characterized by an identification label and the time frame (i.e. starting date and ending date) of validity.

At a certain moment, either one or no instance shall be valid, therefore time frames of validity shall not overlap.

- relationship linking one version of the object with the instance representing the previous version;
- indefinite number of relationships (named "classification criteria"), which may be added dynamically at run-time and that allow to classify the entire class and/or individual attributes according to multiple classification criteria, defined in the "Concept" class of the model.

6.2 UML diagram

All the classes in the following Figure 4 are specified in 6.3, except the HISA Concept class, which is specified in 7.1.3.2.

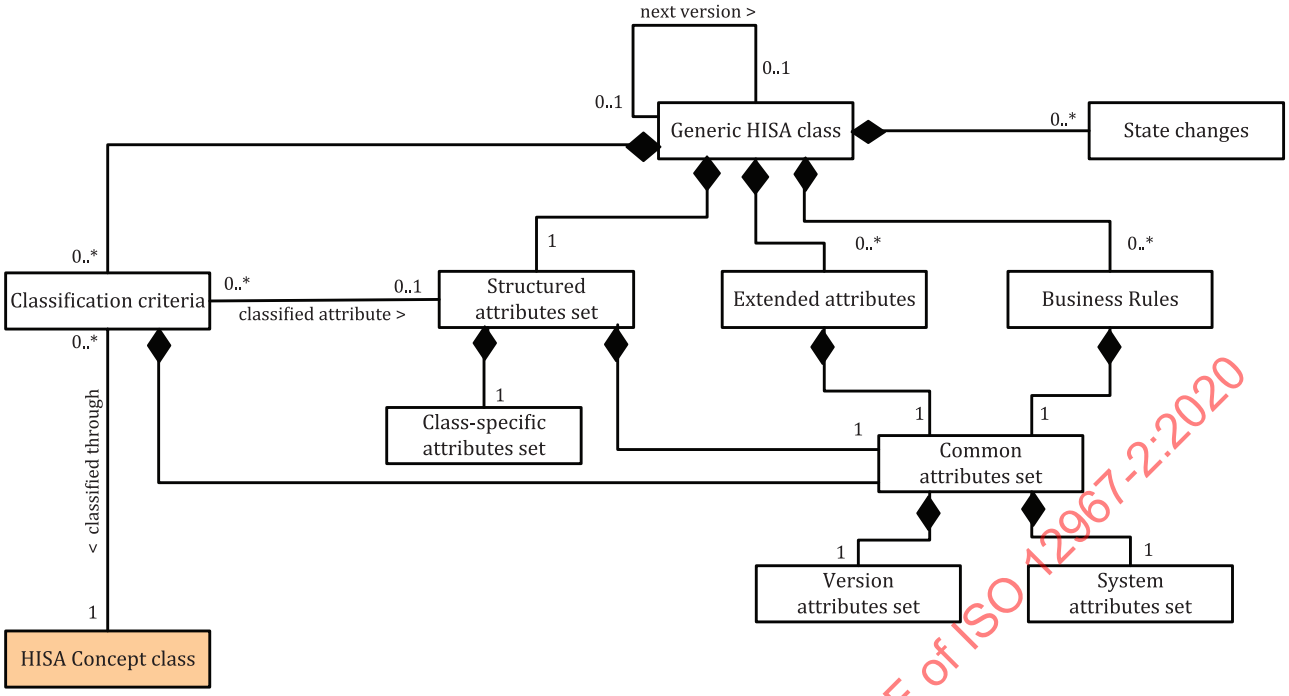

Figure 4 — The generic HISA class

6.3 Specification of Generic HISA Class

6.3.1 Generic meta-class

Class identifier: GenericHISAClass			
Description	This meta-class represents the HISA information objects belonging to the information model		
Associated classes		**Type of association**	**Multiplicity**
StructuredAttributes		Composition	1
ExtendedAttributes		Composition	0..*
BusinessRules		Composition	0..*
StateChanges		Composition	0..*
ClassificationCriteria Relating the instance with multiple classifications		Composition	0..*
Versioning Relating the instance with its previous version, if it exists		Association	0..1
Attributes	**Type**	**Description**	
none			

6.3.2 Class: Set of structure attributes

Class identifier: StructuredAttributes			
Description	Set of all structured attributes of the HISA information object consisting of the composition of a) the specific attributes peculiar to the HISA information object and b) the set of common attributes that shall be present in all classes		
Associated classes		**Type of association**	**Multiplicity**
CommonAttributes		Composition	1
ClassSpecificAttributes		Composition	1
Attributes	**Type**	**Description**	
none			

6.3.3 Class: Set of class specific attributes

Class identifier: ClassSpecificAttributes			
Description	Set of attributes specific to the individual HISA information object		
Associated classes		**Type of association**	**Multiplicity**
none			
Attributes	**Type**	**Description**	
Dependent on the specific object		Detailed for each class in the relevant specifications	

6.3.4 Class: Set of common attributes

Class identifier: CommonAttributes			
Description	Set of all attributes common to all HISA information objects		
Associated classes		**Type of association**	**Multiplicity**
SystemAttributes		Composition	1
VersionAttributes		Composition	1
Attributes	**Type**	**Description**	
none			

6.3.5 Class: Set of system attributes

Class identifier: SystemAttributes			
Description	attributes, common to all objects, supporting general requirements in terms of accountability, auditing, etc. of the instance		
Associated classes		**Type of association**	**Multiplicity**
none			
Attributes	**Type**	**Description**	
instanceID	ObjectIdentifier	Permanent, unchangeable, unique identifier of the instance of the class.	
displayName	String	Short, human-readable description of the object, that may be abbreviated for display purposes.	
userCode	Identifier	Short, human-readable code of the object, allowing to uniquely identify the instance of the class.	
timestamp	InternalTimestamp	Internal Timestamp of the last update of the instance	
creationTime	DateTime	Identifies time and date of the original creation of the instance	
creationAgent	ObjectIdentifier	Identifier (i.e. instanceID) of the individual agent that has initially created the instance.	

creationUnit	ObjectIdentifier	Identifier (i.e. instanceID) of the unit of the organization that has initially created the instance
updateTime	DateTime	Identifies time and date of the last update of the instance.
updateAgent	ObjectIdentifier	Identifier (i.e. instanceID) of the individual agent that has executed the last modification in the instance.
updateUnit	ObjectIdentifier	Identifier (i.e. instanceID) of the unit of the organization that has executed the last modification in the instance.
authorization	String	Specific constraints with respect to the authorization rights on reading, updating or deleting the specific instance.
isDeleted	Boolean	If True, specifies that the instance has been logically deleted.
isFrozen	Boolean	If True, specifies that the instance cannot be modified.

6.3.6 Class: Set of version attributes

Class identifier: VersionAttributes			
Description	attributes, common to all objects, supporting the definition and management of multiple versions of the instance of the object		
Associated classes		**Type of association**	**Multiplicity**
none			
Attributes	**Type**	**Description**	
sequence	Ordinal	Progressive sequence number of the version	
startValidityDate	DateTime	Starting date of validity of the version of the instance	
endValidityDate	DateTime	Ending date of validity of the version of the instance	

6.3.7 Class: Extended attributes

Class identifier: ExtendedAttributes			
Description	Formatted or unformatted texts, multimedia data or structured information as defined by a different standard, which may be attached/removed dynamically at run-time to the instance to record further information in addition to those already specified by the StructuredAttributes		
Related terms	See also “Encapsulated data”, as defined in ISO 21090:2011.		
Notes	Attributes extend those defined in ISO 21090:2011.		
Associated classes		**Type of association**	**Multiplicity**
CommonAttributes		Composition	1
Attributes	**Type**	**Description**	
sequence	Ordinal	Progressive sequence number of the property	
type	String	Specification of the semantics of the property NOTE The classification criteria to be adopted is usually defined and published locally in each individual implementation.	
mediaType	String	Identifies, according to the MIME datatypes and notations, the encoding of the data and a method to interpret or render the data	
charset	String	Where applicable, specifies, according to the IANA character set, the character set and character encoding used.	
language	String	Name of language used, if data is formatted text (according to ISO 639 (all parts))	

compression	String	If data are compressed, indicates the compression algorithm that was used
reference	URI	URI reference to a location external to the system if the data are not natively stored in the middleware
integrityCheck	Array of Byte	A short binary value representing a cryptographically strong checksum over the binary data
integrityCheckAlgorithm	String	Specifies the algorithm used to compute the integrity check value
data	Array of Byte	Actual value of the datum
alternateString	String	Textual title of the multi-media property, to be displayed in lieu of multimedia display

6.3.8 Class: State changes

Class identifier: StateChanges			
Description	Properties that may be added dynamically at run-time to document the updates made to the "SpecificAttributes" of the class		
Associated classes		**Type of association**	**Multiplicity**
none			
Attributes	**Type**	**Description**	
sequence	Ordinal	Progressive sequence position of the property	
dateOfChange	DateTime	Identifies the time in which the change was made	
authorOfChange	identifier	Identifier (i.e. instanceID) of the individual agent that has performed the change	
oldInstance	Set<String>	Identifiers and values of all attributes of the instance, prior to the change	
newValues	Set<String>	Identifiers of the attributes that have been changed and new values assigned to each of them	

6.3.9 Class: Business rules

Class identifier: BusinessRule			
Description	Properties that may be added dynamically at run-time to the record to specify rules and criteria (e.g. legal, clinical, organizational, operational) that are applicable when operating with the instance in certain contexts		
Associated classes		**Type of association**	**Multiplicity**
none			
Attributes	**Type**	**Description**	
sequence	Ordinal	Progressive sequence position of the property	
title	String	Title of the rule property	
context	String	Specification of the context (if any) where the rule is applicable. The notation and criteria to be adopted for the specification of such datum shall be defined locally by the individual implementations.	
value	String	Text of the rule	

6.3.10 Class: Classification criteria

Classification Criteria			
Description	Properties that may be added dynamically at run-time to the record to classify the instance and/or individual attributes according to different terminologies and other classification concepts (e.g. legal, clinical, organizational, operational) rules and criteria that are applicable when operating with the instance in certain contexts		
Associated classes		**Type of association**	**Multiplicity**
StructuredAttributesSet Identifies the specific attribute of the instance being classified with the external classification item		Binary association	0..1 If no attribute is specified, the classification applies to the entire instance of the class
HISAConcept Specifies the classification item to be related to the instance and to the attribute (if referred with the relation "classified attribute")		Binary association	0..*
Attributes	**Type**	**Description**	
context	String	Identification of the context of applicability of the classification	

7 The reference information models

7.1 Classification objects

7.1.1 Aim

The classification package groups the information services that support the rest of the healthcare information system in the management of the concept "descriptors" (classifications, code sets, etc.) used in the information system. The information handled by the classification package includes:

— terms defined in a concept vocabulary;

— semantic types which are applied to classify the terms in the concept vocabulary;

— types of rules which are used to define relationships or dependencies between different entities, as well as between different individual items, on the basis of particular values of their attributes;

— actually defined semantic relationships;

— rules that are associated with particular entities or individual items, describing knowledge about how to manage them in actual applications.

— package identifier (for any coded reference to this group of objects): cm.

7.1.2 UML information model

The UML model for classification objects is shown in Figure 5.

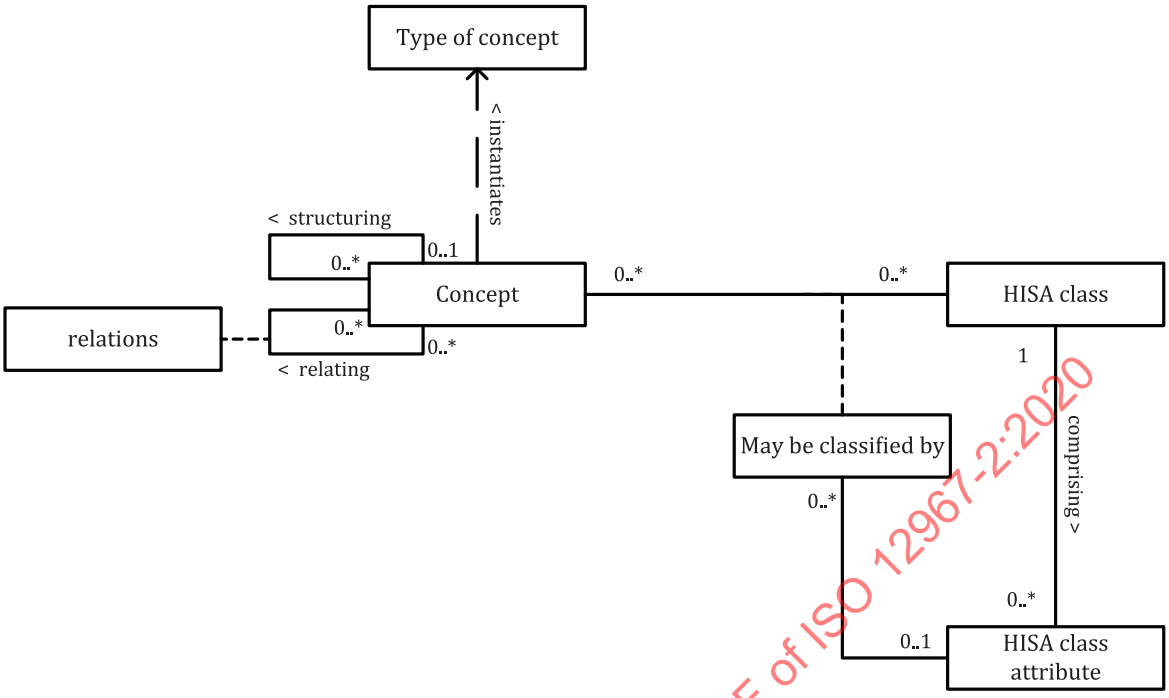

Figure 5 — UML model for classification objects

7.1.3 Specification of the individual classes

7.1.3.1 Class: Type of concept

Class identifier: TypeOfConcept			
Description	Types of concepts being adopted in the system for describing the HISA objects		
Associated classes		**Type of association**	**Multiplicity**
Concept		Parent of dependency	
Attributes	**Type**	**Description**	
Id	Identifier	One identifier that is used to uniquely identify the type of concept	
description	String	A phrase by which the concept is described in a manner that is intended to be unambiguous in the given language	

7.1.3.2 Class: Concept

Class identifier: Concept			
Description	Concept used to describe a HISA object, i.e. an element of a classification, a code in a code set, etc.		
Notes	The attributes defined for this class conform to the “Coded Value” data type as defined in ISO 21090:2011		
Examples	The concept class will be handling different sorts of concept systems used when HISA classes are instantiated that are required for different applications: epidemiological, territorial, statistical, clinical, economical, etc. Hierarchical classifications, as well as other forms of terminologies, can be applied through the structuring relations.		
Associated classes		**Type of association**	**Multiplicity**
TypeOfConcept		Dependency	0..*
HISAClass Information objects that may be classified by means of the concept		Binary association Through association class “May be classified by”	0..*

Concept (structuring) Concepts being aggregated and structured in a hierarchy by means of the concept		Binary association	0..*
Concept (relating) Concepts being related for different reasons with the concept		Binary association Through association class "relations"	0..*
Attributes	**Type**	**Description**	
Id	Identifier	One identifier that is used to uniquely identify the concept	
description	String	A phrase by which the concept is described in a manner that is intended to be unambiguous in the given language	
codeValue	String	The conventional value of the concept in the given language	
language	String	Identification of the language used for the name and preferred term of the concept.	
codingSchemeName	String	Name of the coding schema	
codingSchemeVersion	String	Version of the coding schema	

7.1.3.3 Class: HISA class

Class identifier: HISAClass			
Description	Information objects instantiated in the middleware		
Associated classes		**Type of association**	**Multiplicity**
TypeOfConcept		Dependency	0..*
HISAClass Information objects that may be classified by means of the concept		Binary association Through association class "May be classified by"	0..*
Concept Concepts according to which instances of the class may be classified		Binary association Through association class "May be classified by"	0..*
HISA class attribute Attributes of the HISA class		Binary association	1..*
Attributes	**Type**	**Description**	
id	Identifier	One identifier that is used to uniquely identify the class NOTE For those classes specified in this document, this value will be structured according to the notation. <packageID>.<classID>, individually representing the identifiers of the package and of the class as defined in this document	
description	String	A phrase by which the concept is described in a manner that is intended to be unambiguous in the given language	

7.1.3.4 Class: HISA class attribute

Class identifier: HISAClassAttribute		
Description	Attributes of the information objects instantiated by the middleware	
Associated classes	**Type of association**	**Multiplicity**
HISAClassInformation objects that comprise the attribute	Binary association Through association class "May be classified by"	1

Attributes	Type	Description
id	Identifier	One identifier that is used to uniquely identify the attribute NOTE For those classes specified in this document, this value will be structured according to the notation. <packageID>.<classID>.<attribute> individually representing the identifiers of the package , of the class and of the attribute as defined in this document
description	String	A phrase by which the attribute is described in a manner that is intended to be unambiguous in the given language
dataType	String	Specification of the data type of the allowed values

7.1.3.5 Association class: Relations among concepts

Class identifier: Relations			
Description	Association class allowing to relate different concepts to each other for different purposes (e.g. synonyms, clinical and organizational reasons, etc.)		
Associated classes		**Type of association**	**Multiplicity**
Concept First concept being related		Binary association	1
Concept Second concept being related		Binary association	1
Attributes	**Type**	**Description**	
sequence	Ordinal	Sequence order of the second concept in the list	
context	String	Context of applicability of the relation	
reason	String	Reason of applicability of the relation	
startDate	DateTime	Starting time of validity of the relation	
endDate	DateTime	Ending time of validity of the relation	
properties	String	Properties and other information depending on the relation between the two concepts	

7.1.3.6 Association class: May be classified by

Class identifier: MayBeClassifiedBy		
Description	Association class identifying the concepts that may be used to classify the instances of the various information objects of the HISA model, as well as the specific attributes of each class	
Associated classes	**Type of association**	**Multiplicity**
Concept Concept that can be used for the classification	Association class	1
HISAClass HISA class that may be classified through the concept	Association class	1
HISAClassAttribute Specific attribute of the HISA class that may be classified through the concept	Binary association	0..1 NOTE If no attribute is specified, then the classification relates to the class instance meant as a whole.

Attributes	Type	Description
sequence	Ordinal	Sequence order of the second concept in the list
context	String	Reason and context of applicability of the classification
IsOptional	Boolean	Specifies whether the classification of the related instance/ attribute is optional or mandatory

7.2 Subject of care objects

7.2.1 Aim

The subject of care package groups the information services which support the rest of the healthcare information system in the identification of the subject of care, including person identification and demographic data, and basic administrative "placeholders" for managing a variety of clinical and administrative issues related to the treatment, care and administration of subjects of care.

Package identifier (for any coded reference to this group of objects): pm.

7.2.2 UML information model

All non-coloured classes belonging to the subject of care cluster of objects in are specified in 7.2.3. The clinical information and health issue classes are specified in 7.4.3.1 and 7.4.3.3. The activity class is specified in 7.3.3.2. The agent, individual agent, and the organization element are specified 7.6.3.2, 7.6.3.4 and 7.6.3.3, respectively. The staff member is specified in 7.5.3.10.

The UML model for subject of care objects is shown in Figure 6.

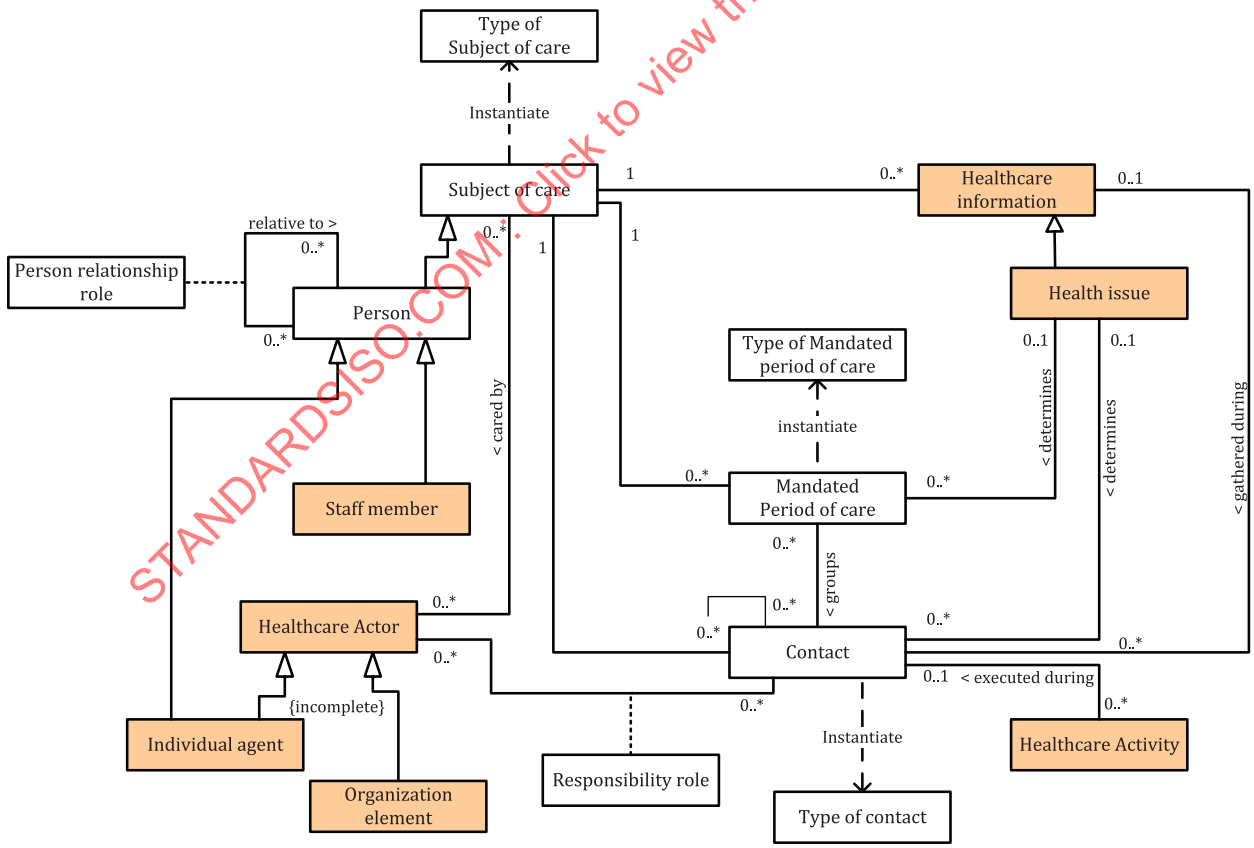

Figure 6 — UML model for subject of care objects

7.2.3 Specification of the individual classes

7.2.3.1 Class: Type of subject of care

Class identifier: TypeOfSubjectOfCare			
Description	Type of entity who seeks to receive, is receiving or has received healthcare (CONTSYS)		
Related terms	Type of entity scheduled to receive, receiving or having received health care services (as previously defined in ISO 12967-2:2009)		
Associated classes		**Type of association**	**Multiplicity**
SubjectOfCare		Dependency	
Attributes	**Type**	**Description**	
id	SET<String>	Identifier(s) that is (are) used to uniquely identify the type of subject of care	
description	String	A phrase by which the object is described in a manner that is intended to be unambiguous in the given language	

7.2.3.2 Class: Subject of care

Class identifier: SubjectOfCare			
Description	Entity who seeks to receive, is receiving or has received healthcare (CONTSYS)		
Related terms	Entity scheduled to receive, receiving or having received health care services (as previously defined in ISO 12967-2:2009)		
Notes	In this document, subject of Care is mainly intended as an individual person.		
Examples	None		
Associated classes		**Type of association**	**Multiplicity**
TypeOfSubjectOfCare		Dependency	
Person (subtype) Those Subjects of Care being human beings		Generalization	
Contact Contacts had by the subject of care		Binary association	0..*
PeriodOfCare Period(s) of care related to the subject of care		Binary association	0..*
ClinicalInformation Healthcare information related to the subject of care		Binary association	0..*
Agent Healthcare Actor(s) (individuals and organizations) that take care of the subject of Care		Binary association	0..*
Attributes	**Type**	**Description**	
id	String	Unique identifier of the subject of care	
description	String	A phrase by which the object is described in a manner that is intended to be unambiguous in the given language	

7.2.3.3 Class: Person

Class identifier: Person			
Description	Individual human being, who (possibly) seeks to receive, is receiving or has received healthcare		
Related terms	Individual human being, scheduled to receive, receiving or having received health care services. (as previously defined in ISO 12967-2:2009)		
Associated classes		**Type of association**	**Multiplicity**
SubjectOfCare (*supertype*)		Generalization	
StaffMember (*subtype*) Those persons also working as staff members in the organization		Generalization	
Individual agent (*subtype*) Those persons also acting as healthcare actors of the system in the organization		Generalization	
Person (Relative) Relative(s) of the person		Binary association Through association class role	0..*
Attributes	**Type**	**Description**	
id	SET<String>	Identifier(s) that is (are) used to uniquely identify the person	
name	SET<String>	A name or names by which the person is, or has been, known	
birthTime	DateTime	Date and possibly time of birth	
deceasedTime	DateTime	Date and time of death	
gender	String	(Administrative) gender of the person	
address	SET<String>	Postal address(es) associated with the person	
telcom	SET<URI>	Communication data associated with the person	

7.2.3.4 Class: Type of contact

Class identifier: TypeOfContact			
Description	Class handling all types of contact, describing the actual contacts		
Associated classes		**Type of association**	**Multiplicity**
Contact		Dependency	
Attributes	**Type**	**Description**	
id	String	Identifier(s) that is (are) used to uniquely identify the type of contact	
description	String	A phrase by which the object is described in a manner that is intended to be unambiguous in the given language	

7.2.3.5 Class: Contact

Class identifier: Contact			
Description	Time interval during which healthcare activities are performed for a subject of care (CONTSYS)		
Related terms	Situation on the uninterrupted course of which one health care provider performs health care services for a subject of care (as previously defined in ISO 12967-2:2009)		
Notes	The Contact is an administrative placeholder for managing the set of health issues recorded, activities performed, resources used, subject of care and health care providers involved, etc. during the period of time the Contact lasts. Healthcare information systems may be implemented without using the Contact as an administrative container. Thus, all associations from this class to other classes are modelled with multiplicities 0..1 or * at the Contact class end. However, if the Contact class is implemented, the associations should have multiplicities 1 or 1..* at this end.		
Examples	An ambulatory visit, an in-patient stay, a day-hospital stay, telemedical supervision, telephone advisory, etc.		
Associated classes		**Type of association**	**Multiplicity**
SubjectOfCare Subject of care to whom the contact relates		Binary association	1
PeriodOfCare Mandated period of care in which the contact is clustered		Binary association	0..*
Activity Healthcare Activity(ies) performed in the interest of the patient during the contact		Binary association	0..*
ClinicalInformation Healthcare information on the subject of Care that are gathered during the contact		Binary association	0..*
HealthIssue Health issue of the subject of Care that is determining the contact		Binary association	0..*
Agent Healthcare Actor(s) responsible, at various levels, for the Contact during its various phases		Binary association Through association class “Responsible for”	1..*
Attributes	**Type**	**Description**	
id	Identifier	Unique identifier for the Contact	
startTime	DateTime	Date and time when the contact is started (or is planned to start, depending on the life-cycle status)	
endTime	DateTime	Date and time when the contact is ended (or is planned to end, depending on the life-cycle status)	
startReason	String	Reason for the initiation of the contact	
endReason	String	Reason for terminating the contact	
status	String	Status of the contact; described, at least, through values: “Planned”, “Active”, “Terminated”, “Annulled”	

7.2.3.6 Association class: Healthcare actor responsibility role

Class identifier: AgentResponsibilityRole			
Description	Healthcare actors responsible for the contact during its evolution. The responsibility is different for a healthcare actor if it is an individual agent or an organizational unit		
Related terms	Agents responsible for the contact during its evolution. The responsibility is different for an agent if it is an individual agent or an organizational unit (as previously defined in ISO 12967-2:2009)		
Notes	In ISO 12967-2:2009 the association class was named “Agent responsibility role”.		
Associated classes		**Type of association**	**Multiplicity**
Agent Healthcare actor responsible for the contact		Binary association	1
Contact		Binary association	1
Attributes	**Type**	**Description**	
role	String	Specification of the type of involvement of the Agent, described, at least, through values: “Referring”, “Caring”	
startTime	DateTime	Date and time when the Agent starts to be involved in the contact according to the specified “Role”	
endTime	DateTime	Date and time when the Agent terminates being involved in the contact according to the specified “Role”	
startReason	String	Reason for the starting of involvement in the contact	
endReason	String	Reason for the termination of involvement in the contact	

7.2.3.7 Class: Type of mandated period of care

Class identifier: TypeOfPeriodOfCare			
Description	Class handling all types of mandated period of care, being a set of healthcare activity periods where a healthcare provider is mandated to perform the healthcare activities required to address specific health needs.		
Related terms	Class handling all types of mandated period of care, describing the actual period of care through which contacts are grouped (as previously defined in ISO 12967-2:2009)		
Notes	In ISO 12967-2:2009 the class was named “Type of period of care”.		
Associated classes		**Type of association**	**Multiplicity**
PeriodOfCare		Dependency	
Attributes	**Type**	**Description**	
id	String	Identifier(s) that is (are) used to uniquely identify the type of period of care	
description	String	A phrase by which the object is described in a manner that is intended to be unambiguous in the given language	

7.2.3.8 Class: Mandated period of care

Class identifier: PeriodOfCare	
Description	Set of healthcare activity periods where a healthcare provider is mandated to perform the healthcare activities required to address specific health needs.
Related terms	Construct that groups health issues and/or contacts and associated elements that are recorded in the health information system regarding a subject of care under the clinical framework of one particular health Issue (as previously defined in ISO 12967-2:2009)
Notes	The mandated period of care thus corresponds to a folder of a problem-oriented patient electronic record, for a specific problem (health issue). In ISO 12967-2:2009 the class was named “Period of care”.

Associated classes		Type of association	Multiplicity
TypeOfPeriodOfCare		Dependency	
SubjectOfCare Subject of care to whom the period of care relates		Binary association	1
Contact Contacts being grouped in the period of care		Binary association	0..*
HealthIssue Health issue of the subject of care that has determined the starting of the period of care		Binary association	1
Attributes	**Type**	**Description**	
Id	Identifier	Unique identifier for the period of care	
description	String	A phrase by which the object is described in a manner that is intended to be unambiguous in the given language	
startTime	DateTime	Date and time when the period of care is started (or is planned to start, depending on the life-cycle status)	
endTime	DateTime	Date and time when the period of care is ended (or is planned to end, depending on the life-cycle status)	

7.2.3.9 Association class: Person relationship role

Class identifier: PersonRelationshipRole			
Description	Persons can have different relationships with each other, e.g. mother of, married to, etc.		
Associated classes		**Type of association**	**Multiplicity**
Person First person in relationship (i.e. the Relative)		Binary association	0..*
Person Other person in relationship (i.e. the "Mother", "Tutor", etc.)		Binary association	0..*
Attributes	**Type**	**Description**	
role	String	Specification of the type of relationship between the persons, described, for example, through values: "Parent", "Tutor", "Married to".	
startTime	DateTime	Date and time when the relationship starts according to the specified "Role"	
endTime	DateTime	Date and time when the relationship terminates according to the specified "Role"	
reason	String	Reason for the relationship	

7.3 Activity management objects

7.3.1 Aim

The activity package groups the information services which support the rest of the healthcare information system in the management of the healthcare activities, and the life cycles of these activities as they are planned to be, are being or have been carried out in the various parts of the healthcare enterprise.

It also groups the information services which support the rest of the healthcare information system in the management of the elements of clinical guidelines and clinical planning as relates to particular health issues (i.e. standard plans) or particular subjects of care (i.e. patient plans).

Package identifier (for any coded reference to this group of objects): am

7.3.2 UML information model

All non-coloured classes belonging to the activity management cluster of objects in Figure 7 are specified in 7.3.3. The healthcare information, the demand for care class, the association class Activity C.I., and the association class role of agent in C.I. life cycle are specified in 7.4.3.1, 7.4.3.2, 7.4.3.10 and 7.4.3.8, respectively. The contact class is specified in 7.2.3.5. The type of resource and resource classes are specified in 7.5.3.1 and 7.5.3.8. The agent class is specified in 7.6.3.2. The staff member is specified in 7.5.3.10.

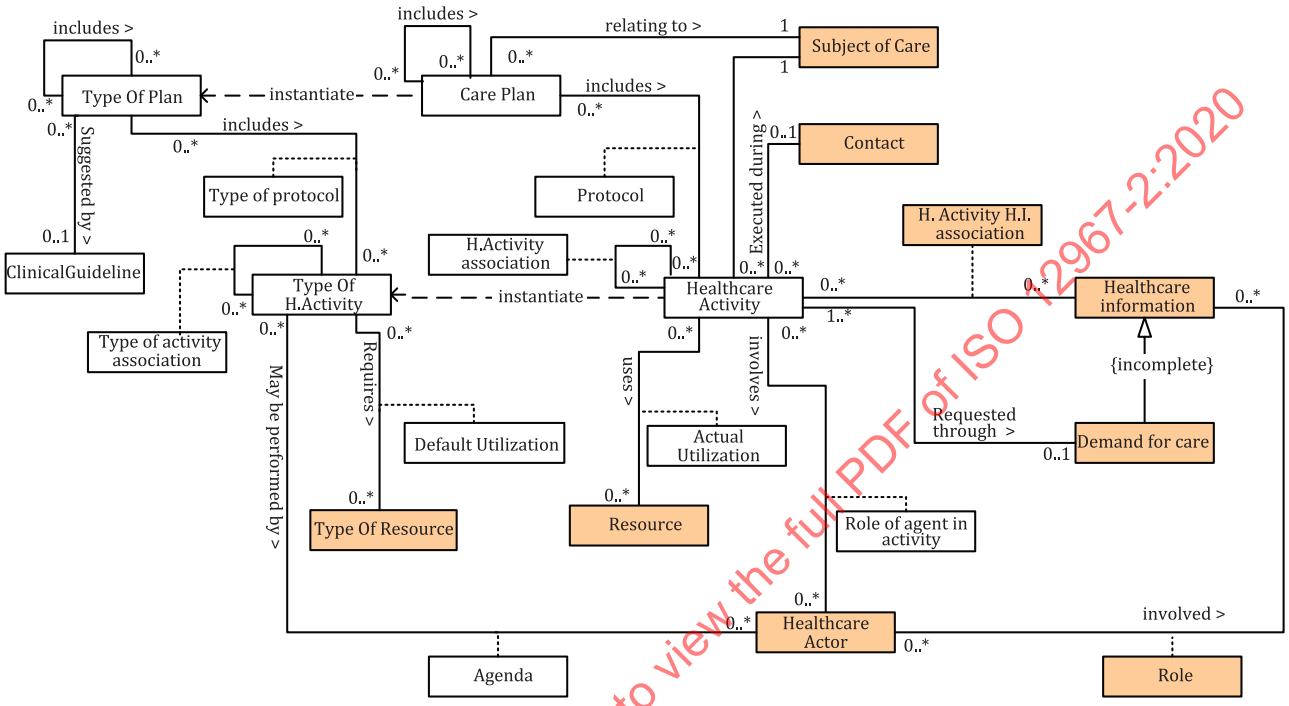

Figure 7 — UML model for activities objects

7.3.3 Specification of the individual classes

7.3.3.1 Class: Type of healthcare activity

Class identifier: TypeOfActivity		
Description	Class handling all types of activities, describing the actual healthcare activities and interventions carried out within the healthcare organization, whereas Healthcare Activity is an activity intended directly or indirectly to improve or maintain a health state (CONTSYS)	
Related terms	Class handling all types of activities, describing the actual activities and interventions carried out within the healthcare organization (as previously defined in ISO 12967-2:2009)	
Notes	In ISO 12967-2:2009 the class was named “Type of Activity”.	
Associated classes	**Type of association**	**Multiplicity**
TypeOfActivity Hierarchy of types of healthcare activities	Binary Association	0..*
TypeOfPlan	Binary Association through Association Class TypeOfProtocol	0..*
TypeOfResource	Binary Association through Association Class Default Utilization	0..*

Agent Healthcare actor(s) that perform the type of activity		Binary Association through Association Class Agenda	0..*
Activity		Dependency	
Attributes	**Type**	**Description**	
id	Identifier	Unique identifier for the type of healthcare activity	
description	String	A phrase by which the object is described in a manner that is intended to be unambiguous in the given language	
duration	Double	Average duration of the type of healthcare activity	
durationMeasure	Unit	Unit of measure of the average duration of the type of healthcare activity	
cost	Double	Average cost of the type of healthcare activity	

7.3.3.2 Class: Healthcare activity

Class identifier: Activity			
Description	Activity intended directly or indirectly to improve or maintain a health state (CONTSYS)		
Related terms	Activity performed for a subject of care by a healthcare provider with the intention of directly or indirectly improving or maintaining the health of that subject of care (as previously defined in ISO 12967-2:2009)		
Examples	Observation, intervention, procedure, medication, drug dispensation, drug administration, transportation, etc.		
Notes	In ISO 12967-2:2009 the class was named "Activity".		
Associated classes		**Type of association**	**Multiplicity**
SubjectOfCare Subject of care for whom the activity is performed		Binary association	0..1
Agent Healthcare actor(s) involved with different roles during the life cycle of the activity		Binary association through Association Class Role	0..*
ClinicalInformation Helathcare information related to a healthcare activity (e.g. relevant for the execution of the h. activity, generated as outcomes of the healthcare activity)		Binary association through Association Class ActivityClinicalInformationAssociation	0..*
Plan Care Plan in which the activity is organized		Binary association through Association Class Protocol	0..1
Resource Resource(s) used for the execution of the healthcare activity		Binary association through Association Class Actual Utilization	0..*
Contact Contact during which the healthcare activity is performed		Binary association	0..1
TypeOfActivity		Dependency	
Attributes	**Type**	**Description**	
id	Identifier	Unique identifier for the Healthcare Activity	
status	String	Status of the activity in its life cycle from the initial request to the completion	
requestTime	DateTime	Date and time of request	
execRequest	DateTime	Date and time requested for the execution of the healthcare activity	

execStartTime	DateTime	Date and time when the execution of the healthcare activity has been started
execEndTime	DateTime	Date and time when the execution of the healthcare activity has been completed
urgency	String	Level of urgency of the healthcare activity
cost	Double	Actual cost for the execution of the healthcare activity
duration	Double	Actual duration of the execution of the healthcare activity

7.3.3.3 Class: Type of care plan

Class identifier: TypeOfPlan			
Description	Class handling all types of care plans, describing the dynamic, personalized plan including identified needed healthcare activity, health objectives and healthcare goals, relating to one or more specified health issues in a healthcare process (CONTSYS)		
Related terms	Class handling all types of care plans, describing the plans through which interventions and activities are carried out for actually treating patients within the healthcare organization (as previously defined in ISO 12967-2:2009)		
Notes	In ISO 12967-2:2009 the class was named "Type of plan"		
Associated classes		**Type of association**	**Multiplicity**
Plan		Dependency	
TypeOfPlan (includes) Implements a hierarchy in the types of care plans, allowing to structure a type of care plan by combining other types		Binary association	0..*
TypeOfActivity Type of healthcare Activities (to be) included in the type of plan		Binary association through Association Class TypeOfProtocol	0..*
ClinicalGuideline Clinical Guidelines that suggest the implementation of the Type of Plan		Binary association	0..1
Attributes	**Type**	**Description**	
id	String	Identifier(s) that is (are) used to uniquely identify the type of care plan	
description	String	A phrase by which the object is described in a manner that is intended to be unambiguous in the given language	

7.3.3.4 Class: Care Plan

Class identifier: Plan			
Description	Dynamic, personalized plan including identified needed healthcare activity, health objectives and healthcare goals, relating to one or more specified health issues in a healthcare process (CONTSYS)		
Related terms	Bundle of activities addressing the treatment and care of one particular health issue of one particular subject of care, as defined by a healthcare provider as a standard planning element encompassing all activities to be performed to achieve the specified clinical objective for the given health issue (as previously defined in ISO 12967-2:2009)		
Notes	In ISO 12967-2:2009 the class was named "Plan".		
Associated classes		**Type of association**	**Multiplicity**
SubjectOfCare Subject of care to whom the plan refers		Binary association	0..1

Activity Healthcare Activities (to be) executed through the care plan		Binary association through Association Class Protocol	0..*
Plan (includes) Implements a hierarchy in the plans, allowing to structure a plan by combining other plans		Binary association	0..*
TypeOfPlan		Dependency	
Attributes	**Type**	**Description**	
Id	String	Unique identifier of the plan	
description	String	A phrase by which the object is described in a manner that is intended to be unambiguous in the given language	
definitionTime	DateTime	Date and time of definition of the care plan	
reason	String	Motivation of the care plan	

7.3.3.5 Association Class: Type of healthcare activity association

Class identifier: TypeOfActivityAssociation			
Description	Class handling all types of associations between types of healthcare activities, describing the sequences and dependencies of the types of healthcare activities included in the structure for actually treating patients within the healthcare organization. A set of systematically developed statements specifying the roles and dependencies between types of healthcare activities as part of an aggregation.		
Related terms	Class handling all types of associations between types of activities, describing the sequences and dependencies of the types of activities included in the structure for actually treating patients within the healthcare organization. A set of systematically developed statements specifying the roles and dependencies between types of activities as part of an aggregation (as previously defined in ISO 12967-2:2009		
Notes	In ISO 12967-2:2009 the class was named “Type of activity association”.		
Associated classes		**Type of association**	**Multiplicity**
TypeOfActivity Type of healthcare activity (to be) referred in the aggregation		Binary association	1
TypeOfActivity Type of Healthcare Activities (to be) included in the aggregation		Binary association	1
Attributes	**Type**	**Description**	
sequence	Ordinal	Sequence order of the Type of Healthcare Activity in the specification of the aggregation	
rules	String	Dependencies, preparations, and other rules applicable for the execution of the Type of Healthcare Activity within the aggregation	
reason	String	Reason for aggregating the types of healthcare activities	

7.3.3.6 Association Class: Healthcare activity association

Class identifier: ActivityAssociation	
Description	Class handling all associations between healthcare activities, describing the sequences and dependencies of the healthcare activities included in the structure. A set of systematically developed statements specifying the roles and dependencies between healthcare activities as part of an aggregation.

Related terms	Class handling all associations between activities, describing the sequences and dependencies of the activities included in the structure A set of systematically developed statements specifying the roles and dependencies between activities as part of an aggregation (as previously defined in ISO 12967-2:2009)		
Notes	In ISO 12967-2:2009 the class was named “Activity association”.		
Associated classes		**Type of association**	**Multiplicity**
Activity Healthcare Activity (to be) referred in the aggregation		Binary association	1
Activity Healthcare Activities (to be) included in the aggregation		Binary association	1
Attributes	**Type**	**Description**	
sequence	Ordinal	Sequence order of the healthcare activity in the specification of the aggregation	
rules	String	Dependencies, preparations and other rules applicable for the execution of the healthcare activity within the aggregation	
reason	String	Reason for aggregating the healthcare activities	

7.3.3.7 Association Class: Type of protocol

Class identifier: TypeOfProtocol			
Description	Class handling all types of protocols, describing the sequences and dependencies of the types of healthcare activities included in plans for actually treating patients within the healthcare organization. A set of systematically developed statements specifying the roles and dependencies between planned healthcare activities as part of a clinical care plan.		
Examples	“Type of Activity B starts two days after Type of activity A”, “If the result of Type of Activity A is <result> then start Type f Activity B as soon as possible, or else start Type of Activity C within one day”		
Related terms	Class handling all types of protocols, describing the sequences and dependencies of the types of activities included in plans for actually treating patients within the healthcare organization. A set of systematically developed statements specifying the roles and dependencies between planned activities as part of a clinical plan (as previously defined in ISO 12967-2:2009)		
Associated classes		**Type of association**	**Multiplicity**
TypeOfPlan Type of Care Plan (to be) referred in the type of protocol		Binary association	1
TypeOfActivity Type of Healthcare Activities (to be) included in the type of protocol		Binary association	1
Attributes	**Type**	**Description**	
sequence	Ordinal	Sequence order of the Type of Healthcare Activity in the specification of the Type Of Care Plan	
rules	String	Dependencies, preparations, and other rules applicable for the execution of the Type of Healthcare Activity within the Type of Care Plan	

7.3.3.8 Association Class: Protocol

Class identifier: Protocol			
Description	A set of systematically developed statements specifying the roles and dependencies between planned healthcare activities as part of a care plan		
Examples	"Activity B starts two days after activity A", "If the result of Activity A is <result> then start Activity B as soon as possible, or else start Activity C within one day"		
Related terms	A set of systematically developed statements specifying the roles and dependencies between planned activities as part of a plan (as previously defined in ISO 12967-2:2009) Customized clinical guideline (CONTSYS)		
Associated classes		**Type of association**	**Multiplicity**
Activity Healthcare Activity involved in the protocol		Binary association	1
Plan Plan in which the healthcare activity is organized		Binary association	1
Attributes	**Type**	**Description**	
sequence	Ordinal	Sequence order of the activity in the plan	
rule	String	Rule to be applied for the execution of the healthcare activity, inherited from the corresponding item in "Type of Protocol" and customized according to the specific needs of the actual Care Plan	

7.3.3.9 Association Class: Actual utilization

Class identifier: ActualUtilization			
Description	Detail of resources used for the execution of one healthcare activity		
Associated classes		**Type of association**	**Multiplicity**
Activity Healthcare Activity using the resource		Binary association	1
Resource Resource used by the healthcare activity		Binary association	1
Attributes	**Type**	**Description**	
sequence	Ordinal	Sequence order of the resource in the list	
planStartTime	DateTime	Planned starting date and time of utilization of the resource	
planEndTime	DateTime	Planned ending date and time of utilization of the resource	
planQuantity	Double	Planned quantity of resource used	
actualStartTime	DateTime	Actual starting date and time of utilization of the resource	
actualEndTime	DateTime	Actual ending date and time of utilization of the resource	
actualQuantity	Double	Actual quantity of resource used	
unitOfMeasure	Unit	Unit of measure of the used quantity	
reason	String	Reason of utilization of the resource	
modality	String	Modality of utilization (e.g. administration for drugs)	
cost	Double	Actual unit cost related to the utilization of the resource	

7.3.3.10 Association Class: Default utilization

Class identifier: DefaultUtilization			
Description	Baseline of resources generally used for the execution of one type of healthcare activity		
Associated classes		**Type of association**	**Multiplicity**
TypeOfActivity Type of healthcare activity using the type of resource		Binary association	1
Type of resource Type of resource being used by the type of healthcare activity		Binary association	1
Attributes	**Type**	**Description**	
sequence	Ordinal	Sequence order of the resource in the list	
quantity	Double	Quantity of resource used	
unitOfMeasure	Unit	Unit of measure of the used quantity	
reason	String	Reason of utilization of the resource	
modality	String	Modality of utilization (e.g. administration for drugs)	
cost	Double	Unit cost of utilization of the Type of Resources	

7.3.3.11 Association Class: Role of healthcare actor in healthcare activity

Class identifier: RoleOfAgentInActivity			
Description	Role of one healthcare actor in the life cycle of one healthcare activity		
Notes	In ISO 12967-2:2009 the class was named "Role of Agent in Activity".		
Associated classes		**Type of association**	**Multiplicity**
Activity		Binary association	1
Agent		Binary association	1
Attributes	**Type**	**Description**	
sequence	Ordinal	Sequence order of the healthcare actor in the list	
startTime	DateTime	Starting time of involvement of the healthcare actor	
endTime	DateTime	Ending time of involvement of the healthcare actor	
role	String	Role of the healthcare actor (e.g. requestor, planner, executor, etc.)	

7.3.3.12 Association Class: Agenda

Class identifier: Agenda			
Description	Agenda and rules according to which one type of healthcare activity can be planned and performed by one healthcare actor		
Related terms	Agenda and rules according to which one type of activity can be planned and performed by one agent (as previously define in ISO 12967-2:2009)		
Associated classes		**Type of association**	**Multiplicity**
TypeOfActivity		Binary association	1
Agent		Binary association	1
Attributes	**Type**	**Description**	
startTime	DateTime	Starting date and time of the agenda period	
endTime	DateTime	Ending date and time of the agenda period	
rules	String	Rules according to which the healthcare activity is planned and performed by that healthcare actor	

7.3.3.13 Class: Clinical guideline

Class identifier: ClinicalGuideline			
Description	Healthcare activities to be performed with regard to specified health issues (CONTSYS)		
Related terms	A set of systematically developed statements to assist the decision of health care providers about activities to be provided with regard to a specific health issue (as previously defined in ISO 12967-2:2009)		
Associated classes		**Type of association**	**Multiplicity**
TypeOfPlan TypeOfPlan(s) (to be) referred to the Clinical Guideline		Binary association	0..*
Attributes	**Type**	**Description**	
id	Identifier	Unique identifier for the clinical guideline	
endDate	DateTime	Date and time until which the clinical guideline is valid	
approvedTime	DateTime	Date and time of approval of the clinical guideline	

7.4 Clinical and health information objects

7.4.1 Aim

The clinical information package groups the information objects which support the rest of the healthcare information system in the management of the clinical and health information recorded in the healthcare information system in relation to the treatment and care of each subject of care.

Package identifier (for any coded reference to this group of objects): hm

7.4.2 UML information model

All non-coloured classes belonging to the Clinical Information cluster of objects in Figure 8 are specified in 7.4.3. The contact class is specified in 7.2.3.5, while the subject of care class is specified in 7.2.3.2. The agent class is specified in 7.6.3.2. The activity class is specified in 7.3.3.2.

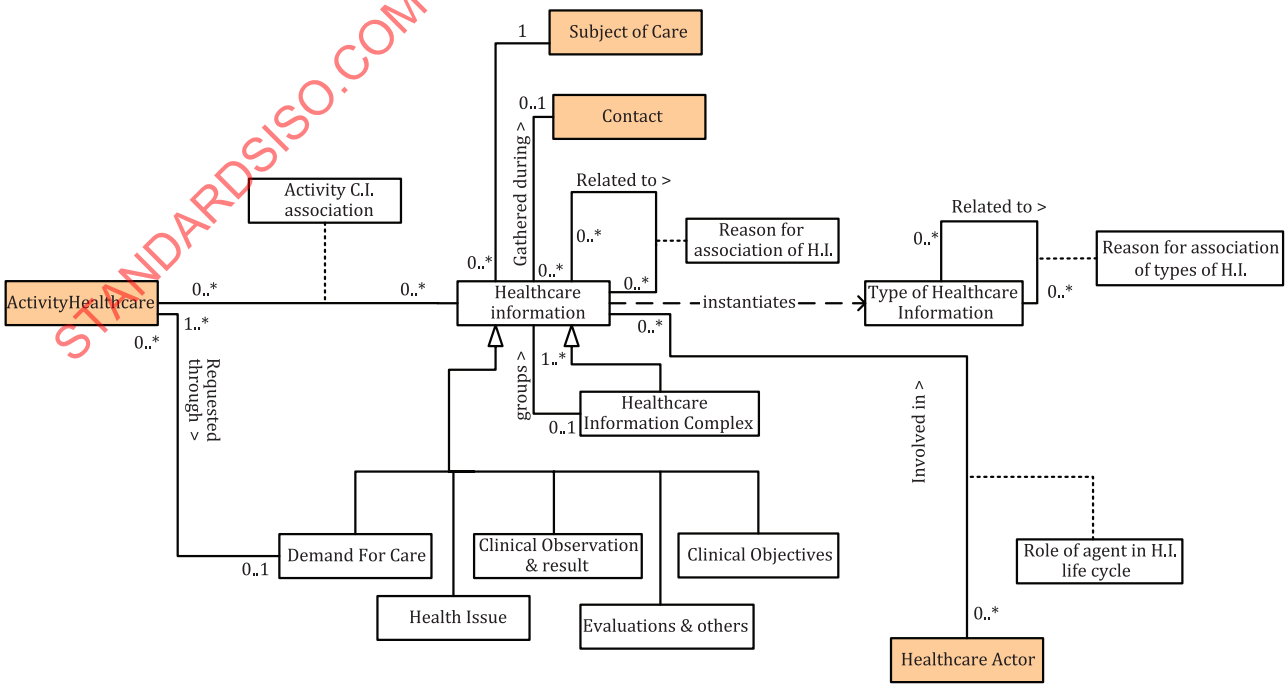

Figure 8 — UML model for clinical and health information objects

7.4.3 Specification on the individual classes

7.4.3.1 Class: Healthcare information

Class identifier: ClinicalInformation		
Description	Information about a person relevant to his or her healthcare (CONTSYS)	
Related terms	Information about the health or treatment and care of a subject of care, as recorded in the healthcare information system by on behalf of a healthcare provider (as previously defined in ISO 12967-2:2009)	
Examples	Recorded diagnoses, advice given to the subject of care, objectives of healthcare activities, results of healthcare activities, clinical values and measurements (temperature), anamnesis, etc.	
Notes	In ISO 12967-2:2009 the class was named “Clinical Information”	
Associated classes	**Type of association**	**Multiplicity**
HealthIssue	Generalization	
ClinicalObservationAndResult	Generalization	
EvaluationAndOthers	Generalization	
Clinical Objective:	Generalization	
Demand for care:	Generalization	
ClinicalInformationComplex Healthcare information obtained as aggregation of other clinical information	Generalization	
SubjectOfCare Subject of care to whom the Healthcare Information pertains	Binary association	1
Contact Contact through which the Healthcare information has been gathered	Binary association	0..*
Agent Healthcare Actors involved in the collection, validation of the clinical information	Binary association through Association Class Role	0..*
Activity Healthcare Activities to which the clinical information is related (e.g. relevant for the execution or generated as outcome)	Binary association through association class ActivityClinicalInformationAssociation	0..*
ClinicalInformation Other healthcare information related, for various reasons with the healthcare information	Binary association	0..*
ClinicalInformation Healthcare information grouped in the Clinical information Complex	Binary association	1..*
TypeOfClinicalInformation	Dependency	

Attributes	Type	Description
id	Identifier	Unique identifier for the Clinical information
value	Any	Recorded value of the Clinical information
unitMeasure	Unit	Unit of measure applicable
status	String	Status of the Clinical Information during its life cycle, including, at least, “To be validated”, “Validated”, “Annulled” as possible values

7.4.3.2 Class: Demand for care

Class identifier: DemandForCare			
Description	Demand for healthcare provider activities expressed by a healthcare actor (CONTSYS)		
Related terms	Demand expressed by a health care provider and/or subject of care that healthcare services be provided to a subject of care (as previously defined in ISO 12967-2:2009)		
Associated classes		**Type of association**	**Multiplicity**
ClinicalInformation (supertype)		Generalization	
Activity Healthcare Activities requested in the Demand for Care		Binary association	0..*
Attributes	**Type**	**Description**	
(Inherits the attributes of the Healthcare Information Class)			

7.4.3.3 Class: Health issue

Class identifier: HealthIssue			
Description	Representation of an issue related to the health of a subject of care as identified by one or more healthcare actors (CONTSYS)		
Related terms	Issue related to the health of a subject of care, as defined by a specific health care party (as previously defined in ISO 12967-2:2009)		
Associated classes		**Type of association**	**Multiplicity**
ClinicalInformation (supertype)		Generalization	
Attributes	**Type**	**Description**	
(Inherits the attributes of the Healthcare Information Class)			

7.4.3.4 Class: Clinical observation and result

Class identifier: ClinicalObservationAndResult			
Description	Information about the clinical observations and result as clinical measurements (temperature), result of healthcare activities, etc. of a subject of care		
Related terms	Information about the clinical observations and result as clinical measurements (temperature), result of activities, etc. of a subject of care (as previously defined in 12967-2:2009).		
Associated classes		**Type of association**	**Multiplicity**
ClinicalInformation (supertype)		Generalization	
Attributes	**Type**	**Description**	
(Inherits the attributes of the Healthcare Information Class)			

7.4.3.5 Class: Evaluation and other

Class identifier: EvaluationAndOther			
Description	Information about the evaluations of a subject of care		
Related terms			
Associated classes		**Type of association**	**Multiplicity**
ClinicalInformation (supertype)		Generalization	
Attributes	**Type**	**Description**	
(Inherits the attributes of the Healthcare Information Class)			

7.4.3.6 Class: Clinical objective

Class identifier: ClinicalObjective			
Description	Desired achievement of one or more healthcare activities, considered as an intermediate operational step to reach a specific health objective (CONTSYS)		
Related terms	Desired or intended purpose and results of an activity (as previously defined in ISO 12967-2:2009)		
Associated classes		**Type of association**	**Multiplicity**
ClinicalInformation (supertype)		Generalization	
Attributes	**Type**	**Description**	
(Inherits the attributes of the Healthcare Information Class)			

7.4.3.7 Class: Healthcare information Complex

Class identifier: ClinicalInformationComplex			
Description	Healthcare information obtained as aggregation of other healthcare information		
Related terms	Clinical information obtained as aggregation of other clinical information (as previously defined in ISO 12967-2:2009)		
Examples	Any complex aggregation of clinical information		
Notes	In ISO 12967-2:2009 the name of the class was Clinical Information Complex		
Associated classes		**Type of association**	**Multiplicity**
ClinicalInformation (supertype)		Generalization	
ClinicalInformation		Binary association	0..1
Attributes	**Type**	**Description**	
(Inherits the attributes of the Clinical Information Class)			

7.4.3.8 Association Class: Role of agent in H.I. life cycle

Class identifier: RoleOfAgentInClinicalInformationLifeCycle			
Description	Reasons why the healthcare actor is involved in the life cycle of one healthcare Information item		
Related terms	Reasons why the agent is involved in the life cycle of one Clinical Information (as previously defined in ISO 12967-2:2009)		
Notes	In ISO 12967-2:2009 the class was named “Association Class: Role of agent in C.I. life cycle”		
Associated classes		**Type of association**	**Multiplicity**
ClinicalInformation		Binary association	1
Agent		Binary association	1

Attributes	Type	Description
startTime	DateTime	Starting date and time of involvement of the healthcare actor
endTime	DateTime	Ending date and time of involvement of the healthcare actor
role	String	Role of the agent in the life cycle of the Healthcare Information, including values “Collector” and “Validating Agent”.

7.4.3.9 Association Class: Reason for association of healthcare information

Class identifier: ReasonForAssociationOfClinicalInformation			
Description	Relations among individual healthcare information for various purposes (e.g. structuring, dependency, substitution, etc.)		
Related terms	Relations among individual clinical information for various purposes (e.g. structuring, dependency, substitution, etc.) (as previously define in ISO 12967-2:2009)		
Notes	In ISO 12967-2:2009 the class was named “Reason for association of clinical information”		
Examples			
Associated classes		**Type of association**	**Multiplicity**
ClinicalInformation First healthcare Information being related		Binary association	1
ClinicalInformation Second healthcare information being related		Binary association	1
Attributes	**Type**	**Description**	
sequence	Ordinal	Sequence order of the second healthcare information in the list	
reason	String	Reason why the two items of healthcare information are related, including values: “Aggregation” (when the first healthcare information is an aggregation, containing the second one for certain purposes) and “Substitution” (when the first healthcare information is annulled and substituted with the second one)	
context	String	Context and rules according to which the second healthcare information is related to the first one	

7.4.3.10 Association Class: Activity H.I. association

Class identifier: ActivityClinicalInformationAssociation			
Description	Reasons why the Activity is related to one Healthcare Information		
Related terms	Reasons why the Activity is related to one Clinical Information (as previously defined in 12967-2:2009)		
Notes	In ISO 12967-2:2009 the class was named “Activity C.I. association”		
Associated classes		**Type of association**	**Multiplicity**
ClinicalInformation		Binary association	1
Activity		Binary association	1
Attributes	**Type**	**Description**	
startTime	DateTime	Starting date and time of relationship	
endTime	DateTime	Ending date and time of relationship	
role	String	Role of the relationship amongst the Healthcare Activity and the Healthcare Information, including values “Generated by” (i.e. healthcare information generated as a result of the healthcare activity) and “Relevant for” (i.e. healthcare information that is relevant for the execution of a healthcare activity).	

7.4.3.11 Class: Type of healthcare information

Class identifier: TypeOfClinicalInformation			
Description	Class handling all types of healthcare information, describing the contents of actual health-related classes measured and observed within the healthcare organization		
Related terms	Class handling all types of clinical information, describing the contents of actual health-related classes measured and observed within the healthcare organization (as previously defined in ISO 12967-2:2009)		
Notes	In ISO 12967-2:2009 the class was named “Type of clinical information”		
Examples	None		
Associated classes		**Type of association**	**Multiplicity**
Clinical Information		Dependency	
TypeOfClinicalInformation Type of Clinical Information being related		Binary association Through association class “Reason”	0..*
Attributes	**Type**	**Description**	
id	String	Identifier(s) that is (are) used to uniquely identify the type of healthcare Information	
description	String	A phrase by which the object is described in a manner that is intended to be unambiguous in the given language	
domainValues	String	Domain of the possible values that can be obtained by the Type of Healthcare Information	

7.4.3.12 Association Class: Reason for association of type of healthcare information

Class identifier: ReasonForAssociationOfTypesOfClinicalInformation			
Description	Relations among type of clinical information for various purposes		
Related terms	Relations among type of clinical information for various purposes (as previously defined in ISO 12967-2:2009)		
Notes	In ISO 12967-2:2009 the class was named “Reason for association of type of clinical information”		
Examples			
Associated classes		**Type of association**	**Multiplicity**
TypeOfClinicalInformation First type of healthcare Information being related		Binary association	1
TypeOfClinicalInformation Second Type of Healthcare Information being related		Binary association	1
Attributes	**Type**	**Description**	
sequence	Ordinal	Sequence order of the second type of healthcare information in the list	
reason	String	Reason why the two type of healthcare information are related.	
context	String	Context and rules according to the second type of healthcare information is related to the first one (e.g. for structuring the second healthcare information into a more complex document/dossier represented by the first healthcare information)	

7.5 Resource management objects

7.5.1 Aim

The resource management cluster groups the information services that support the rest of the healthcare information system in the management of the resources used in relation to healthcare activities.

Package identifier (for any coded reference to this group of objects): rm

7.5.2 UML information model

All non-coloured classes belonging to the resource management cluster of objects in Figure 9 are specified in 7.5.3. The person class is specified in 7.2.3.3. The agent class is specified in 7.6.3.2 and the organization and the individual agent are specified in 7.6.3.3 and 7.6.3.4. The classes type of activity, activity, actual utilization, and default utilization are specified in 7.3.3.1, 7.3.3.2, 7.3.3.9 and 7.3.3.10 respectively.

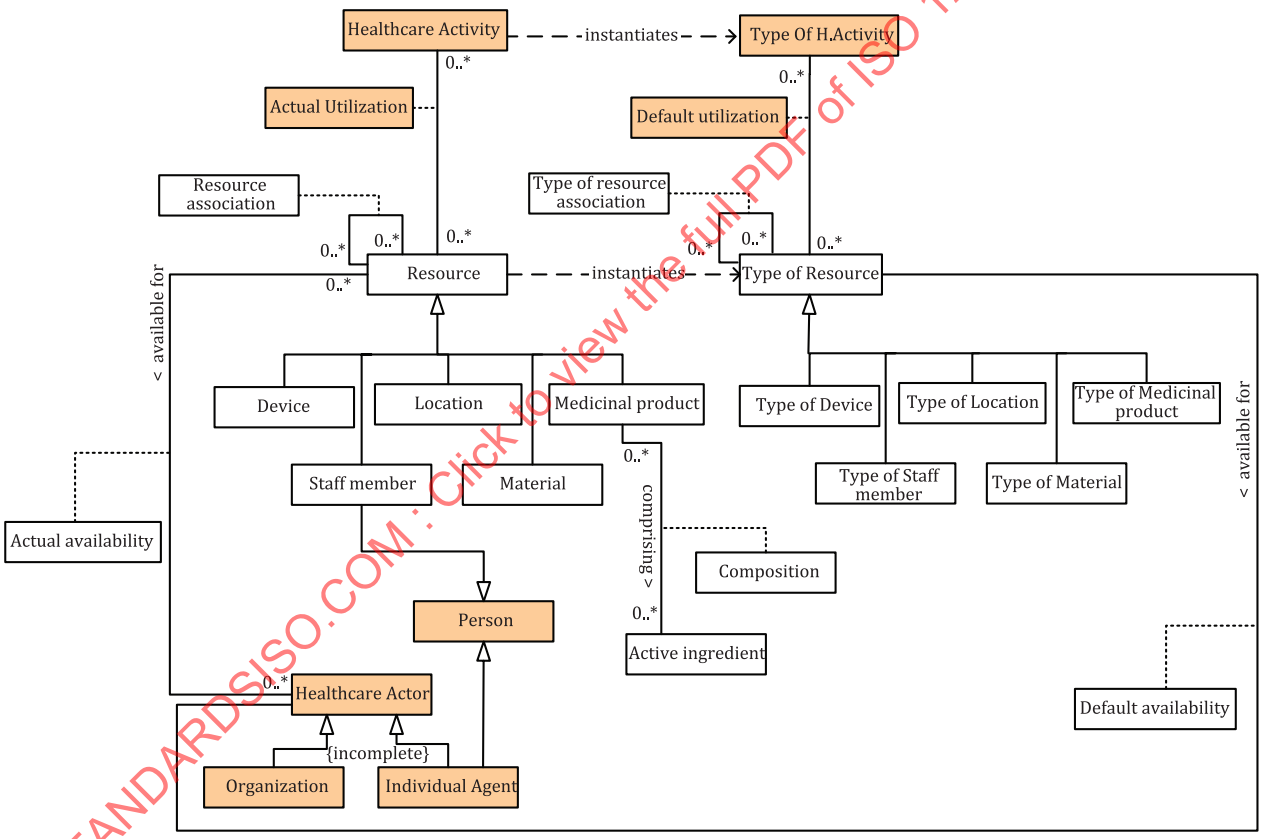

Figure 9 — UML model for resource management objects

7.5.3 Specification of the individual classes

7.5.3.1 Class: Type of the individual classes

Class identifier: TypeOfResource		
Description	Class describing all types of resources used within the organization	
Associated classes	**Type of association**	**Multiplicity**
Resource	Dependency	
TypeOfDevice (subtype)	Generalization	

TypeofStaffMember (subtype)		Generalization	
TypeOfLocation (subtype)		Generalization	
TypeOfMaterial (subtype)		Generalization	
TypeOfMedicinalProduct (subtype)		Generalization	
TypeOfActivity Types of activities generally using the Type of Resource		Binary association through Association Class DefaultUtilization	0..*
Agent General criteria for the assignment and availability of the Type of Resources to one Healthcare Actor		Binary association through Association Class DefaultAvailability	0..*
Attributes	**Type**	**Description**	
id	Identifier	Unique identifier of the type of resource	
description	String	A phrase by which the object is described in a manner that is intended to be unambiguous in the given language	
unitMeasure	Unit	Default Unit of Measure for the utilization of the type of resource	
administration	String	Default administration modality for the type of resource	
unitCost	String	Average unit cost of the type of resource	

7.5.3.2 Class: Type of devices

Class identifier: TypeOfDevice			
Description	Class describing the types of devices and equipment used within the organization		
Associated classes		**Type of association**	**Multiplicity**
TypeOfResource		Generalization	
Attributes	**Type**	**Description**	
(Inherits the attributes of the TypeOfResource Class)			

7.5.3.3 Class: Type of staff member

Class identifier: TypeOfStaffMember			
Description	Class describing the types of staff members employed in the organization		
Examples	e.g. “Physician”, “Nurse”, “Administrative personnel”, etc.		
Associated classes		**Type of association**	**Multiplicity**
TypeOfResource		Generalization	
Attributes	**Type**	**Description**	
(Inherits the attributes of the TypeOfResource Class)			

7.5.3.4 Class: Type of location

Class identifier: TypeOfLocation			
Description	Class describing the types of locations available within the organization		
Associated classes		**Type of association**	**Multiplicity**
TypeOfResource		Generalization	
Attributes	**Type**	**Description**	
(Inherits the attributes of the TypeOfResource Class)			

7.5.3.5 Class: Type of material

Class identifier: TypeOfMaterial			
Description	Class handling the types of materials used within the organization		
Associated classes		**Type of association**	**Multiplicity**
TypeOfResource		Generalization	
Attributes	**Type**	**Description**	
(Inherits the attributes of the TypeOfResource Class)			

7.5.3.6 Class: Type of medicinal product

Class identifier: TypeOfMedicinalProduct			
Description	Class handling the types of medicinal products used within the organization		
Associated classes		**Type of association**	**Multiplicity**
TypeOfResource		Generalization	
Attributes	**Type**	**Description**	
(Inherits the attributes of the TypeOfResource Class)			

7.5.3.7 Association Class: Type of resource association

Class identifier: TypeOfResourceAssociation			
Description	Types of Resources can be grouped to describe possible aggregations of types of locations, types of materials, etc.		
Associated classes		**Type of association**	**Multiplicity**
TypeOfResource First type of resource in relationship		Binary association	0..*
TypeOfResource Other type of resource in relationship		Binary association	0..*
Attributes	**Type**	**Description**	
role	String	Specification of the type of relationship between the types of resources.	
startTime	DateTime	Date and time when the relationship starts according to the specified "Role"	
endTime	DateTime	Date and time when the relationship terminates according to the specified "Role"	
reason	String	Reason for the starting of the relationship	

7.5.3.8 Class: Resource

Class identifier: Resource			
Description	asset that is utilized or consumed during the execution of a healthcare activity (adapted from CONTSYS)		
Related terms	Actual resources available and used in the organization (as previously defined in ISO 12967-2:2009		
Examples	Individual staff, drugs, physical premises, actual materials, available equipment, devices, etc.		
Associated classes		**Type of association**	**Multiplicity**
StaffMember (*subtype*)		Generalization	
Drug (*subtype*)		Generalization	
Location (*subtype*)		Generalization	
Material (*subtype*)		Generalization	

Device (*subtype*)		Generalization	
MedicinalProduct (*subtype*)		Generalization	
TypeOfResource		Dependency	
Activity Healthcare Activity(ies) that have used the resource		Binary Association through Association Class ActualUtilization	0..*
Agent Healthcare Actor(s) for whom the Resource is available		Binary Association through Association Class ActualAvailability	0..*
Attributes	**Type**	**Description**	
id	Identifier	One identifier that is used to uniquely identify the resource	
description	String	A phrase by which the object is described in a manner that is intended to be unambiguous in the given language	
unitMeasure	Unit	Unit of Measure for the utilization of the resource	
unitCost	Double	Unit cost of the resource	

7.5.3.9 Association Class: Resource association

Class identifier: ResourceAssociation			
Description	Resources can be grouped to describe possible aggregations of types of drugs, locations, types of materials, etc.		
Associated classes		**Type of association**	**Multiplicity**
Resource First resource in relationship		Binary association	0..*
Resource Other resource in relationship		Binary association	0..*
Attributes	**Type**	**Description**	
role	String	Specification of the type of relationship between the resources.	
startTime	DateTime	Date and time when the relationship starts according to the specified “Role”	
endTime	DateTime	Date and time when the relationship terminates according to the specified “Role”	
reason	String	Reason for the starting of the relationship	

7.5.3.10 Class: Staff member

Class identifier: StaffMember			
Description	Individual employed or working for the healthcare organization		
Associated classes		**Type of association**	**Multiplicity**
Resource (*supertype*)		Generalization	
Person (supertype)		Generalization	
Attributes	**Type**	**Description**	
qualification	String	Qualification of the staff member	
name	SET<String>	A name or names by which the individual staff member is, or has been, known	

7.5.3.11 Class: Medicinal product

Class identifier: MedicinalProduct			
Description	Any substance or combination of substances that can be administered to human beings for treating or preventing disease, with the view to making a medical diagnosis or to restore, correct, or modify physiological functions (CONTSYS)		
Related terms	Individual medicinal product (as previously defined in ISO 12967-2:2009		
Associated classes		**Type of association**	**Multiplicity**
Resource (*supertype*)		Generalization	
Attributes	**Type**	**Description**	
(Inherits the attributes of the Resource class)			

7.5.3.12 Class: Location

Class identifier: Location			
Description	Information about actual locations available in the organization		
Related terms			
Associated classes		**Type of association**	**Multiplicity**
Resource (*supertype*)		Generalization	
Attributes	**Type**	**Description**	
(Inherits the attributes of the Resource class)			

7.5.3.13 Class: Device

Class identifier: Device			
Description	Information about a piece of equipment or a device		
Related terms	Medical device: any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of — diagnosis, prevention, monitoring, treatment or alleviation of disease, — diagnosis, monitoring, treatment, alleviation of or compensation for an injury, — investigation, replacement, modification, or support of the anatomy or of a physiological process, — supporting or sustaining life, — control of conception, — disinfection of medical devices, — providing information for medical purposes by means of in vitro examination of specimens derived from the human body, and which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means (CONTSYS) Note to entry: This definition has been developed by the Global Harmonization Task Force (GHTF).		
Associated classes		**Type of association**	**Multiplicity**
Resource (*supertype*)		Generalization	
Attributes	**Type**	**Description**	
(Inherits the attributes of the Resource class)			

7.5.3.14 Class: Material

Class identifier: Material			
Description	Information about other materials and services used (e.g. consumables, assets, etc.)		
Associated classes		**Type of association**	**Multiplicity**
Resource (*supertype*)		Generalization	
Attributes	**Type**	**Description**	
(Inherits the attributes of the Resource class)			

7.5.3.15 Association Class: Actual availability of resources

Class identifier: ActualAvailability			
Description	Association Class describing the availability of each individual Resource with respect to each Healthcare Actor of the organization		
Related terms	Association Class describing the availability of each individual Resource with respect to each Agent of the organization (as previously defined in ISO 12967-2:2009)		
Associated classes		**Type of association**	**Multiplicity**
Agent		Binary association	1
Resource		Binary association	1
Attributes	**Type**	**Description**	
startDate	DateTime	Starting date and time of availability of the resource	
endDate	DateTime	Ending date and time of availability of the resource	
quantity	Double	Actual quantity of availability	
unitMeasure	Unit	Unit of measure of the available quantity	

7.5.3.16 Association Class: Standard availability of types of resources

Class identifier: StandardAvailability			
Description	Association Class relating Agents and Types Of Resources, to define the standard availability of the latter for each healthcare actor of the organization		
Related terms	Association Class relating Agents and Types Of Resources, to define the standard availability of the latter for each agent of the organization (as previously defined in ISO 12967-2:2009)		
Associated classes		**Type of association**	**Multiplicity**
Agent		Binary association	1
TypeOfResource		Binary association	1
Attributes	**Type**	**Description**	
minQuantity	Double	Minimum quantity of that type of resource to be available to the healthcare actor	
maxQuantity	Double	Maximum quantity of that type of resource to be available to the healthcare actor	
unitMeasure	Unit	Unit of measure for the specified quantities	
rule	String	Constraints and other rules according to which the resource is available to the healthcare actor	

7.5.3.17 Class: Active ingredient

Class identifier: ActiveIngredient			
Description	The pharmacologically active parts of medicinal products		
Associated classes		**Type of association**	**Multiplicity**
Medicinal Product Medicinal Product(s) containing the Active Ingredient		Binary association Through association class “Composition”	0..*
Attributes	**Type**	**Description**	
id	Identifier	One or more identifiers that are used to uniquely identify the Active ingredient	
description	String	A phrase by which the object is described in a manner that is intended to be unambiguous in the given language	

7.5.3.18 Association Class: Composition

Class identifier: Composition			
Description	Active Ingredients contained in one Medicinal Product		
Associated classes		**Type of association**	**Multiplicity**
Medicinal Product		Binary association	1
Active Ingredient		Binary association	1
Attributes	**Type**	**Description**	
quantity	Double	Quantity of active ingredient present in the medicinal product	
unitMeasure	Unit	Unit of measure of the specified quantity	

7.6 User and authorization objects

7.6.1 Aim

This package groups the information services that support the rest of the healthcare information system in the management of the following:

— authorization rules that govern the access control within the healthcare information system;

— organizational structure of the enterprise;

— user management;

— package identifier (for any coded reference to this group of objects): um

7.6.2 UML information model

All non-coloured classes belonging to the user and authorization cluster of objects in Figure 10 are specified in 7.6.3. The person class is specified in 7.2.3.3, while the contact and the agent’s role in the contact are specified in 7.2.3.5 and 7.2.3.6. The classes type of activity, activity, agenda, and role of agent in activity are specified in 7.3.3.1, 7.3.3.2, 7.3.3.12 and 7.3.3.11, respectively. The clinical information class and the role of the agent in the life cycle of the clinical information class are specified in 7.4.3.1 and 7.4.3.8. The HISA class and HISA class attributes are specified in 6.3.