

Medical informatics — Request and report messages for diagnostic service departments

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National foreword

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It is being issued in the Draft for Development series of publications and is of a provisional nature due to the limited duration of the European prestandard. It should be applied on this provisional basis, so that information and experience of its practical application may be obtained.

Comments arising from the use of this Draft for Development are requested so that UK experience can be reported to the European organization responsible for its conversion into a European Standard. A review of this publication will be initiated 2 years after its publication by the European organization so that a decision can be taken on its status at the end of its three-year life. The commencement of the review period will be notified by an announcement in *Update Standards*.

According to the replies received by the end of the review period, the responsible BSI Committee will decide whether to support the conversion into a European Standard, to extend the life of the prestandard or to withdraw it. Comments should be sent in writing to the Secretary of BSI Technical Committee IST/35, Medical informatics, at 389 Chiswick High Road, London W4 4AL, giving the document reference and clause number and proposing, where possible, an appropriate revision of the text.

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

Cross-references

The British Standards which implement international or European publications referred to in this document may be found in the BSI Standards Catalogue under the section entitled “International Standards Correspondence Index”, or by using the “Find” facility of the BSI Standards Electronic Catalogue.

Summary of pages

This document comprises a front cover, an inside front cover, pages i and ii, the ENV title page, pages 2 to 177 and a back cover.

This standard has been updated (see copyright date) and may have had amendments incorporated. This will be indicated in the amendment table on the inside front cover.

Amendments issued since publication

Amd. No.	Date	Comments

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Informatique de santé — Messages de
demandes et de comptes rendus de service de
diagnostic

Medizinische Informatik — Anforderungen —
und Ergebnismitteilungen für diagnostische
Dienstleistungsstellen

This European Prestandard (ENV) was approved by CEN on 1997-02-09 as a prospective standard for provisional application. The period of validity of this ENV is limited initially to three years. After two years the members of CEN will be requested to submit their comments, particularly on the question whether the ENV can be converted into an European Standard (EN).

CEN members are required to announce the existence of this ENV in the same way as for an EN and to make the ENV available promptly at national level in an appropriate form. It is permissible to keep conflicting national standards in force (in parallel to the ENV) until the final decision about the possible conversion of the ENV into an EN is reached.

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CEN

European Committee for Standardization
Comité Européen de Normalisation
Europäisches Komitee für Normung

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Foreword

This European Prestandard has been prepared by Technical Committee CEN/TC 251 “Medical informatics”, the secretariat of which is held by IBN.

According to the CEN/CENELEC Internal Regulations, the national standards organisations of the following countries are bound to announce this European Prestandard: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

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Introduction

The increased use of data processing and telecommunications 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 standards.

Computer systems are used for the storage and processing of information in many diagnostic service departments. Many of those asking for and receiving results of investigations also use computer systems to store and process patient related information. This information includes details of investigations requested and results received. Diagnostic service departments carry out investigations requested by healthcare parties and send the results of these investigations to requesters and sometimes to other healthcare parties.

Electronic transfer of requests and results, reduces the need for manual data entry and the risk of transcription errors. It also results in greater efficiency, leading to better healthcare provision. Standards are required to facilitate electronic transfer of requests for, and results of, investigations between the many systems currently used.

Implementation of this European Prestandard will therefore:

- a) facilitate the electronic transfer of orders for diagnostic services from requesting healthcare parties, to diagnostic service departments;
- b) facilitate the electronic transfer of reports from diagnostic service departments to requesters and other healthcare parties;
- c) reduce the need for human intervention in information interchange between applications used by diagnostic service departments and those used by other healthcare parties;
- d) minimise the time and effort required for the introduction of information interchange agreements;
- e) reduce the development effort required by suppliers to allow communication between a wide range of applications in this field;
- f) reduce the cost of information interchange between diagnostic service departments and parties requesting diagnostic service department services.

When implementing information exchange based on this European Prestandard, data security services including confidentiality provisions must be ensured according to the laws actually in force in the different CEN member countries.

The method by which this European Prestandard has been developed is based on the recommendations of the CEN Report "Investigation of Syntaxes for Existing Interchange Formats to be used in Healthcare" (CR 1350:1993). Extensions to the method, proposed by CEN TC251 PT3-025 while this document was being drafted, have also been applied where possible and relevant.

This standard is intended for use by message developers. Its provisions are directly relevant to suppliers of computer systems for use in diagnostic service departments, 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 diagnostic service departments, hospitals, general practices, clinical departments and specialist clinics.

The main normative provisions in this European Prestandard are expressed in clauses 4 and 5 and apply to the General Message Descriptions (GMDs), clause 7.

The symbols used in this Prestandard have the meaning as defined in normative Annex A for the purposes of this Prestandard only. Informative Annex B explains how the Domain Information Model relates to actual requests and reports. Informative Annex C gives a number scenarios as examples of message use.

A supporting document to this ENV entitled "Generic EDIFACT message implementation guide for diagnostic service request and report messages" is being prepared. This will contain message definitions using the EDIFACT (Electronic data interchange for administration, commerce and transport) standard ISO 9735, in line with the procedures for submission of EDIFACT-based standards of the UN/ECE. These message definitions will be Implementable Message Specifications (IMSs) conforming with this European Prestandard. The supporting document will also contain message implementation guidelines for these messages. They should be considered an essential component of the IMS providing a generic EDIFACT implementation specification for use in Europe.

The supporting document will be submitted to CEN for ballot as a CEN Report. The EDIFACT message definitions that it contains will also be submitted to the UN/ECE as a proposal for a United Nations Standard Message (UNSM). Arrangements between CEN and the Western European EDIFACT Board ensure that UNSMs can become ENVs. The supporting document will therefore become an ENV in its own right through separate standardisation procedures.

1 Scope

1.1 This European Prestandard specifies general messages to enable electronic exchange of requests for, and reports of, diagnostic services. The information exchanges covered are those between computer systems used by diagnostic service departments and computer systems used by healthcare parties requesting, or receiving results of, diagnostic services.

1.2 Within limits identified by subsequent clauses of this scope statement, this European Prestandard is applicable to messages requesting, or reporting on the results, of the following diagnostic services:

- Radiology;
- Nuclear medicine;
- Ultrasound;
- Other imaging techniques (e.g. magnetic resonance tomography);
- Electrophysiology;
- Physiological function tests;
- Diagnostic audiology;
- Cytology;
- Anatomic pathology;
- Histopathology; and
- Post-mortem studies (autopsies).

The messages specified also allow the inclusion of clinical observations about the patient where these are required to perform or interpret the results of these studies.

1.3 This European Prestandard is not applicable to messages requesting or reporting on the results of diagnostic laboratory specialties already covered by ENV 1613:

- Clinical Chemistry;
- Clinical Biochemistry;
- Toxicology;
- Clinical Immunology;
- Immunohaematology;
- Haematology;
- Clinical Microbiology (including Bacteriology, Mycology, Parasitology and Virology).

1.4 This European Prestandard is not applicable to messages requesting or reporting on blood transfusion services.

1.5 This European Prestandard does not specify the manner in which diagnostic service department services are divided between specialties as this varies in accordance with different national and local practices.

1.6 The messages specified by this European Prestandard, supplement those specified in other related standards, such as ENV 1613. In some borderline situations more than one member of this family of standards may meet the requirements. In these circumstances, the decision as to which messages are applicable to particular departments or studies in particular healthcare environments should be agreed by communicating parties.

1.7 The scope of the messages specified by this European Prestandard, comprises requests and results related to investigations carried out by diagnostic service departments on patients. This European Prestandard is applicable whether the healthcare party communicating with the diagnostic service department is a person (such as a doctor or other healthcare professional) or an organisation (such as a hospital, clinic or department). A diagnostic service department may itself act as the healthcare party submitting requests to, or receiving results from other diagnostic service departments. However, this European Prestandard has not been developed to meet the needs of messages that are specific to communications between one diagnostic service department and another.

1.8 This European Prestandard is applicable to requests for diagnostic services to be performed on:

- patients;
- samples, obtained from a patient, submitted to the diagnostic service department by the requester;
- samples that are to be obtained, from a patient, by the diagnostic department in response to a request for an investigation;
- materials or information resulting from a previous diagnostic service (e.g. a second opinion on films from a previous diagnostic service procedure).

It is also applicable to modifications or cancellations of previously issued requests.

1.9 This European Prestandard is applicable to reports of the results of diagnostic services. The report message it specifies supports the communication of partial, supplementary, complete and cumulative reports.

It is also applicable to modifications and cancellations of previously issued reports.

1.10 This European Prestandard permits diagnostic service report messages to be sent whether or not a diagnostic service request message has been received.

1.11 This European Prestandard also specifies diagnostic service plan report messages. These may be sent before a diagnostic service has been undertaken to communicate information about the acceptance of a diagnostic service request and the planning and progress of the requested diagnostic services. These messages also allow the diagnostic service provider to send the service requester instruction for preparation of the patient prior to the investigation.

1.12 The messages specified in this European Prestandard do not support standing orders for diagnostic services.

1.13 The messages specified in this European Prestandard do not support the communication of graphical, image or dynamic signal information that forms part of a request for or result of a diagnostic service. However, provision is made within the messages for external references to files which may contain these types of information.

1.14 This European Prestandard has not been developed to meet the needs of messages supporting administration, financing, management, interpersonal mail or external quality control, nor of messages communicating sample collection lists, work lists or queries.

1.15 The provisions of this European Prestandard have been validated in the domains and for the purposes described above. However, messages conforming to this European Prestandard may be considered by some user communities to meet their needs for purposes outside this scope. Use of the messages in such circumstances is not precluded by the scope.

1.16 While the messages specified in this European Prestandard may convey clinical and administrative information concerning patients, the way in which this information is treated in this European Prestandard does not constrain the development of future standards for the electronic healthcare record or for other clinical and administrative messages.

2 Normative references

This European Prestandard incorporates by dated or undated reference, provisions from other publications. These normative references are cited in the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments and revisions of any of these publications apply to this European Prestandard only when incorporated in it by amendment and revision. For undated references the latest edition of the publication referred to applies.

CR 1350:1993, *Investigation of syntaxes for existing interchange formats to be used in Healthcare*.

ENV 1064:1993, *Medical Informatics — Computerised Electrocardiography Interchange Format*.

ENV 1068:1993, *Medical Informatics — Healthcare Information Interchange — Registration of Coding Schemes*.

ISO 639:1988, *Symbols for languages, geographical areas and authorities*.

ISO 646:1991, *Information technology — ISO 7-bit coded character set for information interchange*.

ISO 2382:1987, *Information processing — Vocabulary — Part-4: Organisation of data*.

ISO 3166:1988, *Codes for representation of names of countries*.

ISO 4217:1990, *Codes for the representation of currencies and funds*.

ISO 5281:1977, *Information interchange — Representation of human sexes*.

ISO 6523:1984, *Data interchange — Structure for the identification of organisations*.

ISO 8824-1:1993, *Information technology — Open Systems Interconnection — Abstract Syntax Notation One (ASN. 1) — Part-1: Specification of basic notation*.

ISO 8601:1988, *Data elements and interchange formats — Information interchange — Representation of dates and times*.

ISO 8859:1987, *Information Processing — Registration of graphics character subrepertoires — Eight-bit single byte coded graphic character sets — Part-1: Latin No 1*.

ISO 9735:1992, *Electronic data interchange for administration, commerce and transport (EDIFACT) — Application level syntax rules*.

ENV 1613, *Medical Informatics — Messages for exchange of laboratory information*.

ENV 1614, *Medical Informatics — Structure for nomenclature, classification and coding of observable properties in clinical laboratory sciences*.

3 Definitions and abbreviations

For the purposes of this standard, the following definitions (listed in alphabetical order) apply:

3.1

analysed object

something derived from or to be derived from a patient as part of a diagnostic investigation

NOTE 1 Analysed object is a generalisation that includes samples taken from a patient and physical or digital records of information derived from a patient as part of a diagnostic service. An analysed object that is not a sample is referred to as a study product.

NOTE 2 An analysed object need not exist in a tangible form but may represent something observed briefly by a diagnostic service provider.

EXAMPLES

1. An X-ray image, a series of X-ray images, part of an X-ray image. The image may exist in a digitised form or as a film.
2. An electrocardiograph (ECG) monitor tracing or a twelve lead ECG.
3. An organ removed during surgery or post-mortem, a biopsy, a particular slide containing a section taken from a biopsy.
4. A view observed through an endoscope, an observation during an echocardiographic examination.

3.2

clinical information

information about a patient, relevant to the health or treatment of that patient, that is recorded by or on behalf of a healthcare professional

NOTE Clinical information about a patient may include information about the patient's environment or about related people or animals where this is relevant.

[ENV 1613]

3.3

code meaning

element within a coded set

EXAMPLE : "Paris Charles-De-Gaulle" which is mapped on to the three-letter abbreviation "CDG" by the coding scheme for three-letter abbreviations of airport names

[ENV 1068]

3.4**code value**

result of applying a coding scheme to a code meaning

EXAMPLE: “CDG” as the representation of “Paris Charles-De-Gaulle” in the coding scheme for three-letter representations of airport names

[ENV 1068]

[ISO 2382:1987], modified

3.5**coding scheme**

collection of rules that maps the elements of one set on to the elements of a second set

[ENV 1068]

[ISO 2382:1987], modified

3.6**diagnostic investigation**

a clinical investigation that is, or may be, requested or reported using a message specified in accordance with this European Prestandard

NOTE 1 A diagnostic investigation may be indicated by the terms the requester uses when making a request, or by the terms used by the diagnostic service provider to refer to an investigation or to actions undertaken while performing an investigation.

NOTE 2 A diagnostic investigation may be subdivided into several separate constituent investigations. Each constituent investigation is also considered as diagnostic investigation (e.g. examination of a biopsy may include macroscopic and microscopic examinations. Furthermore, the microscopic examination may apply to several separate sections of the sample and different staining techniques may have been applied to some sections).

EXAMPLES: Chest X-ray, erect abdominal X-ray, intravenous pyelogram, obstetric ultrasound, CT scan, electrocardiography, lung function tests, cervical cytology, endoscopy, post-mortem examination of a body, post-mortem examination of a particular organ, examination of a biopsy, microscopic examination of a particular section taken from a biopsy and stained in a particular way, interpretation of the results of a histological examination, interpretation of the change in the appearance of an opacity on a series of X-ray films.

3.7**diagnostic service plan report**

a message from a diagnostic service provider containing information about their plans for undertaking one or more diagnostic investigations

3.8**diagnostic service provider**

authorised healthcare party qualified to perform diagnostic investigations and to validate the resulting diagnostic service report

NOTE A diagnostic service provider is usually a diagnostic service department and/or a member of its staff.

3.9**diagnostic service report**

a message from a diagnostic service provider containing information about the results of one or more diagnostic investigations

3.10**diagnostic service request**

a message from a diagnostic service requester containing requests for one or more diagnostic investigations and related information that may be required by the intended diagnostic service provider

3.11**diagnostic service requester**

authorised healthcare party issuing a diagnostic service request

3.12

domain information model

conceptual model describing common concepts and their relationships for communication parties required to facilitate exchange of information between these parties within a specific domain of healthcare

NOTE In this Prestandard the abbreviation DIM is used.

[ENV 1613]

3.13

general message description

subset of a domain information model prescribing the information content and semantic structure of a message used to meet one or more identified information interchange requirements

NOTE General message descriptions are independent of the syntax used for constructing an actual message. They provide statements of the information interchange requirements in a form that can be implemented using different syntaxes.

NOTE In this Prestandard the abbreviation GMD is used.

[ENV 1613]

3.14

healthcare administrative information

information about a patient that is requested or required by a healthcare party to enable, finance or manage the provision of healthcare services to that patient

3.15

healthcare coding scheme designator

unique permanent identifier of a healthcare coding scheme registered for use in information interchange under the terms of ENV 1068

NOTE In this Prestandard the abbreviation HCD is used.

[ENV 1068]

3.16

healthcare organisation

organisation responsible for the direct or indirect provision of healthcare services

NOTE A healthcare organisation may be used stand-alone or as a superstructure containing departments and sub-departments.

[ENV 1613]

3.17

healthcare party

organisation or person responsible for the direct or indirect provision of healthcare to an individual, or involved in the provision of healthcare-related services such as environmental measurement results

[ENV 1613]

3.18

healthcare professional

person who is entrusted with the direct or indirect provision of defined healthcare services to a patient or population of patients

EXAMPLE: Primary care physician, dentist, nurse, social worker, veterinary surgeon, technologist, radiographer, medical secretary or clerk.

[ENV 1613]

3.19

healthcare service

service provided with the intention of directly or indirectly improving the health of the people, populations or animals to whom it is provided

[ENV 1613]

3.20**hierarchical general message description**

a general message description presented as a nested hierarchy of related objects rather than as a network of inter-related objects

NOTE In this Prestandard the abbreviation H-GMD is used.

3.21**implementable message specification**

specification of a general message description in a particular message syntax

NOTE In this Prestandard the abbreviation IMS is used.

[ENV 1613]

3.22**interchange format**

specification of a message type according to a given message syntax, covering the identification of the message type components, their arrangement, representation and interrelationships

[ENV 1613]

3.23**message syntax**

system of rules and definitions specifying the basic component types of messages, their interrelationships and their arrangement

[ENV 1613]

3.24**message type**

an identified, named and structured set of functionally related information which fulfils a specific business purpose

3.25**organisation**

unique framework of authority within which a person or persons act, or are designated to act towards some purpose

NOTE Groupings or subdivisions of an organisation may also be considered as organisations where there is need to identify them for information interchange.

[ISO 6523:1984]

3.26**procedure step**

individually distinct activity performed as part of a diagnostic service and directly relevant to interpretation of an analysed object

NOTE 1 A procedure step may occur or may be carried out prior to, or during, an investigation.

EXAMPLES

1. Fasting before an investigation.
2. Exercise during an electrocardiograph.
3. Administration of contrast medium during a radiographic examination.

3.27**sample**

one or more parts taken or to be taken from a system and intended to provide information on that system or on a subsystem, or to provide a basis for decision on either of these

NOTE The system from which a sample is taken may be a patient or may itself be a sample. The sample is assumed to be representative of the system. The term specimen is sometimes used with the same meaning.

[ENV 1613]

3.28

study product

an identifiable record of information derived from a patient as part of a diagnostic service. It may take the form of a physical object or may consist of digital information in an electronic information system

NOTE 1 A study product differs from a sample in that a sample is something taken from a patient whereas a study product is a recording of information derived from a patient. A consequence of this distinction is that a study product can be copied. Furthermore, if the study product is represented in a digital form it can be held within or transferred between computer systems.

EXAMPLES

1. An X-ray image, a series of X-ray images, part of an X-ray image. The image(s) may exist in a digitised form or as a film.
2. An electrocardiograph (ECG) monitor tracing or a twelve lead ECG. The tracing may exist on paper or as a digitised signal.

3.29

transmitted message

message instance created in a message syntax in alignment with a particular message profile and therefore in full conformance with the relevant general message description and implementable message specification

[ENV 1613]

3.30 Abbreviations

The following abbreviations are used for the terms defined in this European Prestandard.

DIM	Domain Information Model
ECG	Electrocardiograph
GMD	General Message Description
HCD	Healthcare Coding scheme Designator
H-GMD	Hierarchical General Message Description
IMS	Implementable Message Specification

4 Requirements

4.1 Messages for transmission of orders or requests for diagnostic investigations, covered by the scope of this European Prestandard, shall enable electronic interchange of the semantic content defined in the General Message Descriptions for Diagnostic Service Request Messages in clause 7.

4.2 Messages for transmission of reports of diagnostic services covered by the scope of this European Prestandard shall enable electronic interchange of the semantic content defined in the General Message Descriptions for Diagnostic Service Report Messages in clause 7.

4.3 Messages for transmission of information about the acceptance or rejection of diagnostic service requests, and the scheduling and preparation for diagnostic investigations covered by the scope of this European Prestandard, shall enable electronic interchange of the semantic content defined in the General Message Descriptions for Diagnostic Service Plan Report Messages in clause 7.

4.4 Implementable message specifications (IMS) shall conform to the General Message Descriptions defined in this ENV. They shall support both mandatory and optional objects, attribute groups and attributes as defined in the General Message Descriptions of this ENV. They shall also support the relationships between objects as defined by the General Message Descriptions.

4.5 Implementable message specifications should be expressed in terms of a syntax which is an International Standard except where the healthcare user requirements cannot be met by using such a Standard syntax.

4.6 Unless the syntax in which an IMS is expressed specifically supports the types of relationships shown in the General Message Descriptions, the IMS shall follow the structure of the appropriate Hierarchical General Message Descriptions (H-GMD) in clause 7. The precise order of the objects, attribute groups and attributes shown in the H-GMD need not be followed where an alternative ordering simplifies implementation. However, to conform with this European Prestandard the relationships between objects and the overall nesting structure shall be as shown in the H-GMD.

5 Communication roles and supported services

5.1 General

This clause defines the communication roles to which the specifications of this European Prestandard shall apply in relation to the exchange of diagnostic service department information. It establishes the relationships between the communication roles and the General Message Descriptions, as well as the relationships amongst the General Message Descriptions (GMDs). Annex C (informative) specifies scenarios based upon which the communication roles, the General Message Descriptions and the supported services are derived.

5.2 Message groups

The messages defined in this European Prestandard fall into three groups. Each group comprises specific *new* and *modification* messages and a *cancellation* message which may be shared with one or more of the other groups. The message groups are defined in Table 1.

Table 1 — Message groups

Group of messages	New message	Modification message	Cancellation message
<i>diagnostic service request</i>	new diagnostic service request	diagnostic service request modification	diagnostic service request cancellation
<i>diagnostic service report</i>	new diagnostic service report	diagnostic service report modification	diagnostic service report cancellation
<i>diagnostic service plan report</i>	new diagnostic service plan report	diagnostic service plan report modification	diagnostic service report cancellation

5.3 Communication roles

5.3.1 For each group of messages defined in this European Prestandard there are two key communicating roles: the message originating role and the message receiving role. These roles are assumed by three types of healthcare parties: diagnostic service requesters, diagnostic service providers and copy destinations. A copy destination is a party who is neither the requester of the diagnostic service nor the provider but who, for any reason, is nominated to receive a copy by the message originator.

5.3.2 A communicating party has a message receiving role in relation to any message for which he/she is nominated as a copy destination.

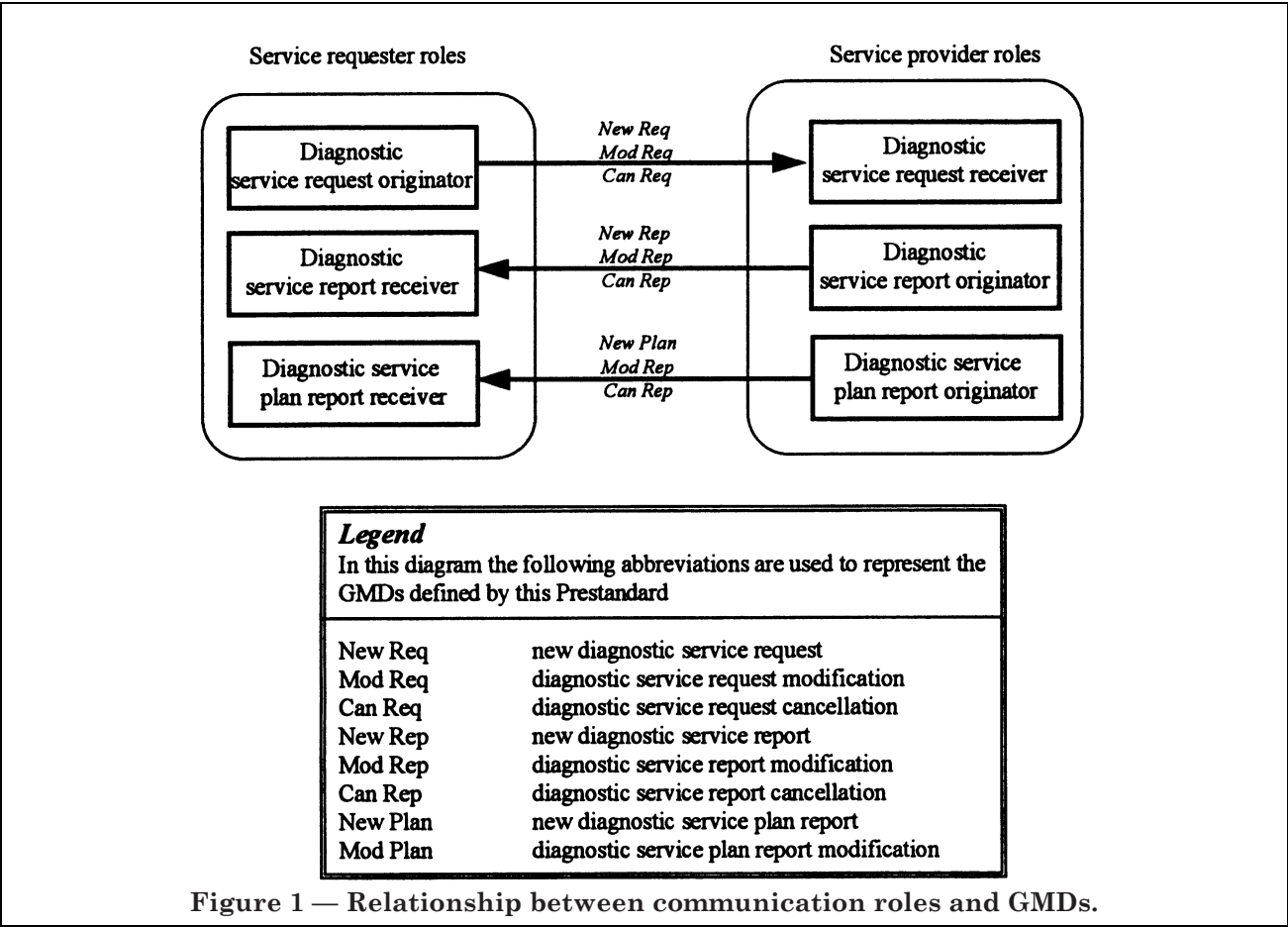
5.3.3 A single healthcare party may have different roles in relation to different types of messages. For example, a general practitioner may have a diagnostic service request originating role and a diagnostic service report receiving role.

5.3.4 A single healthcare party may have different roles in relation to the same type of message. For example, a person who undertakes endoscopic examinations may receive requests for these and may originate requests for histological examinations of samples taken during the examination.

5.3.5 A healthcare party may act as an intermediary in the exchange of information between the message originator and ultimate recipient of the message. Such an intermediary may be an organisation which receives requests for a wide range of services and routes them to appropriate providers. Another example is a service provider who passes on all or part of an order to be dealt with by a third party. For the purposes of this European Prestandard such intermediaries can be treated as having both message originating and message receiving roles. However, if an intermediary passes a message on in an unchanged form, they may be ignored from the perspective of the communicating roles and services described in this European Prestandard.

5.4 Communication roles and General Message Descriptions

5.4.1 The message types that may be sent and received by a communication party depend upon their communication roles. The following subclauses identify the originating and receiving roles for each of the message types specified in this European Prestandard. The main points are illustrated by Figure 1.



- 5.4.2 Parties with a diagnostic service request originating role can send message instances based upon:
- the new diagnostic service request General Message Description;
 - the diagnostic service request modification General Message Description;
 - the diagnostic service request cancellation General Message Description.
- 5.4.3 Parties with a diagnostic service request receiving role can receive message instances based upon:
- the new diagnostic service request General Message Description;
 - the diagnostic service request modification General Message Description;
 - the diagnostic service request cancellation General Message Description.
- 5.4.4 Parties with a diagnostic service report originating role can send message instances based upon:
- the new diagnostic service report General Message Description;
 - the diagnostic service report modification General Message Description;
 - the diagnostic service report cancellation General Message Description.
- 5.4.5 Parties with a diagnostic service report receiving role can receive message instances based upon:
- the new diagnostic service report General Message Description;
 - the diagnostic service report modification General Message Description;
 - the diagnostic service report cancellation General Message Description.

5.4.6 Parties with a diagnostic service plan report originating role can send message instances based upon:

- the new diagnostic service plan report General Message Description;
- the diagnostic service plan report modification General Message Description;
- the diagnostic service report cancellation General Message Description.

5.4.7 Parties with a diagnostic service plan report receiving role can receive message instances based upon:

- the new diagnostic service plan report General Message Description;
- the diagnostic service plan report modification General Message Description;
- the diagnostic service report cancellation General Message Description.

5.5 Communication roles and supported services

5.5.1 The services that shall be supported by a communicating party depend upon their roles in relation to each of the groups of messages specified in this European Prestandard.

5.5.2 The services that shall be supported by a communication party with a message originating role for a group of messages are:

- issue *new* message instances which comply with the appropriate General Message Description and which convey in a complete and exact way the information as intended by the sender and as to be understood by the receiver;
- issue *modification* message instances which comply with the appropriate General Message Description and which convey in a complete and exact way the information as intended by the sender and as to be understood by the receiver;
- issue *cancellation* message instances which comply with the appropriate General Message Description and which convey in a complete and exact way the information as intended by the sender and as to be understood by the receiver;
- issue these message instances in accordance with the message origination rules for these messages (see 5.6).

5.5.3 The services that shall be supported by a communication party with a message receiving role are:

- receive *new* message instances which comply with the appropriate General Message Description and which allow the complete and exact understanding of the information as intended by the requester;
- receive *modification* message instances which comply with the appropriate General Message Description and which allow the complete and exact understanding of the information as intended by the requester;
- receive *cancellation* message instances which comply with the appropriate cancellation General Message Description and which allow the complete and exact understanding of the information as intended by the requester;
- process *modification* and *cancellation* message instances in such a way as to reconcile the *modification* or *cancellation* information with the relevant *new* message instance and any previous *modification* message instances.
- inform the healthcare party with the message originating role about message instances which are not in accordance with the message origination rules (see 5.6).

5.6 Message origination rules

5.6.1 For any of the groups of messages shown in Table 1 the following rules apply. These rules are illustrated by the state transition diagram (see Figure 2).

5.6.2 A message originator may send an instance of the *new* message GMD to any message receiver at any time, provided that he/she has not already sent a message, of the same type, with the same identification, to the same message receiver.

5.6.3 A message originator may send an instance of the *cancellation* message GMD to a message receiver, if he/she has previously sent a *new* message, to which the cancellation message refers, to the same message receiver. A message originator shall not send an instance of the *cancellation* message GMD to a message receiver, if he/she has previously sent a *cancellation* message applicable to the same *new* message to the same message receiver.

5.6.4 A message originator may send an instance of the *modification* message GMD to a message receiver, if he/she has previously sent a *new* message, to which the modification message refers, to the same message receiver. A message originator shall not send an instance of the *modification* message GMD to a message receiver, if he/she has previously sent a *cancellation* message, applicable to the same *new* message, to the same message receiver. Any number of instances of a *modification* message may be sent in respect of the same instance of a *new* message.

5.6.5 Communicating parties may agree that after a specified period of time, or when activities requested by a message have been completed, the message should be considered to be closed. This European Prestandard does not specify the rules under which closure of a message should take place. However, once a message is deemed to be closed a message originator shall not send further instances of the *modification* messages, or any instance of the *cancellation* message applicable to the closed message, to the message receiver.

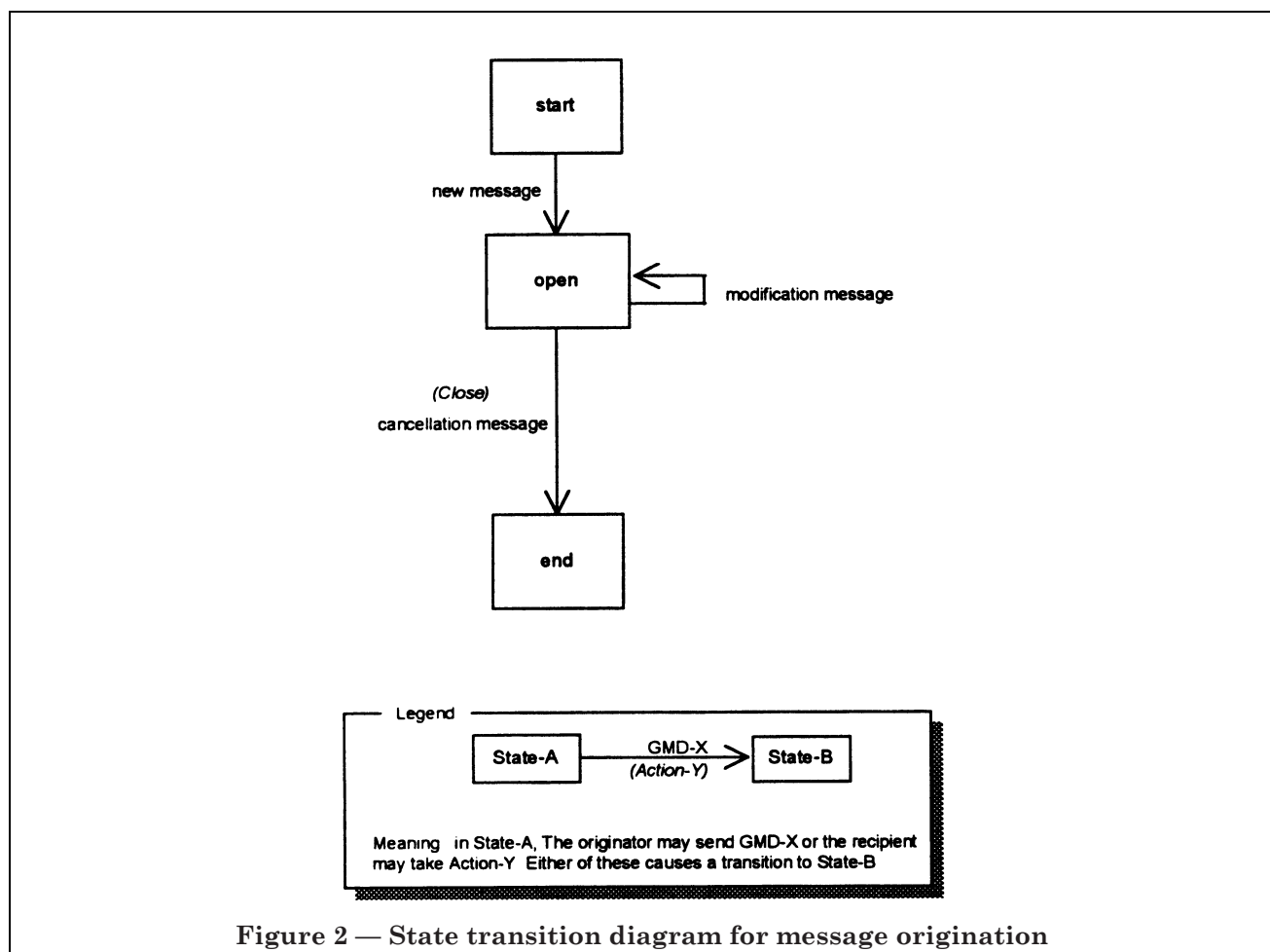


Figure 2 — State transition diagram for message origination

6 Domain information model

6.1 Introduction

6.1.1 The modelling approach

The Domain Information Model (DIM) and the General Message Descriptions (GMDs) were built based on the approach defined by CR 1350 “Investigation of syntaxes for existing interchange formats to be used in Healthcare” and the technique described by P. Coad and E. Yourdon¹⁾. The DIM is presented as a series of diagrams (see 6.2) and as textual descriptions (see 6.3 and 6.4).

¹⁾ Peter Coad, Edward Yourdon, Object Oriented Analysis, 2nd edition, 1991, Yourdon Press, NJ 07632.

6.1.2 Diagrammatic presentation of the DIM

The diagrammatic presentation shows the subjects, classes and class-&-objects about which information may need to be conveyed in diagnostic service request and report messages. The diagrams show the relationships between these components and these shall be interpreted in accordance with the instructions and key to the symbols used given in Normative Annex A. Informative Annex B provides a textual explanation of how the models relate to real world requirements for communication between those requesting and those providing diagnostic services.

6.1.3 Textual description of the DIM

The textual description describes each object and details its relationships, attributes and attribute groups. The attributes and attribute groups themselves are described under sub headings within the relevant object description. The data type of each attribute is defined using an abbreviation which shall be interpreted in accordance with the data-type definitions in Table 2 (on Page 22).

The attribute layer specification in clause 7 specifies which of the attributes and attribute groups defined in the DIM shall be supported by messages that conform to this European Prestandard.

The descriptions in this section are not formal definitions of terms but are descriptions of items of information required in information interchanges related to requesting and reporting diagnostic services. The attributes, relationships and specialisations of the objects described are limited to those that are relevant to messages within the scope of this European Prestandard. Therefore, the model and associated descriptions are not exhaustive representations of the information required by communicating parties. Other attributes, relationships and specialisations may be required to support the same objects in the context of the information systems used by individual communicating parties.

6.1.4 Repetition of DIM components

A requirement for repetition of an object is indicated through the cardinalities of the relationships shown in the diagrammatic representation of the DIM. These relationships are also described under the heading “Relationships” in the textual description of each object.

Repetition of an attribute within an object or attribute group is indicated by the prefix “L-” before the attribute name.

Repetition of an attribute group within an object or within another attribute group is indicated by the prefix “L-” before the attribute group name.

NOTE There is a difference between a repeated attribute and an attribute with one of the “list of” data-types described in Table 2 (i.e. LC, LC/S and LC + S). The use of a “list of” data type means that a list of values may be required to represent a single instance of that attribute. The repetition of an attribute implies that there may be a set of distinct instances of the attribute within an object or attribute group. For example:

- A clinical observation may be expressed using a coding scheme that uses several separate axes to encode a single concept (e.g. topography, aetiology, disease, etc.) and might be further qualified by text. Thus the data-type for the attribute “observation description” (see 6.3.21) is “list of coded values and string” (LC + S);
- There may be several separate reasons for making a diagnostic service request. Each of these may be represented as a combination of a code value and/or free text. Thus the attribute “reason for request of diagnostic service request” (see 6.3.14) is shown as “L-reason for diagnostic service request” and has the data-type “coded value and string” (C + S).

6.2 Domain Information Model diagrams

6.2.1 Diagnostic service requests and reports: Top level model

References to textual descriptions of objects shown in: Diagnostic service requests and reports: Top level model

analysed object: 6.3.2	copy destination: 6.3.8
diagnostic investigation: 6.3.9	diagnostic investigation plan item: 6.3.10
diagnostic investigation result item: 6.3.11	diagnostic service provider: 6.3.12
diagnostic service report: 6.3.13	diagnostic service request: 6.3.14
diagnostic service requester: 6.3.15	patient: 6.3.23
payment guarantor: 6.3.27	related diagnostic service provider: 6.3.31
requested diagnostic investigation: 6.3.34	

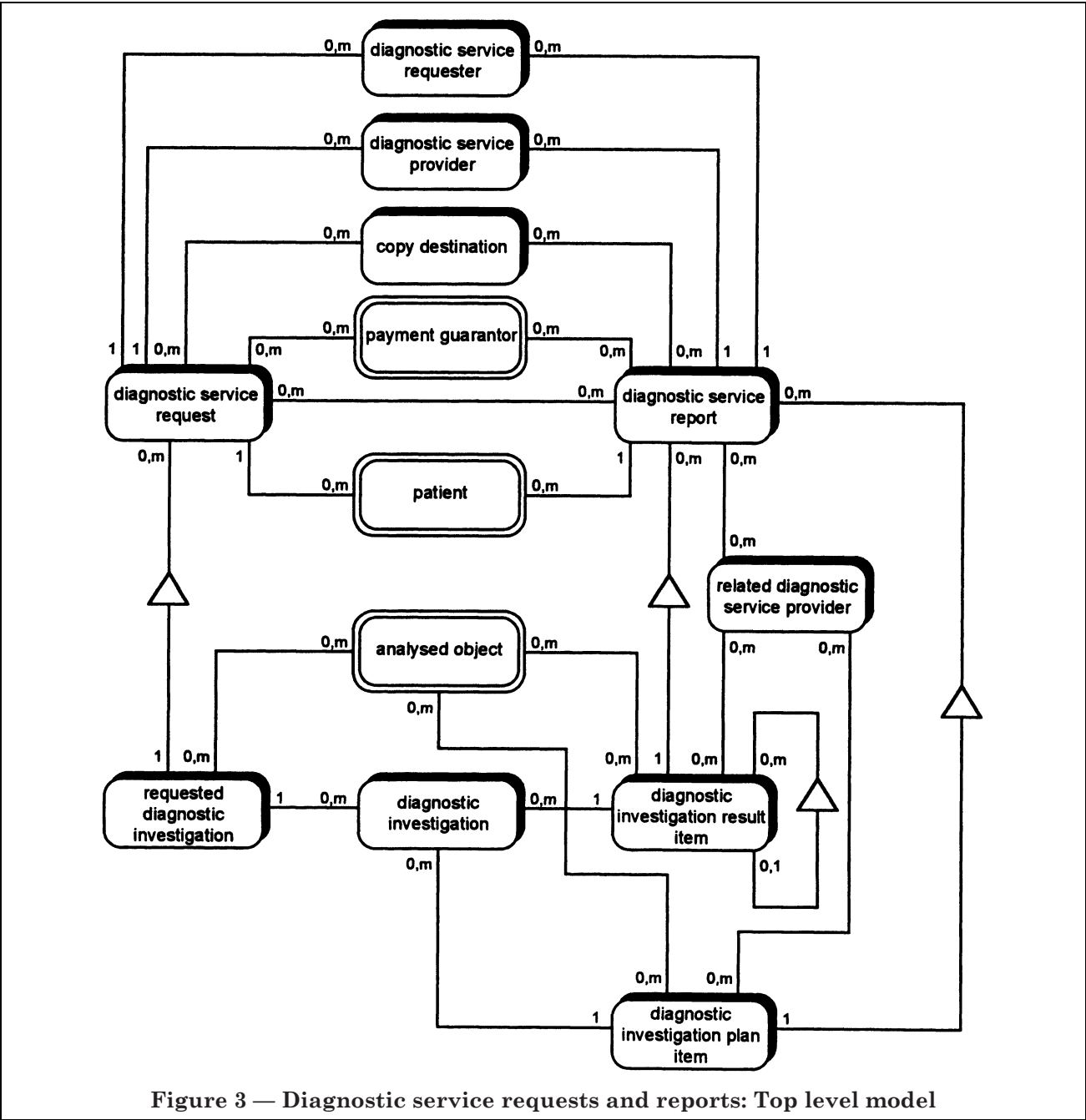


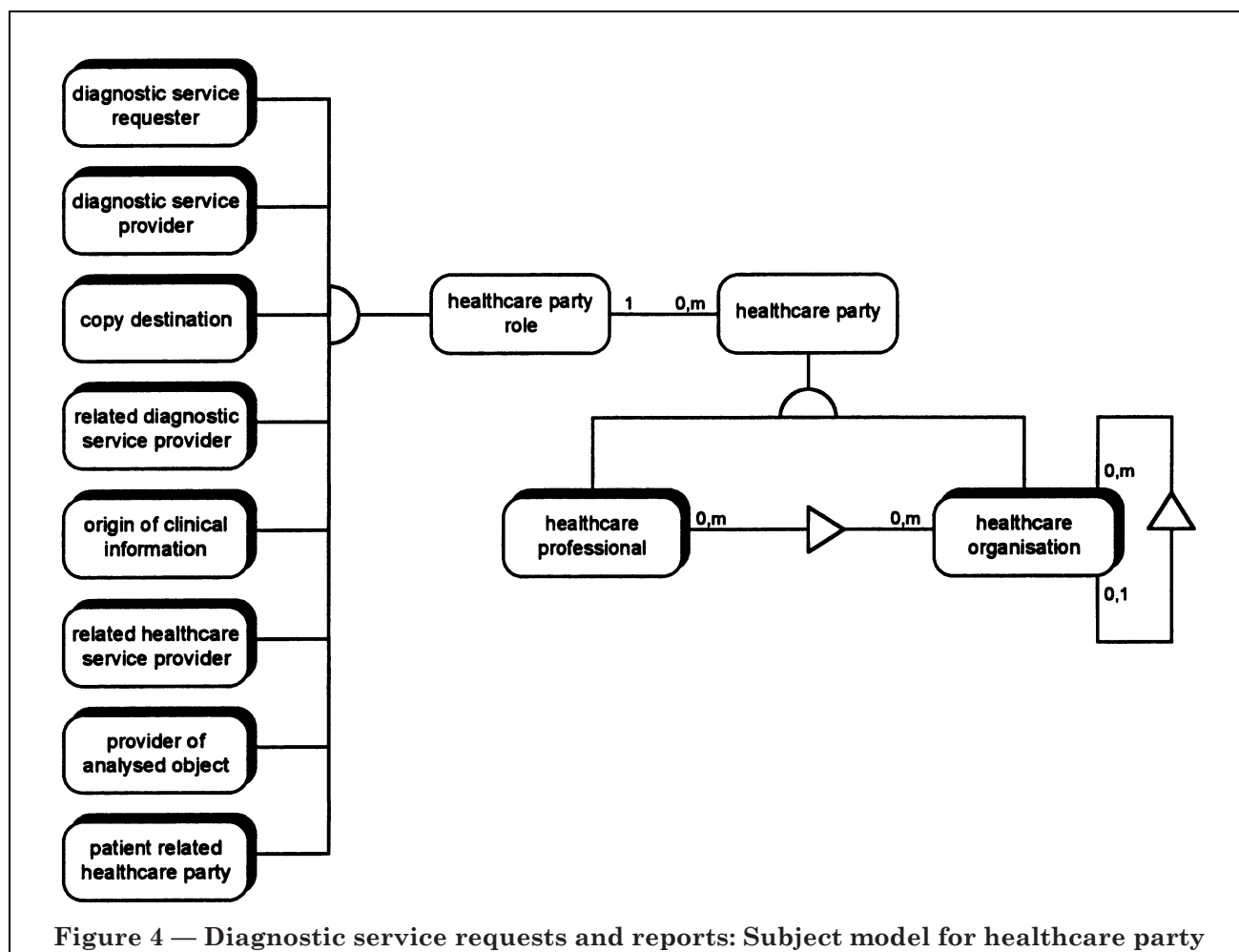
Figure 3 — Diagnostic service requests and reports: Top level model

6.2.2 Diagnostic service requests and reports: Subject model for healthcare party

References to textual descriptions of objects shown in: Diagnostic service requests and reports: Subject model for healthcare party

- copy destination: 6.3.8
- diagnostic service requester: 6.3.15
- healthcare party: 6.3.18
- healthcare professional: 6.3.20
- patient related healthcare party: 6.3.25
- related diagnostic service provider: 6.3.31

- diagnostic service provider: 6.3.12
- healthcare organisation: 6.3.17
- healthcare party role: 6.3.19
- origin of clinical information: 6.3.22
- provider of analysed object: 6.3.29
- related healthcare service provider: 6.3.32



6.2.3 Diagnostic service requests and reports: Subject model for patient

References to textual descriptions of objects shown in: *Diagnostic service requests and reports: Subject model for patient*

clinical information item: 6.3.3

clinical investigation result item: 6.3.5

observation: 6.3.21

patient: 6.3.23

patient related healthcare party: 6.3.25

referenced study product: 6.3.30

clinical investigation: 6.3.4

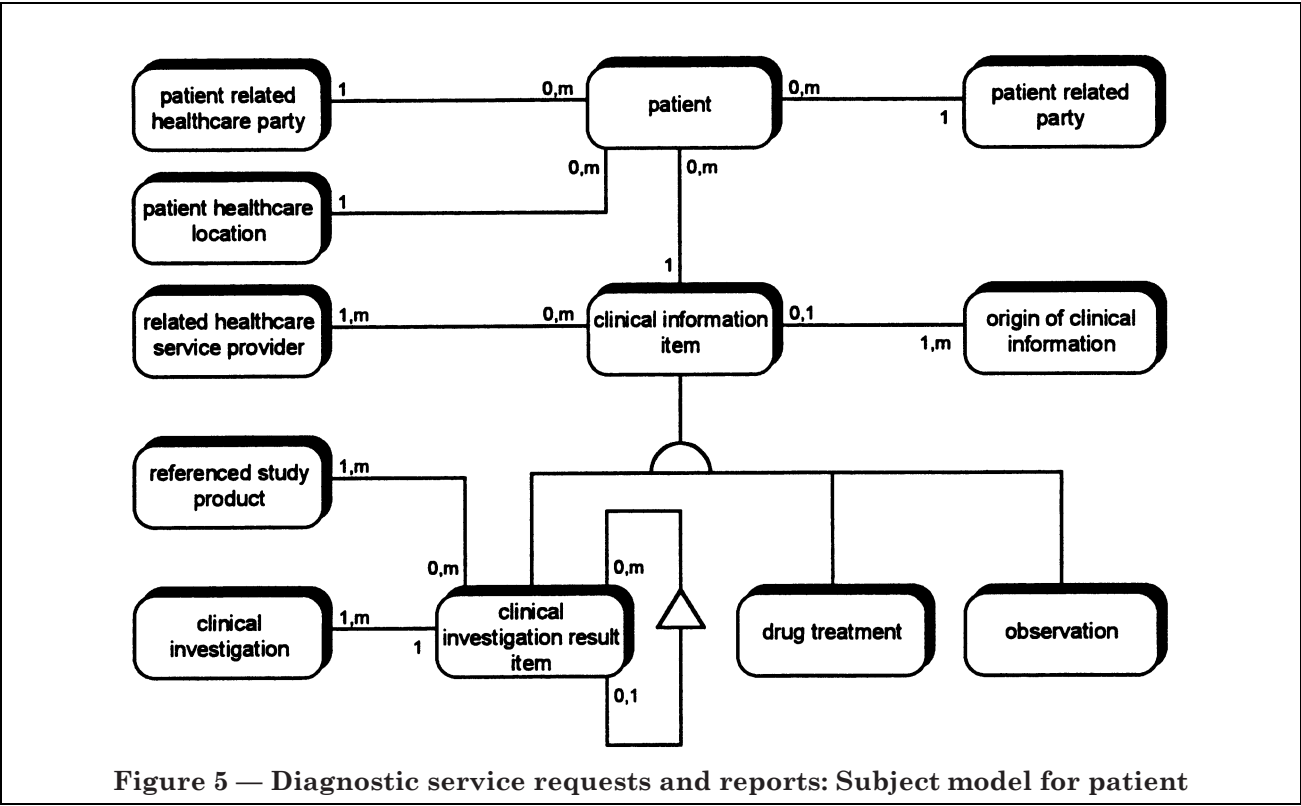
drug treatment: 6.3.16

origin of clinical information: 6.3.22

patient healthcare location: 6.3.24

patient related party: 6.3.26

related healthcare service provider: 6.3.32



6.2.4 Diagnostic service requests and reports: Subject model for analysed object

References to textual descriptions of objects shown in: Diagnostic service requests and reports: Subject model for analysed object

- analysed object: 6.3.2

procedure step: 6.3.28

requested analysed object: 6.3.33

study product: 6.3.36
- collected analysed object: 6.3.6

provider of analysed object: 6.3.29

sample: 6.3.35

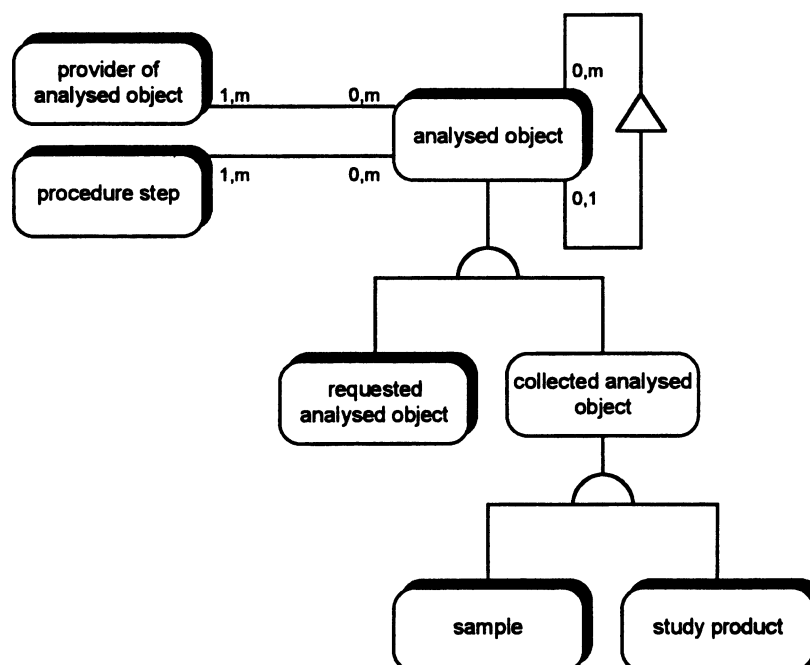


Figure 6 — Diagnostic service requests and reports: Subject model for analysed object

6.2.5 Diagnostic service requests and reports: Subject model for payment guarantor

References to textual descriptions of objects shown in: Diagnostic service requests and reports: Subject model for payment guarantor

contract authorisation: 6.3.7

payment guarantor: 6.3.27

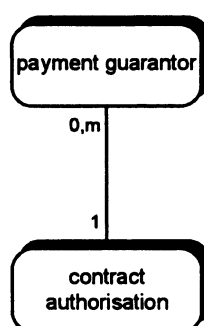


Figure 7 — Diagnostic service requests and reports: Subject model for payment guarantor

Table 2 — Description of data types

Data-type	abbreviation	Definition
string	S	A string of characters from the ISO 8859 character sets.
calendar date	CD	String limited to the representation of year, month and day (definition according to ISO 8601).
time of calendar date	TOCD	String limited to the representation of the year, month, day, hour, minutes, seconds and local time differential factor.
Boolean	B	A simple type with two distinguished value. Possibilities are true or false (definition according to ISO 8824).
integer	I	A simple type with distinguished values which are the positive and negative whole numbers including zero (definition according to ISO 8824).
real	R	A simple type whose distinguished values are members of the set of real numbers (definition according to ISO 8824).
coded value	C	Compound type consisting of 3 components: • HCD (Healthcare Coding Scheme Designator as in ENV 1068) or ICD (International Coding Scheme Designator as in ISO 6523): data type string, mandatory component, • Code value: data type string, mandatory component, • Code meaning: data type string, optional component.
coded value or string	C/S	Value which may either be represented by a coded value or by a string.
coded value and string	C+S	Value which may be represented by a coded value, or by a string, or by a combination of a coded value and a string. (NOTE If both code value and string are included the string qualifies the code value providing finer granularity).
list of coded values	LC	Value which may be represented by a repetition of coded values. As for coded value (Type C), but concatenation of codes may be needed for a single attribute value.
list of coded values or string	LC/S	Value which may be represented by a repetition of coded values or by a string. As for coded value or string (Type C/S), but concatenation of codes may be needed for a single attribute value
list of coded values or string	LC+S	Value which may be represented by a list of coded values, by a string, or by a combination of a list of coded values and a string. As for coded values and string (type C + S), but concatenation of codes may be needed for a single attribute value.
coded value without code meaning	V	This data type consists of 2 components: • HCD (Healthcare Coding Scheme Designator as in ENV 1068) or ICD (International Coding Scheme Designator as in ISO 6523): data type string, mandatory component, • Code value: data type string, mandatory component. Coding is required.
Attribute group	AG	Compound data type used to group together a set of logically coherent attributes and/or other attribute groups that are used in specific contexts.
Common attribute group	CAG	Compound data type used to group together a set of logically coherent attributes, that are used in a common manner in several different contexts.
	CAG (a)	Common attribute group of type <i>address</i> . For details see 6.4.1.
	CAG (la)	Common attribute group of type <i>language</i> . For details see 6.4.2.
	CAG (lo)	Common attribute group of type <i>location</i> . For details see 6.4.3.
	CAG (m)	Common attribute group of type <i>monetary details</i> . For details see 6.4.4.
	CAG (tr)	Common attribute group of type <i>patient transport</i> . For details see 6.4.5.
	CAG (n)	Common attribute group of type <i>person name details</i> . For details see 6.4.6.
	CAG (t)	Common attribute group of type <i>telecommunication</i> . For details see 6.4.7.

6.3 Textual description of the objects, their relationships and attributes

6.3.1 General

This description is a complement to the Domain Information Model drawings. The objects are listed in alphabetical order, numbered and underlined. Attributes are grouped under the object to which they belong and are underlined. Attribute groups are printed in italics and underlined. Indentation is used to indicate the components of an attribute group. To emphasise the indentation, the names of components of attribute groups are prefixed with “>” and the names components of an attribute group within another attribute group are prefixed with “»”. Attribute groups common to several objects are detailed in clause 6.4.

6.3.2 analysed object

Description

Information about something derived from or to be derived from a patient as part of a diagnostic investigation.

NOTE 1 Analysed object is a generalisation that includes samples taken from a patient and physical or digital records of information derived from a patient as part of a diagnostic service. An analysed object that is not a sample is referred to as a study product.

NOTE 2 An analysed object need not exist in a tangible form but may represent something observed briefly by the provider of the analysed object. In this case the class & object “analysed object” is present in its generalised form without any of its specialisations.

Purpose

This class & object serves several uses a) to indicate that a request relates to an existing sample, image, etc or requires the collection of such an object, b) to allow a request or result to refer to a physical or digital record made during an investigation, c) to associate results with a particular set of circumstances or procedure steps, d) to record the party responsible for obtaining an object such as a sample, an image or a recorded signal separately from the service provider responsible for reporting on that object.

Example(s):

An X-ray image, a series of X-ray images, part of an X-ray image. The image may exist in a digitised form or as a film.

An electrocardiograph (ECG) monitor tracing or a twelve lead ECG.

An organ removed during surgery or post-mortem, a biopsy, a particular slide containing a section taken from a biopsy.

A view observed through an endoscope, an observation during an echocardiographic examination.

Relationships

— Part/Whole of: Each instance of *analysed object* may be a part of zero or one other instance of the same object.

Analysed object may be part of or derived from another analysed object.

— Whole/Part: Each instance of *analysed object* may consist of any number of other instances of the same object.

An analysed object may be made up of or used to derive other analysed objects.

— Generalisation: Each instance of *analysed object* may exist as one of the following specialisations: *requested analysed object* or *collected analysed object*.

An analysed object may already exist (collected analysed object) or may be required to complete a requested or planned diagnostic investigation (requested analysed object).

— Instance connection: Each instance of *analysed object* may be associated with any number of instances of *procedure step*.

Analysed objects may be obtained during or following specified procedure steps.

— Instance connection: Each instance of *analysed object* may be associated with any number of instances of *provider of analysed object*.

Analysed objects may be obtained by specified providers of analysed object.

— Instance connection: Each instance of *analysed object* may be associated with any number of instances of *requested diagnostic investigation*.

Analysed objects may be provided with or required for requested diagnostic investigations.

— Instance connection: Each instance of *analysed object* may be associated with any number of instances of *diagnostic investigation result item*.

Analysed objects may be the basis for diagnostic investigation result items.

— Instance connection: Each instance of *analysed object* may be associated with any number of instances of *diagnostic investigation plan item*.

Analysed objects may be derived from or reported in a planned investigation (diagnostic investigation plan item).

Attributes:

<u>analysed object type</u>	Data Type: C/S
NOTE What the analysed object is.	
<u>identification of analysed object by diagnostic service requester</u>	Data Type: S
<u>identification of analysed object by diagnostic service provider</u>	Data Type: S
Example(s): Sample number, X-ray film number, an identification of a videotape and position on a videotape.	
<u>L-handling precautions/handling warnings</u>	Data Type: C/S
<u>L-analysed object, preservation material</u>	Data Type: C/S
<u>L-diagnostic service requester's comment</u>	Data Type: C/S
<u>L-diagnostic service provider's comment</u>	Data Type: C/S
<u>L-analysed object measurement</u>	Data Type: AG
Example(s): The size of a biopsy sent for histology, the volume of aspirate sent for cytology, the length of an ECG tracing.	
> <u>kind of quantity</u>	Data Type: C/S
Description: The type of measurement.	
Example(s): Length, height, weight, volume.	
> <u>numerical value of analysed object measurement</u>	Data Type: R
> <u>unit of numerical value of analysed object measurement</u>	Data Type: C
<u>anatomical origin of analysed object</u>	Data Type: LC + S
<u>acquisition procedure</u>	Data Type: LC/S
NOTE Procedure or protocol name.	
Example(s): X-ray, venepuncture, excision.	
<u>L-textual description of equipment parameters</u>	Data Type: S
Description: Settings of the piece of equipment used to acquire the analysed object during the period of acquisition, expressed as free text.	
<u>patient position during acquisition</u>	Data Type: C/S
NOTE This refers to posture rather than geographical location.	
Example(s): Standing, lying, supine.	

6.3.3 clinical information item

Description

Information about a patient, relevant to the health or treatment of that patient, that is recorded by or on behalf of a healthcare professional.

NOTE 1 Clinical information about a patient may include information about the patient's environment or about related people.

NOTE 2 The modelling of this object has been kept generic since other future standards will address more specific requirements.

Example(s):

Family history (e.g. father diabetic), symptoms (e.g. headache), signs (e.g. hepatomegaly), problems (e.g. weight loss or loss of body mass), diagnoses (e.g. thyrotoxicosis, both known and tentative), quantities (e.g. mass, length, body surface area), drugs (e.g. warfarin), diet (e.g. fat free), operative procedures (e.g. pancreatotomy), information given to the patient or relative.

Relationships

— Instance connection: Each instance of *clinical information item* is associated with one instance of *patient*.

Clinical information is provided in relation to a particular patient.

— Instance connection: Each instance of *clinical information item* may be associated with zero or one instance of *origin of clinical information*.

Clinical information items may be obtained from a record known to have been made by an origin of clinical information.

— Generalisation: Each instance of *clinical information item* may exist as one of the following specialisations: *observation*, *drug treatment* or *clinical investigation result item*.

Clinical information items may be information about the patient's state of health or medical history (observation), medication that the patient is taking or has taken (drug treatment) or the result of a previous investigation (clinical investigation result item).

— Instance connection: Each instance of *clinical information item* may be associated with any number of instances of *related healthcare service provider*.

Clinical information item may refer to healthcare parties (related healthcare service providers) who have a specified role in relation to the recorded information.

Attributes:

date and time of clinical information

Data Type: TOCD

Description: Date and (if appropriate) time of the occurrence of a clinically relevant event.

NOTE 1 For use when it is not important to indicate a period of applicability for a clinical information item.

This may be because a clinical information item indicates a brief event (see examples) or because it indicates a prolonged event whose start and end dates are unknown, uncertain, ill-defined or considered unimportant. Consequently a single date may legitimately be associated with "diabetes mellitus type II" even though this leaves unspecified whether it is the date when the disease process began, when symptoms appeared, when the diagnosis was considered or confirmed, or when medical intervention was considered necessary.

NOTE 2 Sometimes this date and time is called physiologic date and time.

Example 1: Date and time of: Grand Mal fit, hypoglycaemic coma, total colectomy, blast (explosion) injury, exposure to tuberculosis.

period of clinical information

Data Type: AG

NOTE This attribute group consists of the attributes start date and time of a clinical information item and end date and time of a clinical information item.

> start date and time of clinical information

Data Type: TOCD

Description: Beginning of a period of applicability of clinical information.

NOTE For use when it is important to convey the continuation of the clinical information item's applicability over a period of time. If used with a date value in the past and without an end date/time, it indicates continuation to the present time.

Example(s): (compare with examples for date and time of clinical information) start date and time of: epilepsy, diabetes mellitus type I, myoglobinuria, productive cough, thyrotoxicosis, heart failure, warfarin treatment.

> end date and time of clinical information

Data Type: TOCD

Description: End of a period of applicability of clinical information.

NOTE May be used without a start date/time if it is the moment when the clinical information item ceased to be applicable that is of greatest relevance.

Example(s): End date and time of antibiotic treatment.

type of clinical information

Data Type: C/S

Example(s): Diagnosis, symptom, physical sign, occupation, problem, diagnostic procedure, therapeutic procedure, surgical procedure, drug treatment, advice, idiosyncrasies, previous laboratory or diagnostic investigation results.

language of clinical information

Data Type: V

Description: Language in which clinical information is expressed.

NOTE Represented by the abbreviations specified in ISO 639.

6.3.4 *clinical investigation*

Description

Information about a laboratory, physiological, radiological or other healthcare examination. A clinical investigation leads to the production of one or more results which may contribute to an assessment of the patient on whom, or in relation to whom, it is performed.

NOTE 1 The information content of this object relates to the general case of an investigation rather than a specific instance of that investigation. This information can be viewed as being derived from a master file of possible clinical investigations.

NOTE 2 The context in which clinical investigation is used within the messages in this domain includes any investigation which is not the subject of the current request or report.

Relationships

— Instance connection: Each instance of *clinical investigation* is associated with one or more instances of *clinical investigation result item*.

A clinical investigation may be reported upon through one or many clinical investigation result items.

Attributes:

identification of clinical investigation

Data Type: C/S

Description: Unique and unambiguous identification of a clinical investigation.

NOTE This identifies an investigation that may be represented in a central catalogue of investigations. It does not identify a specific instance of that information in a message.

Example(s): Serum bilirubin concentration, Gastroscopy.

L-specification to clinical investigation

Data Type: C/S

Description: Coded or plain text description of information complementary to a clinical investigation.

L-comment to clinical investigation

Data Type: C/S

6.3.5 *clinical investigation result item*

Description

Set of information including all essential or useful data relevant to the result of a single clinical investigation.

NOTE 1 A clinical investigation result item may be subdivided into several constituent clinical investigation result items. Therefore, a clinical investigation result item may include the overall result of a clinical investigation comprising several constituent investigations or the results of one of the constituent investigations.

NOTE 2 A clinical investigation result item comprises one or more of: a numeric, textual or coded representation of a result. It also includes additional data that is essential to the interpretation of the result including: the status of the result, relevant dates and times, units of measurement and designation of the coding scheme from which code values in the result item are derived.

NOTE 3 A clinical investigation result item may be the result of any investigation or measurement that has been performed in the past. Results that are the subject of the current report message should be represented as diagnostic investigation result items not as a clinical investigation result items.

Example(s):

The result of a previous diagnostic investigation included as background information in a request.

The results of laboratory investigations that may be relevant to the safety of a diagnostic investigation (e.g. creatinine clearance in a intravenous pyelogram request).

The weight or height of the patient.

Relationships

— Specialisation: Each instance of *clinical investigation result item* is a specialisation of an instance of the more general class *clinical information item*.

Clinical investigation result items are one form of clinical information item.

— Part/Whole of: Each instance of *clinical investigation result item* may be a part of zero or one other instance of the same object.

A clinical investigation result item may form part of another more general clinical investigation result item.

— Whole/Part: Each instance of *clinical investigation result item* may consist of any number of other instances of the same object.

A clinical investigation result item may comprise other clinical investigation result items that provide more detailed information.

— Instance connection: Each instance of *clinical investigation result item* is associated with one instance of *clinical investigation*.

A clinical investigation result item is the result of a clinical investigation.

— Instance connection: Each instance of *clinical investigation result item* may be associated with any number of instances of *referenced study product*.

A clinical investigation result item may refer to referenced study products on which it was based.

Attributes:

<u>service type of clinical investigation result item</u>	Data Type: V
NOTE 1 To specify unambiguously the action to be performed with the information sent, e.g. when the status of the result has changed.	
NOTE 2 Two types of modification are distinguished by the service type. An extension adds further information but does not otherwise change previous information. A correction indicates that existing information is corrected or superseded by the supplied information.	
Examples: New, cancel, extend, correct.	
<u>identification of clinical investigation result item</u>	Data Type: S
Description: Identifier assigned to a clinical investigation result item.	
NOTE Users of clinical or diagnostic investigation systems may wish to identify an instance of a clinical investigation result item uniquely and unambiguously.	
<u>numerical measurement result</u>	Data Type: AG
NOTE This attribute group consists of the attributes arithmetic comparator, numerical value of a measurement result, unit of measurement result.	
> <u>arithmetic comparator</u>	Data Type: V
Examples: >, >=, =, <=, <.	
> <u>numerical value of a measurement result</u>	Data Type: R
Example(s): 140 when a result is 140 mmol/l.	
> <u>unit of measurement result</u>	Data Type: C/S
<u>uncertainty interval of a measurement result</u>	Data Type: AG
Description: Value range, not statistically based, defining a lower and upper limit between which a measurement result falls.	
NOTE 1 Is related to precision and detection limits, not to accuracy.	
NOTE 2 This attribute group consists of the attributes lower limit of uncertainty interval of a measurement value, upper limit of uncertainty interval of a measurement value and unit of uncertainty interval values.	
Example 1: 0 – 10 mg.	
> <u>lower limit of uncertainty interval of a measurement value</u>	Data Type: R
> <u>upper limit of uncertainty interval of a measurement value</u>	Data Type: R
> <u>unit of uncertain interval values</u>	Data Type: C/S
<u>date value of a clinical investigation result item</u>	Data Type: TOCD
Description: Value of result expressed as a date.	
Example(s): Estimated date of obstetric delivery.	
<u>text value of a clinical investigation result item</u>	Data Type: LC/S
Description: A result expressed using text or codes.	
NOTE In early implementations and according to specific interchange agreements this attribute may be used to carry in free style the entire clinical investigation result item value.	
<u>deviating result indicator</u>	Data Type: V
Description: Indicator of degree of deviation from reference values of a measurement result.	
<u>date and time of clinical investigation</u>	Data Type: TOCD
NOTE To indicate the date and time at which the clinical investigation was finished.	
<u>status of clinical investigation result item</u>	Data Type: V
Examples: Unverified, pending, new, intermediate, modified.	

L-comment to clinical investigation result item

Data Type: C/S

NOTE To cover any kind of free-style comment related to a clinical investigation result item.

L-reference limit

Data Type: AG

NOTE This attribute group consists of the attribute group numerical reference limit of quantity and of the attributes textual reference limit of quantity, reference population definition and type of reference interval.

> numerical reference limit of quantity

Data Type: AG

NOTE This attribute group consists of the attributes numerical value of lower reference limit of quantity, numerical value of upper reference limit of quantity and unit of numerical reference limit values.

» numerical value of lower reference limit of quantity

Data Type: R

Description: Value characterising the lower end of a cumulative number fraction distribution of values obtained from a well-defined population by statistical means.

NOTE It is often assumed that the lower reference limit is the 0.025-fractile for the distribution of a healthy population having other relevant properties matching those of the patient (sex, age, race).

» numerical value of upper reference limit of quantity

Data Type: R

Description: Value characterising the upper end of a cumulative number fraction distribution of values obtained from a well-defined population by statistical means.

» unit of numerical reference limit values

Data Type: C/S

> textual reference limit of quantity

Data Type: LC/S

NOTE A reference limit may be expressed as a string (e.g. "Between 10 and 20 %").

> reference population definition

Data Type: LC/S

NOTE To indicate the meaning of the reference limit.

Example(s): sex, age, race, smoker/non-smoker, clinical status.

> type of reference interval

Data Type: V

Examples: Therapeutic (in the case of drug-monitoring).

6.3.6 collected analysed object**Description**

An analysed object that has already been collected or acquired.

Relationships

— Specialisation: Each instance of *collected analysed object* is a specialisation of an instance of the more general class *analysed object*.

A collected analysed object is an analysed object that already exists.

— Generalisation: Each instance of *collected analysed object* exists as one of the following specialisations: *sample* or *study product*.

A collected analysed object may either be something taken from a patient (a sample) or recorded information derived from a diagnostic service performed on a patient (a study product).

Attributes:period of analysed object acquisition

Data Type: AG

> start date and time of acquisition

Data Type: TOCD

> end date and time of acquisition

Data Type: TOCD

duration of analysed object acquisition

Data Type: AG

> numerical value of duration

Data Type: R

> unit of duration

Data Type: V

6.3.7 contract authorisation**Description**

Information about authorisation pertaining to the provision of diagnostic services.

Relationships

— Instance connection: Each instance of *contract authorisation* is associated with one instance of *payment guarantor*.

contract authorisation is the responsibility of a payment guarantor.

Attributes:

<u>service agreement type</u>	Data Type: V
Description: Identification of the service agreement or contract type covering this diagnostic service.	
Examples: Private insurance, local health authority contract, employee scheme.	
<u>service agreement identification</u>	Data Type: C/S
Description: Identification of the service agreement or contract covering this diagnostic service	
<u>authorisation</u>	Data Type: AG
Description: Details of the authorisation to proceed with this diagnostic service	
> <u>date and time of authorisation</u>	Data Type: TOCD
> <u>authorisation number</u>	Data Type: S
Description: Identifier issued by the authoriser.	
> <u>valid until date/time</u>	Data Type: TOCD
Description: Date and time at which authorisation ceases.	
<u>comment to authorisation</u>	Data Type: C/S

6.3.8 copy destination

Description

Information about a party, other than the diagnostic service provider or diagnostic service requester, to which a copy of the diagnostic service request or report either is sent or should be sent.

Relationships

— Instance connection: Each instance of *copy destination* may be associated with any number of instances of *diagnostic service request*.

A healthcare party may be the copy destination for diagnostic service requests.

— Instance connection: Each instance of *copy destination* may be associated with any number of instances of *diagnostic service report*.

A healthcare party may be the copy destination for diagnostic service reports.

— Specialisation: Each instance of *copy destination* is a specialisation of an instance of the more general class *healthcare party role*.

Copy destination is type of a healthcare party role.

Attributes:

<u>L-role of copy destination</u>	Data Type: AG
> <u>message to which copy destination applies</u>	Data Type: C/S
Description: An indication of whether the copy destination applies to the current message or to a message which may be sent by the recipient of the message.	
NOTE 1 In the case of a diagnostic service request message, a copy destination may be a recipient of a copy of that diagnostic service request message or an intended recipient of a copy of a diagnostic service report or diagnostic service plan report relating to the requested diagnostic investigations.	
NOTE 2 In the case of a diagnostic service report or diagnostic service plan report message, a copy destination is usually a recipient of a copy of that diagnostic message.	
NOTE 3 In the case of cancellation messages the only valid value would be the current message and this attribute is therefore not applicable.	
Example 1: Request message, plan report message(s), report message(s), report message (final report only).	
> <u>intended communication method</u>	Data Type: C

Description: The method of communication by which the diagnostic service requester suggests or suggested a copy destination should be sent a copy of a message.

NOTE This is applicable to any instance of this attribute group other than those in cancellation messages.

Example(s): EDI, E-mail, Fax, post, via service requester, via service provider.

> actual communication method

Data Type: C

Description: The method of communication by which a copy destination was (or is being) sent a copy of a message.

NOTE This is applicable only in instances of the attribute group in which the message to which the copy destination applies is the current message.

Example(s): EDI, E-mail, Fax, post, via service requester, via service provider, none, failed.

6.3.9 diagnostic investigation

Description

Information about a healthcare examination which may be requested or reported using a message that falls within the scope of this European Prestandard (see 1.2). A diagnostic investigation leads to the production of one or more results which may contribute to an assessment of the patient on whom, or in relation to whom, it is performed.

NOTE 1 The information content of this object relates to the general case of an investigation rather than a specific instance of that investigation. This information can be viewed as being derived from a master file of possible diagnostic investigations.

NOTE 2 A diagnostic investigation may be indicated by the terms the requester uses when making a request, or by the terms used by the diagnostic service provider to refer to an investigation or to actions undertaken while performing an investigation.

NOTE 3 A diagnostic investigation may be subdivided into several separate constituent investigations. Each constituent investigation is also considered as a diagnostic investigation (e.g. examination of a biopsy may include macroscopic and microscopic examinations and the microscopic examination may apply to several separate sections of the sample possibly using different staining techniques).

Purpose

To carry the diagnostic investigation related information that must be shared between a diagnostic service provider and a diagnostic service requester. It is to be considered as one component of the central specification or catalogue of diagnostic investigations that can be ordered or reported upon.

Example(s):

Chest X-ray, erect abdominal X-ray, intravenous pyelogram, obstetric ultrasound, CT scan, electrocardiography, lung function tests, cervical cytology, endoscopy, post-mortem examination of a body, post mortem examination of a particular organ, examination of a biopsy, microscopic examination of a particular section taken from a biopsy and stained in a particular way, interpretation of the results of a histological examination, interpretation of the change in the appearance of an opacity on a series of X-ray films.

Relationships

— Instance connection: Each instance of *diagnostic investigation* may be associated with any number of instances of *requested diagnostic investigation*.

A diagnostic investigation defines the nature of investigations requested by requested diagnostic investigations.

— Instance connection: Each instance of *diagnostic investigation* may be associated with any number of instances of *diagnostic investigation result item*.

A diagnostic investigation defines the nature of the investigations reported by diagnostic investigation result items.

— Instance connection: Each instance of *diagnostic investigation* may be associated with any number of instances of *diagnostic investigation plan item*.

A diagnostic investigation defines the nature of the investigation planned by diagnostic investigation plan items.

Attributes:identification of diagnostic investigation

Data Type: C/S

Description: A unique identifier of a particular diagnostic investigation.

NOTE 1 This single attribute may be sufficient to identify the required, planned or reported diagnostic investigation if it can be unambiguously identified using a coding scheme, terminology or catalogue shared by the diagnostic service requester and diagnostic service provider.

NOTE 2 Alternatively a diagnostic investigation may be specified using one of the following three attribute groups: diagnostic study, observable property or measurable quantity.

Example 1: A chest X-ray, an electrocardiograph, interpretation of an X-ray, an anatomic pathological examination of a biopsy.

diagnostic study

Data Type: AG

Description: A structured representation of a procedure carried out as a part of a diagnostic service which, when performed, may result in several observations or properties or measurements of quantities but which cannot be uniquely associated with a single such observation or measurement.

NOTE 1 This attribute group may be used if the same type of study may be applied many different samples, organs or body structures (e.g. plain X-rays, of limbs or parts of limbs, anatomic pathological examinations, etc.).

NOTE 2 If identification of diagnostic investigation is not present one and only one of the following attribute groups must be present in each instance of the diagnostic investigation object: diagnostic study, observable property, measurable quantity.

Example 1: A chest X-ray, in systematic notation: "Chest; X-ray".

> system

Data Type: C/S

Description: Demarcated arrangement of a set of components and a set of relationships between these components.

NOTE 1 See ENV 1614.

NOTE 2 The component parts of a system and therefore the system itself may be subjected to a diagnostic study.

NOTE 3 A system which contains other systems (sub-systems) may be referred to as a "super-system" of those systems.

Example 1: Examples of systems relevant to diagnostic services are: a man, an organ or anatomical structure, a biopsy sample, an anatomic pathological section, an electrocardiograph tracing, an X-ray image.

> study type

Data Type: C/S

Description: Nature of a study carried out on the specified system.

Example(s): Plain X-ray, anatomic pathological examination.

observable property

Data Type: AG

Description: A structured representation of an attribute of a phenomenon, body or substance that may be distinguished qualitatively and subjected to observation.

NOTE If identification of diagnostic investigation is not present one and only one of the following attribute groups must be present in each instance of the diagnostic investigation object: diagnostic study, observable property, measurable quantity.

Example(s): The colour of a biopsy sample, in systematic notation: e.g. ECG; T-wave; inverted.

> System

Data Type: C/S

Description: Demarcated arrangement of a set of components and a set of relationships between these components.

NOTE 1 See ENV 1614.

NOTE 2 The component parts of a system and therefore the system itself may have observable properties.

NOTE 3 A system which contains other systems (sub-systems) may be referred to as a "super-system" of those systems.

Example 1: Examples of systems relevant to diagnostic services are: a man, an organ or anatomical structure, a biopsy sample, an anatomic pathological section, an electrocardiograph tracing, an X-ray image.

> component

Data Type: C/S

Description: Definable part of a system.

NOTE See ENV 1614.

Example(s): Pathological cells in a biopsy from an organ, the shape of the T-wave in a part of an ECG, bone density in part of an X-ray image.

> property

Data Type: C/S

Description: Nature of a set of observable properties necessary for arranging their values on a scale.

NOTE 1 See ENV 1614.

NOTE 2 Authoritative lists of properties are issued by ISO (in ISO 31), IFCC, and IUPAC.

Example 1: Length, colour, mass, transparency.

measurable quantity

Data Type: AG

Description: A structured representation of an attribute of a phenomenon, body or substance that may be distinguished qualitatively and determined quantitatively.

NOTE 1 Measurable quantity is a subordinate concept to observable property.

NOTE 2 If identification of diagnostic investigation is not present one and only one of the following attribute groups must be present in each instance of the diagnostic investigation object: diagnostic study, observable property, measurable quantity.

Example 1: Foetal biparietal diameter in systematic notation: Foetus; head; diameter; measured by ultra sound; biparietal diameter.

> system

Data Type: C/S

Description: Demarcated arrangement of a set of components and a set of relationships between these components.

NOTE 1 See ENV 1614.

NOTE 2 The component parts of a system and therefore the system itself may have measurable quantities.

NOTE 3 A system which contains other systems (sub-systems) may be referred to as a "super-system" of those systems.

Example 1: Examples of systems relevant to diagnostic services are: a man, an organ or anatomical structure, a biopsy sample, an anatomic pathological section, an electrocardiograph tracing, an X-ray image.

> component

Data Type: C/S

Description: Definable part of a system.

NOTE See ENV 1614.

Example(s): Number of pathological cells in a biopsy from an organ, the length of the Q-Q interval in a part of an ECG, the biparietal diameter of a foetus in an ultrasound image.

> quantity

Data Type: C/S

Description: Nature of a set of measurable quantities necessary for arranging their values on a scale according to magnitude.

NOTE 1 Authoritative lists of quantities are issued by ISO (in ISO 31), International Federation of Clinical Chemistry (IFCC) and International Union of Pure and Applied Chemistry (IUPAC).

NOTE 2 This concept was formerly called "kind-of-quantity" by IFCC/IUPAC.

Example 1: Length, pressure, voltage (e.g. on an electrocardiograph), volume, flow rate.

> principle of measurement

Data Type: C/S

Description: Scientific basis of a measurement.

Example(s): Thermoelectric effect applied to the measurement of temperature.

> method of measurement

Data Type: C/S

Description: Logical sequence of operations, described generically, used in the performance of measurements.

> measurement procedure

Data Type: C/S

Description: Set of operations, described specifically, used in the performance of particular measurements according to a given method of measurement.

NOTE A measurement procedure is usually sufficiently detailed to enable an operator (or team of operators) to carry out a measurement without significant additional information; terms such as method of measurement, assay and test are not synonyms of measurement procedure.

> measuring equipment

Data Type: C/S

Description: Complete set of measuring instruments and other equipment including any reagents assembled to carry out specified measurements.

L-specifications to diagnostic investigation

Data Type: C/S

Description: Coded or plain text description of information complementary to a diagnostic investigation.

NOTE See ENV 1614.

Example(s): Specification that a measurement was made using a particular procedure and/or reference.

without interpretation

Data Type: B

Description: An indication of an diagnostic investigation in which the analysed object is produced without an interpretation made by the diagnostic service provider.

NOTE If this attribute is true any associated diagnostic investigation result item simply reports that the procedure was carried out and refers the recipient to the analysed object(s) produced.

Examples: A “chest X-ray — without interpretation” is a diagnostic investigation that provides a requester with a film which he/she may then read and interpret. A “chest X-ray with interpretation” is a more complete diagnostic investigation in which the requester receives a report of the X-ray including an interpretation by a radiologist.

interpretation only

Data Type: B

Description: An indication of an diagnostic investigation in which an existing analysed object obtained previously is interpreted.

NOTE If this attribute is true a new study is not carried out on the patient and any associated requested diagnostic investigation must be related to at least one analysed object.

Examples: Interpretation of existing an chest X-ray is considered as a diagnostic investigation although the patient is not actually X-rayed to undertake it.

L-diagnostic investigation cost

Data Type: AG

NOTE The diagnostic investigation cost is related to the cost of having performed the diagnostic investigation. It may be used to convey the “attributable cost”.

> monetary detail of investigation cost

Data Type: CAG(m)

NOTE This common attribute group is detailed in 6.4.4.

L-comment to diagnostic investigation

Data Type: C/S

6.3.10 diagnostic investigation plan item

Description

Information about a plan made by a diagnostic service provider to undertake or decline to undertake a single diagnostic investigation on a patient or on behalf of a patient.

NOTE 1 A diagnostic service provider may: accept, reject, schedule, postpone, reschedule, cancel or complete, a diagnostic service investigation requested by a diagnostic service requester.

NOTE 2 A diagnostic service provider may: propose, schedule, postpone, reschedule, cancel or complete, a diagnostic service investigation that has not been explicitly requested by a diagnostic service requester.

NOTE 3 Instructions for preparations to be carried out by the diagnostic service requester may be included in a diagnostic service plan.

Relationships

— Part/Whole of: Each instance of *diagnostic investigation plan item* is a part of one instance of *diagnostic service report*.

Diagnostic investigation plan items report plans for individual investigations in a diagnostic service report.

— Instance connection: Each instance of *diagnostic investigation plan item* may be associated with any number of instances of *related diagnostic service provider*.

Diagnostic investigation plan items may note the intended roles of related diagnostic service providers in undertaking planned investigations.

— Instance connection: Each instance of *diagnostic investigation plan item* is associated with one instance of *diagnostic investigation*.

A diagnostic investigation plan item is the plan for undertaking a specified diagnostic investigation.

— Instance connection: Each instance of *diagnostic investigation plan item* may be associated with any number of instances of *analysed object*.

A diagnostic investigation plan item may include information about the intention to collect and/or report on analysed objects.

Attributes:

service type of diagnostic investigation plan item

Data Type: V

Description: The action required to process information included in the message.

NOTE 1 This attribute is used to specify unambiguously the action to be performed with the information sent. In the case of a new diagnostic service report, the only value allowed is new.

NOTE 2 Two types of modification are distinguished by the service type. An extension adds further information but does not otherwise change previous information. A correction indicates that existing information is corrected or superseded by the supplied information.

Examples: New, cancel, extend, correct.

identification of diagnostic investigation plan item

Data Type: S

Description: Identifier assigned to a diagnostic investigation plan item.

NOTE 1 Users of clinical or diagnostic service department information systems may wish to identify an instance of a diagnostic investigation plan item uniquely and unambiguously.

NOTE 2 A unique reference must be given to a plan item when it is first produced if a subsequent correction is to be undertaken successfully at the receiver's application.

planning stage

Data Type: C

Description: The stage that has been reached in planning the delivery of this diagnostic investigation.

Example(s): Accepted, proposed, scheduled, completed, rejected, postponed, cancelled.

status of plan

Data Type: V

Examples: interim, confirmed.

comment on plan status

Data Type: C/S

Description: A note of any conditions on which an plan is dependent.

Example(s): An abdominal radiological investigation may be planned for a particular date but this may depend on the patient's menstrual cycle.

date and time of planning

Data Type: TOCD

Description: The date and time at which the planning stage indicated was reached by the diagnostic service provider.

Example(s): The date on which a request was accepted, the date on which an appointment was made.

planned date and time

Data Type: TOCD

Description: The date and time on which the diagnostic service provider plans to undertake the diagnostic investigation.

NOTE In the case of a change to the planned date this attribute contains the new planned date and time.

expected delay before diagnostic service

Data Type: AG

> numeric value of expected delay

Data Type: I

NOTE The delay is based on the date and time of planning or if this is absent the date and time of issue of the diagnostic/specialist service report. This is especially relevant if the report is a modification as the report issue date may have changed but the date upon which the expected delay is based may be unchanged.

> unit of expected delay

Data Type: V

Examples: days, weeks, months, years.

planned investigation location

Data Type: CAG(lo)

Description: The place where the diagnostic service provider plans to carry out the investigation.

NOTE This common attribute group is detailed in 6.4.3.

Example(s): The radiology department, a particular ward or sub-department.

L-patient preparation instructions

Data Type: C/S

Description: Instructions from the diagnostic service provider about preparation of the patient to be carried out by or on behalf of the diagnostic service requester.

Example(s): Low fibre diet for two days followed by normal bowel prep protocol.

request for additional information

Data Type: S

Description: A request from the diagnostic service provider for further information about the patient to be provided by the diagnostic service requester.

Example(s): Please provide further information about the patient's renal function.

L-patient advice instructions

Data Type: S

Description: Advice from the diagnostic service provider to the patient.

Example(s): Do not eat for 12 hours before the investigation.

advice sent direct to patient

Data Type: B

Description: An indicator that the patient advice instructions either have or have not been sent directly to the patient by the diagnostic service provider

NOTE If the patient advice instructions are present and advice sent direct to patient is false the diagnostic service requester is responsible for instructing the patient appropriately.

L-administrative outcome

Data Type: C/S

Description: Information relevant to further action.

NOTE If a request that is rejected or a planned investigation is postponed there may be further plans (e.g. a new appointment may be issued automatically or only on further request). The reason for postponement may impact future plans (e.g. non attendance for the appointment, admission or death of the patient).

Example(s): Patient did not attend appointment, patient died, another appointment given, open appointment, appointment to be given at a later date, no further arrangements will be made.

L-comment to diagnostic investigation plan item

Data Type: C/S

NOTE 1 To cover any kind of free-style comment relating to the diagnostic investigation plan item.

NOTE 2 This should not be used for instructions to the requester as these should be included in the attribute patient preparation instructions and/or patient advice instructions.

patient transport arrangements

Data Type: CAG(tr)

Description: Arrangements made or to be made to transport the patient to and from the planned diagnostic service.

NOTE This common attribute group is detailed in 6.4.5.

6.3.11 diagnostic investigation result item**Description**

Information that forms the result of a single diagnostic investigation undertaken on a specified patient.

NOTE 1 A diagnostic investigation result item may be subdivided into several constituent diagnostic investigation result items. Therefore, a diagnostic investigation result item may include the overall result of a diagnostic investigation comprising several constituent investigations or the results of one of the constituent investigations.

NOTE 2 A diagnostic investigation result item comprises one or more of: a numeric, textual or coded representation of a result. It also includes additional data that is essential to the interpretation of the result including: the status of the result, relevant dates and times, units of measurement and designation of the coding scheme from which code values in the result item are derived.

NOTE 3 The diagnostic investigation result item is used only for conveying results that are the subject of the current report. When the results of previous diagnostic investigations are carried in a request message, they should be represented as clinical investigation result items.

Relationships

— Part/Whole of: Each instance of *diagnostic investigation result item* is a part of one instance of *diagnostic service report*.

Diagnostic investigation result items contain the results of individual investigations that are grouped together in a diagnostic service report.

— Instance connection: Each instance of *diagnostic investigation result item* may be associated with any number of instances of *analysed object*.

Diagnostic investigation result items may indicate the analysed objects from which the results were derived.

— Instance connection: Each instance of *diagnostic investigation result item* is associated with one instance of *diagnostic investigation*.

A diagnostic investigation result item is the result of a specified diagnostic investigation.

— Instance connection: Each instance of *diagnostic investigation result item* may be associated with any number of instances of *related diagnostic service provider*.

A diagnostic investigation result item may be produced by or endorsed by specified related diagnostic service providers.

— Part/Whole of: Each instance of *diagnostic investigation result item* may be a part of zero or one other instance of the same object.

Diagnostic investigation result items may form part of another more general diagnostic investigation result item.

— Whole/Part: Each instance of *diagnostic investigation result item* may consist of any number of other instances of the same object.

A diagnostic investigation result item may comprise other diagnostic investigation result items that provide more detailed information.

Attributes:

service type of diagnostic investigation result item

Data Type: V

Description: The action required to process information included in the message.

NOTE 1 This attribute is used to specify unambiguously the action to be performed with the information sent. In the case of a new diagnostic service report, the only value allowed is new. In the case of a diagnostic service report cancellation the diagnostic investigation result item object is not applicable.

NOTE 2 Two types of modification are distinguished by the service type. An extension adds further information but does not otherwise change previous information. A correction indicates that existing information is corrected or superseded by the supplied information.

Examples: New, cancel, extend, correct (e.g. when a corrected result value is sent), add addendum (e.g. when a supplementary comment or qualification is added to a result).

identification of diagnostic investigation result item

Data Type: S

Description: Identifier assigned to a diagnostic investigation result item.

NOTE 1 Users of clinical or diagnostic service department information systems may wish to identify an instance of a diagnostic investigation result item uniquely and unambiguously.

NOTE 2 A unique reference must be given to a result item when it is first produced if a subsequent correction is to be undertaken successfully at the receiver's application.

numerical measurement result

Data Type: AG

NOTE This attribute group consists of the attributes arithmetic comparator, numerical value of a measurement result, unit of measurement.

> arithmetic comparator

Data Type: V

NOTE Used to indicate that a measurement is greater than or less than a specified value (e.g. a measurement is outside the ranges that can be accurately measured by the procedure applied.)

Examples: >, >=, =, <=, <.

> numerical value of a measurement result

Data Type: R

Example(s): "140", when a result is 140 mmol/l.

> unit of measurement result

Data Type: CS

Example(s): “mmol/l”, when a result is 140 mmol/l.

> uncertainty interval of a measurement result

Data Type: AG

Description: Value range, not statistically based, defining a lower and upper limit between which a measurement result falls.

NOTE 1 Is related to precision and detection limits, not to accuracy.

NOTE 2 This attribute group consists of the attributes lower limit of uncertainty interval of a measurement value, upper limit of uncertainty interval of a measurement value and unit of uncertainty interval values.

Example 1: 0 – 10 mg.

» lower limit of uncertainty interval of a measurement value

Data Type: R

» upper limit of uncertainty interval of a measurement value

Data Type: R

» unit of uncertainty interval values

Data Type: C/S

Description: Chosen reference quantity that may be used in comparing magnitudes of quantities of the same kind.

date value of a diagnostic investigation result item

Data Type: TOCD

Description: Value of result expressed as a date.

Example(s): Estimated date of obstetric delivery.

L-text expression of a diagnostic investigation result item

Data Type: AG

Description: A result expressed in text.

> heading of diagnostic investigation of result item

Data Type: C/S

Description: A heading for a section of text.

NOTE This attribute provides an optional heading for one or more paragraphs of text or code values that comprise an instance of the “text expression of a diagnostic investigation result item” attribute group.

Example(s): Macroscopic appearance, microscopic appearance, interpretation.

> L-text value of diagnostic investigation result item

Data Type: LC+S

Description: A result expressed using text or codes.

NOTE Each instance of this attribute in the “text expression of a diagnostic investigation result item” attribute group represents a paragraph of text.

deviating result indicator

Data Type: V

Description: Indicator of degree of deviation from reference values of a measurement result.

date and time of diagnostic investigation

Data Type: TOCD

Description: The date and time of the reported investigation.

NOTE 1 This is the time that the patient was subjected to the investigation rather than the time at which the result for obtained or reported.

NOTE 2 In the case of an investigation that is conducted over a period of time further information can be included in associated instances of analysed object and/or procedure step.

status of diagnostic investigation result item

Data Type: V

Description: The status of the investigation and/or report.

Examples: Unverified, pending, new, intermediate, modified, final report.

date and time of diagnostic investigation result item status change

Data Type: TOCD

NOTE To indicate the date and time at which the status of a result or of an investigation changed to its communicated status.

comment to diagnostic investigation result item

Data Type: C/S

NOTE To cover any kind of free-style comment related to a diagnostic investigation result item.

Example(s): Not completed due to reaction to X-ray contrast medium.

L-reference limit

Data Type: AG

NOTE This attribute group consists of the attribute group numerical reference limit of quantity and of the attributes textual reference limit of quantity, reference population definition and type of reference interval.

> numerical reference limit of quantity

Data Type: AG

NOTE This attribute group consists of the attributes numerical value of lower reference limit of quantity, numerical value of upper reference limit of quantity and unit of numerical reference limit values.

» numerical value of lower reference limit of quantity

Data Type: R

Description: Value characterising the lower end of a cumulative number fraction distribution of values obtained from a well-defined population by statistical means.

NOTE It is often assumed that the lower reference limit is the 0.025-fractile for the distribution of a healthy population having other relevant properties matching those of the patient (sex, age, race).

» numerical value of upper reference limit of quantity

Data Type: R

Description: Value characterising the upper end of a cumulative number fraction distribution of values obtained from a well-defined population by statistical means.

» unit of numerical reference limit values

Data Type: C/S

> textual reference limit of quantity

Data Type: LC/S

NOTE A reference limit may be expressed as text (e.g. "Between 10 and 20 %").

> reference population definition

Data Type: LC/S

NOTE To indicate the meaning of the reference limit.

Example(s): sex, age, race, smoker/non-smoker, clinical status.

> type of reference interval

Data Type: V

Examples: Therapeutic (in the case of drug-monitoring).

6.3.12 diagnostic service provider

Description

Information about an authorised healthcare party qualified to perform diagnostic services and to validate the resulting diagnostic service report.

Relationships

— Instance connection: Each instance of *diagnostic service provider* may be associated with any number of instances of *diagnostic service request*.

A diagnostic service provider may receive diagnostic service requests.

— Instance connection: Each instance of *diagnostic service provider* may be associated with any number of instances of *diagnostic service report*.

A diagnostic service provider may issue diagnostic service reports.

— Specialisation: Each instance of *diagnostic service provider* is a specialisation of an instance of the more general class *healthcare party role*.

Diagnostic service provider is a type of *healthcare party role*.

Attributes:

Objects of this class has no specific attributes. Their attributes are those of healthcare party

6.3.13 diagnostic service report

Description

Information about a set of one or more diagnostic investigation result items or diagnostic investigation plan items pertaining to one patient.

Purpose

To represent a single diagnostic service report, as it is issued by a diagnostic service provider. The object covers also the specific cases of diagnostic service reports (e.g. result modification). Each instance of a diagnostic service report carries the information common to a group of diagnostic investigation result items or diagnostic investigation plan items reported at the same moment.

Relationships

— Instance connection: Each instance of *diagnostic service report* may be associated with any number of instances of *diagnostic service request*.

- A diagnostic service report may be a response to diagnostic service requests.
- Instance connection: Each instance of *diagnostic service report* is associated with one instance of *diagnostic service requester*.
- A diagnostic service report is sent to a diagnostic service requester.
- Instance connection: Each instance of *diagnostic service report* is associated with one instance of *diagnostic service provider*.
- A diagnostic service report is issued by a diagnostic service provider.
- Instance connection: Each instance of *diagnostic service report* may be associated with any number of instances of *related diagnostic service provider*.
- A diagnostic service report may be produced or endorsed by specified related diagnostic service providers.
- Instance connection: Each instance of *diagnostic service report* may be associated with any number of instances of *copy destination*.
- A diagnostic service report may be copied to other healthcare parties (copy destinations).
- Instance connection: Each instance of *diagnostic service report* is associated with one instance of *patient*.
- A diagnostic service report applies to one patient.
- Instance connection: Each instance of *diagnostic service report* may be associated with any number of instances of *payment guarantor*.
- A diagnostic service report may indicate the person(s) or organisation(s) who are responsible for payment for (and/or who authorised) the reported investigations (payment guarantor).
- Whole/Part: Each instance of *diagnostic service report* may consist of any number of instances of *diagnostic investigation result item*.
- A diagnostic service report may include the results of several investigations (diagnostic investigation result items).
- Whole/Part: Each instance of *diagnostic service report* may consist of any number of instances of *diagnostic investigation plan item*.
- A diagnostic service report may include information about plans for several investigations (diagnostic investigation plan items).

Attributes:

- | | |
|---|-----------------|
| <u>service type of diagnostic service report</u> | Data Type: V |
| Description: This attribute identifies the diagnostic service report as a whole as being a new report, or a modification or cancellation of a previous report. | |
| NOTE Two types of modification are distinguished by the service type. An extension adds further information but does not otherwise change previous information. A correction indicates that existing information is corrected or superseded by the supplied information. | |
| Examples: New, extend, correct, cancel. | |
| <u>identification of diagnostic service report by diagnostic service provider</u> | Data Type: S |
| Description: Identifier assigned by a diagnostic service provider to a diagnostic service report. | |
| NOTE This identifier must be globally unique across all messages originating from a particular diagnostic service provider. The diagnostic service provider should not assign the same identifier to any other message that conforms with a European Standard or European Prestandard promulgated by CEN Technical Committee 251 Medical Informatics. | |
| <u>issue date and time of diagnostic service report</u> | Data Type: TOCD |
| Description: The date on which this report was issued by the diagnostic service provider. | |
| <u>authorisation date and time of diagnostic service report</u> | Data Type: TOCD |
| NOTE There is often a difference between the date on which a report is issued and the date on which it was authorised by the service provider. If a report is dictated it may be issued in an unauthorised form before it has been formally endorsed by the responsible healthcare professional. | |

status of diagnostic service report

Data Type: V

Description: The values of this attribute can be used to indicate the status of the report as a whole, particularly as regards its degree of completeness. Used together with the service type of diagnostic service report and the service type of diagnostic service provider investigation result item, it will facilitate the post-processing of reports by the diagnostic service report receiving information system.

Examples: Partial report, supplementary report, final supplementary report, complete report, cumulative report, order received by diagnostic service provider, order being worked on.

urgency of diagnostic service report

Data Type: V

Description: Indication by the diagnostic service provider of the urgency with which the receiver should examine and consider the report.

NOTE This information may allow a receiving system to draw some reports to the special attention of users.

Examples: High priority, medium priority, low priority.

report receipt acknowledgement request

Data Type: B

Description: Indication of whether or not the issuer of a report requests acknowledgement of the report receipt by the recipient.

L-diagnostic service provider's comment

Data Type: C/S

Description: Comment from the diagnostic service provider that cannot be expressed by any other existing attribute.

report language

Data Type: V

Description: The language in which the diagnostic service report is expressed.

NOTE Represented by the abbreviations specified in ISO 639.

reference to diagnostic service report to be modified or cancelled

Data Type: AG

Description: Reference to a previous diagnostic service report which this message is modifying or cancelling.

NOTE This attribute group consists of the attributes identification of original diagnostic service report by diagnostic service provider and issue date and time of original diagnostic service report.

> identification of original diagnostic service report by diagnostic service provider Data Type: S

Description: Identifier assigned by a diagnostic service provider to a diagnostic service report which is to be modified or cancelled.

> issue date and time of original diagnostic service report

Data Type: TOCD

Description: Issue date and time of the diagnostic service report which is to be modified or cancelled.

L-reference to another diagnostic service report

Data Type: AG

Description: Reference to another diagnostic service report which contains information relevant to the current diagnostic service report.

NOTE This attribute group consists of the attributes identification by diagnostic service provider of referenced diagnostic service report and issue date and time of referenced diagnostic service report.

> identification by diagnostic service provider of referenced diagnostic service report

Data Type: S

Description: Identifier assigned by a diagnostic service provider to a diagnostic service report to which reference is being made.

> issue date and time of referenced diagnostic service report

Data Type: TOCD

reason for cancellation

Data Type: C/S

Description: Reason for the cancellation of the report.

6.3.14 *diagnostic service request*

Description

Information about a set of one or more requested diagnostic investigations submitted to a diagnostic service provider, pertaining to one patient.

Purpose

To represent a single diagnostic service request, as issued by a diagnostic service requester. The object covers the specific service types of diagnostic service requests (new diagnostic service requests, diagnostic service request modifications, diagnostic service request cancellations). Each instance of a diagnostic service request carries the information common to a (group of) requested diagnostic investigation(s), ordered, changed or cancelled at the same moment.

Relationships

— Instance connection: Each instance of *diagnostic service request* is associated with one instance of *diagnostic service requester*.

A diagnostic service request is issued by a diagnostic service requester.

— Instance connection: Each instance of *diagnostic service request* is associated with one instance of *diagnostic service provider*.

A diagnostic service request is submitted to a diagnostic service provider.

— Instance connection: Each instance of *diagnostic service request* may be associated with any number of instances of *copy destination*.

A diagnostic service request may be copied to other healthcare parties (copy destinations) and/or may indicate that responses to the request are to be copied to other healthcare parties (copy destinations).

— Instance connection: Each instance of *diagnostic service request* may be associated with any number of instances of *diagnostic service report*.

A diagnostic service request may lead to diagnostic service reports.

— Instance connection: Each instance of *diagnostic service request* is associated with one instance of *patient*.

A diagnostic service request relates to one patient.

— Whole/Part: Each instance of *diagnostic service request* may consist of any number of instances of *requested diagnostic investigation*.

A diagnostic service request may include requests for individual investigations (requested diagnostic investigations).

— Instance connection: Each instance of *diagnostic service request* may be associated with any number of instances of *payment guarantor*.

A diagnostic service request may indicate the person(s) or organisation(s) who are responsible for payment for (and/or who have authorised) the requested investigations (payment guarantor).

Attributes:

service type of diagnostic service request

Data Type: V

Description: This attribute identifies the diagnostic service request as a whole as being a new order, or a modification or cancellation of a previous order.

NOTE Two types of modification are distinguished by the service type. An extension adds further information but does not otherwise change previous information. A correction indicates that existing information is corrected or superseded by the supplied information.

Examples: New, extend, correct, cancel.

identification of diagnostic service request by diagnostic service requester

Data Type: S

Description: identifier assigned by a service requester to a diagnostic service request.

NOTE This identifier must be globally unique across all messages originating from a particular diagnostic service requester. The diagnostic service requester should not assign the same identifier to any other message that conforms with a European Standard or European Prestandard promulgated by CEN Technical Committee 251 Medical Informatics.

identification of diagnostic service request by diagnostic service provider

Data Type: S

Description: identifier assigned by a service provider to a diagnostic service request. <u>issue date and time of diagnostic service request</u>	Data Type: TOCD
Description: Date and time at which a diagnostic service request is completed within the requesting information system. NOTE This is not the date/time at which the order is dispatched to the Message Handling Service or network service provider.	
<u>date and time of receipt of diagnostic service request</u> Description: Date and time at which a diagnostic service request is received by a diagnostic service provider.	Data Type: TOCD
NOTE This can be important in case of delay. <u>due date and time of diagnostic service report</u> Description: Date and time at which a diagnostic service report should be produced by the diagnostic service provider as indicated by the diagnostic service requester.	Data Type: TOCD
<u>reporting priority of diagnostic service request</u> Description: Priority of the reporting of results as indicated by a requester in a diagnostic service request. Examples: Results should be reported immediately (e.g. via telephone).	Data Type: V
<u>commenting level of detail of diagnostic service report</u> Description: Level of detail that the requester wishes to receive in the diagnostic service provider's comments upon the diagnostic service report. Examples: Full and detailed, brief, none.	Data Type: V
<u>payment category</u> Description: Indication on how the cost for the healthcare services is being paid for in the context of the diagnostic service request.	Data Type: C
<u>L-availability of patient</u> Description: Dates or times when the patient is or is not available for the requested diagnostic service. Example(s): Not available during August, would prefer an appointment on a Tuesday afternoon.	Data Type: S
<u>patient notification method</u> Description: The way in which the patient is to be notified that they should attend for the diagnostic service at a particular time and place. Example(s): Phone call to ward, message via requester, mail or phone message direct to patient.	Data Type: S
<u>L-reason for diagnostic service request</u> Description: Clinical information indicating the rationale for ordering given diagnostic service provider investigation(s). NOTE Non-clinical information is conveyed in diagnostic service requester's comments. Example(s): Suspected anaemia, antenatal risk assessment, recent infection, immunity status, return from malarious area.	Data Type: C+S
<u>L-diagnostic service requester's comment</u> Description: Any comment from a diagnostic service requester which is not the reason for request of the diagnostic service request.	Data Type: C/S
<u>reason for cancellation</u> Description: Reason for the cancellation of the request. NOTE This attribute is only concerned with the cancellation of a previously issued request, not the requesting that an instance of a diagnostic investigation be cancelled or deferred	Data Type: C/S
<u>diagnostic service request receipt acknowledgement request</u> Description: Indication of whether or not the issuer of a diagnostic service request requests acknowledgement of the order receipt by the recipient.	Data Type: B
<u>requester to receive report indicator</u>	Data Type: B

Description: An indication of whether the requester wishes to receive the report of the requested services.

NOTE It is generally assumed that the requester requires a report of any services that they request. However, this indicator can be used to indicate that they do not require a copy. In this situation the order message will usually specify at least one "copy destination" to whom the report should be sent. This may be useful when a diagnostic service is requested immediately before an arranged transfer of the patient to the care of another healthcare party.

reporting language requested

Data Type: V

Description: Language in which the result should be expressed.

NOTE Represented by the abbreviations specified in ISO 639.

language of diagnostic service request

Data Type: V

Description: The language in which the diagnostic service request is expressed.

NOTE Represented by the abbreviations specified in ISO 639.

reference to diagnostic service request to be modified or cancelled

Data Type: AG

Description: Reference to a previous diagnostic service request which this message is modifying or cancelling.

NOTE This attribute group consists of the attributes identification of original diagnostic service request by diagnostic service requester, identification of original diagnostic service request by diagnostic service provider and issue date and time of original diagnostic service request.

> identification of original diagnostic service request by diagnostic service requester

Data Type: S

Description: Identifier assigned by a diagnostic service requester to a diagnostic service request which is to be modified or cancelled.

> identification of original diagnostic service request by diagnostic service provider

Data Type: S

Description: Identifier assigned by a diagnostic service provider to a diagnostic service request which is to be modified or cancelled.

> issue date and time of original diagnostic service request

Data Type: TOCD

Description: Issue date and time of the diagnostic service request which is to be modified or cancelled.

L-reference to another diagnostic service request

Data Type: AG

Description: Reference to a previous diagnostic service request which has relevance to the diagnostic service request currently being requested/reported on.

NOTE 1 A requester may wish to make reference to an earlier diagnostic service request for the same individual or a reporter may wish to indicate another diagnostic service request to which the diagnostic service report relates.

NOTE 2 This attribute group consists of the attributes identification of referenced diagnostic service request by diagnostic service requester, identification of referenced diagnostic service request by diagnostic service provider and issue date and time of referenced diagnostic service request.

> identification of referenced diagnostic service request by diagnostic service requester

Data Type: S

Description: Identifier assigned by a diagnostic service requester to a diagnostic service request to which reference is being made.

> identification of referenced diagnostic service request by diagnostic service provider

Data Type: S

Description: Identifier assigned by a diagnostic service provider to a diagnostic service request to which reference is being made.

> issue date and time of referenced diagnostic service request

Data Type: TOCD

L-reference to another diagnostic service report

Data Type: AG

Description: Reference to a previous diagnostic service report which has relevance to the diagnostic service request currently being requested/reported on.

NOTE 1 A requester may wish to make reference to an earlier diagnostic service report for the same individual.

NOTE 2 This attribute group consists of the attributes identification of referenced diagnostic service report by diagnostic service provider and issue date and time of referenced diagnostic service report.

> identification of referenced diagnostic service report by diagnostic service provider Data Type: S

Description: Identifier assigned by a diagnostic service provider to a diagnostic service report to which reference is being made.

> issue date and time of referenced diagnostic service report Data Type: TOCD

number of objects to be analysed accompanying a diagnostic service request Data Type: I

patient transport arrangements Data Type: CAG(tr)

NOTE This common attribute group is detailed in 6.4.5.

6.3.15 diagnostic service requester

Description

Information about an authorised healthcare party issuing a diagnostic service request.

Relationships

— Instance connection: Each instance of *diagnostic service requester* may be associated with any number of instances of *diagnostic service request*.

A diagnostic service requester may issue diagnostic service requests.

— Instance connection: Each instance of *diagnostic service requester* may be associated with any number of instances of *diagnostic service report*.

A diagnostic service requester may receive diagnostic service reports.

— Specialisation: Each instance of *diagnostic service requester* is a specialisation of an instance of the more general class *healthcare party role*.

Diagnostic service requester is a type of healthcare party role.

Attributes:

— Objects of this class has no specific attributes. Their attributes are those of healthcare party

6.3.16 drug treatment

Description

Information about a patient's previous, planned or current treatment with a substance or chemical compound for the prevention, alleviation or treatment of a medical condition.

NOTE 1 This differs from procedure step where the specific intention is to administer the drug or undertake a procedure for diagnostic purposes prior to or as part of a diagnostic investigation. Drug treatment may influence the results and/or interpretations of diagnostic investigations; this includes those drugs whose administration is being monitored by measurement of drug levels; may include "presentation" (e.g. tablets, capsules, injection, inhaler, syrup) as well as the drug itself.

NOTE 2 This should not be used for conveying prescriptions or treatment instructions as this is outside the scope of this European Prestandard.

Relationships

— Specialisation: Each instance of *drug treatment* is a specialisation of an instance of the more general class *clinical information item*.

Drug treatments are one form of clinical information item.

Attributes:

drug information status Data Type: V

Description: Information which describes the status of the drug treatment information.

Examples: Reported (treatment information reported by sender to receiver of the message), prescribed (treatment for which a prescription has been issued to the patient), prescription ceased (pre-existing prescription stopped), dispensed (drug for which a supply has been dispensed to the patient — recognises implicitly that it was also prescribed), recommendation to prescribe (that the colleague receiving the message should prescribe), recommendation to cease (that the colleague receiving the message should cease treatment), patient advised to take, patient advised to cease.

identification of drug

Data Type: C/S

NOTE 1 This identification may provide either a brand identification or the generic identification of the drug. In addition, it may identify the form of presentation (e.g. tablets, inhaler, patch).

NOTE 2 The scope of this attribute includes the possibility of it conveying both drug identification information and form of presentation information since code lists which combine these are in widespread current use. It is expected that in the future this information will be carried in several distinct attributes.

Example 1: Salbutamol inhaler, salbutamol syrup, Ventolin, paracetamol, warfarin tablets, soluble insulin, lignocaine, dobutamine, gluten-free flour.

L-dosage and administration specification of drug

Data Type: LC+S

Description: Information which, together with the drug identification, provides a full specification of the patient's treatment with the drug.

NOTE 1 Form of presentation (e.g. tablets, inhaler); route of administration (e.g. oral, sublingual, topical, intravenous injection); unit dose (e.g. 3 tablets, 250 mg, 2 puffs); dosage regime (e.g. one unit dose three times daily, one twice daily and two at night, one before administration trigger, one after administration trigger, one at 10:00 am); maximum permitted daily dose (e.g. 8 unit doses); trigger for administration (e.g. chest pain, meals, exercise); precautions (e.g. stop if indigestion, report any sore throat).

NOTE 2 Form of presentation not normally included if indicated by the identification of the drug.

Example 1: 100 micrograms daily (of drug thyroxine), 3 mg in the evening (of drug warfarin tablets), 2 puffs before exercise (of drug salbutamol inhaler) 1 mg patch twice weekly (of drug oestrogen), 80 mg intravenously every 8 h (of drug gentamicin injection), 2 tablets by mouth every four hours as required for pain, with a maximum of eight tablets a day (of drug paracetamol).

intended duration of drug treatment

Data Type: AG

Description: Information on the length of time that the party recommending or prescribing the drug intends that it be taken.

> Numerical duration of drug treatment

Data Type: AG

NOTE This attribute group consists of the attributes numerical value of duration of drug treatment and unit of value of duration of drug treatment.

» numerical value of duration of drug treatment

Data Type: I

» unit of value of duration of drug treatment

Data Type: V

Examples: Day, week, month, year.

> textual description of intended duration of drug treatment

Data Type: C/S

Example(s): Short term (no further prescriptions expected after current one expires), intermittent (periods of continuous treatment interspersed by periods of non-treatment), long term (continuing "repeat" prescriptions expected), lifetime (continue indefinitely), continue for 3 months, continue until haemoglobin > 12.

days supply

Data Type: I

quantity of drug supplied

Data Type: AG

NOTE This attribute group consists of the attributes numerical value of quantity and unit of quantity.

> numerical value of quantity of drug supplied

Data Type: R

> unit of quantity of drug supplied

Data Type: V

comment to drug treatment

Data Type: S

NOTE To convey any unstructured comment about the patient's treatment with the drug.

6.3.17 healthcare organisation**Description**

Information about an organisation responsible for the direct or indirect provision of healthcare services, or involved in the provision of healthcare related services.

Relationships

— Specialisation: Each instance of *healthcare organisation* is a specialisation of an instance of the more general class *healthcare party*.

A healthcare organisation is a type of healthcare party.

— Whole/Part: Each instance of *healthcare organisation* may consist of any number of instances of *healthcare professional*.

A healthcare organisation may include healthcare professionals as members of staff or through other contractual relationships.

— Part/Whole of: Each instance of *healthcare organisation* may be a part of zero or one other instance of the same object.

Healthcare organisations may be part of a larger healthcare organisation.

— Whole/Part: Each instance of *healthcare organisation* may consist of any number of other instances of the same object.

A healthcare organisation may consist of several departments which are in themselves healthcare organisations.

Attributes:

name of healthcare organisation

Data Type: S

type of healthcare organisation

Data Type: V

Examples: University hospital, private diagnostic service provider.

6.3.18 *healthcare party*

Description

Information about an organisation or person responsible for the direct or indirect provision of healthcare services, or involved in the provision of healthcare related services.

Relationships

— Instance connection: Each instance of *healthcare party* may be associated with any number of instances of *healthcare party role*.

A healthcare party may have different healthcare party roles in relation to the information contained in a message.

— Generalisation: Each instance of *healthcare party* exists as one of the following specialisations: *healthcare organisation* or *healthcare professional*.

A healthcare party may either be an organisation (a healthcare organisation) or a person (a healthcare professional).

Attributes:

partner-agreed identification of healthcare party

Data Type: S

Description: Identification of a healthcare party agreed upon between communication parties.

healthcare registration identification

Data Type: V

Description: Unique and official identification of a healthcare party, in general issued by an authorised organisation such as a governmental or international body.

identification of healthcare party by diagnostic service requester

Data Type: S

identification of healthcare party by diagnostic service provider

Data Type: S

L-address

Data Type: CAG(a)

NOTE This common attribute group is detailed in 6.4.1.

L-telecommunication

Data Type: CAG(t)

NOTE This common attribute group is detailed in 6.4.7.

L-language details

Data Type: CAG(Ia)

Description: Language(s) spoken or understood.