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dans le domaine de la santé

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INVOLVED PERSONS

The specification is based on the work of experts of the healthcare sector of Luxembourg and has been created during several sessions with the CDA Workgroups initiated by HL7 Luxembourg.

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1. INTRODUCTION

This implementation guide provides the specification of the CDA Header for the Luxembourgish healthcare sector. The specification has been created through a process of several meetings, discussions and reviews together with members of HL7 Luxembourg.

Goal is to provide a consistent specification which can be used by IT-staff of the healthcare sector or by vendors to create compliant CDA documents for the exchange of medical documents in the Luxembourgish healthcare system and with the national eHealth platform in Luxembourg.

The clinical documents that are exchanged or shared within the DSP (Dossier de Santé Partagé) must be conformed to the specifications of the HL7 Clinical Document Architecture release 2.0 (HL7 CDA R2) standard. This standard allows the exchange of clinical documents in xml format compliant with the CDA.xsd and assures the accessibility and readiness, stewardship and the consistency related to the Healthcare professionals responsibilities.

A CDA document (Clinical Document architecture) is divided in two main parts:

- A header where general information needed to the stewardship of the document; it allows the qualification of the document, describes the participants of the document, the relationship between documents and any other information used for its integration in the care process. The information of the header is generally common to all clinical documents that are shared or exchanged in the DSP system;
- A body where clinical information are presented. The clinical information could be unstructured such as a PDF document or an image or could be structured containing xml data.

This document describes **constraints** that apply to the data required for the general CDA Document Header. The header must be used as the default header of different CDA documents defined for general exchange. Nevertheless it is possible to derive specializations of this header for different medical domains. In this case, the specific constraints will be clearly identified (see conventions).

This document is one of a set of documents that will create the Healthcare Interoperability framework of Luxembourg.

It is assumed that readers of the document have a basic knowledge about HL7 and CDA and the purpose of use as a document format for the exchange and sharing of medical information.

1.1. AUDIENCE

This document is intended for software developers, consultants and the national agency staffs responsible for the implementation of the DSP system in Luxembourg and the integration of the clinical software to the DSP system and all local or national health information exchange who wish to create/process clinical documents according to this specification.

1.2. REFERENCE

ISO/HL7 27932 :2008 - HL7 Clinical Document Architecture, Release 2.0 (CDA R2)

1.3. METHODOLOGY

Two CDA workgroups were initiated together with HL7 Luxembourg, one for the laboratory and one for the radiology domain, which has worked on the specification of the general CDA Header described in this document.

Additionally for the development of the implementation guide for the CDA-Header the specifications and experiences gathered in other countries were taken into account.

Excellent specification work has been done in Austria by the ELGA GmbH¹ and in France by ASIP Santé². These Implementation guidelines were taken in to account as well as the HL7 Implementation guide for CDA R2 and the epSOS³ CDA specifications.

In addition, we reviewed the testing tools called IHE Gazelle Model Based Validation (<http://gazelle.ihe.net/content/cda-model-based-validation>) where several existing templates are available including the epSOS templates for Patient Summary, ePrescription and eDispensation.




Figure 1: Document upload window for Gazelle CDA Validation

The Agence eSanté Luxembourg provides a test and validation environment for CDA documents⁴. This environment is based on the Gazelle⁵ testbed platform tool from IHE Europe and can be used by software developers to check their software compliance.

¹ ELGA GmbH, get more information at <http://www.elga.gv.at>

² See also: <http://esante.gouv.fr>

³ epSOS: <http://www.epsos.eu>

⁴ The CDA validation environment for Luxembourg can be reached following this link:
<http://gazelle.agence-esante.lu>

⁵ The Gazelle tool can be accessed using the following link: <http://gazelle.ihe.net>

1.4. USE OF TEMPLATES

Templates are collections of constraints that specify and validate agreed-to requirements for exchange. Collecting individual constraints and assigning a unique template identifier to the collection establishes a shorthand mechanism for the instance creator to assert conformance to those constraints. The template identifier itself carries no semantics. Validation errors against a template must not be construed as anything other than failure to meet the exact requirements of the template, and absence of a template identifier need not be construed as failure to meet the constraints required by the template.

1.5. CONVENTIONS

This document specifies a conformance « profile » the base standard for this specification is the HL7 document Architecture release v2.0 and therefore this specification is a localized profile. Not every aspect of the CDA R2 may be described in this guide. Requirements that have not further constraints to the base standard and which can be validated through CDA.xsd do not have corresponding conformance statements.

1.5.1. Conformance requirements

Conformance requirements for this specification are of two types:

- Those that are collected within a published template of CDA/V3 conformance statements
- Those that are not associated with a published template. Where they are not associated with a published template, they are numbered sequentially and listed with the following format :

CONF-LU-ex1: *This is an example conformance requirement original to this specification.*

Where conformance requirements from another Implementation Guide are associated with a template, they are included through assertion of that template Identifier and listed in two ways:

CONF-LU-ex2: *All constraints from this section are from the CCD Medications section. See for CCD medications conformance requirements. This section **SHALL** include the epSOS medication template identifier for the medications section (2.16.840.1.113883.10.20.1.8).*

- In Appendix B, they are listed using the original numbering sequence from the Source Guide:
- Medications (Template ID: 2.16.840.1.113883.10.20.1.8)
- CCD-CONF-299: CCD **SHOULD** contain exactly one and **SHALL NOT** contain...

1.5.2. Vocabulary conformance

Value set constraints can be “STATIC,” meaning that they are bound to a specified version of a value set, or “DYNAMIC,” meaning that they are bound to the most current version of a value set. A simplified constraint is used when binding to a single code.

- Syntax for vocabulary binding to DYNAMIC or STATIC value sets is as follows:

*The value for (“pathName of coded element”) (**SHALL** | **SHOULD** | **MAY**) be selected from ValueSet valueSetOID localValueSetName (DYNAMIC | STATIC (valueSetEffectiveDate)).*

CONF-LU-ex3: *The value for “ClinicalDocument / code” **SHALL** be selected from ValueSet 2.16.840.1.113883.1.11.10870 DocumentType DYNAMIC.*

CONF-LU-ex4: The value for “ClinicalDocument / code” **SHALL** be selected from ValueSet 2.16.840.1.113883.1.11.10870 DocumentType STATIC 20061017.

- Syntax for vocabulary binding to a single code is as follows:

The value for (“pathname of coded element”) (**SHALL** | **SHOULD** | **MAY**) be
[“code” [“displayName”] codeSystemOID [codeSystemName] STATIC.

CONF-LU-ex5: The value for “ClinicalDocument / code” **SHALL** be “34133-9”
“Summarization of episode note” 2.16.840.1.113883.6.1 LOINC STATIC.

1.5.3. KEYWORDS

The keywords **SHALL**, **SHALL NOT**, **SHOULD**, **SHOULD NOT**, **MAY**, and **NEED NOT** in this document are to be interpreted as described in the HL7 Version 3 Publishing Facilitator's Guide. The table below describes the terminology based on this HL7 Guide:

Meaning	Term	Negation term
Required/Mandatory	SHALL	SHALL NOT
Best Practice/Recommendation	SHOULD	SHOULD NOT
Acceptable/Permitted	MAY	NEED NOT

Table 1: Keywords

1.6. CDA DOCUMENT DEFINITION

All the definitions are originated from HL7 CDA Normative edition.

The HL7 Clinical Document Architecture is a document markup standard that specifies the structure and semantics of clinical documents for the purpose of exchange. A clinical document is a documentation of clinical observations and services with the following characteristics:

- **Persistence:** a clinical document continues to exist in an unaltered state, for a time period defined by local and regulatory requirements;
- **Stewardship:** a clinical document is maintained by an organization entrusted with its care;
- **Potential for authentication:** a clinical document is an assemblage of information that is intended to be legally authenticated;
- **Context:** a clinical document establishes the default context for its contents;
- **Wholeness:** authentication of a clinical document applies to the whole and does not apply to portions of the document without the full context of the document;
- **Human readability:** a clinical document is human readable.

A CDA document is a defined and complete information object that can include text, images, sounds, and other multimedia content.

1.6.1. Concepts of the Clinical Document Architecture

A CDA contains a header and a body. The header provides “administrative” information on authentication, encounter, patient, and other participants involved in the encounter.

The body contains the clinical report and be either an unstructured blob or can be comprised of structured markup. A structured body is divided up into recursively nestable document sections. Each section can contain a single narrative block and any number of CDA entries and external references. The narrative block represents content to be rendered, whereas entries represent structured content provided for computer processing and encodes content present in the narrative block of the same section. CDA entries can nest and reference external objects.

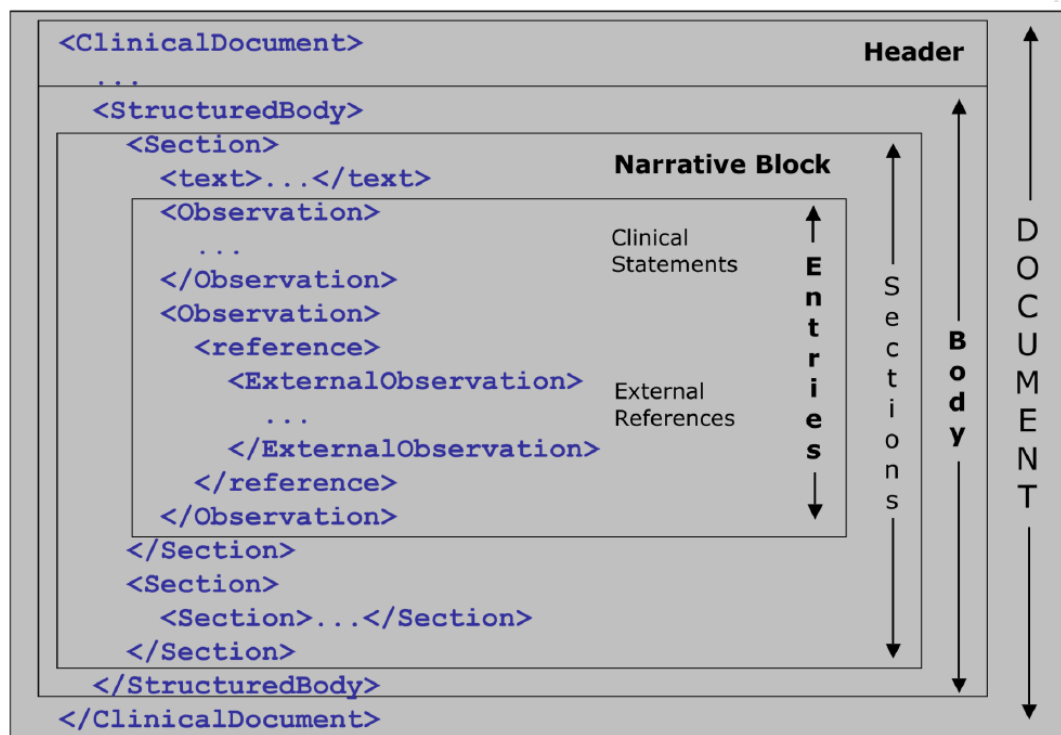


Figure 2: Structured Clinical Document Architecture (CDA)

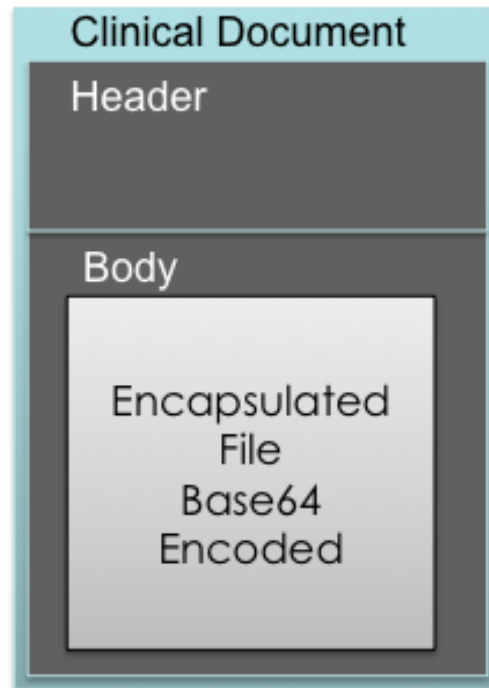


Figure 3: Unstructured Clinical Document Architecture (CDA) including file

1.7. REVISED CYCLE AND EVALUATION

The development and maintenance of the document follows a number of principles to ensure stability of the specifications.

The first of these principles is that extensions and clarifications **MUST** maintain backward compatibility with previous version of the specifications in order to maintain interoperability with systems that have already implemented CDA documents based on the specifications defined here.

The Agence eSanté will publish annually and/or when necessary the specifications following the process:

- The Agence eSanté develops extensions to support new functionalities identified by the Luxemburgish health community or by the Agence eSanté and issues them for public comment
- The Agence eSanté addresses all comments received during the public comment (PC) period and publishes an updated version of the specification which contains the stable part of the document from the previous version and the new development.
- The new version of the document is used to update the set of testing tools available for testing the implementation performed by the solutions.
- Periodically (e.g. annually), the Agence eSanté considers change proposals of the current version of the specification. After resolution of the issues, the comments are prepared for their integration to the new version of the specification (annually) or if the issues are critical and the resolution has to be immediately operational, the minor version is published.

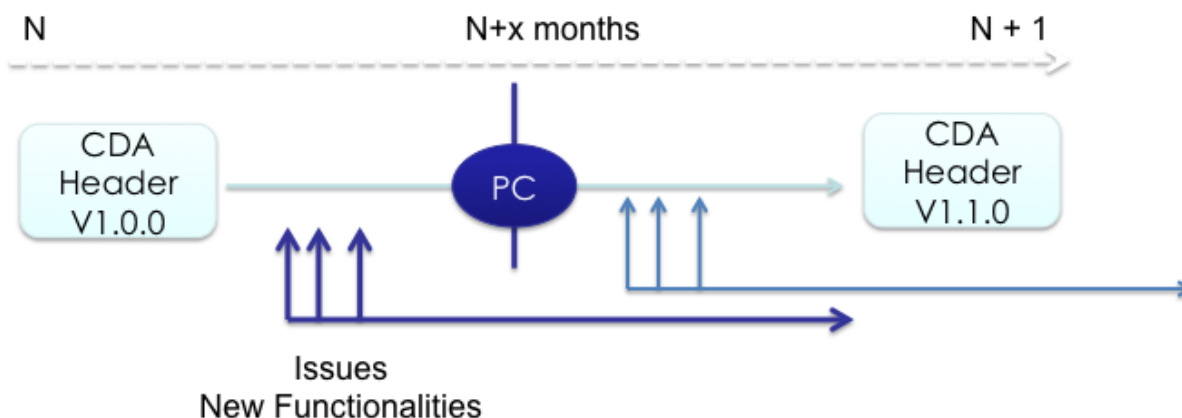


Figure 4: Cycle of maintenance (PC : Public Comment)

2. DATA TYPES AND DEFINITIONS

Through the specification of the details of the CDA document, certain HL7 v3 standard data types are used. The most commonly used ones will be described here for better understanding. Additionally the definition of more complex types defined for the Luxembourgish healthcare sector is specified here also once (e.g. Address, Telecom ...).

2.1. ATTRIBUTE NULLFLAVOR

All the classes of the HL7 RIM are derived from the InfrastructureRoot and inherit its attributes. The attribute @nullFlavor is used when the content of the element cannot be filled with an appropriate value. A code value is therefore selected given the reason why the element is not filled.

The rules for the usage and the kind of the @nullFlavor attribute which could be used related to an element of the CDA, is specified in detail in this implementation guideline.

Value	Comment	Definition
UNK	Unknown	A proper value is applicable, but not known.
NASK	Not Asked	This information has not been sought (e.g., patient was not asked)
ASKU	Asked but Unknown	Information was sought but not found (e.g., patient was asked but didn't know)
NAV	Temporarily Unavailable	Information is not available at this time but it is expected that it will be available later.
NI	No information	The value is exceptional (missing, omitted, incomplete, improper). No information as to the reason for being an exceptional value is provided. This is the most general exceptional value. It is also the default exceptional value.
MSK	Masked	There is information on this item available but it has not been provided by the sender due to security, privacy or other reasons. There may be an alternate mechanism for gaining access to this information.

Table 2: NullFlavor values

2.2. INSTANCE IDENTIFIER (II) DATA TYPE

The HL7 Instance Identifier data type (II) is used in CDA specifications to identify uniquely different instances of e.g. documents, persons, etc.

The instance identifier data type is a complex data type consisting of the fields described in the table below.

Complex data type/attributes		DT	Card	Description
II				Instance identifier
	@root	UID	[1..1]	Namespace of the identifier, could either be an OID or UUID.
	@extension	ST	[0..1]	Unique identifier used in the system/institution/namespace referenced by the value of the @root attribute.
	@assigningAuthorityName	ST	[0..1]	Human readable name of the institution/office which provides the id, so e.g. the name linked to the OID.
	@displayable	BL	[0..1]	Boolean flag to indicate whether the identifier stored is intended to be displayed to humans for data entry.

Table 3: Instance Identifier (II) data type

As shown in the table above, the root attribute must be provided with a unique value which could be either an:

- **OID⁶**: Sequence of non-negative integers separated by periods, no leading zero, unlimited length. E.g. 2.16.840.1.113883.6.1 for LOINC.

Practical considerations indicate that OID components should be limited to values between 1 and $2^{31} - 1$ (about 2 billion values), because some application libraries are using arrays of integers for storing or comparing the components of an OID. OIDs SHALL be less than 64 characters in length to support exchange in information systems which using other standards like e.g. DICOM.

OIDs which have to be used in the healthcare sector of Luxembourg can be obtained from the Agence eSanté.

Or

- **UUID⁷**: Appears like XXXXXXXX-XXXX-XXXX-XXXX-XXXXXXXXXXXX where each X is a single hexadecimal digit (in upper case)

⁶ Conformant to ISO/IEC 9834-1. For further information on OID usage please consult "HL7 Implementation Guidance for Unique Object Identifiers", at <http://www.hl7.org>

⁷ Conformant to ISO/IEC 9834-8:2005

OIDs SHALL be used as the preferred identifier scheme in HL7 CDA documents conformant to this specification.

Example

```
<id root="1.3.182.1"
      extension="1234567890121"
      assigningAuthorityName="Agence eSanté"
/>
```

2.2.1. Unique identifiers for healthcare institutions

Unique identifiers for health professionals and institutions will be provided by the Healthcare Provider Directory (HPD). The identifier will be structured⁸ in the following way:

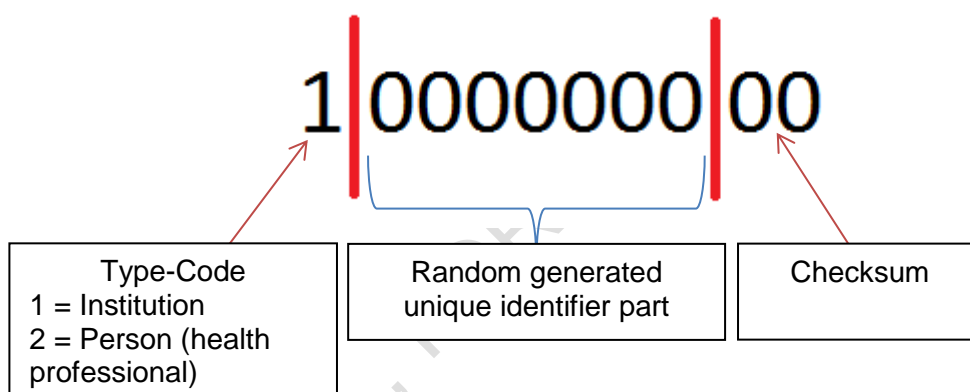


Figure 5: Structure of the healthcare institution identifier

This unique identifier will be useful inside of CDA documents to specify as part of an Instance Identifier @root attribute the namespace e.g. for the ClinicalDocument/id and for other id's where the namespace of an institution has to be given.

Since the specification of HL7 proposes to use an OID as the preferred representation, the unique identifier given by the HPD will be transformed into an OID and registered in the OID-Registry. Taking the constraints and practical considerations for OIDs into account, the conversion from the hpdID into an OID will be performed the following way:

- The last two digits (checksum) of the hpdID from the HPD will be removed.
- The type-code and the random generated part which remain, will be concatenated to the OID for the instance identifiers of healthcare organizations (1.3.182.3.1.1)

⁸ Conformant to the Specification about unique identification of health professionals and institutions – Agence eSanté

Example:

hpdID 1123123134 for Institution "Better health hospital"

- Remove the two digits of the checksum:
1123123134 => 11231231
- Concatenate the result to the OID for instance identifiers for healthcare organizations:
1.3.182.3.1.1.11231231

Health professionals, represented and identified in the CDA document e.g. as authenticator, legalAuthenticator etc. should be represented as described in the following chapter (2.2.2).

2.2.2. Unique identifier for health professionals

Health professionals shall be identified by the unique identifier provided on the national level (hpdID). They may also be identified related to the domain and namespace of the institution they are working for. In both cases it will be necessary to provide the root and extension elements of the identifier.

The hpdID should be used and the way to represent a health professional uniquely as part of the II data type, is to reference in the root attribute to the identification-mechanism of the hpdID, with the OID 1.3.182.4.1. This specifies that the identifier given in the extension attribute of the II data type is a national healthcare professional identifier given by the HPD.

Example:

```
<id root="1.3.182.4.1"
    extension="2123123237"
    assigningAuthorityName="HPD Agence eSanté"
/>
```

If only the local identifier for a health professional can be provided, then the root part shall contain the unique identifier (as an OID) of this institution's health professional identifier namespace. The extension part shall contain the identifier of the health professional inside the institution (namespace given by the root attribute).

Example:

```
<id root="1.3.182.3.1.1.11231231.3"
    extension="12-1123123"
    assigningAuthorityName="Better health hospital"
/>
```

2.3. CODED ELEMENTS

HL7 V3 provides several data types for coded elements which are used in the CDA document. These data types are defined to allow different levels of constraints in the expression of coded values, from including just the code, to including several code systems and using qualifiers to change the meaning of the code included.

Data type	Name	Description	V2.x equivalent
CS	Coded Simple	Represents only the code	CNE
CV	Coded Value	Provides information about the code and code system	CWE
CE	Coded with Equivalents	To provide information about the code system, code system version and the original text. Inclusion of translation in other coding systems is also possible.	CWE/CNE
CD	Concept Descriptor	Like CE but additionally allow to provide a list of qualifiers that can change the semantics of the concept, if the coding system allows this.	-----

Table 4: HL7 V3 coded elements data types

As part of the HL7 CDA specification mostly the CS and CE data types are used for coded elements. The following sub-chapters will describe the requirements in detail for the two types.

2.3.1. CS – Coded Simple

With this data type only the code is provided, no information about the code system and version is explicitly given. This is only useful in cases where the context (specification) fixes the code system and version already.

Element/Attribute	DT	Card	Description
code	CS / CNE		Code element
@code	ST	[1..1]	The code value

Table 5: Coded Simple (CS)

Example:

```
<languageCode code="fr-LU"/>
<signatureCode code="S"/>
```

2.3.2. CE – Coded with Equivalents

The CE (CWE/CNE in HL7 v2) data type allows providing the type version and value data type.

Wherever it is used in this specification and not specified differently, it should be conformant and represent the form described in the specification below.

Element/Attribute		DT	Card	Description
code		CE/CWE/CNE		Code element
	@code	ST	[1..1]	The code value
	@codeSystem	UID	[1..1]	The unique identifier (mainly an OID) defining the codesystem used (e.g. 2.16.840.1.113883.6.1 for LOINC)
	@codeSystemName	ST	[0..1]	Human readable form, textual representation describing the code system (e.g. LOINC).
	@codeSystemVersion	ST	[0..1]	Codesystem version e.g. 4.2
	@displayName	ST	[1..1]	Human readable form/representation of the code value.
	originalText	ED	[0..1]	The text as seen and/or selected by the user who entered the data which represents the intended meaning of the user. Could be the original text or a reference (from an entry to a narrative block). If an element is coded based on free text written by a physician, the free text would be included here.
	reference	TEL.URL	[0..1]	Referenced element, can be given instead of the originalText inside the element directly.
	@value	URL	[1..1]	Contains the real URL to the referenced element in the narrative block e.g.

					#dischargesummary-1
	translation		SET<CE>	[0..*]	Optional set of codes, representing the equivalent coded information in other code systems.

Table 6: Coded with Equivalents (CE)

Examples:

Minimal example containing code, codeSystem and displayName only:

```
<code code="48765-2"
      codeSystem="2.16.840.1.113883.6.1"
      displayName="Glucose [Moles/volume] in Serum or Plasma 1.5
                  hours post dose glucose"/>
```

Example containing optional information and original text:

```
<code code="48765-2"
      codeSystem="2.16.840.1.113883.6.1"
      codeSystemName="LOINC"
      codeSystemVersion="2.42"
      displayName="Glucose [Moles/volume] in Serum or Plasma 1.5
                  hours post dose glucose">
  <originalText>Glycémie 90 min</originalText>
</code>
```

Example containing optional information and a reference to the narrative text section:

```
<code code="48765-2"
      codeSystem="2.16.840.1.113883.6.1"
      codeSystemName="LOINC"
      codeSystemVersion="2.42"
      displayName="Glucose [Moles/volume] in Serum or Plasma 1.5 hours
                  post dose glucose">
  <originalText>
    <reference value="#labtest-1"/>
  </originalText>
</code>
```

Example containing optional information and a fictive translation to another code system:

```
<code code="48765-2"
  codeSystem="2.16.840.1.113883.6.1"
  codeSystemName="LOINC"
  codeSystemVersion="2.42"
  displayName="Glucose [Moles/volume] in Serum or Plasma 1.5 hours
    post dose glucose">
  <originalText>
    <reference value="#labtest-1"/>
  </originalText>
  <translation>
    codeSystem="1.2.3.4.5.6.7.8"
    codeSystemName="fictive codesystem"
    codeSystemVersion="1"
    <originalText>
      <reference value="#comm-1"/>
    </originalText>
  </translation>
</code>
```

3. CDA HEADER CONSTRAINTS FOR LUXEMBURG

3.1. GENERAL DEFINITIONS

The encoding **SHALL** be UTF-8. And the XML Version 1.0 **SHALL** be used with CDA.

CONF-LU-1: The encoding **SHALL** be UTF-8.

Example:

```
<?xml version="1.0" encoding="UTF-8"?>
```

The majority of applications handling non XML documents are using the ISO-8859-1 or ISO-8859-15 encoding. These applications must transcode between the two sets of characters ISO-8859 and UTF-8 for CDA documents.

The encapsulated content in base64 in an unstructured body of a CDA document **SHALL** keep their initial set of characters.

The root of the ClinicalDocument is from the namespace of HL7 V3 at "urn:hl7-org:v3". In case the document requirements are not met by the standard. It is allowed to include elements from a different namespace than "urn:hl7-org:v3".

CONF-LU-2: The root of the clinical document header in Luxembourg **SHALL** be from the urn:hl7-org:v3 namespace.

CONF-LU-3: The classCode **SHALL** be present with value "DOCCLIN" (CodeSystem 2.16.840.1.113883.5.6 HL7ActClass) STATIC

CONF-LU-4: The moodCode **SHALL** be present with value "EVN" (CodeSystem 2.16.840.1.113883.5.1001 HL7 ActMood) STATIC

Example:

```
<?xml version="1.0" encoding="UTF-8"?>
<ClinicalDocument xmlns="urn:hl7-org:v3" xmlns:voc="urn:hl7-org:v3/voc"
  xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
  classCode="DOCCLIN" moodCode="EVN">
  ...
</ClinicalDocument>
```

3.1.1. Address

The `addr` element is used to provide information about the address of persons and organizations. We distinguish between two different representations of the address, one with separate fields for storing the name of the street and the house number and another representation where this information is stored in one field.

The creator of the CDA document can choose between these two possibilities, related to the information which can be provided from the source system.

3.1.1.1. Address using separate fields for street name and house number

Element/Attribute		DT	Card	Description
<code>addr</code>		AD		
	<code>@use</code>	CS	[1..1]	Information about the usage or context of the address information. E.g. home, work, ... Possible values SHALL be from Value Set: eSanté_AddressUse . The data type is specified in chapter: 2.3.1
	<code>streetName</code>	ADXP	[1..1]	Name of the street, without the house number
	<code>houseNumber</code>	ADXP	[1..1]	House number
	<code>postalCode</code>	ADXP	[1..1]	ZIP code
	<code>city</code>	ADXP	[1..1]	Name of the city
	<code>state</code>	ADXP	[0..1]	Region
	<code>country</code>	ADXP	[1..1]	Country code, three letters code from ISO-3166 alpha 3
	<code>additionalLocator</code>	ADXP	[0..1]	Additional address information to precise the location e.g. station in hospital, room number, floor

Table 7: Address specification using separate fields for street name and house number

Example:

```
<addr use="H">
  <streetName>Rue des Tomains</streetName>
  <houseNumber>1</houseNumber>
  <postalCode>2540</postalCode>
  <city>LUXEMBOURG</city>
  <country>LUX</country>
</addr>
```

3.1.1.2. Address using streetAddressLine

Element/Attribute		DT	Card	Description
addr		AD		
	@use	CS	[1..1]	Information about the usage or context of the address information. E.g. home, work, ... Possible values SHALL be from Value Set: eSanté_AddressUse . The data type is specified in chapter: 2.3.1
	streetAddressLine	ADXP	[1..1]	Name of the street including the house number
	postalCode	ADXP	[1..1]	ZIP code
	city	ADXP	[1..1]	Name of the city
	state	ADXP	[0..1]	Region
	country	ADXP	[1..1]	Country code, three letters code from ISO-3166 alpha 3
	additionalLocator	ADXP	[0..1]	Additional address information to precise the location e.g. station in hospital, room number, floor

Table 8: Address specification using streetAddressLine

Example:

```
<addr use="H">
  <streetAddressLine>Rue des Tomains 1</streetName>
  <postalCode>2540</postalCode>
  <city>LUXEMBOURG</city>
  <country>LUX</country>
</addr>
```

3.1.2. Telecom

The telecom element is used in different classes of the CDA-RMIM to provide contact data of persons and organizations. It is defined by the RFC 2806.

Element/Attribute		DT	Card	Description
telecom		TEL		Element for the representation of contact information.
	@use	CS	[0..1]	Information about the usage or context of the communication information. E.g. home, work, ... Possible values SHALL be from Value Set: eSanté_TelecomAddressUse .
	@value	ST	[1..1]	The real contact data e.g. telephone number, email address. The type of communication is part of the value, as a prefix and SHALL be from Value Set: eSanté_URLScheme . For format conventions see chapter: 3.1.2.1

Table 9: Telecom specification

3.1.2.1. Format conventions for telecom values

To be able to distinguish between different types of communications, the @value attribute must contain as a prefix the identifier of the communication scheme, e.g. "tel", "mailto", ... followed by an ":" and the communication URL.

If telephone or fax numbers are provided ("[tel](#):" or "fax:"), they **SHOULD** contain the country code for which this number is valid e.g. "+352, +49, +33, ...". If the country code is omitted, the number provided is assumed as a number valid for the country related to the realmCode (see 3.3.1), which must be "LU" for documents which are conformant to this specification.

So the general layout is: "<communication_scheme>:<URL>"

The different communication schemes which are supported **SHALL** be from Value Set: [eSanté_URLScheme](#).

Examples:

```
<!-- Telephone number -->
<telecom value="tel:+352-12345" use="H"/>

<!-- E-mail -->
<telecom value="mailto:John.Doe@doe.com"/>

<!-- FTP -->
<telecom value="ftp://serveur/dossiermedicalpartagé"/>

<!-- Unknown telephone number, in cases where telephone is required but
not known -->
<telecom nullFlavor="UNK" value="tel:"/>
```

3.1.3. Name representation

Similar to the address representation, the specification of the name part in CDA could consist of a collection of different elements. The HL7 specification divides names up into three types: persons, organizations and other identities including e.g. places.

3.1.3.1. Simple name representation

The simple name representation is provided for cases where the structure of a name of a person is not given. When using this representation, all the parts of a name are put together in one field. It is recommended that this representation SHALL NOT be used for providing information about the patient. It can be used in exceptional cases where the creator of the CDA document has no detailed information about the structure of the name, e.g. name of guardians.

Element/Attribute		DT	Card	Description
name		PN	[1..1]	Simple name representation in one field
	@use	CS	[0..1]	Describes the usage of the name, e.g. for an artist. If @use is omitted then it is the legal name of the person. Possible values SHALL be from Value Set: eSanté_NameUse

Table 10: Simple name specification

Examples:

```
<name>Mr. John Doe</name>
```

Or

```
<name @use="A">Mr. John Doe</name>
```

3.1.3.2. Names of a person

Element/Attribute		DT	Card	Description
name		PN	[1..1]	Name representation of a person
	@use	CS	[0..1]	Describes the usage of the name, e.g. for an artist. If @use is omitted then it is the legalname of the person. Possible values SHALL be from Value Set: eSanté_NameUse
	prefix	EN.PREFIX	[0..*]	Set of prefixes for the name of the

					person. Honorific prefixes have to be used e.g. academic titles. The prefix is not meant to be used for salutation e.g. Mr., Mdm.
		@qualifier	CS	[0..1]	Meaning or type of prefix, e.g. AC for academic title. Possible values SHALL be from Value Set: eSanté_NamePartQualifier
	family		EN.FAMILY	[1..*]	Sequence of family names. At least one name must be given.
		@qualifier	CS	[1..1]	Meaning of the value in the family field. E.g. Maiden name (Birthname). Possible values SHALL be from Value Set: eSanté_NamePartQualifier
	given		EN.GIVEN	[1..*]	Sequence of given names. At least one name must be given. In cases where the given names are separated in the source system, this field can be used several times.
		@qualifier	CS	[1..1]	Specifies the type of the value of the given name. Possible values SHALL be from Value Set: eSanté_NamePartQualifier
	suffix		EN.SUFFIX	[0..*]	Suffix related to this name e.g. academic title.
		@qualifier	CS	[1..1]	Meaning of the suffix. Possible values SHALL be from Value Set: eSanté_NamePartQualifier

Table 11: Names of a person specification

Examples:

Minimal structured name information

```
<name>
  <family>Jordan</family>
  <given>Jean-Paul</given>
</name>
```

More qualified name information

```
<name>
  <prefix @qualifier="AC">Dr.</prefix>
  <family>Jordan</family>
  <family @qualifier="BR">Johnson</family>
  <given>Jeannette</given>
  <given>Maria</given>
  <suffix @qualifier="AC">MBA</suffix>
</name>
```

3.1.3.3. Names of organizations

Element/Attribute	DT	Card	Description
name	ON	[1..1]	Name representation of organizations

Table 12: Specification of simple name representation for organizations

Example:

```
<name>My-Clinic Inc.</name>
```

Alternative :

Element/Attribute	DT	Card	Description
name	ON	[1..1]	Name representation of organizations
@use	CS	[0..1]	Describes the usage of the name. If @use is omitted then it is the legalname of the organization. Possible values SHALL be from Value Set: eSanté_NameUse
prefix	EN.PREFIX	[0..*]	Set of prefixes for the name of the organization.
@qualifier	CS	[1..1]	Meaning of the prefix. Possible values SHALL be from Value Set: eSanté_NamePartQualifier
suffix	EN.SUFFIX	[0..*]	Suffixes related to this organization e.g. legal status
@qualifier	CS	[1..1]	Meaning of the suffix. Possible values SHALL be from Value Set: eSanté_NamePartQualifier

Table 13: Specification of detailed name representation for organizations

Example:

More qualified name information

```
<name>HL7 Luxembourg
  <suffix qualifier='LS'>asbl</suffix>
</name>
```

3.1.4. Date and Time Representation

Date and time values are used in different classes of the CDA R-MIM. Based on the context different representation of date and times are possible, the representations which have to be used in Luxembourg will be specified here.

The HL7 V3 specification provides different data types for the representation of dates.

3.1.4.1. Date

Wherever a date can be provided it SHALL be in the format:

Format	Element	Description
YYYYMMDD		
	YYYY	The year, e.g. 2013
	MM	The month, e.g. 01
	DD	The day, e.g. 31

Table 14: Simple date specification

Example:

```
<!-- The creation date of the document -->
<effectiveTime value="20130605"/>
```

3.1.4.2. Date and Time

In cases where a certain point of time has to be provided more precise, containing information about the date and time of an event, the timestamp given SHALL contain information about the timezone (offset from UTC) and SHALL be in the format:

Format	Element	Description
YYYYMMDDhhmmss[+/-]ZZzz		
	YYYY	The year, e.g. 2013
	MM	The month, e.g. 01
	DD	The day, e.g. 31
	hh	The hour (in 24 hour representation), e.g. 13
	mm	The minute, e.g. 12

	ss	The second, e.g. 23
	+ or -	Positive or negative offset from UTC
	ZZ	The offset in hours
	zz	The offset in minutes

Table 15: Date and time (timestamp) specification

The timezone SHALL also reflect the clock changes in summertime or wintertime.

Examples:

If we have an event in winter at the 01.01.2013 at 10:00 o'clock local time, it has to be represented as:

```
<!-- The creation date of the document -->
<effectiveTime value="20130101100000+0100"/>
```

If we have an event in summer at the 01.06.2013 at 10:00 o'clock local time, it has to be represented as:

```
<!-- The creation date of the document -->
<effectiveTime value="20130601100000+0200"/>
```

3.1.4.3. Time interval

The IVL_TS data type is specified in HL7 V3 for the representation of time intervals. It is often used to record a time interval over which an event occurred or will occur. Although the IVL_TS data type allows the setting of different representations of an interval, this specification limits the definition of possible intervals and adds common restrictions, to allow only the usage of the lower and upper bound of the interval, using <low> and <high> either alone or together.

Element/Attribute		DT	Card	Description
effectiveTime		IVL_TS		Time interval
	low	TS	[1..1]	Lower bound, beginning of the interval. If the lower value is not known nullFlavor="UNK" SHALL be used.
	@value	TS	[1..1]	Start of the interval.
	high	TS	[1..1]	Upper bound, end of the interval. If the end of the interval is not known nullFlavor="UNK" SHALL be used.
	@value	TS	[1..1]	End of the interval.

Table 16: Time interval specification

If the interval is used to describe a point in time, the low and high attribute SHALL have the same value.

Example:

Interval using IVL_TS data type

```
<effectiveTime>
  <low value="20130605"/>
  <high value="20130607"/>
</effectiveTime>
```

Representing a point in time using IVL_TS data type

```
<!-- IVL_TS interval data type used to describe a point in time -->

<effectiveTime>
  <low value="20130605100000+0100"/>
  <high value="20130605100000+0100"/>
</effectiveTime>
```

3.1.5. Organization representation

Organization
classCode*: <= ORG
determinerCode*: <= INSTANCE
id: SET<II> [0..*]
name: SET<ON> [0..*]
telecom: SET<TEL> [0..*]
addr: SET<AD> [0..*]
standardIndustryClassCode: CE CWE [0..1]
<= OrganizationIndustryClass

Figure 6: Organization description

The entity "Organization" is referenced by certain elements in the CDA specification. The specification of the structure to represent an organization in this chapter should be used for all the occurrences.

Element/Attribute			DT	Card	Description
organization					
	id		II	[0..*]	Set of identifiers representing/identifying the organization. Must be compliant to the specification of the II data type in chapter: 2.2 So e.g the national unique identifier for healthcare institutions (hpdlID) from the
		@root	UID	[1..1]	
		@extension	ST	[1..1]	

				HPD could be used.
	name	ON	[1..1]	Name representation of the organization SHALL be compliant to the specification of organization names in chapter: 3.1.3.3
	telecom	TEL	[0..*]	Communication data of the organization. Information provided SHALL be compliant to specification of telecom elements in chapter: 3.1.2
	addr	AD	[0..*]	Address of the organization. Information provided SHALL be compliant to specification of address elements in chapter: 3.1.1

Table 17: Organization specification

Example:

```
<representedOrganization>
  <id root="1.3.182.3.1.1.1231231.34"
    assigningAuthorityName="Agence eSanté HPD"/>
  <name>Better health hospital</name>
  <telecom value="tel:+352-12345"/>
  <telecom value="fax:+352-12345-67"/>
  <addr>
    <streetAddressLine>Rue des Tomains 1</streetAddressLine >
    <postalCode>2540</postalCode>
    <city>LUXEMBOURG</city>
    <country>LUX</country>
  </addr>
</representedOrganization>
```

3.1.6. Person representation

Person
classCode*: <= PSN
determinerCode*: <= INSTANCE
name: SET<PN> [0..*]

Figure 7: Person description

The entity "Person" is referenced by certain elements in the CDA specification. The specification of the structure to represent a person in this chapter SHALL be used for all the occurrences.

Element/Attribute		DT	Card	Description
person				
	name	PN	[1..*]	At least one name for the person SHALL be provided. The content of the "name" attribute must be valid as specified in chapter: 3.1.3.2

Table 18: Person specification

Example:

```
<relatedPerson>
  <name>
    <prefix @qualifier="AC">Dr.</prefix>
    <family>Jordan</family>
    <family @qualifier="BR">Johnson</family>
    <given>Jeannette</given>
    <given>Maria</given>
    <suffix @qualifier="AC">MBA</suffix>
  </name>
</relatedPerson>
```

3.1.7. AssignedEntity representation

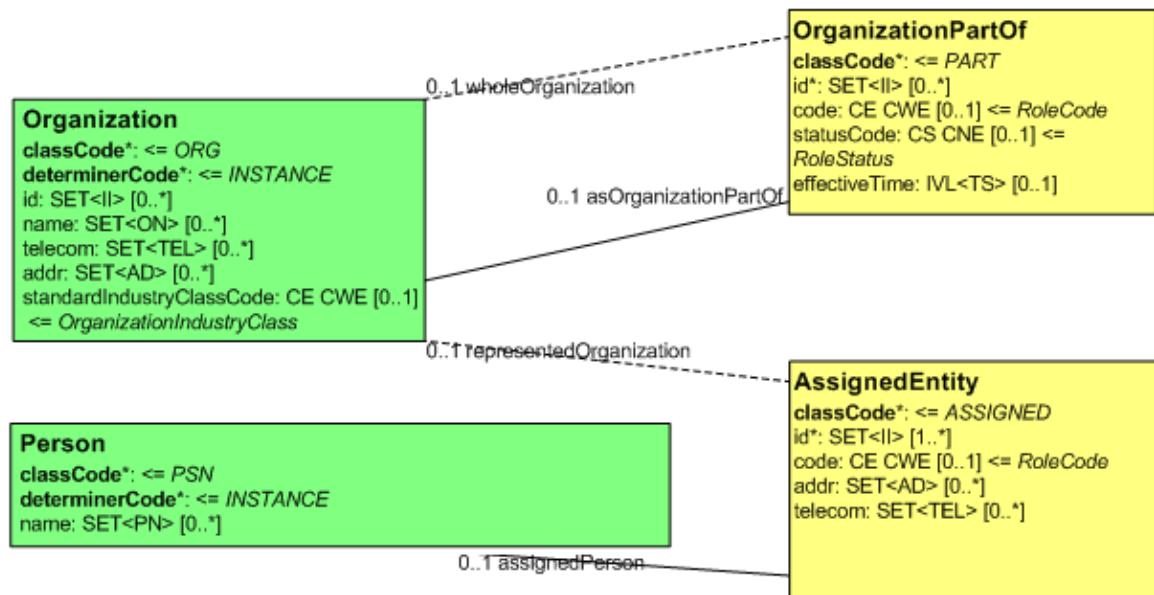


Figure 8: AssignedEntity description

The role "AssignedEntity" is referenced by certain elements in the CDA specification. The player of the role "AssignedEntity" is an assignedPerson, which is a kind of healthcare provider or employee e.g. doctor, nurse, ... For the assignedPerson the information about

the represented organization, so the organization for which the health professional is working for, can also be given (representedOrganization).

The specification of the structure to represent an “AssignedEntity” in this chapter **SHALL** be used for all the occurrences.

CONF-LU-5: If the AssignedEntity role is provided, one person **SHALL** be present as assignedPerson.

Element/Attribute		DT	Card	Description
assignedEntity		POCD_MT000040. AssignedEntity		
	id	II	[1..*]	<p>At least one identifier for the assignedEntity SHALL be given. It is the identifier representing the assignedPerson.</p> <p>The identifier must be compliant to the specification of the II data type in chapter: 2.2</p> <p>If the identifier is not known the following nullFlavors are allowed:</p> <ul style="list-style-type: none"> NI: There is no identifier for this person. UNK: An identifier exists but is not known.
	code	CE/CWE	[0..1]	<p>If known a code can be provided, otherwise the element MAY be omitted.</p> <p>Possible values SHALL be from Value Set: eSanté_RoleCode.</p> <p>The structure of the information about the code SHALL be compliant to the specification in chapter: 2.3.2</p>
	address	AD	[0..*]	<p>Address of the person referenced as the assigned Person. The address information provided SHALL be conformant to the specification in chapter: 3.1.1</p>
	telecom	TEL	[0..*]	<p>Communication data of the person referenced as the assigned Person. The communication data provided SHALL be conformant to the specification in chapter: 3.1.2</p>

Table 19: Assigned Entity specification

Element/Attribute	DT	Card	Description
assignedPerson	POCD_MT000040. AssignedPerson	[1..1]	Person representation as specified in chapter: 3.1.6

Table 20: Assigned Entity / assigned Person element

Element/Attribute	DT	Card	Description
representedOrganization	POCD_MT000040. Organization	[0..1]	Organization representation as specified in chapter: 3.1.5

Table 21: Assigned Entity / represented organization

Example:

```
<dataEnterer>
  <assignedEntity>
    <id root="1.3.182.4.1" extension="2123456789"/>
    <addr>
      <streetAddressLine>Rue des Tomains 1</streetAddressLine >
      <postalCode>2540</postalCode>
      <city>LUXEMBOURG</city>
      <country>LUX</country>
    </addr>

    <telecom value="tel:+352-12345" use="WP"/>
    <assignedPerson>
      <name>
        <prefix @qualifier="AC">Dr.</prefix>
        <family>Jordan</family>
        <family @qualifier="BR">Johnson</family>
        <given>Jeannette</given>
        <given>Maria</given>
        <suffix @qualifier="AC">MBA</suffix>
      </name>
    </assignedPerson>
  </assignedEntity>
</dataEnterer>
```

3.1.8. RelatedEntity Representation

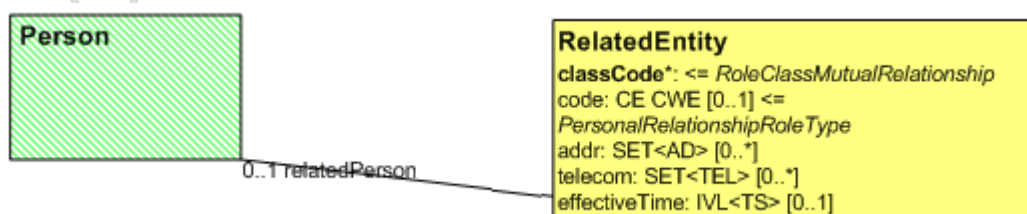


Figure 9: RelatedEntity description

The relatedEntity class is used to provide information about persons who are in a defined relationship with the patient. The type of relationship can be specified by providing the appropriate code

CONF-LU-6: If the RelatedEntity role is provided, one person **SHALL** be present as the relatedPerson.

Element/Attribute		DT	Card	Description
relatedEntity		POCD_MT000040. RelatedEntity		
	@classCode	CS	[1..1]	Defines the type of relationship. Possible values SHALL be from Value Set: eSanté_RoleClassMutualRelationship
	code	CE/CWE	[0..1]	This code MAY be given to further specify the relationship. If given, possible values SHALL be from Value Set eSanté_PersonalRelationshipRoleType If known a code MAY be provided, otherwise the element MAY be omitted. The structure of the information about the code SHALL be compliant to the specification in chapter: 2.3.2
	address	AD	[0..*]	Address of the person referenced as the assigned Person. The address information provided SHALL be conformant to the specification in chapter: 3.1.1
	telecom	TEL	[0..*]	Communication data of the person referenced as the assigned Person. The communication data provided SHALL be conformant to the specification in chapter: 3.1.2
	relatedPerson	POCD_MT000040. Person	[1..1]	Information about the related person, SHALL be compliant as specified in chapter: 3.1.6

Table 22: RelatedEntity specification

3.2. CDA HEADER STRUCTURE

The clinical document is made up of three different kinds of elements in the following order

- **RIM Attributes** of the ClinicalDocument class, appear in the CDA Header in that order in which they are appear in the CDA R-MIM
- **Participants** attached to the ClinicalDocument class, are in the context of the creation of the document. This includes people, organizations, medical devices and applications that might be responsible for the creation of the document. Each participation associates the document to a role. The participation association describes the functional role, and the role class describes the structural role.
- **Related acts** attached to the ClinicalDocument class, are related to this CDA document and are part of the CDA Header. Prior (related) documents, specific services performed, the patient encounter to which this document belongs to, orders related to the document and the consent provided by the patient could be stored.

RIM Attributes	Participants	Related acts
id	recordTarget/patientRole	relatedDocument
code	author	documentationOf
title	dataEnterer	inFulfillmentOf
effectiveTime	informant	authorization
confidentialityCode	custodian	componentOf
languageCode	informationRecipient	
setId	legalAuthenticator	
versionNumber	authenticator	
	participant	

Table 23: Overview of CDA-Header elements

The following table lists the items present in the CDA-Header in the order of the schema XML in this general CDA-Header specification for Luxembourg. Lines in grey contain attributes which are not used in the current version of the specification.

Element	Comment	Chapter
realmCode	Localization (Luxembourg)	3.3.1
typeId	CDA document	3.3.2
templateID	Conformity declaration	3.3.3

id	Document Id	3.4.1
code	Type of document (ex: history, patient Summary, discharge Summary,...)	3.4.2
title	Title of the document	3.4.3
effective Time	Document creation time (when the document first came being)	3.4.4
confidentialityCode	Level of confidentiality of the document (see value set)	3.4.5
languageCode	Human language of character data (see value set)	3.4.6
setID	Identifier common across all document revisions. Not used	3.4.7
versionNumber	Version successive replacement documents. Not used	3.4.7
recordTarget	Medical record that this document belongs to (Patient)	3.5.1
author	Human or machines that authored the document	3.5.2
dataEnterer	Participant who has transformed a dictated note into text	3.5.3
Informant	Person who provides relevant information such as the parent of a comatose patient	3.5.4
Custodian	Organization in charge of maintaining the document	3.5.5
Information Recipient	Recipient who receives a copy of the document	3.5.6
legalAuthenticator	Participant who has legally authenticated the document	3.5.7
authenticator	Participant who has attested to the accuracy of the document	3.5.8
participant	Other participant not explicitly mentioned by other classes	3.5.9
relatedDocument	Reference to parent document	3.6.1
inFulfillmentOf	Orders that are fulfilled by this document	3.6.2
documentationOf	Main act(s) being documented	3.6.3
authorization	Consents associated with this document. Not used	0
componentOf	Setting of the clinical encounter during which the documented act(s) of serviceEvent occurred	3.6.5

Table 24: References to specification chapters

3.3. INFRASTRUCTURE ELEMENTS

The three elements realmCode, typeId, templateId are so called “infrastructure elements” (and not RIM attributes). They can occur in *any* RIM class appearing in the CDA document, not only in the header of a CDA document.

3.3.1. realmCode

CONF-LU-7: The realm code indicates the localization of the clinical document using this specification. The code **SHALL** be filled with “LU” (Code from ISO 3166-1-alpha-2) **STATIC**

Element/Attribute	DT	Card	Description
realmCode	CS	[1..1]	
@code	ST	[1..1]	Constant value: “LU” (Code from ISO 3166-1-alpha-2)

Table 25: realmCode specification

Example:

```
<realmCode code="LU"/>
```

3.3.2. typeId

CONF-LU-8: A ClinicalDocument/typeId element **SHALL** be present having the following values: @root=“2.16.840.1.113883.1.3” @extension=“POCD_HD000040”

Element/Attribute	DT	Card	Description
typeId	II	[1..1]	
@root	UID	[1..1]	Constant value : “2.16.840.1.113883.1.3”
@extension	ST	[1..1]	Constant value : “POCD_HD000040”

Table 26: typeId specification

Example:

```
<typeId root="2.16.840.1.113883.1.3" extension="POCD_HD000040"/>
```

3.3.3. templateId

The templateId indicates the declaration of conformity for the clinical document. Depending on the type of the document, one or several templateId(s) may be indicated.

These templateId(s) which have to be used related to the different document types are specified in the implementation guidelines of the relevant document type e.g. laboratory report, discharge summary.

The following list is not exhaustive.

CONF-LU-9: To indicate conformance to the general header specifications of the clinical document in Luxembourg defined in this specification document, the ClinicalDocument/templateId **SHALL** be present with the following value: @root="1.3.182.11.1"

Element/Attribute	DT	Card	Description
templateId	II	[1..1]	
@root	UID	[1..1]	Constant value: "1.3.182.11.1" General CDA Document Specification for Luxembourg

Table 27: templateId specification

Additionally, other templateIds can be added to confirm the compliance to further specifications like e.g. for laboratory or radiology report. There is no limit in the numbers of templateIds provided.

Example:

```
<templateId root="1.3.182.11.1"/>
```

CONF-LU-10: To indicate conformance to level 1 (which also asserts compliance with all general or non-level specific constraints), ClinicalDocument/templateId elements **MAY** be present with the following value: @root="2.16.840.1.113883.10.20.10"

Element/Attribute	DT	Card	Description
templateId	II	[1..1]	
@root	UID	[1..1]	'2.16.840.1.113883.10.20.10'

Table 28: CDA Level 1 conformance templateId

Example:

```
<templateId root="2.16.840.1.113883.10.20.10"/>
```

CONF-LU-11: To indicate conformance to level 2 features (which also asserts compliance with level 1 requirements and asserts the presence of section codes), ClinicalDocument/templateId elements **MAY** be present with the following value: @root="2.16.840.1.113883.10.20.20"

Element/Attribute	DT	Card	Description
templateId	II	[1..1]	
@root	UID	[1..1]	'2.16.840.1.113883.10.20.20'

Table 29: CDA Level 2 conformance templateId

Example:

```
<templateId root="2.16.840.1.113883.10.20.20"/>
```

CONF-LU-12: To indicate conformance to level 3 features (which also asserts compliance with level 2 requirements and asserts the presence of CDA entries in some sections), ClinicalDocument/templateId elements **MAY** be present with the following value: @root="2.16.840.1.113883.10.20.30"

Element/Attribute	DT	Card	Description
templateId	II	[1..1]	
@root	UID	[1..1]	'2.16.840.1.113883.10.20.30'

Table 30: CDA Level 3 conformance templateId

Example:

```
<templateId root="2.16.840.1.113883.10.20.30"/>
```

CONF-LU-13: For a unstructured document, to indicate conformance to the specifications of the profile IHE XDS-SD published by IHE international in the ITI Technical framework, ClinicalDocument/templateId elements **MAY** be present with the following value: @root="1.3.6.1.4.1.19376.1.2.20"

Element/Attribute	DT	Card	Description
templateId	II	[1..1]	
@root	UID	[1..1]	"1.3.6.1.4.1.19376.1.2.20"

Table 31: IHE XDS-SD conformance templateId

Example:

```
<templateId root="1.3.6.1.4.1.19376.1.2.20"/>
```

Full Example:

```
<ClinicalDocument xmlns="urn:hl7-org:v3" xmlns:voc="urn:hl7-org:v3/voc"
  xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
  classCode="DOCCLIN" moodCode="EVN">

  <!-- ** CDA Header ** -->
  <realmCode code="LU"/>
  <typeId root="2.16.840.1.113883.1.3" extension="POCD_HD000040"/>
  <templateId root="1.3.182.11.1" />
  ...
</ClinicalDocument>
```

3.4. RIM-ATTRIBUTES

3.4.1. id (Document Id)

The ClinicalDocument/id is used to provide a worldwide unique identifier for a CDA document instance. The II (instance identifier) data type is used for the id and is described in chapter 2.2 in detail.

The instance which creates the document SHALL provide this unique identifier, either by providing a unique OID for the document itself (@root) or by providing the OID of the institution (@root) and the unique identifier of the document in the namespace of this institution (@extension).

If several versions of a document are created successively, each document SHALL be identified uniquely and therefore SHALL have a unique ClinicalDocument/id.

Element/Attribute		DT	Card	Description
id		II	[1..1]	Unique identifier for the document instance. II data type as specified in chapter: 2.2
	@root	UID	[1..1]	OID of institution/office namespace for document identifiers SHALL be used, then @extension must be a unique identifier for the document. If the OID represents a unique identifier for this document itself, then @extension can be omitted. See also chapter: 2.2.1
	@extension	ST	[0..1]	Unique documentid used in the system/institution described by the OID value of the @root attribute.
	@assigningAuthorityName	ST	[0..1]	Human readable name of the institution/office which provides the id, so e.g. the name linked to the OID.
	@displayable	BL	[0..1]	Boolean flag to indicate whether the identifier stored is intended to be displayed to humans for data entry.

Table 32: ClinicalDocument/id specification

OIDs are limited by this specification to no more than 64 characters in length for compatibility with other standards and Implementation Guides.

CONF-LU-14: The ClinicalDocument/id/@root attribute **SHALL** be a syntactically correct OID.

CONF-LU-15: OIDs **SHALL** be no more than 64 characters in length.

CONF-LU-16: The ClinicalDocument/id element **SHALL** not be a nullFlavor attribute.

CONF-LU-17: If the OID represents a unique identifier for this document, than

- @extension can be omitted.
- CONF-LU-18:** If the OID of the institution's documentId namespace **SHALL** be used, then @extension must be a unique identifier for the document.
- CONF-LU-19:** assigningAuthority and displayable **MAY** be omitted

Example:

```
<id root="1.3.182.3.1.1.1231231.34.1" extension="A7102400008_1"/>
```

3.4.2. code – Document type

The code indicates the type of document. The preferred set of codes for the document type definition in HL7 CDA is based on LOINC. Possible values **SHALL** be from Value Set: **eSanté_DocType**.

- CONF-LU-20:** The ClinicalDocument/code element **SHALL** be found in the list of LOINC codes defined in the Value Set "eSanté_DocType" for Luxembourg and specifies the type of the clinical document.
- CONF-LU-21:** The ClinicalDocument/code element **SHALL** not be a NullFlavor attribute.

Element/Attribute		DT	Card	Description
code		CE	[1..1]	Code specifying the document type. See also chapter: 2.3.2
	@code	CS	[1..1]	Possible values SHALL be from Value Set: eSanté_DocType .
	@codeSystem	UID	[1..1]	OID of the nomenclature "2.16.840.1.113883.6.1"
	@displayName	ST	[1..1]	Label of the code
	@codeSystemName	ST	[0..1]	Name of the nomenclature "LOINC"

Table 33: ClinicalDocument/code specification

Note:

The preferred nomenclature which has to be used for the document type, according to HL7, is LOINC.

LOINC classifies documents on four main axes :

- Type of document
- Type of service described
- Kind of author
- Location of the service provided

It is good practice not to use the detailed codes, the more general instead because the service, author, location are described in the CDA Header already.

Nevertheless the code chosen must be compliant with the content of the document.

Valid codes according to this specification **SHALL** be from Value Set: **eSanté_DocType**.

Example:

```
<code code="11502-2"
      codeSystem="2.16.840.1.113883.6.1"
      codeSystemName="LOINC"
      displayName="Laboratory Report.Total"/>
```

3.4.3. title

CONF-LU-22: The ClinicalDocument/title element **SHALL** be present and specifies the name used for this document

CONF-LU-23: The ClinicalDocument/title element **SHALL** not be a nullFlavor attribute

Element/Attribute	DT	Card	Description
title	ST	[1..1]	Title of the document. Must be related to the type of the document and should not contain patient identifying data.

Table 34: ClinicalDocument/title specification

Example:

```
<title> Compte rendu d'analyses biologiques </title>
```

3.4.4. effectiveTime

EffectiveTime represents the creation time of the document. If the CDA document is a transformation from an original document in some other format, the ClinicalDocument.effectiveTime is the time the original document has been created. The time when the transformation occurred is not currently represented in CDA.

CONF-LU-24: The ClinicalDocument/effectiveTime element **SHALL** be present and specifies the creation time of the document. All history and physical documents authored by direct input to a computer system should record an effectiveTime that is precise to the second. When authored in other ways, for example, by filling out a paper form that is then transferred into an EHR system, the precision of effectiveTime may be less than to the second.

CONF-LU-25: The ClinicalDocument/effectiveTime element **SHALL** not be a NullFlavor attribute.

CONF-LU-26: The format **SHALL** be YYYYMMDDhhmmss[+/-]HHMM

Element/Attribute		DT	Card	Description
effectiveTime		TS	[1..1]	
	@value	TS	[1..1]	Value of the time at the initial creation of the document. Even if the document will be created in more than one step, the first creation time has to be used. Provided information has to be conformant with the specification in chapter: 3.1.4

Table 35: ClinicalDocument/effectiveTime specification

Example: Document created on 01 January 2013 at 09:10:05 in Luxembourg

```
<effectiveTime value="20130101091005+0100"/>
```

3.4.5. confidentialityCode

The confidentiality code is a required contextual component of CDA and expresses the level of confidentiality assigned to the entire document. Unless any use case contradicts the following option, the ClinicalDocument/confidentialityCode will be given the constant value "Normal".

CONF-LU-27: The ClinicalDocument/confidentialityCode **SHALL** be present

CONF-LU-28: The ClinicalDocument/confidentialityCode **SHALL** be "N", for Normal

Element/Attribute		DT	Card	Description
confidentialityCode		CE	[1..1]	
	@code	CS	[1..1]	Constant value: "N". If a use case exceptionally requires another code, possible values SHALL be from Value Set: eSanté_Confidentiality
	@codeSystem	UID	[1..1]	Constant value : "2.16.840.1.113883.5.25"
	@displayName	ST	[1..1]	Constant value: "Normal"
	@codeSystemName	ST	[1..1]	Constant value : "HL7:Confidentiality"

Table 36: ClinicalDocument/confidentialityCode specification

Example:

```
<confidentialityCode
  code="N"
  codeSystem="2.16.840.1.113883.5.25"
  displayName="Normal"
  codeSystemName="HL7:Confidentiality" />
```

Note:

The value for the confidentialityCode will be set at the creation time of the document and is for information only. It does not automatically apply security constraints. The rules related to the visibility and access of documents are executed on application level and therefore rely on the implementation of the applications who visualize or provide the document content.

3.4.6. languageCode

The ClinicalDocument/languageCode specifies the language of the content of the CDA document.

The language can be specified on three levels:

- Header level: Specifies the language of the whole document, if not changed on body or section level.
- Body level: Specifies the language of the human readable text in the whole body of the CDA document, if not changed on section level.
- Section level: Allows setting of the language used for each section individually.

The languageCode in the header represents the language used by the author of the document and therefore also the language of the title of the document.

CONF-LU-29: The ClinicalDocument/languageCode **SHALL** be present

CONF-LU-30: The ClinicalDocument/languageCode **SHALL** in the form nn-CC

CONF-LU-31: The nn portion **SHALL** be a legal ISO-639-1 language code in lowercase.

CONF-LU-32: The CC portion **SHALL** be a legal ISO-3166-2 country code in uppercase.

CONF-LU-33: The ClinicalDocument/languageCode element **SHALL** not be a NullFlavor attribute.

CONF-LU-34: Possible values for the languageCode@code **SHALL** be taken from the “eSanté_LanguageCode” Value Set, DYNAMIC

Element/Attribute	DT	Card	Description
languageCode	CS	[1..1]	
@code	CS	[1..1]	Possible values SHALL be from Value Set: eSanté_LanguageCode

Table 37: ClinicalDocument/languageCode specification

Example:

```
<languageCode code="fr-LU"/>
```

Note:

Usually, the language provided in the document header will be one of the both mentioned above (fr-LU or de-LU). For unstructured Body content (e.g. PDF) it could also be “lu-LU” e.g. for notes. If so this has to be provided as part of the languageCode element in the CDA-Body.

3.4.7. setId and versionNumber

The setId and versionNumber attributes inside of the CDA header can be used to support document identification and versioning. The setId is an identifier for a set of related documents. The original document and related documents (e.g. replacements) share the same setId over different versions of the document.

The versionNumber attribute contains the version number of a document within the set of documents with the same setId.

If the attributes are provided, the initial version of a document must contain a new value for the setId and a versionNumber set to “1”. For practical reasons, the ClinicalDocument/id value of the original document could be used as the setId. A replacement of this document must use the same setId, a new versionNumber increased by 1 and has a new ClinicalDocument/id.

CONF-LU-35: ClinicalDocument/setId and ClinicalDocument/versionNumber **SHALL** either be given both or both **SHALL** be omitted.

CONF-LU-36: The ClinicalDocument/setId and ClinicalDocument/versionNumber element **SHALL** not be a NullFlavor attribute.

Element/Attribute		DT	Card	Description
setId		II	[1..1]	
	@root	UID	[1..1]	Must be a valid OID, so e.g. the value of the root attribute of the <id> element of the original document.
	@extension	ST	[0..1]	String which uniquely identifies the set according to the namespace given in root.
versionNumber		INT	[1..1]	Integer number. Initial value is "1", must be increased by "1" for further versions.

Table 38: ClinicalDocument/setId and versionNumber specification

Example:

```
<ClinicalDocument xmlns="urn:hl7-org:v3" xmlns:voc="urn:hl7-org:v3/voc"
  xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
  classCode="DOCCLIN" moodCode="EVN">

  <!-- ** CDA Header ** -->
  <realmCode code="LU"/>
  <typeId root="2.16.840.1.113883.1.3" extension="POCD_HD000040"/>
  <templateId root="1.3.182.11.1" />
  <id root="1.3.182.3.1.1.1231231.34.1" extension="A7102400008_1"/>
  ...
  <setId root="1.3.182.3.1.1.1231231.34.2" extension="A7102400008_1"/>
  <versionNumber value="1"/>
  ...
</ClinicalDocument>
```

3.5. PARTICIPANTS

The HL7 CDA Release 2.0 Specification describes various participant scenarios where a single person can participate in several roles. In these cases, the person needs to be listed for each role.

The participants are listed below in the order in which they appear in CDA R2.

3.5.1. recordTarget/patientRole

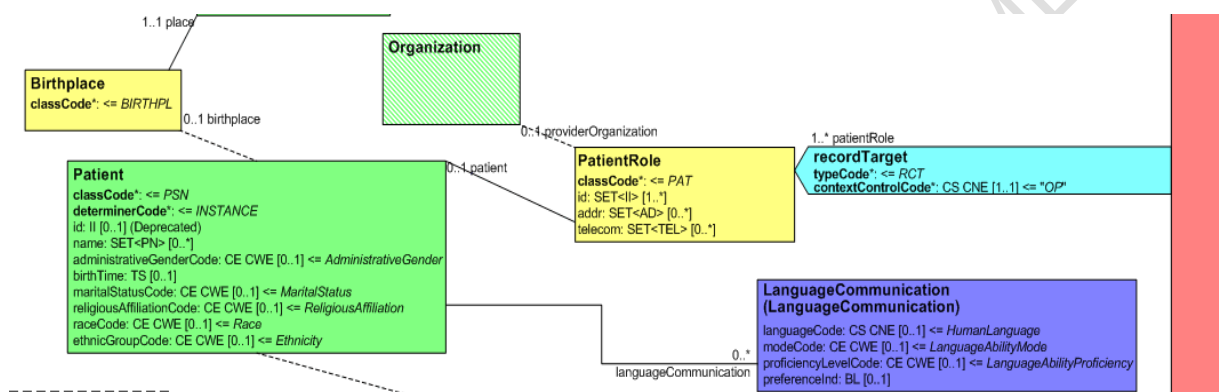


Figure 10: RecordTarget and Patient description

The recordTarget represents the medical record that this document belongs to (the patient or the patients).

CONF-LU-37: At least one ClinicalDocument/recordTarget **SHALL** be present.

CONF-LU-38: Only one ClinicalDocument/recordTarget/patientRole **SHALL** be present.

CONF-LU-39: The providerOrganisation element **MAY** be present.

Element/Attribute	DT	Card	Description
recordTarget	POCD_MT000040 .RecordTarget	[1..1]	
patientRole	POCD_MT000040 .PatientRole	[1..1]	Patient related data
providerOrganization	POCD_MT000040 .Organization	[0..1]	The organization where this patient is acting as the patientRole. This is most commonly the institution which creates the document and can therefore be omitted.

Table 39: recordTarget specification

Example:

```
<recordTarget>
  <patientRole>
    <id root="1.3.182.3.1.1.1231231.34.3" extension="7102400008"/>
    <id root="1.3.182.4.3" extension="19871212134"/>
    <addr use="H">
      <streetName>Rue des Tomaines</streetName>
      <houseNumber>1</houseNumber>
      <postalCode>2540</postalCode>
      <city>LUXEMBOURG</city>
      <country>LUX</country>
    </addr>
    <telecom value="tel:+352-12345" use="H"/>
  <patient>
    <name>
      <family>Jordan</family>
      <given>James</given>
    </name>
    <administrativeGenderCode code="M"
codeSystem="2.16.840.1.113883.5.1"
displayName="masculin" codeSystemName="HL7:AdministrativeGender" />
    <birthTime value="19500522" />
    <birthplace>
      <place>
        <name>LUXEMBOURG</name>
      </place>
    </birthplace>
  </patient>
</patientRole>
</recordTarget>
```

3.5.1.1. recordTarget/patientRole/id – Identifiers

CONF-LU-40: At least one recordTarget/patientRole/id element **SHALL** be given and not be a nullFlavor attribute.

CONF-LU-41: The order of the id's in the set **SHALL** reflect the order given in the specification table below.

CONF-LU-42: The first id of the set **SHALL** represent the local patient identifier of the document providing data source (e.g. hospital).

CONF-LU-43: The first id of the set **SHALL** not be a nullFlavor.

CONF-LU-44: The second and third id element of the set **MAY** be omitted or can be given a nullFlavor.

The id element as part of the PatientRole should be used to provide unique identifiers for the associated patient. The usage of the id field in the Patient entity is deprecated.

There can be more than one identifier for a PatientRole, which is represented by the SET<II> data type of the class.

Element/Attribute	DT	Card	Description
patientRole	POCD_MT000040 .PatientRole	[1..1]	Patient related data
id	II	[1..*]	Unique patient identifiers. The order of the provided identifiers is described in the table below.

Table 40: recordTarget/patientRole specification

At least one unique identifier for the patient has to be provided. This has to be the local patient identifier of the institution which creates the document.

Since there could be more than one unique identifier for patients, the table below defines the order in which the identifiers must occur.

Element/Attribute	DT	Card	Description
id[1]	II	[1..1]	Local patient identifier of the source system
@root	UID	[1..1]	OID of the assigned authority that delivers the identifier
@extension	ST	[1..1]	Value of the identifier
id[2]	II	[0..1]	Social security number (SSN) If not known the following nullFlavor are allowed: <ul style="list-style-type: none"> UNK: A SSN exists but is not

				known <ul style="list-style-type: none"> NI: Patient has no SSN
	@root	UID	[1..1]	OID of the identification mechanism for the social security number. Constant value: 1.3.182.4.3
	@extension	ST	[1..1]	SSN (11-digits)
id[3]		II	[0..1]	National unique person identification number (Numéro d'identification) from the national person register (Registre National des Personnes Physiques). If not known the following nullFlavor are allowed: <ul style="list-style-type: none"> UNK: A identifier exists but is not known NI: Patient has no Identifier
	@root	UID	[1..1]	OID for the identification mechanism for the national unique person identification number. Constant value: 1.3.182.4.4
	@extension	ST	[1..1]	National unique person identifier (13-digits)

Table 41: recordTarget/patientRole/id specification

As stated in the "CONF-LU-41:", the order of the given id's is important and must be like described in the table above.

Note:

The master patient identifier from the MPI (national master patient index) will not be shared with the primary systems and can therefore not be used as one of these identifiers.

3.5.1.1. recordTarget/patientRole/addr

CONF-LU-45: The recordTarget/patientRole/addr element **SHALL** be provided.

CONF-LU-46: The recordTarget/patientRole/addr element **MAY** have a nullFlavor="UNK" if the address is not known.

Element/Attribute		DT	Card	Description
patientRole			[1..1]	
	addr	AD	[1..*]	See section specification in chapter: 3.1.1

Table 42: recordTarget/patientRole/addr specification

3.5.1.2. recordTarget/patientRole/telecom

CONF-LU-47: The recordTarget/patientRole/telecom element **MAY** be provided.

CONF-LU-48: The recordTarget/patientRole/telecom element **MAY** have a nullFlavor="UNK" if the telecom is not known.

Element/Attribute		DT	Card	Description
patientRole			[1..1]	
	telecom	TEL	[0..*]	See section specification in chapter: 3.1.2

Table 43: recordTarget/patientRole/telecom specification

3.5.1.3. recordTarget/patientRole/patient – Patient

CONF-LU-49: The recordTarget/patientRole/patient element **SHALL** be provided.

CONF-LU-50: The recordTarget/patientRole/patient element **SHALL** not have a nullFlavor attribute.

CONF-LU-51: The patient/name element **SHALL** be provided

CONF-LU-52: The patient/name element **SHALL** not be have nullFlavor attribute

CONF-LU-53: The patient/name element **SHALL** be not a simple name representation, instead be structured as specified in chapter: 3.1.3.2

CONF-LU-54: The family name **SHALL** be present.

CONF-LU-55: The maiden name **MAY** be present.

Element/Attribute	DT	Card	Description
patientRole	POCD_MT000040. PatientRole	[1..1]	
patient	POCD_MT000040. Patient	[1..1]	Patient must be provided

Table 44: patientRole/patient specification

3.5.1.3.1. patient/name

Element/Attribute	DT	Card	Description
patient/name	PN	[1..*]	Name of the patient must be provided, see chapter 3.1.3.1 for detailed description

Table 45: patient/name specification

3.5.1.3.2. patient/administrativeGenderCode

CONF-LU-56: A patient/administrativeGenderCode element **SHALL** be present. If unknown, it shall be represented using a nullFlavor="UNK". Values for administrativeGenderCode **SHALL** be drawn from the HL7 AdministrativeGender vocabulary subset defined in the Value Set "eSanté_AdministrativeGender".

Element/Attribute	DT	Card	Description
patient/administrativeGenderCode	CE/CWE	[1..1]	The gender of the patient SHALL be given. If not known the nullFlavor "UNK" SHALL be used.
@code	CS	[1..1]	Possible values SHALL be from Value Set: eSanté_AdministrativeGender
@displayName	ST	[1..1]	
@codeSystem	UID	[1..1]	Constant value: "2.16.840.1.113883.5.1"
@codeSystemName	ST	[1..1]	Constant value: "HL7:AdministrativeGender"

Table 46: patient/administrativeGenderCode specification

3.5.1.3.3. patient/birthTime

CONF-LU-57: A patient/birthTime element **SHALL** be present. The patient/birthTime element **SHALL** be precise at least to the year, and

SHOULD be precise at least to the day. If unknown, it **SHALL** be represented using the nullFlavor="UNK".

Element/Attribute	DT	Card	Description
patient/birthTime	TS	[1..1]	<p>Birthdate of the patient. The format must be as specified in chapter: 3.1.4.1</p> <p>If the value contains also the time, it must be conformant as specified in chapter: 3.1.4.2</p> <p>If not known nullFlavor="UNK" SHALL be used.</p>

Table 47: patient/birthTime specification

3.5.1.3.4. patient/maritalStatusCode

Although maybe not necessary in medical documents, the general header specification allows providing the maritalStatusCode. Providing the marital status MAY be given and captures the current marital status of the patient at the creation time of this document.

CONF-LU-58: The maritalStatusCode, **MAY** be present. If maritalStatusCode, is present, the value **SHALL** be encoded using the subset of the HL7 MaritalStatus vocabulary defined in Value Set "eSanté_MaritalStatus".

Element/Attribute	DT	Card	Description
patient/maritalStatusCode	CE/CWE	[0..1]	The marital status of the patient MAY be given. If not known the element can be omitted.
@code	CS	[1..1]	Possible values SHALL be from Value Set: eSanté_MaritalStatus.
@displayName	ST	[1..1]	
@codeSystem	UID	[1..1]	Constant value: 2.16.840.1.113883.5.2 (HL7)
@codeSystemName	ST	[1..1]	Constant value: "HL7:MaritalStatus"

Table 48: patient/maritalStatusCode specification

3.5.1.3.1. patient/religiousAffiliationCode

Although maybe not necessary in medical documents, the general header specification allows providing the religiousAffiliationCode. The religiousAffiliationCode MAY be given.

CONF-LU-59: The religiousAffiliationCode **MAY** be present. Allowed values **SHALL** be taken from the Value Set "eSanté_ReligiousAffiliation".

Element/Attribute	DT	Card	Description
patient/religiousAffiliationCode	CE/CWE	[0..1]	The religion of the patient MAY be given. If not known the element can be omitted.
@code	CS	[1..1]	Possible values SHALL be from Value Set: eSanté_ReligiousAffiliation .
@displayName	ST	[1..1]	
@codeSystem	UID	[1..1]	Constant value: 2.16.840.1.113883.5.1076
@codeSystemName	ST	[1..1]	Constant value: "HL7: ReligiousAffiliation"

Table 49: patient/religiousAffiliationCode specification

3.5.1.3.2. patient/raceCode and patient/ethnicGroupCode

The information about the ethnic group and race of a patient SHALL NOT be stored as part of the CDA document.

CONF-LU-60: The raceCode and ethnicGroupCode **SHALL NOT** be present.

3.5.1.4. patient/guardian

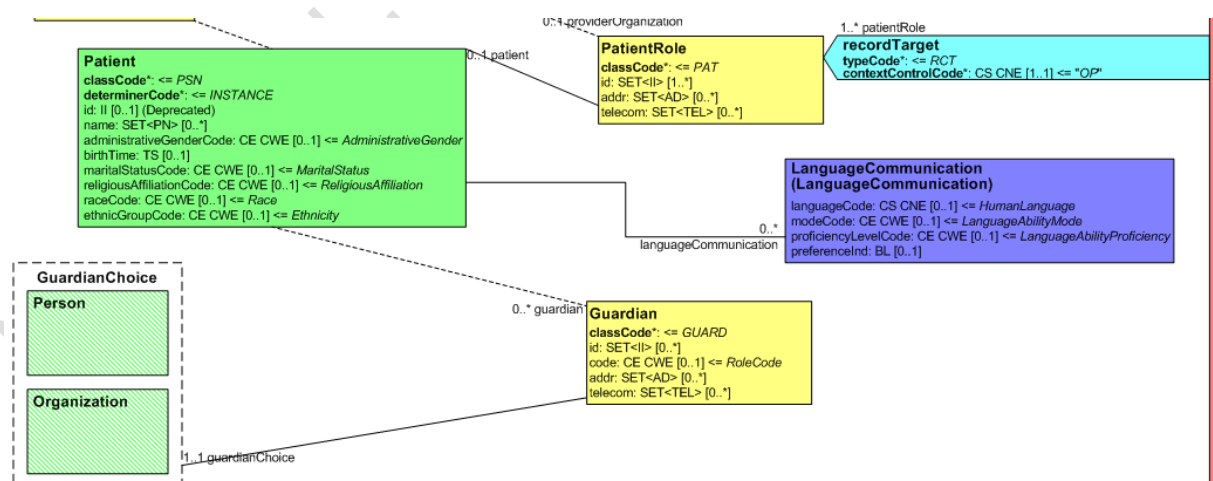


Figure 11: Guardian description

A patient may have one or more guardians who are responsible for the care of the patient. A guardian can either be a person or an organization. Guardian of a patient could be e.g. a

legal representative, when patient is a minor child or could be the responsible person/organization acting for a patient which is unable to do so on his own.

An id for the Guardian MAY be given, but the field can also be omitted.

Either a person **or** organization (guardian/person or guardian/organization) SHALL be provided.

CONF-LU-61: The guardian element **SHOULD** be present when the patient is a minor child.

Element/Attribute			DT	Card	Description
patient/guardian			POCD_MT000040. Guardian	[0..*]	The guardian of patient
	id		II	[0..*]	An id for the guardian MAY be given
		@root	UID	[1..1]	If an identifier for the guardian will be given, the identifiers have to be given in the following order.
		@extension	ST	[1..1]	
code			CE/CWE	[0..1]	Specify type of guardianship, can be omitted if not known
		@code	CS	[1..1]	Possible values SHALL be from Value Set: eSanté_GuardianRole .
		@displayName	ST	[1..1]	Name related to the code.
		@codeSystem	UID	[1..1]	2.16.840.1.113883.5.111 (HL7: (RoleCode))
		@codeSystemName	ST	[1..1]	HL7: RoleCode
address			AD	[0..1]	See chapter: 3.1.1
telecom			TEL	[0..1]	See chapter: 3.1.2
guardianPerson			POCD_MT000040. Person	[0..1]	Either a guardianPerson or a guardianOrganization SHALL be given. Person must be represented as specified in chapter: 3.1.6
guardianOrganization			POCD_MT000040. Organization	[0..1]	Either a guardianPerson or a guardianOrganization SHALL be given. Organization must be represented as specified in chapter: 3.1.5

Table 50: patient/guardian specification

The elements in the table above, which are marked in red, shall be used exclusively. It is only allowed either to use the guardianPerson or the guardianOrganization when representing a guardian.

Example:

```
<patient>
...
  <guardian>
    <id root="1.3.182.4.3" extension="19540317123"/>
    <code code="HUSB" displayName="Husband"
      codeSystem="2.16.840.1.113883.5.111"
      codeSystemName="HL7:RoleCode"/>
    <guardianPerson>
      <name>John Doe</name>
    </guardianPerson>
  </guardian>
...
</patient>
```

3.5.1.5. patient/birthPlace/place

The optional information about the birthplace of a patient can be provided. The name field can be used to provide the name of the birthplace in one field or/and the full address can be provided in the addr field.

CONF-LU-62: The birthplace **MAY** be present

CONF-LU-63: If the birthplace is given either birthplace/place/name or birthplace/place/addr or both **SHALL** be present

Element/Attribute		DT	Card	Description
patient/birthplace/place		POCD_MT000040. Place	[0..1]	Birthplace of the patient
	name	EN	[0..1]	Name of the birthplace
	addr	AD	[0..1]	Address has to be conformant to the specification of address element. See chapter: 3.1.1

Table 51: patient/birthplace/place specification

3.5.2. Author

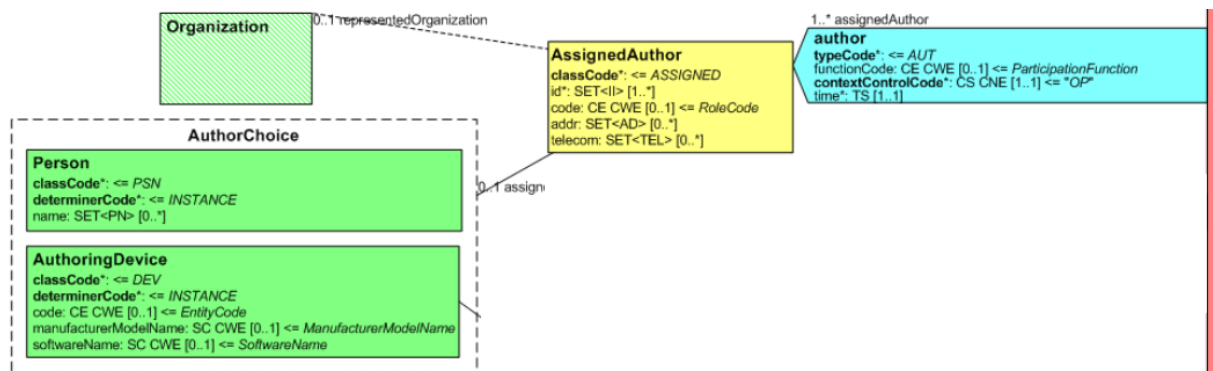


Figure 12: Author description

The Author is the medical content information creator, based on his knowledge e.g. the doctor who dictates the content of a medical report, is the author of the report. The author can either be a person or a device. More than one author could be represented. The specification clearly distinguishes between the author and the dataEnterer of the document. E.g. as current practice in the laboratory domain, the author is also the last person who validates the report.

CONF-LU-64: The assignedAuthor element **SHALL** not have a nullFlavor attribute.

CONF-LU-65: The assignedAuthor **SHALL** be one or more persons (including the patient) or systems that contribute to the elaboration of the document.

CONF-LU-66: The author/time represents the start time of the author's participation in the creation of the clinical document. It **SHALL** be present and **SHALL** be in the format YYYYMMDDhhmmss+/-HHMM.

In cases where the author is a human being, not a device (authoringDevice), the author element should contain:

Element/Attribute	DT	Card	Description
author	POCD_M T000040. Author	[1..*]	Human being as creator of the medical content of the document.
functionCode	CE/CWE	[0..1]	Functional role of the author. Must be represented as described in chapter: 2.3.2 Possible values SHALL be from Value Set: eSanté_AuthorRole .
time	TS	[1..1]	Value of the time when the author participated to the elaboration of the document. SHALL be represented as described in chapter: 3.1.4

Table 52: ClinicalDocument/author specification with functionCode

In cases where the author is a device (authoringDevice), the author element SHOULD contain the following information (see below). The functionCode SHALL be omitted in these cases.

Element/Attribute		DT	Card	Description
author		POCD_M T000040. Author	[1..*]	Device as the creator of the medical content of the document.
	time	TS	[1..1]	Value of the time when the device created the document. Must be represented as described in chapter: 3.1.4

Table 53: ClinicalDocument/author specification simple

Example:

```
<author>
  <time value="20130128091915+0100"/>
  <assignedAuthor>
    <id root="1.2.3.2.3.5.21.2" extension="012345678"/>
    <addr nullFlavor="MSK"/>
    <telecom value="tel:+352-227130588"/>
    <assignedPerson>
      <name>
        <given>Jean</given>
        <family>BAPTISTE</family>
        <prefix>Dr.</prefix>
      </name>
    </assignedPerson>
    <representedOrganization>
      <id root="1.3.182.3.1.1.1231231.34"
        assigningAuthorityName="Agence eSanté HPD"/>
      <name>Better health hospital</name>
      <telecom value="tel:+352-12345"/>
      <addr>
        <streetAddressLine>Rue des Tomains 1</streetAddressLine >
        <postalCode>2540</postalCode>
        <city>LUXEMBOURG</city>
        <country>LUX</country>
      </addr>
    </representedOrganization>
  </assignedAuthor>
</author>
```

3.5.2.1. author/assignedAuthor

In cases where the author of a document is a human being the following rules apply:

Element/Attribute		DT	Card	Description
author/assignedAuthor			[1..1]	
	id	II	[1..*]	Identifier of the author of this document. Usually the local identifier of the author in the primary system or the national identifier hpdID of the health professional from the HPD. Identifiers SHALL be provided in the order as specified in chapter: 3.5.1.1
	code	CE/CWE	[0..1]	Code of the author's specialty. Possible values SHALL be from Value Set: eSanté_AuthorSpecialty Structure of the data type as specified for the representation of coded with equivalents in chapter: 2.3.2
	address	AD	[0..*]	Address of the author, see chapter: 3.1.1
	telecom	TEL	[0..*]	Contact data of the author, see chapter: 3.1.2

Table 54: author/assignedAuthor specification

In cases where the author of a document is an authoring device the following rules apply:

Element/Attribute		DT	Card	Description
author/assignedAuthor			[1..1]	
	id	II	[1..*]	Id of the device inside the institution if there is one given. If not given the nullFlavor should be provided: <ul style="list-style-type: none"> • UNK: There is a identifier existing for the device but not known. • NI: There is no identifier existing for the authoring device.
	@root	UID	[1..1]	
	@extension	ST	[1..1]	

Table 55: author/assignedAuthor specification for authoring devices

3.5.2.1.1. assignedAuthor/assignedPerson

CONF-LU-67: The assignedPerson **SHALL** be provided

Element/Attribute	DT	Card	Description
assignedPerson	POCD_MT000040.Person	[1..1]	Person as specified in chapter: 3.1.6

Table 56: assignedPerson specification

3.5.2.1.2. assignedAuthor/assignedAuthoringDevice

As long as there is no code-set defined for different manufacturers and for the software, the manufacturer and the name of the software can be given as text.

Element/Attribute	DT	Card	Description
assignedAuthoringDevice		[0..1]	
manufacturerModelName	ST	[1..1]	Name of the manufacturer of the software.
softwareName	ST	[1..1]	Name of the software.

Table 57: assignedAuthoringDevice specification

3.5.2.1.3. assignedAuthor/representedOrganization

CONF-LU-68: The representedOrganization **SHALL** be provided

Element/Attribute	DT	Card	Description
representedOrganization	POCD_MT00040.Orga nization	[1..1]	Organization which is represented by the author. Organization must be provided as specified in chapter: 3.1.5

Table 58: representedOrganization specification

3.5.3. dataEnterer

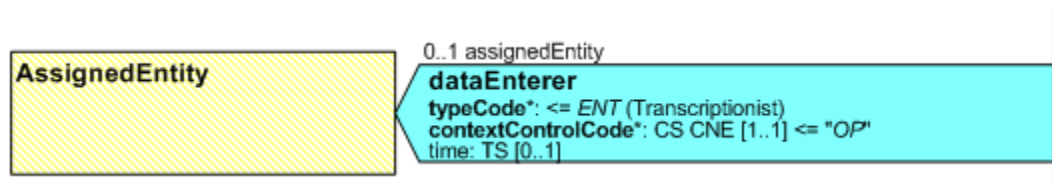


Figure 13: DataEnterer description

The dataEnterer represents the person who enters the information into the clinical document. This could be done by transferring information from other sources or transcriptions e.g. from audio recordings. The dataEnterer e.g. a secretary, does not create new medical information, instead he/she only transfers information from the source medium into the clinical document. The aim for providing such a information is for the support of quality control.

- CONF-LU-69:** When the dataEnterer element is present, the assignedEntity/assignedPerson element **SHALL** be present.
- CONF-LU-70:** The local identifier of the dataEnterer element provided by the primary system **SHALL** be present.
- CONF-LU-71:** The dataEnterer **SHALL** contain at least one assignedEntity.

Element/Attribute	DT	Card	Description
dataEnterer	POCD_MT000040. DataEnterer	[0..1]	Person who enters the data into the system, not the author of the information content of the document.
time	TS	[0..1]	Starting time of the data enterer's participation, the time when the document is written. SHALL be compliant as specified in chapter: 3.1.4

Table 59: ClinicalDocument/dataEnterer specification

Element/Attribute	DT	Card	Description
assignedEntity	POCD_MT000040. AssignedEntity	[1..1]	The assignedEntity as a person in the role dataEnterer of the document. The information SHALL be compliant to the specification in chapter: 3.1.7

Table 60: dataEnterer/assignedEntity specification

Example:

```
<dataEnterer>
  <time value="20130128091915+0100"/>
  <assignedEntity>
    <id root="1.2.3.2.3.5.21.2" extension="012345678"/>
    <addr nullFlavor="MSK"/>
    <telecom value="tel:+352-227130588"/>
    <assignedPerson>
      <name>
        <given>Jean</given>
        <family>BAPTISTE</family>
        <prefix>Dr.</prefix>
      </name>
    </assignedPerson>
  </assignedEntity>
</dataEnterer>
```

3.5.4. Informant

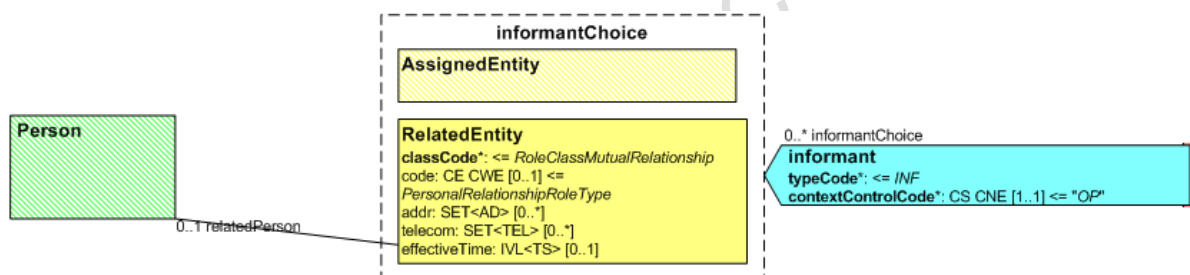


Figure 14: Informant description

The optional information providers are additional sources of information related to the patient. The Informant represents the person (Healthcare Providers with a role such as a nurse or a related person) who gives information that will be used when the clinical document is created. The main purpose is to use this information for follow-up or evaluation of the information which has been provided.

If the person who provides additional information is another healthcare provider or person working in an organization, the **assignedEntity** class should be used.

The **relatedEntity** class should be used to provide information about persons who are in defined relationship with the patient like e.g. legally authorized persons or informal persons like e.g. family members, caregiver or friends. The *code* element can be used to specify the relationship.

The main purpose is to capture the identity of the person providing the information, and the relationship to the patient.

CONF-LU-72: The informant MAY be present.

Element/Attribute	DT	Card	Description
informant	POCD_MT0000 40.Informant12	[0..*]	More than one informant can be provided. Each informant can either be an assignedEntity or a relatedEntity.
assignedEntity	POCD_MT0000 40.AssignedEntity	[0..1]	Used for an identified informant like health professional providing information about the patient's treatment which is used in the document. The AssignedEntity representation is defined in chapter: 3.1.7
relatedEntity	POCD_MT0000 40.RelatedEntity	[0..1]	Informant with a formal or personal relationship to the patient. The type of relationship can be specified with the classCode and code. The RelatedEntity representation is defined in chapter: 3.1.8

Table 61: ClinicalDocument/informant specification

3.5.4.1. informant/assignedEntity

If the person who provides additional information is another healthcare provider or person working in the organization who provides care, the *assignedEntity* class should be used.

CONF-LU-73: When the informant/assignedEntity element is present, the assignedEntity/assignedPerson element **SHALL** be present.

CONF-LU-74: When the informant is a healthcare provider, with an assigned role, the informant **SHALL** be represented using the assignedEntity element.

Element/Attribute	DT	Card	Description
informant/assignedEntity	POCD_MT0000 40.AssignedEntity	[0..1]	The assignedEntity SHALL be represented as specified in chapter: 3.1.7

Table 62: informant/assignedEntity specification

Example:

```
<informant>
  <assignedEntity>
    <id root="1.3.182.4.1" extension="2123456789"/>
    <addr>
      <streetAddressLine>Rue des Tomains 1</streetAddressLine >
      <postalCode>2540</postalCode>
      <city>LUXEMBOURG</city>
      <country>LUX</country>
    </addr>
    <telecom value="tel:+352-12345" use="WP"/>
    <assignedPerson>
      <name>
        <prefix @qualifier="AC">Dr.</prefix>
        <family>Jordan</family>
        <family @qualifier="BR">Johnson</family>
        <given>Jeannette</given>
        <given>Maria</given>
        <suffix @qualifier="AC">MBA</suffix>
      </name>
    </assignedPerson>
  </assignedEntity>
</informant>
```

3.5.4.1. informant/relatedEntity

When the informant is a personal relation or a caregiver without assigned role, that informant is represented in the *relatedEntity* element. The *relatedEntity* class should be used to provide information about persons who are in defined relationship with the patient like e.g. legally authorized persons or informal persons like e.g. family members, caregiver or friends. The *code* element MAY be used to specify the relationship.

The code element of the *relatedEntity* describes the relationship between the informant and the patient.

CONF-LU-75: When the informant/relatedEntity element is present, the relatedEntity/relatedPerson element **SHALL** be present.

Element/Attribute	DT	Card	Description
informant/relatedEntity	POCD_MT0000 40.RelatedEntity	[0..1]	The relatedEntity SHALL be represented as specified in chapter: 3.1.7

Table 63: informant/relatedEntity specification

3.5.5. Custodian

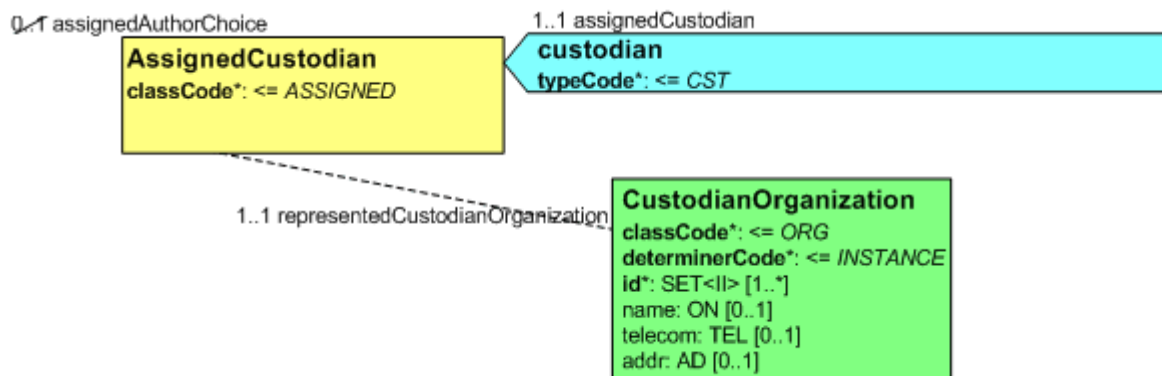


Figure 15: Custodian description

The custodian represents the organization that organizes the stewardship of the clinical document. In most cases this is the same organization as at which the document has been created.

CONF-LU-76: The custodian element **SHALL** be present.

CONF-LU-77: Custodian/assignedCustodian/representedCustodianOrganization/name **SHALL** be present.

Element/Attribute	DT	Card	Description
custodian	POCD_MT00004 0.Custodian	[1..1]	Steward of the document
assignedCustodian	POCD_MT00004 0.AssignedCustodian	[1..1]	
representedCustodianOrganization	POCD_MT00004 0.CustodianOrganization	[1..1]	
id	II	[1..*]	<p>Identifiers of the organization. This should be the identifier given from the healthcare provider directory (HPD). Instance identifier SHALL be conformant as specified in chapter: 2.2</p> <p>If not known the following nullFlavor are allowed:</p> <ul style="list-style-type: none"> NI: Organization has no identifier from the national HPD UNK: Organization has an identifier from the national HPD but this identifier is not known

			name	ON	[1..1]	Name of the organization SHALL be given and SHALL be conformant to specification in chapter: 3.1.3.3
			telecom	TEL	[0..1]	Conformant to specification in chapter: 3.1.2
			addr	AD	[0..1]	Conformant to specification in chapter: 3.1.1

Table 64: ClinicalDocument/custodian specification

Example:

```
<custodian>
  <assignedCustodian>
    <representedCustodianOrganization>
      <id root="1.2.300.2.12.5.21.2" extension="24680135"/>
      <name>Hôpital Louis Legrand</name>
      <telecom value="tel:+3555364678" use="WP"/>
      <addr>
        <streetAddressLine>Rue des Tomains 1</streetAddressLine >
        <postalCode>2540</postalCode>
        <city>LUXEMBOURG</city>
        <country>LUX</country>
      </addr>
    </representedCustodianOrganization>
  </assignedCustodian>
</custodian>
```

3.5.6. informationRecipient

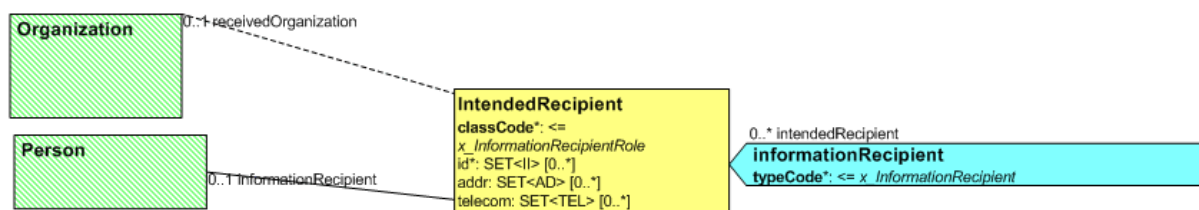


Figure 16: InformationRecipient description

The InformationRecipient represents persons who are recipients of the information. So for example a healthcare provider who will receive a copy of the clinical document (under the control of the patient consent policy).

Element/Attribute	DT	Card	Description
informationRecipient	POCD_MT00004 0.InformationRecipient	[0..*]	

	intendedRecipient	POCD_MT00004 0.IntendedRecipie nt	[1..1]	
--	-------------------	---	--------	--

Table 65: ClinicalDocument/informationRecipient specification

Note:

The recipient information provided will be with the creation of the document. This is an informal information and delivery to this intended recipients is not ensured by the CDA implementation and must be done at the communication layer. It also does not pretend that the document will be provided, maybe at a later time, to other persons.

3.5.6.1. intendedRecipient

The identifiers given as part of the intendedRecipient SHALL be the identifiers of the informationRecipient (Person) not these of the organization.

CONF-LU-78: When the informationRecipient element is present, at least, one informationRecipient/intendedRecipient/informationRecipient **SHALL** be present.

CONF-LU-79: intendedRecipiient/id **MAY** have nullFlavor="UNK" or nullFlavor="NI".

Element/Attribute		DT	Card	Description
intendedRecipient		POCD_MT00004 0.IntendedRecipie nt	[1..1]	
	id	II	[1..*]	Set of identifiers to identify the informationRecipient uniquely (Person as health professional). The instance identifier data type SHALL be used as specified in chapter: 2.2 The following nullFlavor are allowed: <ul style="list-style-type: none"> NI: Person does not have an HPD-Identifier UNK: Person has an HPD-Identifier but this identifier is not known
	@root	uid	[1..1]	OID of the identification mechanism of the identification scheme of the national HPD. OID: 1.3.182.4.1
	@extension	st	[0..1]	The value of the national unique identifier for this health professional

				from the HPD.
	addr	AD	[0..*]	Address as specified in chapter: 3.1.1
	telecom	TEL	[0..*]	Connection data as specified in chapter: 3.1.2
	informationRecipient	POCD_MT00004 0.Person	[1..1]	Personal information about the intended recipient. SHALL be compliant to specification described in chapter: 3.1.6
	receivedOrganization	POCD_MT00004 0.Organization	[0..1]	Organization to which the intended recipient belongs to. SHALL be compliant to specification described in chapter: 3.1.5

Table 66: informationRecipient/intendedRecipient specification

Example:

```
<informationRecipient typeCode="PRCP">
  <intendedRecipient>
    <id nullFlavor="UNK"/>
    <informationRecipient>
      <name>
        <family>Doe</family>
        <given>John</given>
      </name>
    </informationRecipient>
    <telecom value="tel:+352-1234-213"/>
    <receivedOrganization>
      <id root="1.3.182.3.1.1.1231231.34"
        assigningAuthorityName="Agence eSanté HPD"/>
      <name>Better health hospital</name>
      <telecom value="tel:+352-12345"/>
      <telecom value="fax:+352-12345-67"/>
      <addr>
        <streetAddressLine>Rue des Tomains 1</streetAddressLine >
        <postalCode>2540</postalCode>
        <city>LUXEMBOURG</city>
        <country>LUX</country>
      </addr>
    </receivedOrganization>
  </intendedRecipient>
</informationRecipient>
```

3.5.7. legalAuthenticator

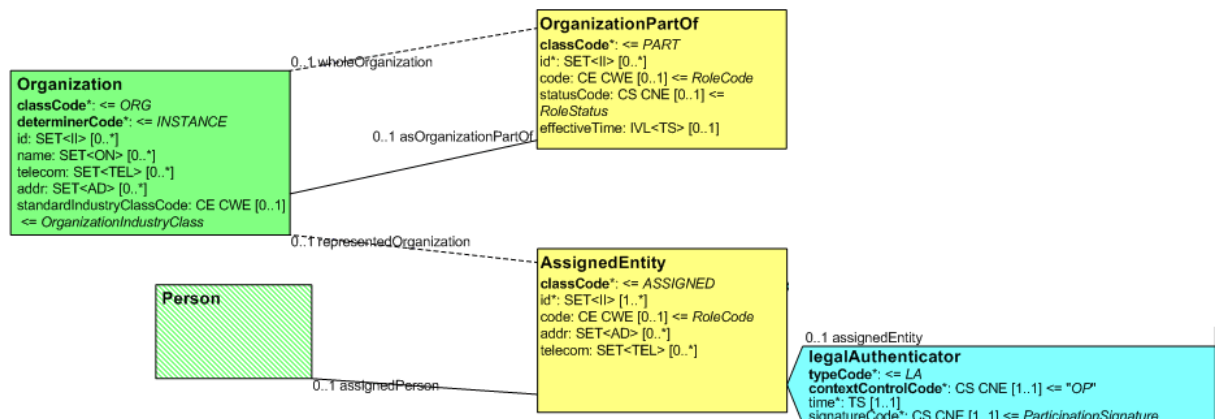


Figure 17: LegalAuthenticator description

The legalAuthenticator represents the legal responsible of the clinical document. In the CDA specification only individuals (e.g. health professionals) can take legal responsibility for the content of the document, on behalf of an organization.

CONF-LU-80: The assignedEntity/assignedPerson element **SHALL** be present

CONF-LU-81: The value of the signatureCode@code **SHALL** be "S"

CONF-LU-82: The assignedEntity/assignedPerson/name **SHALL** be in structured form as specified in chapter: 3.1.3.2

Element/Attribute	DT	Card	Description
legalAuthenticator	POCD_MT000040.LegalAuthenticator	[1..1]	
assignedEntity	POCD_MT000040.AssignedEntity	[1..1]	Assigned person and the organization which is represented by this person. AssignedEntity representation must be conformant to the specification in chapter: 3.1.7
time	TS	[1..1]	Time of the creation of the signature. Format SHALL be conformant to specification in chapter: 3.1.4
signatureCode	CS	[1..1]	
@code		[1..1]	Constant value = "S"

Table 67: ClinicalDocument/legalAuthenticator specification

Note:

If a patient provides medical information e.g. notes or medical information collected with medical devices, as CDA documents, then the patient will be the legalAuthenticator, so the responsible for these data.

Example:

```
<legalAuthenticator>
  <time value="20130407121200+0100"/>
  <signatureCode code="S"/>
  <assignedEntity>
    <id root="1.3.182.4.1" extension="2123456789"/>
    <addr>
      <streetAddressLine>Rue des Tomain 1</streetAddressLine >
      <postalCode>2540</postalCode>
      <city>LUXEMBOURG</city>
      <country>LUX</country>
    </addr>
    <telecom value="tel:+352-12345" use="WP"/>
    <assignedPerson>
      <name>
        <prefix @qualifier="AC">Dr.</prefix>
        <family>Jordan</family>
        <family @qualifier="BR">Johnson</family>
        <given>Jeannette</given>
        <given>Maria</given>
      </name>
    </assignedPerson>
  </assignedEntity>
</legalAuthenticator>
```

3.5.8. authenticator

The authenticator identifies the participant who attested to the accuracy of the information in the document. More than one authenticator could be defined in the header.

CONF-LU-83: The authenticator **MAY** be present. The assignedEntity/assignedPerson element **SHALL** be present when the authenticator is present.

CONF-LU-84: The value of the signatureCode **SHALL** be "S"

CONF-LU-85: Authenticator/assignedEntity/assignedPerson/name **SHALL** be structured as specified in chapter: 3.1.3.2

Element/Attribute		DT	Card	Description
authenticator		POCD_MT000040.Authenticator	[0..*]	
	assignedEntity	POCD_MT000040.AssignedEntity	[1..1]	Assigned person and the organization which is represented by this person. AssignedEntity representation SHALL be conformant to the specification in chapter: 3.1.7
	time	TS	[1..1]	Time of the creation of the signature. Format SHALL be conformant to specification in chapter: 3.1.4
	signatureCode	CS	[1..1]	
	@code		[1..1]	Constant value = "S"

Table 68: ClinicalDocument/authenticator specification

Example:

```
<authenticator>
  <time value="20130407121200+0100"/>
  <signatureCode code="S"/>
  <assignedEntity>
    <id root="1.3.182.4.1" extension="2123456789"/>
    <addr>
      <streetAddressLine>Rue des Tomains 1</streetAddressLine >
      <postalCode>2540</postalCode>
      <city>LUXEMBOURG</city>
      <country>LUX</country>
    </addr>
    <telecom value="tel:+352-123453" use="WP"/>
    <assignedPerson>
      <name>
        <family>John</family>
        <given>Doe</given>
      </name>
    </assignedPerson>
  </assignedEntity>
</authenticator>
```

3.5.9. participant

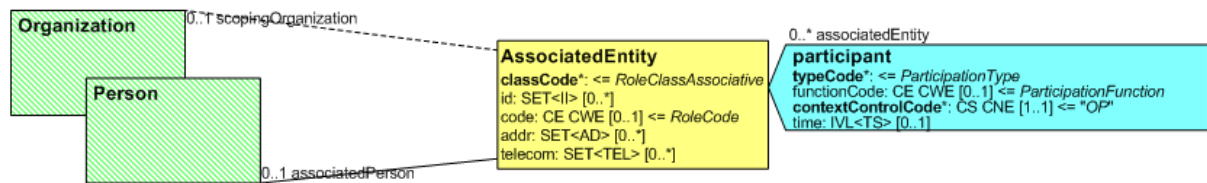


Figure 18: Participant description

The association class “participant” can be used to provide information about other participants related to this document, which are not represented by the other classes of the CDA Header participants section (see chapter: 3.2) So e.g. information about the admitting, attending or referring physicians can be provided here.

To classify the type of participant, mainly the elements typeCode and functionCode of the participant and the classCode of the associatedEntity role are used.

The following table presents the different actors identified as participants, and which code combinations shall be used.

Element	participant/typeCode	participant/functionCode	associatedEntity/classCode	associatedEntity/code
Value set	eSanté_ParticipantTypeCode	eSanté_ParticipationFunction	eSanté_AssociatedEntityClassCode	
Medical contact person Health professional from the document creator which should be contacted for further information (if not the same as the authenticator/author).	CALLBCK	-	PROV	Possible values SHALL be from Value Set: eSanté_Medical Specialty
Referring physician Health professional which is the referrer of the patient.	REF	ADMPHYS	PROV	Possible values SHALL be from Value Set: eSanté_Medical Specialty
Family doctor	IND	PCP	PROV	
Emergency contact Person who should be contacted in the emergency case of the patient, e.g. a family member.	IND	-	ECON	
Personal contact E.g. family members or friends, people	IND	-	PRS	Possible values SHALL be from Value Set:

which are in personal relationship with the patient.				eSanté_Personal RelationshipRole Type
Insurance	HLD	-	POLHOLD	
Next care providers Institutions which provide care to the patient after the treatment in this institution (which has created the document).	IND		CAREGIVER	

Table 69 : Different participants as AssociatedEntity

CONF-LU-86: If participant is provided, the participant/associatedEntity/associatedPerson **SHALL** be provided.

Element/Attribute	DT	Card	Description
participant	POCD_MT0000 40.Participant1	[0..*]	
@typeCode	CS	[1..1]	Code to classify the type of participant e.g. "REF" for referrer. Possible values SHALL be from Value Set: eSanté_ParticipantTypeCode
functionCode	CE/CWE	[0..1]	Functional role of the participant e.g. "ADMPHYS" for the admitting physician, related to the patient's treatment documented in this document instance Possible values SHALL be from Value Set: eSanté_ParticipationFunction
associatedEntity	POCD_MT0000 40.AssociatedEntity	[1..1]	Assigned person and the organization which is represented by this person. AssignedEntity representation SHALL be conformant to the specification in chapter: 3.1.7
@classCode	CS	[1..1]	Specifies the type of the associated person e.g. "PROV" for healthcare provider. Possible values SHALL be from Value Set: eSanté_AssociatedEntityClassCode
id	II	[0..1]	If available, the health professional identifier of this participant may be provided. As specified in chapter: 2.2
code	CE/CWE	[0..1]	Code for defining the role or the assignedEntity finer grained. Element is optional, if given the values SHALL be taken from the Value Sets as described in the table

					above, see Table 69 : Different participants as AssociatedEntity.
		addr	AD	[0..1]	Address of the participant person. SHALL be compliant to specification in chapter: 3.1.1
		telecom	TEL	[1..1]	Communication data of the participant person. SHALL be compliant to specification in chapter: 3.1.2
		associatedPerson	POCD_MT0000 40.Person	[1..1]	Information about the person who is a participant being represented here. Information which has to be provided SHALL be conformant to specification in chapter: 3.1.6
		scopingOrganization	POCD_MT0000 40.Organization	[0..1]	Information about the organization to which the associated person belongs. The information provided about the organization SHALL be compliant as specified in chapter: 3.1.5

Table 70: ClinicalDocument/participant specification

Different representations of participants related to the Luxembourgish healthcare sector will be described in detail after discussion with the workgroup.

3.6. RELATED ACTS

3.6.1. relatedDocument

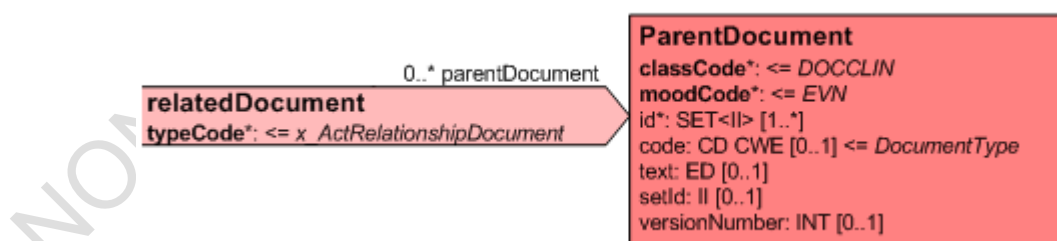


Figure 19: RelatedDocument description

The relatedDocument can be used to report about a predecessor of the current document, which this document is a transformation, addition or replacement.

A clinical document can be replaced by a new document and/or appended with an addendum and/or transforms from some other format (meaning that it has undergone a machine translation from some other format (such as DICOM SR)).

The typeCode attribute of the relatedDocument describes the type of relationship; the following codes are possible as specified by HL7:

typeCode	Text	Description
APND	append	This document is an addendum of the parent document.
RPLC	replace	This document replaces the parent document.
XFRM	transformation	This document is a transformation of the parent document. A transformation is e.g. another representation of the medical content of the parent document. It must not change the content of the original document. So e.g. if a PDF is rendered out of the structured content of the parent CDA document, it could be stored as a transformation of the original document.

Table 71: Allowed typeCodes for related documents

With this specification only the usage of “RPLC” and “XFRM” are allowed.

The following constraints exist:

- A conformant CDA document can **have a single relatedDocument with**:
 - typeCode “RPLC” or “XFRM”
- A conformant CDA document can **have a two relatedDocument entries with**:
 - typeCode “RPLC” and “XFRM”

CONF-LU-87: Only typeCode “RPLC” and “XFRM” **SHALL** be used.

CONF-LU-88: A document can have two relatedDocument entries where one **SHALL** be of typeCode “RPLC” and the other of typeCode “XFRM”.

Element/Attribute	DT	Card	Description
relatedDocument	POCD_MT000040.RelatedDocument	[0..*]	
typeCode	CS	[1..1]	Can be one of the types RPLC or XFRM

Table 72: relatedDocument specification

Example:

```
<relatedDocument typeCode="RPLC">
  <parentDocument>
    <id root="1.3.182.3.1.1231232.37.1" extension="23423423"/>
  </parentDocument>
</relatedDocument>
```

3.6.1.1. relatedDocument/parentDocument

CONF-LU-89: A value for the parentDocument/id attribute **SHALL** be provided

Element/Attribute		DT	Card	Description
parentDocument		POCD_MT000040.ParentDocument	[1..1]	
	id	II	[1..1]	Identifier of the parent document. It SHALL be conformant to the specification of the II data type in chapter: 2.2

Table 73: relatedDocument/parentDocument specification

The id must be the identifier of the parentDocument. The other parameters of the parentDocument like e.g. setId and versionNumber can be gained when retrieving this parent document. Putting values for attributes of this document creates redundancy, therefore they are omitted.

3.6.2. inFulfillmentOf

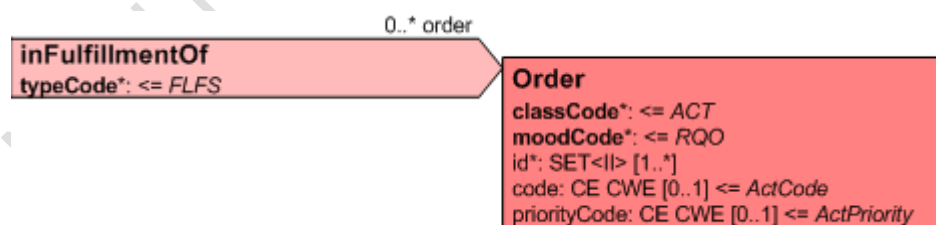


Figure 20: InFulfillmentOf description

The medical content of the CDA document could be produced as the result of a service that was ordered. This element represents the association of the clinical document to an order like e.g. for laboratory tests or an imaging study. Herewith the results can be linked with the original order.

CONF-LU-90: inFulfillmentOf@typeCode **SHALL** have the value “FLFS”

Element/Attribute	DT	Card	Description
inFulfillmentOf	POCD_MT000040.InFulfillmentOf	[0..*]	
@typeCode	CS	[1..1]	Constant value: FLFS

Table 74: inFulfillmentOf specification

3.6.2.1. inFulfillmentOf/order

Element/Attribute	DT	Card	Description
inFulfillmentOf/order	POCD_MT000040.Order	[1..1]	
id	II	[1..*]	Identifier of the order. The identifier SHALL be conformant to the specification in chapter: 2.2

Table 75: inFulfillmentOf/order specification

The code and priorityCode element will not be used.

3.6.2.2. inFulfillmentOf/order/id

CONF-LU-91: At least one order/id **SHALL** be provided

CONF-LU-92: inFulfillmentOf/order/id SHALL have the id's provided in the order as described below

CONF-LU-93: id[2] and id[3] are optional and **MAY** have a nullFlavor of “UNK” or “NI”

The identifiers given should be in the following order:

Element/Attribute	DT	Card	Description
id[1]	II	[1..1]	Unique order id from the order-filler system. The identifier SHALL be conformant to the specification in chapter: 2.2
id[2]	II	[0..1]	If provided, the order id from the prescriber. The identifier SHALL be conformant to the specification in chapter: 2.2 If not known one of the following nullFlavor SHALL be used:

			<ul style="list-style-type: none"> • UNK: A order id from the prescriber exists but is not known • NI: No order id from the prescriber
id[3]	II	[0..1]	<p>If order is based on subcontracting, this field could be used to store the order id of the primary institution. The identifier SHALL be conformant to the specification in chapter: 2.2.</p> <p>If not known one of the following nullFlavor SHALL be used:</p> <ul style="list-style-type: none"> • UNK: A order id from the primary institution exists but is not known • NI: No order id from primary institution

Table 76: order/id specification

Example:

```
<inFulfillmentOf typeCode="FLFS">
  <order classCode="ACT" moodCode="RQO">
    <id root="1.3.182.3.1.1231232.37.5" extension="0338123"/>
  </order>
</inFulfillmentOf>
```

3.6.3. documentationOf

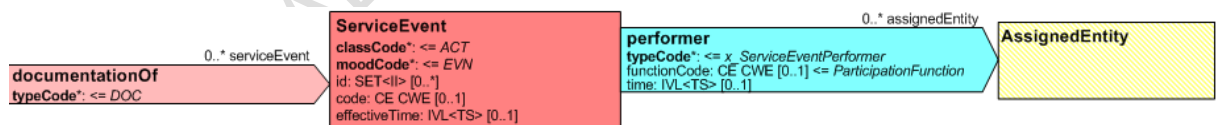


Figure 21: DocumentationOf description

The relationship documentationOf is used to provide information about the medical act (e.g. procedure, diagnostic...) performed for the patient as part of the patient's treatment. The serviceEvent class can be any kind of act that can be represented in the HL7 Act class hierarchy. It is used to give information about the service events which are described in detail in the Body of the CDA document.

The ClinicalDocument/code and the service events which are documented here as documentationOf/serviceEvent must be related and logically complement each other. While the ClinicalDocument/code describes the type of document, e.g. Diagnostic Imaging Report, the service events must be related e.g. X-Ray, Endoscopy...

The timing interval serviceEvent/effectiveTime can be used to describe the duration of this service event, so the time span on which the treatment/care is provided.

Note:

The information about the service event described in this CDA document, are also used and stored as part of the XDS metadata in the XDS-Registry. This information can be used later to search for the appropriate medical document.

CONF-LU-94: At least one serviceEvent **SHALL** be provided.

CONF-LU-95: When a documentationOf is present, effectiveTime low value **SHALL** be present for the main act. If the high value is not known, the nullFlavor "UNK" is allowed.

Element/Attribute			DT	Card	Description
documentationOf			POCD_MT000040.DocumentationOf	[1..*]	
	serviceEvent		POCD_MT000040.ServiceEvent	[1..1]	
		id	II	[0..1]	Optional unique identifier for the service event can be provided, if given by the institution which performs the medical act.
		code	CE/CWE	[1..1]	Code of the service event. The codes which can be used here are related to the specific CDA specification for the document type or medical domain e.g. laboratory and radiology domain. The representation of the code must be compliant to the specification in chapter: 2.3.2 If the code is not known the nullFlavor: UNK is allowed.
		effectiveTime	IVL_TS	[0..1]	Value of the time (interval) when the act (service event) was executed. The given time SHALL be compliant to the specification in chapter: 3.1.4.3 If the effectiveTime should be used to describe a point in time, the low and high attribute should have the same value.

Table 77 : ClinicalDocument/documentationOf specification

Note:

The possible codes e.g. LOINC for laboratory analysis, CIM-10 for diagnosis ... and the meaning of the effectiveTime interval will be precisely defined in the derived specifications which are related to a specific type of medical document.

Example:

```
<documentationOf>
  <serviceEvent>
    <id root="1.3.182.3.1.1.1231231.34.6" extension="2011123"/>
    <code code="18719-5" displayName="Biochimie"
      codeSystem="2.16.840.1.113883.6.1"
      codeSystemName="LOINC"/>
    <effectiveTime>
      <!-- Date when got the request and samples -->
      <low value="201307040922+0100"/>
      <!--Date when this medical act (e.g. test) ended -->
      <high value="201307041605+0100"/>
    </effectiveTime>

    <performer typeCode="PRF">
      <assignedEntity>
        <id root="1.3.182.4.1" extension="2123456789"/>
        <addr>
          <streetAddressLine>Rue des Tomains 1</streetAddressLine >
          <postalCode>2540</postalCode>
          <city>LUXEMBOURG</city>
          <country>LUX</country>
        </addr>

        <telecom value="tel:+352-12345" use="WP"/>
        <assignedPerson>
          <name>
            <prefix @qualifier="AC">Dr.</prefix>
            <family>Jordan</family>
            <given>Jeannette</given>
          </name>
        </assignedPerson>
        <representedOrganization>
          <id root="1.3.182.3.1.1.12312327.27"
            assigningAuthorityName="Agence eSanté HPD"/>

          <name>Better Laboratory</name>
          <telecom value="tel:+352-12345"/>
          <telecom value="fax:+352-12345-67"/>
          <addr>
            <streetAddressLine>Rue des Tomains 1</streetAddressLine :
            <postalCode>2540</postalCode>
            <city>LUXEMBOURG</city>
            <country>LUX</country>
          </addr>

        </representedOrganization>
      </assignedEntity>
    </performer>
  </serviceEvent>
</documentationOf>
```

3.6.3.1. DocumentOf/serviceEvent/performer

Service events are performed by one or more persons, represented as performer in the CDA header. These persons can have different roles (assigned by their organization, e.g. nurse) related to the service event they performed.

Element/Attribute	DT	Card	Description
performer	POCD_MT000040.Performer 1	[0..1]	
@typeCode	CS	[1..1]	E.g. "PRF" for performer. Possible values SHALL be from Value Set: eSanté_ServiceEventPerfo rmerType .
assignedEntity	POCD_MT000040. AssignedEntity	[1..1]	The assigned entity as specified in chapter: 3.1.7

Table 78: serviceEvent/performer specification

3.6.4. authorization

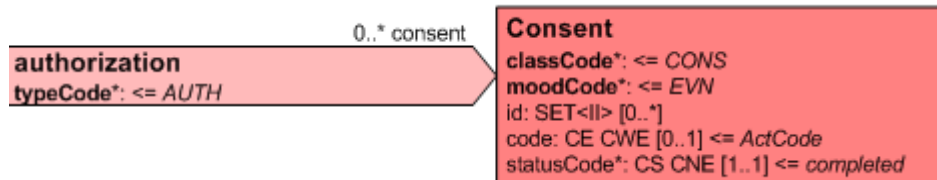


Figure 22: Authorization description

The authorization association can be used with the consent class to link the document with a given consent of a patient.

Since it is not the current practice to provide this information with the medical document of a patient, this information will not need to be provided.

CONF-LU-96: The authorization element **NEED NOT to be used**

Element/Attribute	DT	Card	Description
authorization	POCD_MT000040.Authorizat ion	[0..*]	
consent	POCD_MT000040.Consent	[1..1]	
id	II	[0..*]	Could be used e.g. to identify the document

					containing the signed consent of the patient. If given it must be conformant to the specification of the II data type in chapter: 2.2
		code	CE/CWE	[0..1]	This is the code specifying the type of consent precisely.
		statusCode	CS/CNE	[1..1]	constant value: "completed"

Table 79: ClinicalDocument/authorization specification

3.6.5. componentOf

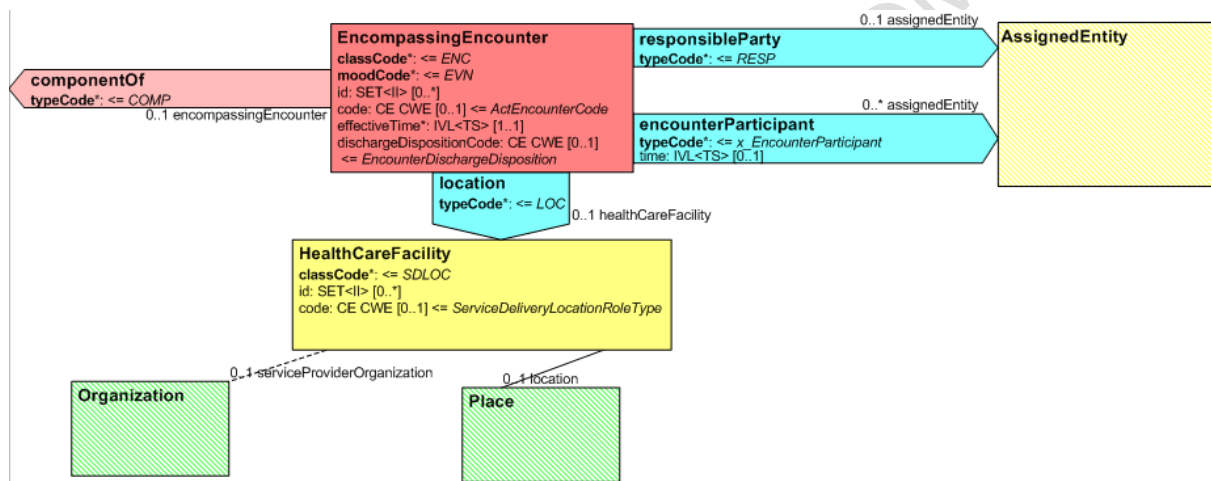


Figure 23: ComponentOf description

The componentOf association represents the link of the clinical document with an encounter. The encompassingEncounter represents the setting of the clinical encounter during which the documented act(s) or service event occurred.

So e.g. if the CDA document is a discharge summary or a transfer letter, this information must be provided. This is specified in the implementation guidelines for the different document types.

CONF-LU-97: encompassingEncounter/effectiveTime **SHALL** be present. If the date of the beginning or the end of the encounter is not known, the nullFlavor "UNK" is allowed.

Element/Attribute	DT	Card	Description
componentOf	POCD_MT000040.Component1	[0..1]	
encompassingEncounter	POCD_MT000040.EncompassingEncounter	[1..1]	

Table 80: ComponentOf specification

NON FINAL, FOR PUBLIC COMMENT

Example:

```
<componentOf>
  <encompassingEncounter>
    <id root="1.3.182.3.1.1.1231231.34.7" extension="11000078"
      assigningAuthorityName="Better Health hospital"/>
    <code code="AMB"
      displayName="Ambulatory"
      codeSystem="2.16.840.1.113883.5.4"
      codeSystemName="HL7:ActCode"/>
    <effectiveTime>
      <low value="20130407163500+0100"/>
      <high nullFlavor="UNK"/>
    </effectiveTime>
    <responsibleParty>
      <assignedEntity>
        <id root="1.3.182.4.1" extension="2123456789"/>
        <addr>
          <streetAddressLine>Rue des Tomains 1</streetAddressLine>
          <postalCode>2540</postalCode>
          <city>LUXEMBOURG</city>
          <country>LUX</country>
        </addr>
        <telecom value="tel:+352-12345" use="WP"/>
        <assignedPerson>
          <name>
            <prefix @qualifier="AC">Dr.</prefix>
            <family>Jordan</family>
            <given>Jeannette</given>
            <given>Maria</given>
          </name>
        </assignedPerson>
      </assignedEntity>
    </responsibleParty>
    <location>
      <healthCareFacility>
        <serviceProviderOrganization>
          <id root="1.3.182.3.1.1.1231231.34"
            assigningAuthorityName="Agence eSanté HPD"/>
          <name>Better health hospital</name>
          <telecom value="tel:+352-12345"/>
          <telecom value="fax:+352-12345-67"/>
          <addr>
            <streetAddressLine>Rue des Tomains 1</streetAddressLine >
            <postalCode>2540</postalCode>
            <city>LUXEMBOURG</city>
            <country>LUX</country>
          </addr>
        </serviceProviderOrganization>
      </healthCareFacility>
    </location>
  </encompassingEncounter>
</componentOf>
```

3.6.5.1. componentOf/encompassingEncounter

The necessity to provide information about the patient encounter is related to the type of document and the service events performed. The decision if such the encounter has to be documented is specified in the implementation guidelines for the specific document types.

CONF-LU-98: encompassingEncounter/id **SHALL** be present.

CONF-LU-99: encompassingEncounter/code **SHALL** be present.

Element/Attribute	DT	Card	Description
encompassingEncounter	POCD_MT000040.EncompassingEncounter	[1..1]	
id	II	[1..1]	Identifier of this patient encounter. Usage of the II identifier must be compliant to the specification in chapter: 2.2
@root	UID	[1..1]	OID of the organizations name scheme for encounter identifier
@extension	ST	[1..1]	Local value of the encounter identifier
@assigningAuthorityName	ST	[0..1]	Name of the office/institution which provides the identifier e.g. "XYZ-Clinic"
code	CE/CWE	[1..1]	Code for the type of patient encounter. Usage of CE type must be conformant to specification in chapter: 2.3.2
@code	ST	[1..1]	Possible values SHALL be from Value Set: eSanté_ActEncounterCode
@displayName	ST	[1..1]	
@codeSystem	ST	[1..1]	Constant value: "2.16.840.1.113883.5.4"
@codeSystemName	ST	[0..1]	Constant value: "HL7:ActCode"
effectiveTime	IVL<TS>	[1..1]	The duration of the encounter. SHALL be conformant as specified in chapter: 3.1.4.3
dischargeDispositionCode	CE/CWE	[0..1]	Code describing what happens to the patient after the encounter was completed. Usage of CE type must be conformant to specification in chapter: 2.3.2 Possible values SHALL be from Value Set:

			eSanté_DischargeDisposition Code.
--	--	--	--------------------------------------

Table 81: componentOf/encompassingEncounter specification

3.6.5.2. responsibleParty

CONF-LU-100: If responsibleParty is given, the
responsibleParty/assignedEntity **SHALL** be present.

Element/Attribute	DT	Card	Description
responsibleParty	POCD_MT00 0040.Respon sibleParty	[0..1]	Person or organization who is primarily responsible for the patient encounter
assignedEntity	POCD_MT00 0040.Assign edEntity	[1..1]	Assigned entity as specified in chapter: 3.1.7

Table 82: componentOf/ responsibleParty specification

The requirement to possibly provide the responsible party and the concrete entity which is responsible for the encounter depends on the type of document and is therefore specified in the implementation guidelines of these document types.

3.6.5.3. encounterParticipant

Additionally to the responsibleParty, other persons can be involved in the patient encounter, like e.g. the person admitting or referring the patient for care.

CONF-LU-101: If encounterParticipant is given, the
encounterParticipant/assignedEntity **SHALL** be present.

Element/Attribute	DT	Card	Description
encounterParticipant	POCD_MT00 0040.Encoun terParticipant	[0..1]	Other persons involved in the patient encounter
@typeCode	CS	[1..1]	Type code for the encounter participants. Possible values SHALL be from Value Set: eSanté_EncounterParticipantT ype.
assignedEntity	POCD_MT00 0040.Assign edEntity	[1..1]	Assigned entity as specified in chapter: 3.1.7

Table 83: componentOf/ encounterParticipant specification

3.6.5.4. location

If the encompassing Encounter has been provided, the location where this event happened shall also be provided.

CONF-LU-102: location/healthCareFacility/serviceProviderOrganization
SHALL be present.

Element/Attribute		DT	Card	Description
location		POCD_MT0000 40.Location	[1..1]	
	healthCareFacility	POCD_MT0000 40.HealthCareF acility	[1..1]	
	serviceProviderOrganization	POCD_MT0000 40.Organization	[1..1]	Healthcare organization at which the patient encounter has been done. The organization must be used as specified in chapter: 3.1.5

Table 84: componentOf/ location specification

Due to the fact that information about the healthcare facility, like e.g. the type could be dynamically requested by accessing the HPD (Health Provider Directory), this data are more accurate than those stored in the document. Therefore the identifier of the organization (serviceProviderOrganization) can be used to request the HPD, since it identifies the organization uniquely.