Graphical OODB modeling for medical information standards (GOMMIS)

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ABSTRACT

Graphical OODB Modeling for Medical Information Standards
(GOMMIS)

by
Nagesh K. Puppala

Our task is to create a graphical representation of the European Prestandard for Medical Informatics on Message Exchange of Laboratory Information. This document, made available to us through Columbia Presbyterian, describes a standardized format for messages to be exchanged between a healthcare provider and a medical laboratory. The prestandard represents important information in a very disconnected way.

We have used OODINI system and language to develop our GOMMIS system. OODINI is a graphical editor for object-oriented database schemas that was developed at NJIT during the past three years. OODINI features a powerful set of icons that cover most concepts of existing Object-Oriented Database(OODB) systems. Our GOMMIS system creates one single unified graphical representation that shows the connections between all the classes and also the connections between classes and attributes. The electronic representation gives us the power and flexibility to manipulate the class information at will. Our project achieved its main purpose of demonstrating that graphical OODB display of medical informatics improves dramatically the possibilities to comprehend a complex application.
GRAPHICAL OODB MODELING FOR MEDICAL INFORMATION STANDARDS (GOMMIS)

by
Nagesh K. Puppala

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This work is dedicated to my parents and to my brother Goutham
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CHAPTER 1

INTRODUCTION

1.1 Motivation

The increased use of data processing and telecommunication capabilities has made possible the interchange of information in machine readable and machine processable formats. As automated interchange of information in healthcare increases, it is essential to provide appropriate information interchange standards.

Computer systems are in use for the storage and processing of information in many clinical laboratories. Similarly many of the requesters of investigations or recipients of reports use other computer systems to store and process information. This information includes details of investigations requested and results received. Electronic transfer of requests and results reduces the need for manual data entry and the risk of transcription errors. It also improves efficiency. Standards are required to facilitate electronic transfer of requests for and results of investigations between the many systems currently used.

In the global effort to standardize communication of medical informatics, the European Committee for Standardization (CEN) came up with standards known as European Prestandard for Medical Informatics on Message Exchange of Laboratory Information. This is a document, made available to us through Columbia Presbyterian hospital, that describes a standardized format for messages to be exchanged between a healthcare provider and a medical laboratory. The Prestandard represents important information in a very disconnected way. The reader has to leaf back and forth for definitions of attributes, classes, and relationships just for answering a simple question.

Keeping all these difficulties in mind, we have developed a single, unified graphical representation of European Prestandard that shows the connection between all the classes
and also the connection between classes and attributes. The electronic representation gives
us the power and flexibility to manipulate the class information at will.

1.2 General Approach

The basis for our work is a document provided to us by Columbia Presbyterian hospital,
known as the European Prestandard. We have created a graphical representation of the
Domain Information Model and different subject models. The graphical schema
representation has gone through several stages of modification as a result of frequent
meetings. We have redefined many relationships to make it more understandable. This
schema has proven to be more expressive and easily learnable than the original document
of the Prestandard.

The rest of this thesis is organized as follows. The European Prestandard is
discussed in Chapter 2. OODINI, the design tool for our schema, has been discussed in
Chapter 3. Chapter 4 describes the GOMMIS system which is the graphical representation
of the European Prestandard, and the results are summarized in the Conclusion section.
CHAPTER 2

THE EUROPEAN PRESTANDARD

2.1 Purpose

This European Prestandard has been prepared under the direction of the European Committee for Standardization (CEN). This Prestandard describes general messages to be used for electronic information interchange between computer systems in clinical laboratories and computer systems used by healthcare parties requesting the services of, or receiving results from, clinical laboratories. The method by which this European Prestandard has been developed is based on the recommendations of the report "Syntax for Information Interchange in Healthcare".

This standard is intended for implementation by message developers. Its provisions are directly relevant to suppliers of computer systems for use in clinical laboratories, hospitals, general practices, clinical departments and specialist clinics. Its provisions are also relevant to those planning, specifying, procuring or implementing information systems for use in clinical laboratories, hospitals, general practices, clinical departments and specialist clinics.

2.2 Implementation of the European Prestandard

The Implementation of European Prestandard yields the following results:

a) It facilitates the electronic transfer of orders for investigation by requesting healthcare parties, to clinical laboratories;

b) It facilitates the electronic transfer of reports from clinical laboratories to requesters and other healthcare parties;

c) It reduces the need for human intervention in information interchange between systems used by clinical laboratories and those used by other healthcare parties;
d) It decreases the time required for the introduction of, or remove the need for, information interchange agreements;

e) It reduces the development effort required by suppliers to allow communication between wide range of applications in this field;

f) It results in foregoing reductions in the cost of information interchange between clinical laboratories and parties requesting clinical laboratory services, thus lowering the costs of such laboratory tests.

2.3 Description

The European Prestandard consists of three major parts. First, there is a list of definitions and explanations of medical terms, elaborated by examples. It is followed by formal specifications which define the communicating systems that shall comply to the specifications of this European Prestandard when exchanging clinical laboratory information. This scenario of specifications establishes the relationships between the communication systems and the General Message Descriptions, as well as the relationship among the different General Message Descriptions.

The second part contains a description of the Domain Information Models involved in the medical messages. These messages are defined by a set of classes representing medical terms, and their interconnections, using a common formalism, due to Coad and Yourdan, for object-oriented analysis. The domain information model is represented by four diagrams

- the laboratory service order and report model
- sample subject model,
- subject of investigation subject model,
- healthcare party subject model.

The third part contains a large set of tables that describe the applicability of attributes to the classes mentioned in the first part. Every attribute is assigned a code as
Mandatory, Optional, or Not Applicable relative to six main types of messages that laboratories are bound to send or receive.

### 2.4 Drawbacks of European Prestandard

The Prestandard represents important information in a very disconnected way. The global representation of Domain Information Model does not show attributes and does not provide the clear picture of relationship between the classes. The reader has to leaf back and forth through definitions, subject models and textual description just for answering a simple question.

Though the European Prestandard proposes good Information Interchange standards, it is still lacking electronic representation of the information, it provides. This was the main reason for us to create a single unified graphical representation of the Prestandard which gives more flexibility and power to its user.

Domain Information Model of European Prestandard are added as Appendix B. Excerpts from CEN document are added as Appendix C for better understanding of the differences between European Prestandard and GOMMIS system.
CHAPTER 3

OODINI

3.1 What is OOdini

OODini (Object-Oriented diagrams, New Jersey Institute of Technology) is a graphical editor for object-oriented schema's that was developed at NJIT during past three years. OOdini features a powerful set of icons that cover most of the concepts of existing Object-Oriented Database (OODB) systems. It allows the user to interactively manipulate the graphical schema representation for OODBs. The system is implemented on a SUN 4/20 workstation. Graphical and interface support are being provided by X, the X toolkit (Xt), and the Motif widget set.

3.2 OOdini as a Design Tool

OODini is a constraint-based graphical editor designed specifically for schema representation. A relationship is constrained to contact a class at both ends. So, during input, OOdini requires the user to fasten each end of a relationship to some class. Moreover, if at later time one of these classes moves, the relationship is automatically moved relative to it. In this way, OOdini guarantees that the integrity of the schema diagram is always maintained, and it relieves the user from a lot of tedious manipulation.

OODini relies heavily on the mouse for interaction with the user. The keyboard is required occasionally in response to a dialog box to input textual data, such as the name of a class. The system also provides facilities for modifying the schema. Such features include interactive movement of schema objects using the mouse as well as interactive deletion.

OODini manages a large drawing canvas, allowing the designer to create very large schemata. This is a very important characteristic of the system since OODBs like GOMMIS typically comprise many hundreds of classes. A tool which provides but a single
"sheet" becomes totally worthless for such applications. Scroll bars are provided to allow the user to reposition the current working window of the canvas. While it is possible to quickly navigate to and view any portion of the canvas, the current working area presents only a small fraction of the entire schema. To give the possibility of viewing the schema "globally" it provides a "roadmap" mechanism. The roadmap serves the following two purposes:

- It provides a global schema view, that is, a reduced view of the schema showing all its elements at one time.
- It provides a means for repositioning the current working area of the canvas. The repositioning is accomplished by moving a "focus rectangle" (i.e., a rectangle representing the current working window) with the mouse.

To fit smoothly into the Motif working environment, the main system screen is laid out with the preferred menu bar and work area arrangement. At the uppermost portion of the main window is the menu bar which contains the normal array of entries, "File", "Edit", "View", "Options". Of note among these is the "print" option in "File" drop down menu, which prints the entire current screen to disk in a Postscript (PS) format and "level" option in "View" drop down menu. OOdini gives an option to view the schema in three levels of detail. For example, by setting the view level to two, attributes are no longer seen and we cannot manipulate them. By setting the view level to three, one can see only generic relationships as inheritance and "set of" among the classes. Relationships and attributes are hidden in this level. OOdini thus serves as a schema browser or OODB orientation device. The Edit menu provides the search feature for tracking down a desired class. This function positions the system's current working window around a given class.

Also included, as part of the OOdini system, is a means for converting the graphical schema into an abstract textual language called OODAL. Once in OODAL, the schema can be readily converted into some existing OODB language.
3.3 How to Read the Schema's

Class and Set Class

- Class is represented as rectangle with its name inside.
- Set Class is a class whose instances are sets of instances of another class and is represented by a rectangle with double-framed border. This rectangle has a joint corner with the singular class.

![Figure 3.1 Class and Set Class](image)

Attributes

An attribute is represented by an ellipse which is connected to a class rectangle via an unlabeled line. The attribute name resides inside the ellipse. An attribute is further classified as essential (i.e., must have a non-null value) when it is represented with circle inscribed in ellipse.

![Figure 3.2 Attributes](image)

User-Defined Relationship

This is represented by a labeled arrow from its class of definition to the target class. Different types of relationships considered are:

- Regular Relationship
- Essential relationship (i.e., non-null pointer) is represented by a circle on the line.
- Multivalued relationship refers to a set of instances.
- Multivalued Essential relationship

\[ \text{essential relationship} \]
\[ \text{essential multivalued relationship} \]
\[ \text{relationship} \]
\[ \text{multivalued relationship} \]

**Figure 3.3 User-defined Relationships**

**Generic Relationship**

Types of generic relationships considered are:

- **Sub-class of**: this enables the expression of specialization and the creation of class hierarchy. This is represented by heavy line directed from the specialized class (subclass) to more general class (superclass).

- **Role of**: this is used for specialization where the subclass is in a different context from that of the superclass. This is represented by heavy dot-dash line.

- **Part of**: this is used to connect a part of a complex or assembled object to its integral object. This is represented by thick, broken line directed from the part to the whole.

\[ \text{subclass} \]
\[ \text{role of} \]
\[ \text{part of} \]

**Figure 3.4 Generic Relationships**
3.4 Future Implementations

There is still ongoing research to enhance the OOdini system. There are plans to add many facilities to OOdini, which we felt are necessary during our design of the GOMMIS system. Some of the utilities under implementation are:

- Adding definitions for classes and attributes. One has to just click on the particular attribute or class to view its definition.

- Adding data types for attributes in the schema itself. Presently one has to make changes in VML code generated, to add data types for the attributes.
CHAPTER 4

GOMMIS

4.1 Introduction

Graphical OODB Modeling for Medical Information Standards (GOMMIS) system was designed based on the European Prestandard defined by CEN. The global schema specifies classes, set classes, attributes, user-defined relationships and generic relationships. This chapter consists of six parts:

- this introduction
- description of main schema.
- description of all the subschemas with brief description of one.
- textual description of objects, attributes and relationships

The subschema's and three levels of display for the main schema and are added as Appendix A.

4.2 Main Schema

The main schema shows the combination of

- Laboratory service order and report
- Sample
- Subject of Investigation
- Healthcare party

The meaning is exactly identical to the other representation, but the combination allows to better understand the relationships between the various classes.

The main schema of GOMMIS system is an enhancement to global schema of European Prestandard not only in its representation but also in its contents. The main schema shows all the classes and their attributes whereas global schema of European
Prestandard does not include Healthcare party in it. One has to consider healthcare party subject model in addition to global model to get complete Domain Information Model. The main schema also shows the attributes of all classes which are not represented in the global schema of the Prestandard.

4.3 Subschema's

We describe the first subschema in a very detailed way while the next subschemas are described only very shortly.

4.3.1 Laboratory Service Order and Report

This subschema highlights the information exchange between "Laboratory Service Requester" and "Laboratory Service Provider".

The "Laboratory Service Order" covers the specific cases like new laboratory service orders, laboratory service order modifications, and laboratory service order cancellations. Each instance of laboratory service order carries information common to a group of requested investigations, ordered, changed or canceled.

4.3.1.1 New Laboratory Service Order

*Purpose:*

A New Laboratory service order is issued by a requester so that a service provider might measure one or more quantities pertaining to one or more specified systems and report the findings to the recipient of the report. The subject of investigation can be a patient, an animal or a material. The New Laboratory Service Order is sent from a requester's computer to a Laboratory Service Provider's computer. The message conveys all the information needed by the laboratory to perform the requested investigations and issue a complete report.
The Laboratory Service Order message is triggered by the requesting computer when the requester gives instructions that an order is to be sent to the laboratory computer.

Examples of scenarios for valid message:

- **GP to hospital laboratory:** The requester in this scenario is the GP and the laboratory service provider is the hospital laboratory. The sample is collected by the GP and sent to the lab separately from the order. Sufficient information must be included with the sample to enable the lab to identify it as belonging to that order. In this case the GP could be the only recipient of the report.

- **Junior hospital doctor to hospital laboratory, phlebotomist collects sample:** The requester is the junior hospital doctor and the laboratory service provider is the hospital laboratory. The hospital consultant in charge of the patient is the supervising healthcare professional. If he is to receive his own copy of the report he will be identified as requiring this in the order. Otherwise the junior doctor will be the only report recipient. In this case the junior doctor is the copy destination and hospital consultant in-charge of the patient is the Intended recipient of the report. The sample is not sent at the same time as the order; instructions are included in the order as to what sample is required from this patient and details of when it should be collected, the location of the patient and specific instructions as to preservation, transport requirements, handling etc. The laboratory will then arrange for the sample to be collected.

- **Clinician requesting glucose tolerance test from hospital laboratory, phlebotomist collects samples:** The clinician would issue one order and the laboratory would organize the pre treatment (glucose loading) and the collection of the samples at the prescribed intervals. The number of samples and the collection intervals may be pre-agreed between the clinician and the laboratory or specified in the order.
**Detailed content of message:**

The order is issued to the laboratory by a requester. The requester is a healthcare party which in turn can be a healthcare professional or a healthcare organization.

The order is received by a laboratory service provider. This is a person or organization qualified to perform the required measurements and issue a report.

Each message will consist of information on one or more patient/animal/materials, single or multiple samples, single or multiple investigations per sample. Multi-disciplinary orders, e.g. one order covering chemistry, hematology and microbiology, are included.

The message also includes a facility to refer to a previous order which may be relevant to the current investigation.

Details of information included in the order are as follows:

**Subject of investigation:** This includes all the data necessary to identify the subject of investigation (whether patient, animal, or material). Demographic or equivalent information is included. If the system is a patient, the following data is also included:

- Patient location
- Details of any supervising healthcare party involved with the treatment of the patient
- Clinical information including
  a) Observations such as symptoms and signs, family history
  b) Treatment such as any drug therapy, diet or relevant operative procedures.

**Sample:** This includes data such as the nature of the sample, sample preservation and transport conditions, date and time of collection, collection procedure, precautions, hazards etc. The sample can either have been collected by the requester, or instructions can be included in the order as to what sample should be collected from where by the laboratory or its agents. In this case instructions can also be provided as to any necessary pre treatment.
Requested investigation(s): The requested investigation(s) are assumed to be from a list of available investigations. An investigation can be an individual investigation such as "sodium ion concentration" or a group or battery of investigations such as "full blood count". A battery would be expanded to its component investigations within the laboratory computer. For example, "full blood count" might be expanded to "red count, white count, differential white count, hemoglobin, mean cell volume..." etc.

The Requested Investigation is a part of exactly one Laboratory Service Order. To define the multiplicity in "part of " generic relationship, this relation is labeled with "m" in enclosed brackets.

Reporting details: The requestor may specify information as to when and to whom the report should be issued. This could include items such as:

- Whether the requestor requires a copy of the report
- Whether copies of the report are required by any other healthcare party and if so their identities and locations
- Date and time by which the report is required.

4.3.1.2 Laboratory Service Order Modification

Purpose:
The modification message contains information on the requestor, laboratory service provider and laboratory service order, together with the details of the additions, substitutions and deletions required. The details of these are as given in laboratory service order described above.

4.3.1.3 Laboratory Service Order Cancellation

Purpose:
A Laboratory service order cancellation is issued when an entire laboratory order is to be canceled by the requestor after the original order has been sent to the laboratory computer.
If for any person the laboratory computer is unable to cancel any part of the order, the cancellation is rejected and a report will be issued in the usual manner.

The laboratory service order message is triggered by the requesting computer when the requester decides to cancel an order that has been sent to the laboratory computer.

*Examples of scenarios for valid message:*

- *The patient has died:* There may then be no purpose in performing the investigation.
- *It becomes apparent that an order is unnecessary:* For example, the clinician discovers that the entire order has already been done at another location.

*Content of message:*

The cancellation message contains information on the order, laboratory service provider and laboratory service order as for the laboratory service order described above.

### 4.3.1.4 Laboratory Service Report

*Purpose:*

A laboratory service report message includes all relevant information sent by the laboratory to the requester in response to the order.

The laboratory service provider decides that there is result information which should be reported. This does not necessarily mean that the work is complete or that a complete report is available.

*Examples of scenarios for valid message:*

- *GP to hospital laboratory, hospital lab cannot perform all investigations and refers some to external laboratory:* In this case the hospital lab sends a sub-order and sample to the external lab. The external lab returns a report for these investigations. When the results were available to the hospital lab they would be combined with the results from the hospital and sent to the GP. Details of which investigations are done by which reference lab would be included in the report.
GP requests respiratory virology screen from hospital laboratory: In this case two orders would be issued at the GP's discretion: one for the acute and one for the convalescent sample. The first report would give the result of the acute sample. The second would require the laboratory to retest the original sample, and a reference to this must be included in the order. When the second report was issued it would include the result for convalescent sample and the retested acute sample, but not the original acute sample result.

Content of message:
The report contains information on results of single or multiple investigations for single or multiple patients/systems. Reports may be complete or incomplete in the sense that an appropriate report may be updated at a later stage as further information becomes available.

Copy report messages are sent to recipients as specified in the laboratory service order. Cumulative reports, i.e. those containing result information from previous orders which has not changed since it was reported, are not covered. No information as to the presentation of the report is included. Details of information included in the report are as follows:

Result Line: This includes all the information necessary to convey any type of specific non-investigation information of a report component. A Result Line is a part of exactly one Laboratory Service Report. Result line may consist of zero or many other result lines. This relation among Result Line's is specified with the setclass "Result Lines". The Result Line may be a member of zero or one "Result Lines".

Related laboratory service provider: Information from related laboratory service providers, e.g. reference laboratories, is included in the report. A Related laboratory service provider is associated with one or many result lines.
4.3.2 Sample

Purpose:
Laboratory service requester collects the sample or sample is collected by laboratory service provider. Any instance of sample is thus either a "Sample to be Collected" or "Collected Sample". "Sample to be Collected" and "Collected Sample" are specialization of "Sample" in same context and thus defined as the "subclass of" "Sample". "Collected Sample" may be a member of zero or many other collected samples. This relationship between "Collected Sample" and "Collected Samples" is "member of". The system from which sample is taken may be a "Subject of Investigation" or may itself be a sample. Thus "sample" is a part of "Subject of Investigation". "Sample Collector" is a healthcare party and thus defined as role of "Healthcare Party" and "Person".

Examples of scenarios:

- In microbiology, when a culture of an initial sample leads to a bacteria, which in turn becomes the sample for a series of sensitivity measurements. In that case, it is sufficient to express the relationship between the blood sample and the subject of investigation, and between the bacteria sample and the blood sample.

- In microbiology, a laboratory service requester may ask sensitivity tests only on a bacteria already obtained. In that case, it may be required to send the additional initial sample information, from which the bacteria was derived also. In this case no investigation is requested for the initial sample.

4.3.3 Subject of Investigation

Purpose:
This subschema highlights the subject of investigation and its relationship to other classes. A "Subject of Investigation" can be a patient, an animal, or material. Thus "Patient", "Animal" and "Material" are defined as "subclass of" "Subject of Investigation". A subject of investigation may be associated with zero or many other subject's of investigation. We
have defined this relationship with set class "Subjects of Investigation". A subject of investigation is a whole of which zero or many samples are collected. Thus sample is a "part of" subject of investigation.

A subject of investigation may be specified by zero or many "Item of clinical information". "Item of clinical information" is generalization of any kind of clinical information relating to a subject of investigation. It carries all the common information related to the different specialization's of the object. Item of clinical information is always specialized into either a "Clinical Observation" or "Treatment Information".

A subject of investigation may be supervised by zero or many "Supervising Healthcare Party". A subject of investigation may be specified by zero or one instances of "Healthcare Administrative Information" objects.

We have also defined a class person which becomes superclass for any class related to person. For example healthcare professional, patient are all "role of" class person.

4.3.4 Healthcare Party

Purpose:

This subschema highlights relationship among different healthcare parties and with other classes. "Laboratory Service Requester", "Laboratory Service Provider", "Healthcare Professional", "Sample Collector", "Related Laboratory Service Provider", "Item of Clinical Information", "Supervising Healthcare Party", "Copy Destination", "Intended Recipient of Copy", "Healthcare Organization" and "Origin of Medical Information" are all specialization of "Healthcare Party" in different contexts and thus defined as "subclass of" "Healthcare Party". "Sample Collector", and "Healthcare Professional", are also the "role of" "Person". "Healthcare Professional" is also defined as "part of" "Healthcare Organization". "Healthcare Organizations" may consist of zero or many healthcare organizations. This relationship is defined by defining the setclass "Healthcare Organizations" which implies that healthcare organization may be a member of zero or
many other healthcare organizations. A healthcare party may be associated with zero or many sample collection locations.

4.4 Textual description of Objects, Relationships and Attributes

This description has to be considered as complement to the schema drawings. The explanation provides the purpose of an object, its relationships to other objects and the attributes for each class.

Animal:

*Object:* the purpose of this object is to allow the specification of the characteristics required when the subject of investigation is an animal.

*Attributes:*
  - name:
  - species:
  - breed:
  - sex:
  - birth date: date and time of birth.
  - death date: date and time of death.

*Relationships:* meaning:
  - with subject of investigation: an animal is a specialization of a subject of investigation.

Clinical Observation:

*Object:* this object carries the information that is common to any type of clinical observation.

*Attributes:*
  - type: type of clinical observation.
  - description: clinical observation description.
  - degree of certainty: degree of certainty of clinical observation.
**Relationships:** meaning:

- with item of clinical observation: a clinical observation is a specialization of an item of clinical observation.
- with measurable quantity: a clinical observation may be specialize into a measurable quantity.

**Collected Sample:**

**Object:** the purpose of this object is to specify the characteristics applying to samples for which no sample collection service is requested from the laboratory service provider (e.g. sample is already collected, sample collector is not the laboratory service provider).

**Attributes:**

- date & time: date and time of sample collection.
- start date & time: start date and time of sample collection.
- end date & time: end date and time of sample collection.
- amount: amount of collected sample.
- unit of amount:
- duration: duration of sample collection.
- unit of duration:
- logistics: transport logistics of collected sample.
- receipt date & time: date and time of receipt of collected sample.
- sampling handling warning: sampling handling warning.
- sampling performed indicator: sampling performed indicator.
- collector's comments: collector's comments.

**Relationships:** meaning:

- with collected sample: a collected sample may be a member of zero or one other collected samples; a collected sample may contain (be the basis for) zero or many other collected samples.
- with sample: a collected sample is a specialization of a sample.
Copy Destination:

Object: this object supports the specification of the healthcare party which receives a copy of the subject of information exchange (either a laboratory service order or laboratory service report). The object is specified in more detail by the healthcare party subschema.

Attributes:
- Inherits the attributes of "Healthcare Party".

Relationships: meaning:
- with laboratory service order: a copy destination may be the copy destination for zero or many laboratory service orders.
- with laboratory service report: a copy destination may be the copy destination for zero or many laboratory service reports.
- with healthcare party: a copy destination is a specialization of a healthcare party.

Drug:

Object: this object carries the information that is required to express drug treatments.

Attributes:
- dosage & specification: information which, together with the drug description, provides a full specification of the subject's treatment with the drug.

Relationships: meaning:
- with treatment information: a drug (treatment) is a specialization of treatment information.

Healthcare Administrative Information:

Object: this object allows to specify the administrative information related to the subject of investigation.

Attributes:
- admission date: date and time that responsibility for the subject's care passed to/is to pass to a secondary healthcare organization.
• discharge date: date and time the subject is discharged from inpatient care at a secondary care institution and responsibility for care passes to a primary healthcare provider.

Relationships: meaning:
• with subject of investigation: healthcare administrative information may specify one or many subjects of investigations.
• with healthcare organization: healthcare administrative information may optionally be associated with a single healthcare organization.

Healthcare Organization:

Object: this object represents any kind of healthcare organization.

Attributes:
• type: type of healthcare organization.
• name: name of healthcare organization.

Relationships: meaning:
• with healthcare party: a healthcare organization is a specialization of a healthcare party.
• with healthcare professional: a healthcare may consist of zero or many healthcare professionals.
• with healthcare administrative information: a healthcare organization may be associated with zero or many instances of healthcare administrative information.
• with healthcare organizations: a healthcare organization may be a member of zero or many healthcare organizations or it may consist of zero or many other healthcare organizations.

Healthcare Party:

Object: this object is the generalization of any type of healthcare party. As such, it contains the common information to any type of healthcare party.
Attributes:

- partner agreed id: identification of a healthcare party agreed upon between communication partners.
- registration id: unique and official identification of a healthcare party, in general issued by an authorized organization such as a governmental or international body.
- id by requester: identification of a healthcare party given by a (laboratory) service requester.
- id by provider: identification of a healthcare party given by a (laboratory) service provider.

Relationships: meaning:

- specialization: a healthcare professional, a laboratory service provider, a laboratory service requester, a sample collector, a related laboratory service provider is a role of healthcare party.
- specialization: a copy destination, an intended recipient of report copy, a supervising healthcare party, origin of clinical information is subclass of healthcare party.
- with sample collection location: a healthcare party may be associated with zero or many sample collection locations.

Healthcare Professional:

Object: this object represents an individual healthcare professional as a specialization of healthcare party.

Attributes:

- type: type of healthcare professional.
- medical specialty: particular subject area or branch of medical science, as practiced by a healthcare professional.
- position: position of healthcare professional.
- qualification: qualification of healthcare professional.
- military rank: military rank of healthcare professional.

*Relationships*: meaning:
- with healthcare party: a healthcare professional is a role of healthcare party.
- with healthcare organization: a healthcare professional may optionally be a member of zero or many healthcare organizations.
- with person: a healthcare professional is role of a person.

**Intended Recipient of Report Copy:**

*Object*: this object supports the specification of healthcare parties which should receive a copy of laboratory service report(s) resulting from a laboratory service order. The object is specified in more detail by healthcare party subschema.

*Attributes*:
- Inherits the attributes of "Healthcare Party".

*Relationships*: meaning:
- with laboratory service order: an intended recipient of a report copy may be mentioned by one or more laboratory service orders.
- with healthcare party: an intended recipient of report copy is a specialization of a healthcare party.

**Investigation:**

*Object*: the purpose of this object is to carry information that is the common universe of discourse between a laboratory service requester and reporter. It is to be considered as one component of the central specification or catalogue of investigations that can be ordered or reported upon.

*Attributes*:
- compound: chemical compound.
- principle of measurement: scientific basis of a measurement.
- method of measurement: logical sequence of operations, described generically, used in the performance of measurements.
• measurement procedure: set of operations, described specifically, used in the performance of particular measurements according to a given method of measurement.

Relationships: meaning:

• with requested investigation: an investigation may be requested through zero or many requested investigations.

• with result line: an investigation may be reported upon through zero or many result lines.

Item of Clinical Information:

Object: this object is a generalization of any kind of clinical information relating to subject of investigation. As such, its purpose is to carry all common information related to the different specialization's of the object.

Attributes:

• date & time: date and (if appropriate) time of the occurrence of a clinically relevant event.

• start date & time: the beginning of a period of applicability of an item of clinical information.

• end date & time: the end of a period of applicability of an item of clinical information.

Relationships: meaning:

• with subject of investigation: item of clinical information is related to exactly one subject of investigation.

• with origin of clinical information: item of clinical information may optionally be associated with a single origin of clinical information.

• specialization: item of clinical information is always specialized into either a clinical observation or treatment information.
Laboratory Service Order:

Object: the purpose of this object is the representation of a single laboratory service order, as it can requested by laboratory service requester. The object covers also the specific cases of laboratory service orders (new laboratory service orders, laboratory service order modifications, laboratory service order cancellations). Each instance of laboratory service order carries the information common to a group of requested investigations, ordered, changed or canceled at the same moment.

Attributes:

- id by requester: code-value assigned by a (laboratory) service requester to a (laboratory) service order for its identification.
- id by provider: code-value assigned by a (laboratory) service provider to a (laboratory) service order for its identification within the laboratory.
- order issue date: date and time at which a (laboratory) service order is completed within the requesting system.
- due date of report: due date and time of laboratory service report.
- receipt date: date and time at which a (laboratory) service order is received by a laboratory.
- service type: service type of (laboratory) service order.
- reporting priority: priority of the reporting of the investigation results, indicated by a requester.
- commenting level: level of detail that the requester wishes to receive in the laboratory service provider's comments upon the (laboratory) service report.
- request reason: clinical information indicating the rational for ordering given investigation(s).
- receipt acknowledgment: indication of whether or not the issuer of a message requests acknowledgment of the message receipt by the recipient.
• payment category:
• no of sample containers: total number of sample containers related to a laboratory service order.
• order language: language of laboratory service order.
• reporting language: reporting language requested.

Relationships: meaning:
• with laboratory service requester: a laboratory service order is requested by a single laboratory service requester.
• with laboratory service provider: a laboratory service order is ordered to a single laboratory service provider.
• with copy destination: a laboratory service order may be copied to zero or many copy destinations.
• with intended recipient of report copy: a laboratory service order may specify zero or many destinations that should receive a copy of the corresponding laboratory service report(s).
• towards laboratory service reports: a laboratory service order may result in zero or many laboratory service reports.
• with subject of investigation: a laboratory service order may relate to one or many subjects of investigation.
• with requested investigation: a laboratory service order may contain one or many requested investigations.

Laboratory Service Provider:

Object: this object supports the specification of the healthcare party which is requested to perform a laboratory service order and which reports the results after investigation. The object is specified in more detail by healthcare party subschema.

Attributes:
• Inherits the attributes of "Healthcare Party".
Relationships: meaning:

- with laboratory service order: a laboratory service provider may be the laboratory service provider for one or many laboratory service orders.
- with laboratory service report: a laboratory service provider may have issued zero or many laboratory service reports.
- with healthcare party: a laboratory service provider is a role of healthcare party.

Laboratory Service Report:

Object: the purpose of this object is the representation of a single laboratory service report, as it is issued by a laboratory service provider. The object covers also the specific cases of laboratory service reports (e.g. result modification). Each instance of a laboratory service report carries the information common to a group of result lines reported at the same moment.

Attributes:

- report id by provider: code-value assigned by a (laboratory) service provider to a (laboratory) service report for its identification.
- issue date of report: issue date and time of laboratory service report.
- report status: status of (laboratory) service report.
- reporting priority: indication by the (laboratory) service provider of the report priority.
- report service type: service type of (laboratory) service report.
- provider’s comment: comment from the report that can not be expressed by any other existing attribute.
- report language:

Relationships: meaning:

- with laboratory service order: a laboratory service report may refer to zero or many laboratory service orders.
• with laboratory service requester: a laboratory service report is associated with a single laboratory service requester.
• with laboratory service provider: a laboratory service report is taken responsibility of by a single laboratory service provider.
• with copy destination: a laboratory service report may be copied to zero or many copy destinations.
• with subject of investigation: a laboratory service report may report on one or many subjects of investigation.
• with result line: a laboratory service report consists of one or many result lines.

Laboratory Service Requester:

Object: this object supports the specification of the healthcare party which is requesting a laboratory service provider to perform a laboratory service order and which receives back the laboratory service report after investigation. The object is specified in more detail by the healthcare party subschema.

Attributes:

• Inherits the attributes of "Healthcare Party".

Relationships: meaning:

• with laboratory service order: a laboratory service requester may be the requester for one or many laboratory service orders.
• with laboratory service report: a laboratory service requester may be the requester associated with zero or many laboratory service reports.
• with healthcare party: a laboratory service provider is a role of healthcare party.

Material:

Object: the purpose of this object is to allow the specification of the characteristics required when the subject of investigation is not a patient and not an animal.
Attributes:

- description: code or free text describing the kind of material and its immediate context.

Relationships: meaning:

- with subject of investigation: a material is specialization of subject of investigation.

Measurable Quantity:

Object: this object carries the information that is required to express a measurement as a clinical observation.

Attributes:

- Inherits the attributes of "Clinical observation" and "Item of Clinical Information".

Relationships: meaning:

- with clinical observation: a measurable quantity is a specialization of a clinical observation.

Origin of Clinical Information:

Object: the purpose of this object is the specification of the healthcare party which is the origin of the item of clinical information. The object is specified in more detail by the healthcare party subschema.

Attributes:

- date & time: date and time of clinical information.

Relationships: meaning:

- with item of clinical information: an origin of clinical information is the source of one or many items of clinical information.
- with healthcare party: an origin of clinical information is a specialization of a healthcare party.
Patient:

Object: the purpose of this object is to allow the specification of the characteristics required when the subject of investigation is a patient.

Attributes:

- partner agreed id: partner agreed patient identification.
- payment id: patient payment identification.
- official id: official patient identification.
- additional id: additional patient identification.
- birth date & time:
- death date & time:
- language: patient language.
- confidentiality: confidentiality constraints on patient data.

Relationships: meaning:

- with subject of investigation: a patient is a specialization of a subject of investigation.

Pre-treatment:

Object: this object represents the action(s) to be taken before collecting one or more samples.

Attributes:

- description: pre treatment description.
- substance: drug or other chemical compound administered as pre treatment.
- route of administration:
- amount: amount of substance administered.
- start time: administration start time.
- end time: administration end time.
- duration: duration of administration.
**Relationships**: meaning:

- with sample: a pre-treatment is (to be) performed in view of the collection of one or many samples.

**Related Laboratory Service Provider:**

*Object*: the purpose of this object is the specification of the healthcare parties which are associated with a given result line, but which are not the laboratory service provider of the laboratory service report as a whole. The object is specified in more detail by the healthcare party subschema.

*Attributes*:

- relationship type: role of a related (laboratory) service provider.

**Relationships**: meaning:

- with result line: a related laboratory service provider is associated with one or many result lines.
- with healthcare party: a related laboratory service provider is a specialization of a healthcare party.

**Requested Investigation:**

*Object*: this object establishes the association between "laboratory service orders" and "investigations". Its purpose is to specify the information that belongs to the association and to establish the associations between the investigation that is requested and the other objects that are needed to define a requested investigation fully.

*Attributes*:

- service type:
- performing priority: priority attached by the requester to the performing of an investigation specified within a (laboratory) service order.
- reporting priority: the priority which the requester wishes the (laboratory) service provider to attach to reporting of the results of the requested investigation.
• due date & time: date and time by which the requester wishes to receive the results of an investigation.

• issue date & time: date and time at which a requested investigation is registered upon the requesting system.

• no of times to perform: number of times to perform a requested investigation.

• commenting level:

• reason for request:

• requester's comments:

Relationships: meaning:

• with laboratory service order: a requested investigation is part of exactly one laboratory service order.

• with investigation: a requested investigation refers to exactly one investigation.

• with sample: a requested investigation is to be performed on zero or many samples.

• with subject of investigation: a requested investigation is to be performed on zero or one subject of investigation.

Result Line:

Object: the purpose of this object is to convey any type of non-investigation specific information of a report component.

Attributes:

• arithmetic comparator:

• numerical value: numerical value of measurement result.

• unit of numerical value: chosen reference quantity that may be used for comparison of quantities of the same kind.

• service type:

• abnormal indicator: abnormal result indicator.

• text value: text value of a result.
• comment: comment to result.
• approval date: date and time of result approval.
• investigation date: date and time of investigation performed.
• measuring system:

Relationships: meaning:
• with laboratory service report: a result line is part of exactly one laboratory service report.
• with subject of investigation: a result line is a result associated to zero or one subject of investigation.
• with sample: a result line is a result associated with zero or more samples.
• with investigation: a result line is the result for exactly one investigation.
• with related laboratory service provider: a result line is associated with maximum one related laboratory service provider.
• with result lines: a result line may consist of zero or many other result lines. A result line may be a member of zero or one "result lines".

Sample:
Object: this object represents the information that is required to specify fully the properties and instructions related to the object on which the investigations must be performed. The object is specified in more detail by the sample subschema.

Attribute:
• requester sample id: code-value assigned by a (laboratory) service requester to a sample for its identification.
• provider sample id: code-value assigned by a (laboratory) service provider to a sample for its identification.
• type: type of sample.
• anatomical origin: anatomical origin of sample.
• handling: handling of sample.
• preservation material: sample preservation material.
• no of containers: number of sample containers.

Relationships: meaning:
• with subject of investigation: a "sample" is a part of a single "subject of investigation", but it may also not be an immediate part of the subject of investigation.
• with requested investigation: on a "sample", there may be zero or many requested investigations to be performed.
• with result line: for a sample, there may be zero or many result lines associated with it.
• with sample collector: a sample may optionally be associated with maximum one sample collector.
• with pre-treatment: a sample may be specified by zero or many pre-treatment actions.
• specialization: a sample is always either a "sample to be collected", or a "collected sample".

Sample Collection Location:

Object: this object supports the specification of the location where the sample is (to be) collected.

Attributes:
• address:
• bed:
• room:
• ward:

Relationships: meaning:
• with sample: a sample collection location is the location where one or many samples are (to be) collected.
• with healthcare party: a sample collection may optionally be associated with a single healthcare party.

Sample Collector:

Object: this object supports the specification of the healthcare party which collected or is to collect the sample. The object is specified in more detail by the healthcare party subschema.

Attributes:

• person name:
• address:

Relationships: meaning:

• with sample: a sample collector is the healthcare party that collected or is to collect one or many samples.
• with healthcare party: a sample collector is a specialization of a healthcare party.

Sample to be Collected:

Object: the purpose of this object is to specify the characteristics applying only to samples for which the laboratory service provider has to organize the sample collection.

Attributes:

• sampling priority: priority, given by the requester, which the sample collector should attach to the task of collection of the sample.
• request date & time: request date and time of sample collection.
• request start date & time: request start date and time of sample collection.
• interval time: time between a first collection and a current collection.
• diff from start time: difference from start sampling time.
• request period: requested time during which sample collection should take place.

Relationships: meaning:

• with sample: a sample to be collected is a specialization of a sample.
Subject of Investigation:

Object: the purpose of this object is to specify the information needed to specify the subject of investigation (patient, animal, material) about which the execution of investigations will allow the collection of additional information.

Attributes:

- id by requester: code assigned by a (laboratory) service requester to a subject (patient, animal, material) for its identification.
- id by provider: code assigned by a (laboratory) service requester to a subject (patient, animal, material) for its identification.
- collection warning: information given to a collector about the subject of investigation that is relevant to a collection of a sample.
- association description: the relationship between associated subjects of investigation.
- communication:

Relationships: meaning:

- with laboratory service order: a subject of investigation may be associated with one or many laboratory service orders.
- with laboratory service report: a subject of investigation may be reported upon by zero or many laboratory service reports.
- with requested investigation: a subject of investigation may be the subject to perform zero or many requested investigations upon.
- with result line: a subject of investigation may be the subject reported upon (immediately) through zero or many result lines.
- with sample: a subject of investigation is the whole of which zero or many samples are collected.
- with supervising healthcare party: a subject of investigation may supervised by zero or many supervising healthcare parties.
• with healthcare administrative information: a subject of investigation may be specified by zero or one instances of healthcare administrative information objects.
• with item of clinical information: a subject of investigation may be specified by zero or many items of clinical information.
• with subjects of investigation: a subject of investigation may be associated with zero or many other subjects of investigation.
• specialization: a subject of investigation is either an animal, a patient, or a material.

**Supervising Healthcare Party:**

*Object:* This object represents the healthcare professional, sub-department or organization officially in-charge of the supervision of the healthcare of a patient.

*Attributes:*
  • Inherits the attributes of the "Healthcare party".

*Relationships: meaning:*
  • with subject of investigation: a supervising healthcare party may supervise one or many subject of investigation.
  • with healthcare party: this class is a specialization of a healthcare party.

**Treatment Information:**

*Object:* This object provides information about medical, or surgical actions performed on or planned to be performed on a subject of investigation for the purpose of preventing or combating disease.

*Attributes:*
  • type:
  • description:

*Relationships: meaning:*
  • with item of clinical information: Treatment Information is a specialization of "Item of clinical Information".
  • specialization: a treatment information may specialize into drug (treatment).
CHAPTER 5

CONCLUSIONS

In this project, we have achieved the main purpose of demonstrating that graphical OODB display of medical informatics improves dramatically the possibilities to comprehend a complex application. Utilizing the graphical representation we have obtained good comprehension of complex new material in a reasonably short time.

We obtained several benefits due to the graphical schema representation of the application. We identify cases where path-methods can be defined for a class and save the specification of the relationships which are redundant once path-methods are allowed. For example, there is a relationship existing from 'Laboratory service order' to 'Copy destination' and to 'Laboratory service report'. There is also a relationship existing from 'Copy destination' to 'Laboratory service report'. By implementing path-method, we can avoid the relation from 'Laboratory service order' to 'Laboratory service report'. Though path-method is discussed here, it has not yet been implemented in GOOMIS system. The Figure 5.1 shows an implementation of a path-method for the above example.

![Figure 5.1 Example for a Path-Method](image)

Also, the identification of several relationships as 'part of' shows the importance of part relationship in medical informatics.
In summary, we have created GOMMIS - an integrated graphical representation for better learning, communication, and manipulation of the medical information exchange Prestandard.
APPENDIX A1

This includes the subschemas for the GOMMIS system. The explanation for these subschemas is given in Chapter 4. This list of figure included is as follows:

Figure A.1 - Laboratory Service Order and Report
Figure A.2 - Sample
Figure A.3 - Subject of Investigation
Figure A4 - Healthcare Party
Figure A.1 Laboratory Service Order and Report
Figure A.3 Subject of Investigation
Figure A.4 Healthcare Party
Figure A.5 shows the Level 1 of main schema which is divided into 9 blocks. The layout of the blocks in the main schema is as shown below:

![Figure A.5 Main Schema-Level 1](image)
Figure A.5 Block 1
Figure A.5 Block 5
Figure A.5 Block 6
APPENDIX A3

This includes Level 2 and Level 3 of the main schema for the GOMMIS system. The list of figures includes is as follows:

Figure A.6 - Main Schema - Level 2
Figure A.7 - Main Schema - Level 3
Figure A.6 Main Schema-Level 2
Figure A.7 Main Schema-Level 3
APPENDIX B

This includes Domain Information Models for the subschemas in the Prestandard document. Figure B.5 is a global representation of Domain Information Model of the schema.
Figure B.1 Laboratory Service Order and Report
Figure B.2 Sample
Figure B.3 Subject of Investigation
Figure B.4 Healthcare Party
Figure B.5 Global representation of Domain Information Model
This includes excerpts from CEN document. This document shows how the Prestandard provides the definition for each class and its attributes. Since the Prestandard has 6 General Message Descriptions (GMD's), attributes are defined as Mandatory, Optional or Not-Applicable for each GMD. It also provides the Prestandard's way of defining the Relationships for each class.
7.8.4. Attribute layer table.

The column labels 1 to 6 identify the general message description, according to the following codes:

1. New laboratory service order
2. Laboratory service order modification
3. Laboratory service order cancellation
4. New laboratory service report
5. Laboratory service report modification
6. Laboratory service report cancellation

<table>
<thead>
<tr>
<th>Object attribute</th>
<th>Data Type</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>Additional specifications</th>
</tr>
</thead>
<tbody>
<tr>
<td>animal (1)</td>
<td></td>
<td>C:S</td>
<td>M</td>
<td>M</td>
<td>NA</td>
<td>M</td>
<td>M</td>
<td>NA (1) in case the exact date/time is unknown year only or year+month or year+month+day are also sufficient</td>
</tr>
<tr>
<td>species of animal</td>
<td></td>
<td>C:S</td>
<td>O</td>
<td>O</td>
<td>NA</td>
<td>O</td>
<td>O</td>
<td>NA</td>
</tr>
<tr>
<td>breed of animal</td>
<td></td>
<td>C:S</td>
<td>O</td>
<td>O</td>
<td>NA</td>
<td>O</td>
<td>O</td>
<td>NA</td>
</tr>
<tr>
<td>name of animal</td>
<td></td>
<td>S</td>
<td>O</td>
<td>O</td>
<td>NA</td>
<td>O</td>
<td>O</td>
<td>NA</td>
</tr>
<tr>
<td>sex</td>
<td></td>
<td>C</td>
<td>O</td>
<td>O</td>
<td>NA</td>
<td>O</td>
<td>O</td>
<td>NA</td>
</tr>
<tr>
<td>date and time of birth</td>
<td>TOCD (1)</td>
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<td>NA</td>
<td>O</td>
<td>O</td>
<td>NA</td>
<td></td>
</tr>
<tr>
<td>animal owner person name details</td>
<td>AG (1)</td>
<td>O</td>
<td>O</td>
<td>NA</td>
<td>O</td>
<td>O</td>
<td>NA (1) this attribute group is equal to the attribute group person name details</td>
<td></td>
</tr>
<tr>
<td>date and time of death</td>
<td>TOCD (1)</td>
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<td>O</td>
<td>NA</td>
<td>O</td>
<td>O</td>
<td>NA (1) in case the exact date/time is unknown year / year+month or year+month+day are also sufficient</td>
<td></td>
</tr>
<tr>
<td>clinical observation (17)</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
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<td>M</td>
<td>NA</td>
<td>M</td>
<td>M</td>
<td>NA</td>
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</tr>
<tr>
<td>clinical observation description</td>
<td>C:S</td>
<td>O</td>
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<tr>
<td>degree of certainty of clinical observation</td>
<td>C:S</td>
<td>O</td>
<td>O</td>
<td>NA</td>
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<td>O</td>
<td>NA</td>
<td></td>
</tr>
<tr>
<td>collected sample (3)</td>
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<td></td>
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<tr>
<td>date and time of sample collection</td>
<td>TOCD</td>
<td>O</td>
<td>O</td>
<td>NA</td>
<td>O</td>
<td>O</td>
<td>NA</td>
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<td>start date and time of sample collection</td>
<td>TOCD</td>
<td>O</td>
<td>O</td>
<td>NA</td>
<td>O</td>
<td>O</td>
<td>NA</td>
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<tr>
<td>end date and time of sample collection</td>
<td>TOCD (1)</td>
<td>O</td>
<td>O (1)</td>
<td>NA</td>
<td>O</td>
<td>O (1)</td>
<td>NA (1) must be present when start date and time of sample collection is present</td>
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<tr>
<td>amount of collected sample</td>
<td>R</td>
<td>O</td>
<td>O</td>
<td>NA</td>
<td>O</td>
<td>O</td>
<td>NA</td>
<td></td>
</tr>
<tr>
<td>unit of amount of collected sample</td>
<td>C</td>
<td>O</td>
<td>O (1)</td>
<td>NA</td>
<td>O</td>
<td>O (1)</td>
<td>NA (1) must be present when amount of collected sample is present</td>
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</tr>
<tr>
<td>duration of sample collection</td>
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<td>NA</td>
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3. DEFINITIONS

(to be reviewed, completed and revised)

REMARK. The definitions, notes and examples given in this list refer to the use of concepts and terms in other parts of the PT008 document (Domain Information Model, General Message Descriptions...). It was not the intention to establish an exhaustive list with all the terms used in the PT008 document. The list has been kept as short as possible and contains only terms for which clarification was needed; nevertheless, the list is still incomplete. The presentation sequence follows the alphabetical order of the objects from the Domain Information Model. The number following each object corresponds with the number, identifying the object in the attributes layer for each object, the attributes are listed in the same sequence as in the Domain Information Model tables.

The symbols used in this part are:
- D = Definition
- E = Example(s)
- N = Note(s)
- I = Internal note(s) (intra-PT, interim)

The format of the present version is not final. The final lay-out will be in accordance with PNE, annex G1 (i.e., for items going into a normative references clause). Names of objects and groupings, which have been listed for clarifying the relationship with attributes, but for which no definitions etc. were given, have been put between ( ). Simple brackets ( ) have been used when parts of names are optional, which is in accordance with the PNE rules.

ANIMAL (1)

D : veterinary investigative services are included within the scope, so animals as well as patients may be subjects of investigation

N : species of animal
- E : dog, mouse, rabbit, rat

N : breed of animal
- D : subspecies or special breed of animal
- N : this may influence e.g. reference intervals

CLINICAL OBSERVATION (17)

D : item of clinical information excluding information about performed or intended treatment of the patient

N : clinical information that does not record on intervention is by nature a clinical observation. The observer may be the patient or related person (information about symptoms, family history, occupation or life style), or a healthcare professional (information about : physical signs, measurements or diagnose)

While information about the nature of a planned or performed treatment is excluded by the definition but clinical observations may be recorded as the results of a treatment or during the course of a treatment
- **Sample.**

  - **Object:** The sample object represents the information that is required to specify fully the properties and instructions related to the object on which the investigations must be performed. The object is specified in more detail by the sample subject model.

  - **Relationships:** meaning:
    
    - with subject of investigation: a "sample" is a part of a single "subject of investigation", but it may also not be part immediately of the "subject of investigation" (see questions).
    
    - with requested investigation: on a "sample", there may be zero or many requested investigations to be performed.
    
    - with result line: for a sample, there may be zero or many result lines associated with it.
    
    - with sample collector: a "sample" may optionally be associated with maximum one "sample collector".
    
    - with sample collection location: a sample may optionally be associated with maximum one sample collection location.
    
    - with pre-treatment: a sample may be specified by zero or many "pre-treatment" actions.
    
    - specialisation: a sample is always either a "sample to be collected", or a "collected sample".

- **Sample collector.**

  - **Object:** this object supports the specification of the healthcare party which collected or is to collect the sample. The object is specified in more detail by the healthcare party subject model.

  - **Relationships:** meaning:
    
    - with sample: a sample collector is the healthcare party that collected or is to collect one or many samples.
    
    - with healthcare party: a sample collector is a specialisation of a healthcare party.

- **Sample to be collected.**

  - **Object:** the purpose of the object is to specify the characteristics applying only to samples for which the laboratory service provider has to organise the sample collection.

  - **Relationships:** meaning:
    
    - with sample: a sample to be collected is a specialisation of a sample.
REFERENCES
