Smart Open Services for European Patients

Open eHealth initiative for a European large scale pilot of

Patient Summary and Electronic Prescription

Work Package 3.5

Semantic Services Definition

D3.5.2

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Referring Documents

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2008-06-30	pdf	Annex I – "Description of Work"		EMP/S.O.S. LSP-eHealth team	
2009-07-29	pdf	D3.2.1 Draft definition of functional service require-ments- Patient Summary	0.6	WP 3.2	Draft_D3.2.1_v0.6.pdf
2009-07-22	doc	D3.1.1 Draft definition of functional service require-ments – ePrescription	2.63	WP 3.1	D3 1 1 epSOS WP 3 1_v2 63.doc
2009-06-12	doc	Methodology to achieve a Common Data Set for an epSOS Patient Summary	0.2	WP 3.5 Group A, ELGA / Dr. Christoph Gillessen	Methodology to achieve a Common Data Set.doc
2009-06-09	doc	Emergency Data Set Mini-mal Patient Data Set - Part 1	0.1.5	MUDr. Jansta, MUDr. Frolkovič, MUDr. Pal-maj, RNDr. Popper	Emergency Data Set-a_v0_1_5.doc
2009-06-09	doc	Emergency Data Set Mini-mal Patient Data Set - Part 2	0.1.5	MUDr. Jansta, MUDr. Frolkovič, MUDr. Pal-maj, RNDr. Popper	EDS-values.doc
2009-06-09	xlsx	WP3_1_Questionnaire_Stru cture_eP_Results_CDA_Ma pping.xlsx	0.1	WP 3.5 Group A, ELGA / Dr. Christoph Gillessen	WP3_1_Questionnaire_S truc-ture_eP_Results_CDA_ Mapping.xlsx
2009-06-09	xlsx	WP3.5_PatientSummary_Co ntent_Structure.xls	0.1	WP 3.5 Group A, ELGA / Dr. Christoph Gillessen	WP3.5_PatientSummary _Content_Structure.xls
2009-07-10	pdf	D3.2.1 Draft definition of functional service require-ments- Patient Summary	0.5	WP 3.2	D3.2.1_v0.5.pdf
2009-07-06	doc	D3.1.1 Draft definition of functional service require-ments – ePrescription	2.61	WP 3.1	D3 1 1 epSOS WP 3 1_v2 61.doc
Fifth edition, 2004	pdf	Rules for the structure and drafting of International Standards	Part 2	ISO/IEC, Directives,	http://www.iec.ch/tiss/iec /Directives-Part2-Ed5.pdf
2009-06-23	doc	CDA Content Modules, Public Comment	1.0	IHE International	IHE_PCC_Content_Mod ules_TI_Draft.doc
2006-06-14	Html	HL7 Version 3 Standard	Version 3, 2006	HL7 International	Implementation Tech-nology Specifications
2009-07-27	Htm	HL7 Version 3 Publishing Facilitator's Guide	Version 3, 2008	HL7 International	http://www.hl7.org/v3bal lot/html/help/pfg/pfg.htm .
2008-10-10	doc	Integrating the Healthcare Enterprise, Patient Care Coordination Technical Framework, Volume 1 and Volume 2	Revision 4	IHE International	IHE_PCC_TF_4 0_Vol_2_2008-10-10.doc
2009-07-31	doc	IHE Patient Care Coordina-tion Technical Framework Supplement. CDA Content Modules Trial Implementa-tion	Version 1	IHE International	IHE_PCC_Content_Mod ules_TI_2009-07-26.doc
2007-04-01	doc	HL7 Implementation Guide: CDA Release 2 – Continuity		HL7 International	CCD-final.doc

Date	Type	Description	Version	Origin	Document
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2008-07-16	doc	HL7 Implementation Guide for CDA Release 2: History and Physical (H&P) Notes (U.S. Realm). Draft Standard for Trial Use, Release 1, Levels 1, 2, and 3		HL7 International	cda4cdt_HandP.doc
2009-07-28	doc	Draft definition of functional service requirements- Patient Summary Data Set	V0.1	WP3.2	PS_dataset_agreed Paris.doc
2009-07-07	pdf	SNOMED Clinical Terms User Guide 2009		IHTSDO	http://www.ihtsdo.org/publications/inside-ihtsdo/
2009	pdf	IHTSDO_Translation_Guidelines_20090309_v1-00.pdf		IHTSDO	http://www.ihtsdo.org/publications/translating-snomed-ct/
2009-04-01	pdf	Classifications and Cross-mapping		IHTSDO	http://www.ihtsdo.org/publications/developing-snomed-ct-content/
2009-07-01	pdf	Technical Implementation Guide		IHTSDO	http://www.ihtsdo.org/publications/implementing-snomed-ct/
2009-07-01	pdf	Technical Reference Guide		IHTSDO	http://www.ihtsdo.org/publications/implementing-snomed-ct/
2009-07-01	pdf	LOINC User's Guide		Regenstrief Institute	http://loinc.org/downloads/files/LOINCManual.pdf
2004	pdf	ICD-10 2nd Edition Volume 2 Instruction Manual		WHO FIC	http://www.who.int/classifications/icd/en/
2005	html	CDA Release 2.0 Normative Web Edition, May, 2005 (Publication: September 2005) NORMATIVE WEB EDITION		(Publication: September 2005)	http://healthinfo.med.dal.ca/hl7intro/CDA_R2_NormativeWebEdition/
2002	Html	XML Implementation Technology Specification - Data Types	Version 1.0	Regenstrief Institute for Health Care	http://aurora.regenstrief.org/v3dt/datatypes-its-xml.html#dtimpl-URL
2003	Word	Hospital Data Project – Final Report		European Union Health Monitoring Programme	
2010	Word	Dose Syntax Abstract Model	Version 0.1	ISO TC215 WG6N10	Dose Sy

1 Executive Summary

1.1 Introduction

The semantic services are an important aspect of the epSOS Large Scale Project since they **address the level of processable information from which medical information is inferred**. The functional requirements of the work packages (WP) 3.1 (ePrescription) and 3.2 (Patient Summary) have identified the content for three documents: ePrescription, eDispensation and the Patient Summary.

Semantic services must take into consideration at times the structure of these documents, assuring that the information is expressed using interoperable syntax, while also taking into account the code systems that are used to represent the information to be coded and translated. Furthermore, semantic services need to provide initial solutions towards semantic interoperability to overcome problems arising from usage of different terminologies and vocabularies. Terminology Access Services are also provided in order to ensure the on-the-fly interoperability between the different Member States.

1.1.1 Work Package Goal

Work package 3.5 (Semantic Services) describes the components necessary to achieve semantic interoperability in the exchange of medical information between the epSOS pilot sites. Semantic interoperability needs common elements such as:

- a common data structure of the three documents to be exchanged (**Pivot Documents**).
- a commonly understood medical terminology based on value sets extracted out of officially existing code systems used in these documents, namely the **epSOS Master Value Sets Catalogue (epSOS MVC).** The content of the epSOS Master Value Sets Catalogue serves as basis for translating to each Member State Language and cross-reference between different code systems, resulting into the **epSOS Master Translation/Transcoding Catalogue (epSOS MTC**). The content of the epSOS MVC will also be provided in an ontology (coded in OWL) to foster semantic interoperability.
- a way of accessing and maintaining the content present in the **epSOS Master Tranlation/Transcoding Catalogue** that is transparent to the user: the **Terminology Access Services interface.**

All these components are needed in order to enable the health care professional to make competent and informed decisions fostering the continuity of care.

1.1.2 Document Layout

"*The Semantic Service Definitions*" document can be considered as a standalone, globally describing the semantic services as applied to the epSOS project. *"The Semantic Services Definitions"* is an integral part of the epSOS project deliverables, therefore a familiarity with the general epSOS structure and concepts is assumed.

In addition to the main document, there is supporting material that has been grouped separately for ease of accessibility, namely into seven appendices:

- ***Appendix A****- Glossary*
- ***Appendix B*** *- Data Elements Correspondence*
- ***Appendix C*** *– Pivot Documents Specifications*
- ***Appendix D*** *- Master Value Set Catalogue Content*

- ***Appendix E*** *- Ontology Specifications*
- ***Appendix F*** *- Terminology Access Services*
- ***Appendix G*** *- EN13606 Implementation*

These appendices provide the necessary information for the implementers. Additional technical material is found in the folder "*Supporting Material*", which are specified files that can be of use to the implementers such as *owl*, *adl* or *wsdl* files. These are files that are meant for the implementers as an aid.

1.2 Overall description

The general flow of information within the semantic services is presented for a better comprehension of the processes involved. The flow of information concerns the content defined by WP3.1 and WP3.2, or the data elements. The data elements lead to an overview of the syntax and the build of a collection of terms grouped thematically into value sets. The value sets are at the basis of the epSOS Master Value Set Catalogue (epSOS MVC), which, when turned over to the National Linguistic Competence Centres gives in turn the epSOS Master Translation/Transcoding Catalogue (epSOS MTC). The epSOS Master Value Set Catalogue (epSOS MVC) is also the basis for the epSOS Ontology. Terminology access services interfaces are defined so that the content of the epSOS Master Translation/Transcoding Catalogue (epSOS MTC) can be easily accessed and maintained. The methodology and the approach chosen are presented, as well as the perimeter of the work realized. In order to get an overview of the results, certain technical concepts are presented so that the readers can familiarize themselves.

2 Information Flow

2.1 Semantic Document Workflow

The Health Care Professional (HCP) of country B sends a request to the NCP of his country (B) so that he can have access to the medical information needed for patient care. This request is forwarded to the NCP of country A, the patient's country of affiliation. NCP-A obtains the medical information for the requested patient and transforms the data, respecting the defined pivot documents syntax and the pivot vocabulary. NCP-A generates the pivot document by data transformation and it also generates a *pdf* version of the documents. It is also to be noted that the original code and the original display name from country A is kept in the pivot document as well as the pivot code and pivot display name. This is further explained in section 2.2.

The pivot document and the *pdf* documents are sent to NCP-B. The pivot document is transformed into the local data format and into the official language used for expressing medical information in Country B. The second transformation is left to the discretion of Country B since mapping onto a national schema and a national code system is outside the scope of this work package. However, some basis will be provided for terminology Translation/Transcoding through the epSOS Master Translation/Transcoding Catalogue (epSOS MTC) and the Terminology Access Services.

The Terminology Access Services interface is intended to provide 'on-the-fly' complete and accurate correspondence between the terminology used in the original document and its interoperable counterpart, and furthermore to the target language[1]. This terminology will be accessed by run-time components, fulfilling the translational requirements, but also by terminology curators, fulfilling the terminology maintenance requirements. It is in the scope of this document to define the standard interfaces to the epSOS MTC, as well as the indications for creating, maintaining and augmenting its contents.

The specifications for the data transformation from the Country A local medical information to the pivot document schema, and the specifications for the data transformation from the pivot document to the Country B local medical information is outside of the scope of this working package. The encryption and signature are out of the scope of WP3.5 and can be referenced to the deliverables of the work packages *3.3 - Architecture* and *3.4 - Common Components.*

The Terminology Access Services with the Run Time Components can be implemented **at the NCP level** or offered as a web service by the NCP **locally to the HCP**, depending on each member state's privacy and security policies. This is especially of importance in Member States (MS) where the data privacy and security policies forbid the direct handling of patient information without being encrypted and signed.

The general flow of information is represented in *Figure 1*.

[1] It must be noted that the Terminology Access Service uses the epSOS Master Translation/Transcoding Catalogue.

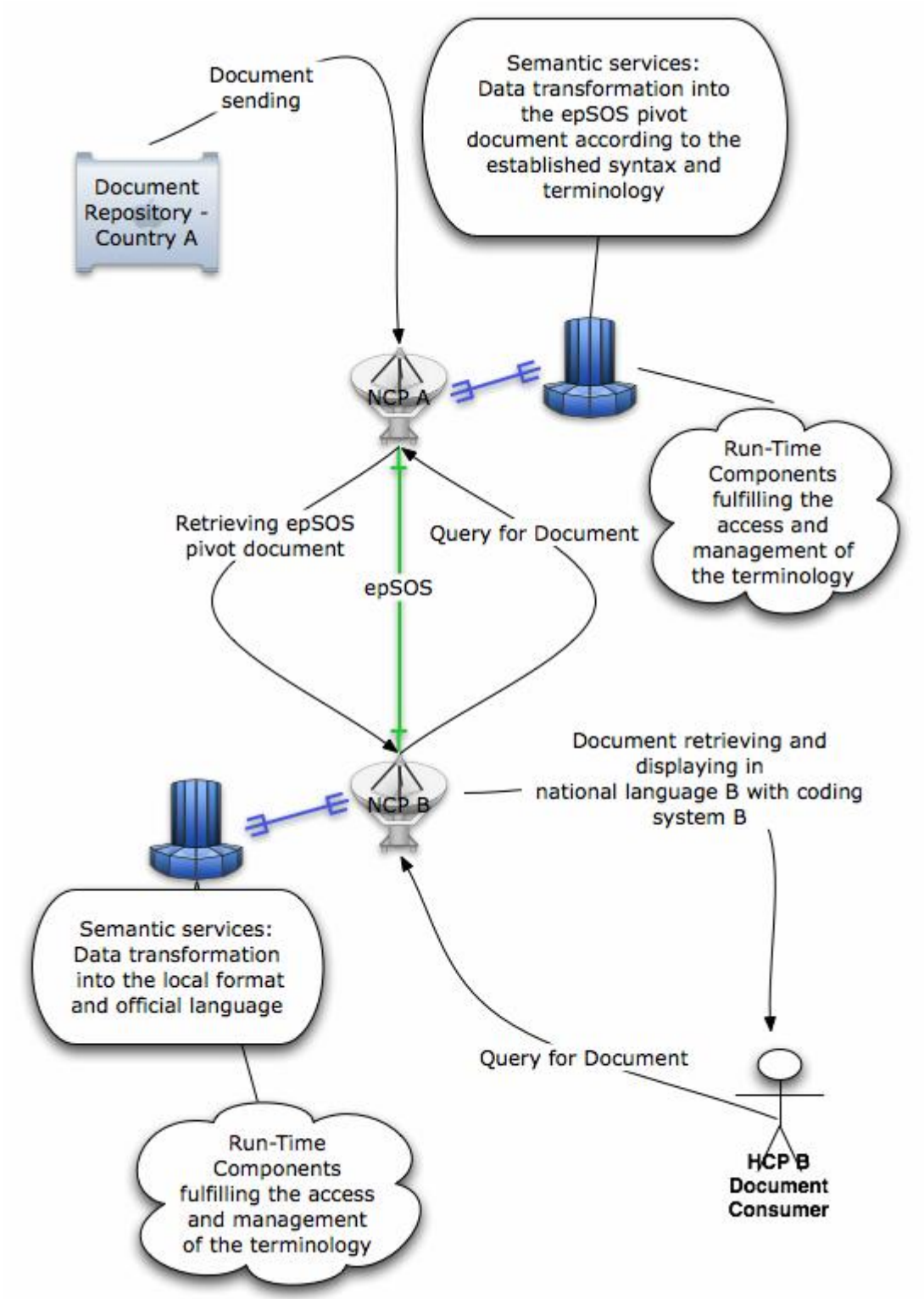

***Figure 1** - General information flow within the semantic services.*

2.2 Semantic Content Workflow

Since code systems such as SNOMED-CT and ICD-10 (to name but two) contain a large number of terms, it is not possible to use them in their entirety within the epSOS context, where some Member States might used different code systems that they will have to cross-reference and/or translate. Certain criteria were used to choose between the most significant terms and arrive to a reasonable man-

ageable content. For example, ICD-10 is a classification consisting of 22 chapters divided into categories having a 3-digits code. Each category is also divided into several sub-categories that provide a more granular level of information about the pathology coded.

International sub-categories are represented by a 4-digits code; the result from the addition of a fourth digit to the 3-digits code of the category which the sub-category belongs to. For instance, S80 is the code for *Superficial injury of lower leg*, while S80.1 is the one for *Contusion of other and unspecified parts of lower leg*.

In informatics it could be said that S80.1 specializes S80, or conversely that S80 generalizes S80.1. Going from one to another code would provide or remove information granularity. For the reasons mentioned above, the epSOS Master Value Set Catalogue uses an ICD-10 subset consisting of around 2000 3-digits codes (vs 12,000+ ICD-10 4-digits codes). English is the language used for displaying the code names. Nevertheless, there is concern that important granularity of information might be lost. In order to prevent the loss of granularity and the accuracy of information, both the original local code as well as the original display name will be sent along with the "translated/transcoded" term and display name as described below.

In these cases, the use case below explains how and where information will be processed:

1. Physician B sees Mr. X who has Country A as country of affiliation and requests from NCP B the patient's information.
2. Transactions to retrieve Mr.X files are initiated between NCP B and NCP A.
3. A document A containing among other information, Mr.X pathologies, created by Physician A is sent to NCP A. Mr.X pathologies are coded with Code A /displayName A (4-digits ICD-10 code, A language). *Note: the same process is valid for regional 5-digits ICD-10 codes.*
4. NCP A translates Code A to epSOS Code (Code E) by removing the fourth digit from Code A.
5. epSOS English Display Name (displayName E) is retrieved from the epSOS MTC, and both Code E and displayName E are entered into a newly created Document E. Code A and DisplayName A are kept within the same document in their original form.
6. After retrieving Document E, NCP B, using Code E display the name in B language from the epSOS MTC.
7. NCP B creates a new document (Document B), places the displayName B into it and sends the document B to the Physician B.
8. Physician B can now see Code B and displayName B, in language B. He can also see the initial Code A and displayName A which were kept into the document for additional information.

The process can be seen in *Figures 2* and *Figure 3*. Please see Appendix *C-Pivot Documents Specifications* for implementation details.

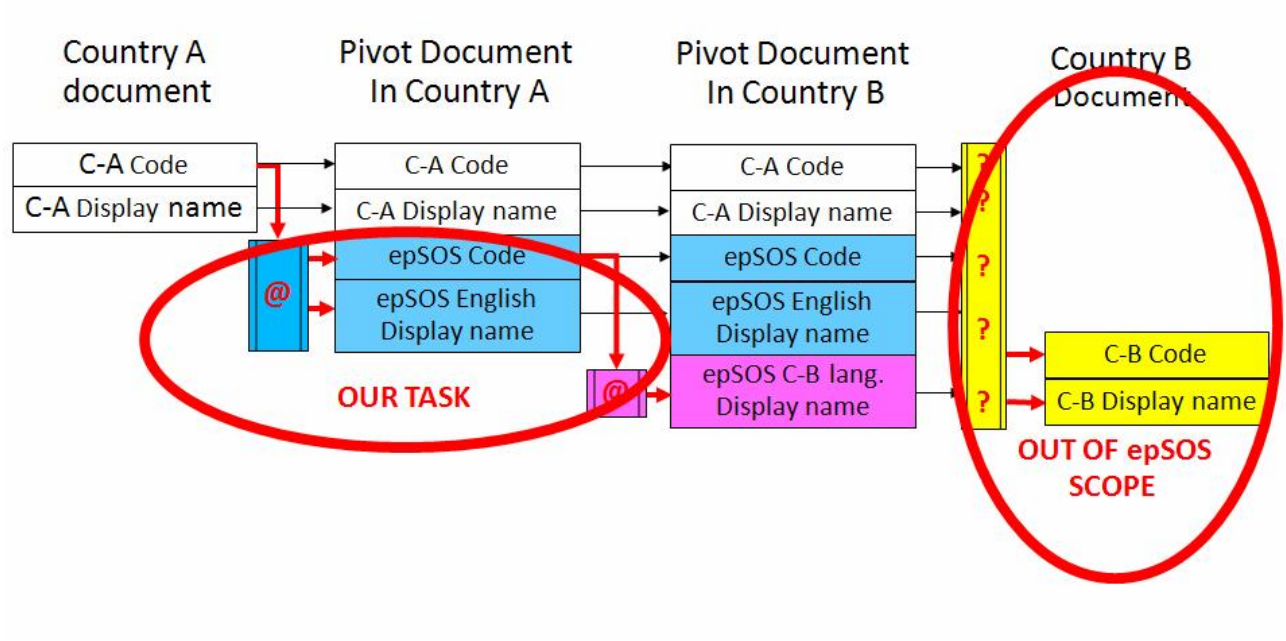

***Figure 2** - Semantic Content Workflow*

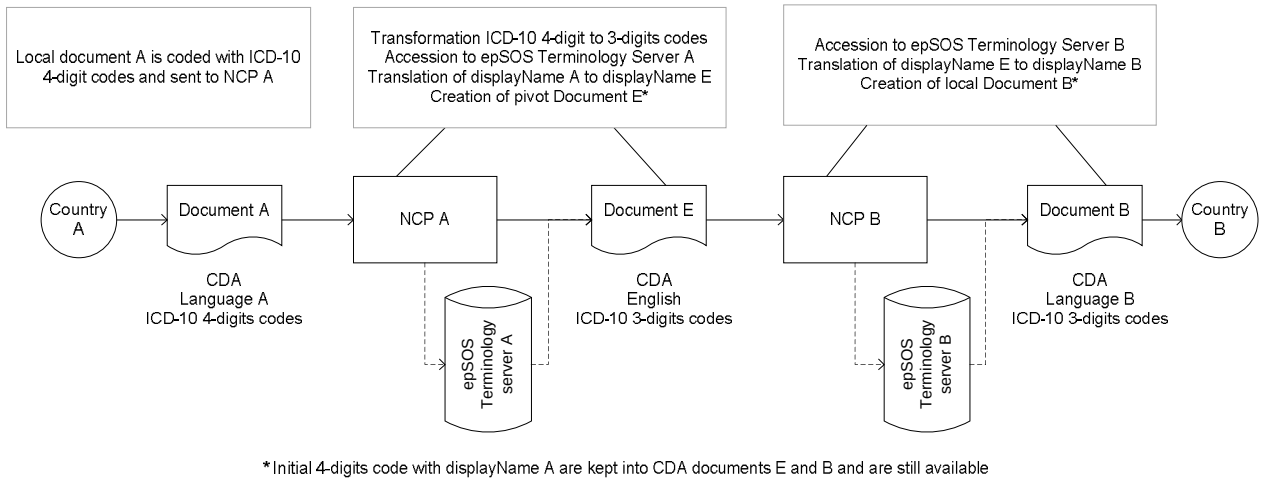

***Figure 3** - Semantic Content Workflow, schematized approach.*

3 Clinical Document Architecture

The standard used for the expression of the data elements defined by WP3.1 and WP3.2 is HL7 CDA with the additional constraints of the HL7 Continuity of Care Document (CCD) and IHE Patient Care Coordination (IHE PCC). The choice was based on the prevalence of the CDA implementation in various countries, the ease of implementation, the current existing industry solutions, and the project's short timelines. These documents contain mandatory text for human interpretation and coded information for software processing, providing a framework for using code systems such as SNOMED-CT, ICD-10, or LOINC for example.

Any of these documents is made up of a header (or the part defining the document, and its identifying information about the patient such as the health care professional, the document type), and the body, or the part containing the clinical content (*Figure 4*)

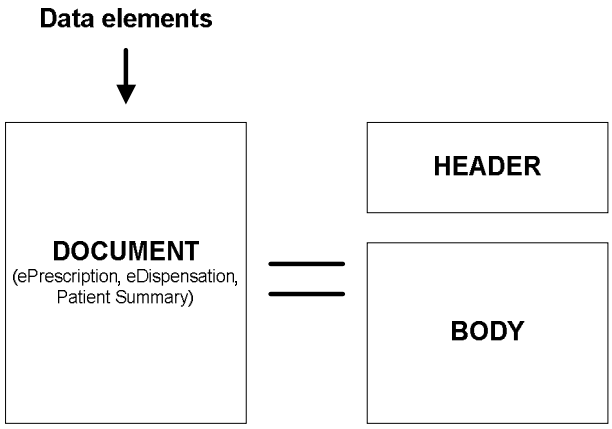

***Figure 4** - The CDA document contains a header with the demographic information and the body with the clinical information.*

The CDA-based clinical documents are referred to as **"pivot documents"** throughout this document.

3.1.1 CDA Basics

In order to understand the work done in WP3.5 the reader is guided through an introduction to CDA.

The following text is an excerpt of the "*CDA Release 2.0 Normative Web Edition, May, 2005* (Publication: September 2005). Please refer to the document for further information.

The header identifies and classifies the document and provides information on authentication, the encounter, the patient, and the involved providers. The purpose of the CDA header is to enable clinical document exchange across and within institutions; facilitate clinical document management; and facilitate compilation of an individual patient's clinical documents into a lifetime electronic patient record. The CDA body can be either an unstructured blob, or can be comprised of structured mark-up. A structured body can be divided up into recursively nested document sections. Every CDA document has exactly one body

Each section can contain a single narrative block and any number of CDA entries and external references.

The CDA narrative block within the section must contain the human readable content to be rendered. Within a document section, the narrative block represents content to be rendered, whereas CDA entries represent structured content provided for further computer processing. CDA entries typically encode content present in the narrative block of the same section. CDA entries represent the structured computer-processable components within a document section. Each section may contain zero to many entries.

Clinical documents contain a wide breadth of content, requiring much of the HL7 Reference Information Model (RIM) to enable a full and complete encoding. The current set of CDA entries have been developed in response to identified requirements and scenarios that are in CDA's scope. Rather than creating specific entries for each scenario, similar requirements are merged to create broader entries, which can then be constrained within a particular realm or implementation.

The sections and the entries can be compared to Lego blocks that are interchangeable and can be used to build an object or another according to the context.

A schematized drawing of a CDA document can be seen underneath, in *Figure 5:*

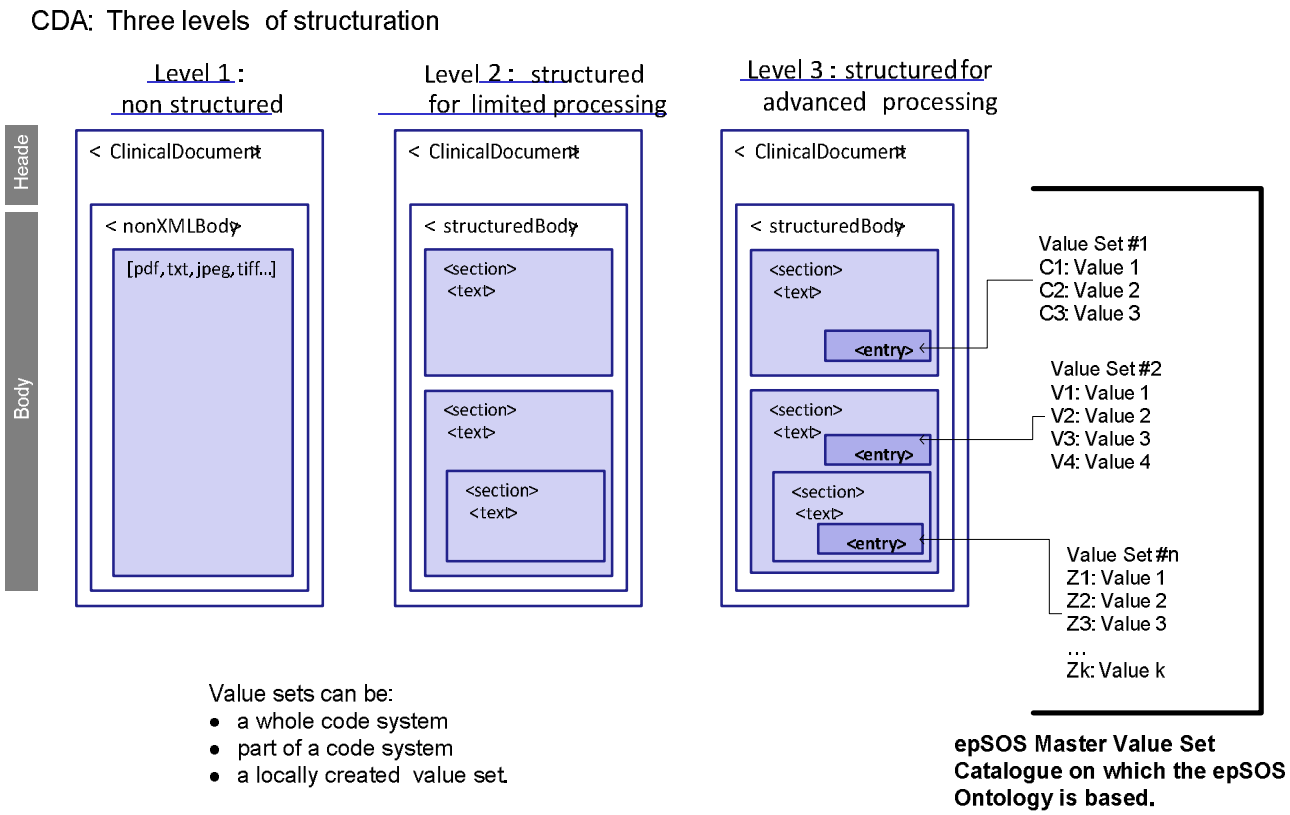

***Figure 5** - The level of structuring in a CDA document. The value sets can also be employed within the coded sections at the Level 2.*

Part of the data elements identified by the WP3.1 and WP3.2 are found in the header. Examples are: first name, last name, gender, document type and document identifier (just to name a few). Other data elements are of a clinical nature and are found in the body of the document, such as the prescribed item, the allergies, the problems and diagnosis, medications and so forth.

The data elements have been presented in a condensed manner in this document in section 11, and they are described in detail in the *Appendix C -Pivot DocumentsSpecifications.*

It is important to note that both the data elements in the header and in the body provide the framework for certain value sets originating from different code systems. The value sets were chosen according to the criteria mentioned in section 4.4.1.

3.1.2 CDA Narrative Block and CDA entries

The body of a CDA document contains sections which may contain two distinctive parts:

- A CDA narrative block MUST be present and MUST contain the human readable content to be rendered. This part must be able to be access from a standard Internet navigator.

- CDA entries may be present in a section and represent structured content for computer processing. The content MUST be already represented in the narrative block. The entries are not always present. If the entries are not present, the section is a “narrative section”.

Below, in Figure X, a narrative block and its corresponding entry is illustrated. The originalText can make reference to the identifier, thereby indicating the original text associated with the attribute in the CDA entry. There is no requirement that CDA entries must reference into the CDA Narrative Block, but the CDA Narrative Block MUST exist. The referencing mechanism can be used where it is important to represent the original text component of a coded CDA entry. In the case of epSOS, this is very important.

```
<section>
   <code code="10153-2" codeSystem="2.16.840.1.113883.6.1"
    codeSystemName="LOINC"/>
   <title>Past Medical History</title>
   <text>
    There is a history of <content ID="a1">Asthma</content>
   </text>
```

Narrative Block

```
   <entry>
      <observation classCode="OBS" moodCode="EVN">
         <code code="84100007"
          codeSystem="2.16.840.1.113883.6.96"
          codeSystemName="SNOMED CT"
          displayName="history taking (procedure)"/>
         <value xsi:type="CD" code="195967001"
          codeSystem="2.16.840.1.113883.6.96"
          codeSystemName="SNOMED CT"
          displayName="Asthma">
            <originalText>
               <reference value="#a1"/>
            </originalText>
         </value>
      </observation>
   </entry>
```

Corresponding coded, structured part

```
</section>
```

***Figure 6** – Referencing into the CDA Narrative Block*

The original text in the Narrative Block will be represented in the original language and will not be translated, translation of free text being out of scope for WP3.5 Semantic Services. For more information please see CDA Normative edition section 4.3.5.

3.1.3 Building on CDA

Throughout this document, ePrescription, eDispensation, and the Patient Summary[2] are defined as electronic clinical documents containing several data elements defined by WP3.1 and WP3.2. Each data element has clinical meaning related to the purpose of the medical document to which it belongs. The definition of each data element as intended by the end users is described in *Appendix B - Data Elements Correspondence.*

The header or body data elements are expressed with their corresponding data types and/or value sets. The data elements which are part of the body are represented through "sections", for example allergies, problems or medical devices for example. These sections have a specific way of being identified so that the industry implementers follow the same instructions and obtain the same results in order to achieve semantic interoperability between the member states. These specifications are described with examples in *Appendix C – Pivot Documents Specifications.*

These documents represent the definition of the payload (or the content) of the transactions taking place between the EU Member States participating in the epSOS pilot project. The transactions are described in *Profile 1* (ePrescription/eDispensation) and *Profile 2* (Patient Summary) produced by WP3.4 *Common Components.* The present document addresses the content of these three documents (also known as the payload), and the metadata[3] defining these documents. The implementation specifications for the metadata are found in *Appendix C - Pivot Documents Specifications.*

CDA is only the first step in achieving semantic interoperability, permitting the existence of documents, with different level of structuring, ranging from a simple *pdf* or *txt* wrapped in an xml envelope to more complex combinations. Other standards such as EN13606 exist but it is out of scope of the WP3.5 to write the mapping between CDA to 13606. Specifications using both standards are written for data elements representation; however mapping between the two formats is out of the scope of this work package.

The content data elements validated by WP3.1 and WP3.2 are mapped onto existing building blocks present in an implementable library, namely *PCC CDA Release 2.0 Content Modules* or sections and/or entries. The IHE profile XDS-SD[4] indicates the format of the body of the CDA document (*txt* or *pdf* using the standard PDF/A).

[2] Medication Summary is considered as part of the Patient Summary.

[3] Metadata are used in this context as the data defining the documents. A more in-depth definition is provided in the appropriate chapter.

[4] IT Infrastructure Technical Framework. Volume 3 (ITI TF-3, Revision 6) Chapter: Transactions 5.2 Scanned Documents Content Module

A content module contains a very coarse hierarchy that is inherent to the standard. CDA Release 2.0 content modules can be seen as building blocks that are organized by document, section, entry and header elements. Each content module has a name or a template identifier.
For more on content modules, please see the IHE Patient Care Coordination (PCC) Technical Framework Volume 2, Revision 5.0, Final Text, August 10, 2009, section 2.3.1 Content Modules.

The mapping onto the existing PCC CDA Release 2.0 Content Modules was done due to a pragmatic reason, namely to meet the project's short time lines, Reusability and extension of the existent standards that have been implemented and tested means no new syntax or vocabularies need to be invented. The CDA Content Modules cover in a great proportion the needs expressed in each document. Each content module defines a section or an entry of a clinical document. Data elements within a section may or may not be coded. If the data element is coded then this is referred to as a coded section and it will contain an entry with a certain number of terms belonging to a code system, or even an entire code system, if applicable. An implementable XML schema is referenced and an example of a part of these schemas is illustrated in *Appendix C – Pivot Documents Specifications.*

Mapping from a national schema to the pivot documents schema is **out of the scope** of the deliverables of WP3.5.

3.1.4 CDA/CCD/PCC - Additional documents

Although mentioned in the referenced documents, the reader is directed for more information towards the following documents:

- "Integrating the Healthcare Enterprise, Patient Care Coordination (PCC) Technical Framework (TF) Revision 5.0", August 10, 2009, Volume 2.

- "IHE Patient Care Coordination Technical Framework Supplement. CDA Content Modules Trial Implementation". July 26th, 2009.

- "HL7 Implementation Guide: CDA Release 2 – Continuity of Care Document (CCD), April 01, 2007.

- HL7 Implementation Guide for CDA Release 2: History and Physical (H&P) Notes (U.S. Realm). Draft Standard for Trial Use, Release 1, Levels 1, 2, and 3, July 16, 2008.

The reader is strongly encouraged to read Section **2.3.1 Content Modules** from the IHE PCC TF (PCC TF:2-2.3.1).

4 epSOS Master Value Sets Catalogue/epSOS Ontology

4.1 Value Sets

A value set is a uniquely identifiable set of valid concept representations where any concept representation can be tested to determine whether or not it is a member of the value set. A value set may be a simple flat list of concept codes drawn from a single code system, or it might be an unbounded hierarchical set of possibly post-coordinated expressions drawn from multiple code systems. A value set is also known as a list of valid concept codes. A valid concept is a concept that would be logically representative of the Value Set that it belongs to, for example for the Value Set "Colours of the rainbow", "yellow" would be a valid concept[5]. A more comprehensive definition is given in the Glossary of this work package. The epSOS Value Sets Catalogue refers to the use cases mentioned in WP3.1 and WP3.2. In its simplest form, a Value Set is a list of identifiers and names. A value set may be represented as only a part of a code system. Value Sets provide important information for the use and implementation of the semantic services. The fact that a term belongs to a particular value set provides information above and beyond the term itself. Value Sets can also define portions of the terminology for use by specific audiences. Note that value sets are not necessarily mutually exclusive and their contents may overlap. In the epSOS domain, the Value Sets have been chosen from existing code systems code by clinicians and standard experts who are able to understand their contextual use case based on the use cases in question.

Each coded elements from the header or from the body of the epSOS pivot documents has a value belonging to a value set in some cases even an entire code system. For example the data element identified by WP3.2 as the List of Current Problems/Diagnosis is mapped onto the CDA Content module section *Active Problems*, within the entry *Problem Concern*. The coded element within the *Problem* entry, in theory, may have values coming from one or more code systems since different countries may have different code systems.

For example a term such as *chronic ischemic heart disease* may be expressed using different terms originating from different code systems:

- 414 Other forms of chronic ischemic heart disease (ICD9CM)
- I25 Chronic ischaemic heart disease (WHOICD10)
- 413838009 Chronic ischemic heart disease (disorder) (SNOMED CT)[6]

Another important consideration is that the display names of these codes are different in each language. For example the chronic ischemic heart disease has also the equivalencies as:

- Chronische ischämische Herzkrankheit, nicht näher bezeichnet (German)
- Χρόνιες ισχαιμικές καρδιακές παθήσεις (Greek)
- Cardiopatía isquémica crónica (Spanish, Castilian)
- Chronická ischemická choroba srdca (Slovak)

[5] IHE IT Infrastructure (ITI) Technical Framework Supplement 2009-2010, Sharing Value Sets (SVS), Trial Implementation Supplement August 22, 2009

[6] It must be noted that SNOMED CT is not currently used in any of the Member States

- Cardiopatia ischemica cronica non specificata (Italian)

However, the Value Set for a particular coded field is chosen from only one code system based on the criteria mentioned in 4.3, and the Member States are responsible for the translation/verification of each of the terms employed.

4.2 Translating/Transcoding

Within the context of epSOS, only one code system was chosen per coded element. It is within the intention of the implementation of the specifications written by WP3.5 to provide the basis for ontology with the necessary Terminology Access Services. Although several attempts exist trying to provide cross-referencing between some codes system, such as ICD-9 to SNOMED CT, the attempt is approximate and a method of quality assurance must be officially devised. No official mapping between code systems exists; therefore only one code system is chosen per coded field. Since transcoding at a Member State level or translation is expected, the number of terms in the value sets must be limited, while providing the largest medical coverage possible.

Thus, each coded element has only one code system associated with it, with its display name in English only. These terms were compiled into an excel file named the epSOS Master Value Sets Catalogue (epSOS MVC) that provides the basis for the epSOS Ontology.

At the same time, the epSOS Master Value Set Catalogue provides the basis for the epSOS Master Translation/Transcoding Catalogue (epSOS MTC). The epSOS MTC provides the means to cross-reference between code systems and for translation of the display name, as seen in *Table 1*, below:

Source	SNOMED CT Code	ATC Code	English Display Name	German	Swedish	Danish
Sweden Top 100	387440002	R05CB01	acetylcysteine	Acetylcystein	Acetylcystein	Acetylcystein
Sweden Top 100	387458008	B01AC06	acetylsalicylic acid	Acetylsalicylsäure	Acetylsalicylsyra	Acetylsalicylsyre
SO 21459	372603003	C03DA	aldosterone antagonist	Aldosteron-Antagonisten		Aldosteron-antagonister
Sweden Top 100	391730008	M05BA04	alendronic acid	Alendronsäure	Alendronsyra	Alendronsyre
Sweden Top 100	349912006	G04CA01	alfuzosin	Alfuzosin	Alfuzosin	Alfuzosin
Sweden Top 100	25246002	M04AA01	allopurinol	Allopurinol	Allopurinol	Allopurinol
Sweden Top 100	111127002	N05BA12	alprazolam	Alprazolam	Alprazolam	Alprazolam
Sweden Top 100	40589005	N06AA09	amitriptyline	Amitriptylin	Amitriptylin	Amitriptylin

***Table 1** - An illustrative part of the epSOS Master Translation/Transcoding Catalogue showing a cross-referencing between the SNOMED CT and ATC, as well as different display names in different languages. Please note that this example it is given only for illustrative purposes and it is not to be used within the Member States. It is the responsibility of the National Linguistic Competency Centre to provide the translation and the mapping between code systems present in the epSOS MTC.*

The epSOS Master Value Sets Catalogue consists of commonly agreed-upon terms used to represent each data element as defined by the users' functional requirements and consists of internationally used concepts such as: ICD10, ICD9, SNOMED CT, LOINC, ATC, and EDQM, with an Eng-

lish display name. Each NCP will contribute by adding the display name corresponding to the epSOS term, according to the rules established in the national extension of the particular code system.

Mapping from a national terminology to the epSOS Ontology is out of scope of the deliverable of WP3.5.

4.3 Code systems selection

In order to simplify and bring to a manageable scale the epSOS Value Sets Catalogue will include different code systems which are chosen according to the following criteria:

- **Internationally Used**

An international code system such as those released by ISO or WHO, for example, has the advantage that it was elaborated by experts having a vast experiences with terminology implementation and application. The internationally used code systems have implementation guidelines that are used at a national level, as well as maintenance guidelines. The code system used in the epSOS Value Sets Catalogue must be internationally recognized. The suitability should be evaluated by experts in the field, both medical and non-medical.

- **In Use**

The second most important criteria in selecting the code system is its use in the MS. A survey is done among the experts working on the epSOS Value Sets Master Catalogue in order to have an accurate representation of the code systems used in each country.

- **Existence of translation in Different Languages**

The existence of translation via version in different languages is another key element to be evaluated, since it will dramatically reduce the activity of translating the epSOS Value Sets Catalogue terms into the local (national) language. If a code system exists in the local (national) version, it is likely that existing translations have been already validated / certified and kept aligned when newer versions are released.

- **Has a Maintenance Process**

A code system that has an official maintenance process is highly desirable. The release of new versions should be taken into account during deciding process. The maintenance process should include specifications for distribution and support.

- **Existence of Transcoding Systems / Services**

The existence of officially defined or at least of consolidated systems / services to perform transcoding from one code system to another one is a desirable element in order to reduce costs and risks. However it is known that this is an important issue that most Standard Organization Bodies are struggling with, and therefore much bigger than the epSOS perimeter. Nevertheless, whenever official attempts exist to map one code system to another it is considered very useful as this provides guidance for mapping.

- **Cost of licenses, implementation and maintenance**

Although for research purposes most of the code system licenses are provided for free, the cost might prove to be prohibitive. In addition to the cost of the licenses, the cost of the implementation and maintenance need to be considered.

- **The code system must be easily implementable**

The code system must be easily implementable based on a sound methodology which takes into account both the syntactic and vocabulary aspects.

4.4 Term selection

The primary goal of the epSOS terminology is to develop cross-border semantic interoperable services with regards to the three documents to be exchanged within the pan-European space. Since no specific terms were indicated by the WP3.1 and WP3.2, the Semantic Services Work Package WP3.5 makes inferences based on the most used data in Europe within a particular context, such as the European Emergency Card for the Patient Summary or the most commonly used terms within a particular context such as the ePrescription. Within this context it is important to indicate whether a part of a code system needs to be used and therefore mapping needs to be done across code systems, or whether an entire code system or a branch thereof needs to be used. The effort that needs to be spent must be judiciously evaluated.

According to restrained scope of the emergency data set it is very difficult to resume the choice to a particular set of terms; nevertheless this is seen as a first step towards achieving semantic interoperability while positively contributing to the European patient safety. The Emergency Data Set has as a purpose to provide the healthcare professional the necessary amount of data so that minimal patient treatment can be administered, weighing the risk and the benefits.

4.4.1 Criteria for concept selection

Since there were no particular indications originating from WP3.1 and WP3.2 the terms to be used within the epSOS project are limited to the most commonly indicated recommendations in the pan-European space.

The following criteria were employed:

- **Relevancy to scope documents**

Several terminology sources should be used for the epSOS Value Sets Catalogue based on the WP3.1 and 3.2 definitions as translated by the Semantic Services WP3.5.

Elements were selected from:

- the European Emergency Health Card.
- the Czech and Slovak proposal of Emergency Data Set (EDS)
- the ISO 21549-3 (Patient Health Card Data – Limited Clinical Data)
- the Hospital Data Project data set
- the HL7 Terminology
- the IHE Recommendations

These data elements define the basic categories of terms in use. However, they are overly general to be used as specification for data exchange.

These data elements should be used as a representation of the data elements, and all the concepts must have clear relation to the specific domain that they are representing and they should be used in its context.

- **Presence in clinical data**

The relevance of the epSOS terms is evaluated with respect to the following criteria.

- **Information sufficient for clinical decision**

Health terminology is very complex and it covers a large area of knowledge requiring lot of effort to organize part of this terminology for specific purpose. It is hard to decide what level of detail should be used, especially when use cases cannot be precisely specified. But having fundamental use case of HCP taking care about citizen of foreign country (possibly in emergency situation) one should always think of what information is really necessary to obtain about given conditions. Sometimes it is necessary to know just presence or absence (e.g. patient was immunized against tetanus), in other cases more specifying attributes are necessary (e.g. type of pace maker, date of last examination, clinical course). These various levels of information and granularity were addressed in the choosing the syntax and the value set that accompany the respective value sets syntax (please see the epSOS Master Value Sets Catalogue (epSOS MVC) as well as the table present at the end of this document). Each coded element was studied as a group, within the health care professionals in the semantic group, resulting in the epSOS MVC (or the epSOS Reference Terminology).

- **Information systems behind**

When we are creating an epSOS Value Set Catalogue, its main purpose has to be kept in mind – it is the representation usable for communication between information systems (e.g. NCP, national systems). The content and representation should follow constraints given by their implementations – semantic services and communication standards. Moreover, current local systems may introduce some more constraints we have to face. The revision of approved technical specification of semantic services is necessary.

- **Frequency of use**

Even within one domain, delimited by scope documents, the number of possible concepts may exceed realization possibilities.

- **Severity (Consequences)**

In contrary to previous criterion, or together with it, severity of the information carried by concept has to be considered. If absence of a particular even very sparse fact can lead to serious harm of patient's health conditions it should be incorporated even if some less important will have to be omitted.

- **Content evaluation and acceptance**

The process of choosing concepts is quite demanding and time consuming. However, it has to be executed properly and evaluation must not be missing. The evaluation should run in parallel with ontology creation, because the extent of the task is major. Evaluation should cover various levels from basic in working group selecting concepts, to project representatives of HCP and medical specialists in all countries involved. Syntactical and orthographical rules of each language have to be held.

- **Reconcilability**

Special emphasis should be put on reconcilability of concept's meaning through chosen term. Generally, self-explanatory terms should be preferred. On international level, higher priority should be given to terms incorporating Latin or Greek elements.

- **Non-ambiguity**

Terms evocating ambiguity should be avoided. The meaning of the concept should be as clearly understandable from the term as possible and what's more for professionals from all medical specialties.

- **Clinical acceptability**

Similarly as by concept selection, following clinicians' preferences is crucial. Qualification and acceptance in practice plays a major role.

- **Consistency and systematic order**

Decisions on which terms to choose, have to be consistent within the framework of the whole terminological system. If it is decided to follow some morphological or syntactical rules for a specific category of concepts, they have to be applied to all terms from this category and all exceptions should be well justified.

The same set of criteria is applicable for translation of the terms into languages of participating countries.

The epSOS Ontology and its maintenanceThe epSOS Ontology is presented as a file in the Web Ontology Language (OWL).[7,8]. Once the initial version of the epSOS Ontology is available it will be distributed over the internet using an URL. A standard interface for the epSOS Ontology is defined. This interface satisfies the needs for 'ad-hoc' accurate translation of the epSOS Ontology contained in the pivot documents in the exchange between NCPs.

Translating from one language to another is never exact; hence translation must minimize the distortion or the loss of meaning, and is supported by a carefully managed mapping of semantically equivalent medical terms and concepts within the reference corpus. Therefore, the interface also

[7] http://www.w3.org/TR/owl-semantics.
[8] http://www.w3.org/TR/owl-features.

supports the various activities related to mapping or cross-referencing of the terms present within the epSOS MTC.

Code systems are usually imported into a repository before mapping activities can be performed. The administrative tasks such as loading, activation and inactivation of various code systems versions are also taken into account when specifying the interface.

In order to find and map semantically equivalent concepts of various code systems, versions and in different languages, system administrators and software managers must have the ability to search codes, terms, and nominal phrases, to browse concept hierarchies within a particular code system, and to define relationships between concepts.

The ontology specification are described in *Appendix E - Ontology Specifications* and the functional requirements needed to perform its maintenance are described *Appendix F - Terminology Access Services.*

There are some characteristics required supporting the evolution of the epSOS Master Value Sets Catalogue which is the basis for the epSOS Ontology over time. It must be noted that these considerations are fairly general and they are typical of any international code systems

- **Context-free identifiers**

Concept identifiers such as codes shall not be tied to a hierarchical position or other contexts; their format shall not carry any meaning (non-semantic identifiers).

- **Persistence of identifiers**

Codes shall not be reused when a concept is obsolete or superseded.

- **Version control**

Updates and modifications to the epSOS value sets shall point to consistent version identifiers (OIDs). Usage in patient records should carry this version information as the interpretation of coded patient data is a function of the terminology used at a point in time. This version information should also be recorded in all audit data stored.

- **Editorial information**

New and revised terms, concepts and synonyms shall have information about their date of entry or effect in the terminological system associated with them, along with pointers to their source and/or authority.

- **Obsolete marking**

Superseded terminological entries shall be so marked, together with their preferred successor. Data may still exist in historical patient records using obsolete terms, their future interpretation and aggregation are dependent upon that term being carried and cross-referenced to subsequent terms.

- **Identification and Registration**

Terminologies that are intended to be used for the purpose of information interchange in health shall have a unique, permanent terminology identifier (OID) registered with an appropriate organization. HL7 Version 3 messages and CDA use OIDs (Object Identifiers) to identify terminological systems. prEN 1068-1 (superseded) proposes a Registration Authority to maintain a register of health coding systems in Europe.

- **Interoperability**

Healthcare terminologies shall conform to International terminological standards and the relationship between the terminology and relevant messaging / information standards shall be explicitly recognized.

If there is need to extend the content of the epSOS terms, this shall be addressed in the maintenance and implementation process.

5 Terminology Access Services

The **terminology access services** provides the interface needed to perform semantically accurate, "on-the-fly" language translation (in terms of the display name) of coded elements present in the pivot documents from one member state language to another, or from one code system to another is another code system if indicated in the epSOS Master Translation/Transcoding Catalogue. The interface also details the transactions needed for the validation of the coded elements used in the pivot documents against the epSOS Ontology codes. Furthermore it describes the functionalities for creating and maintaining the ontology itself such as loading new value sets, adding new terms or codes to the epSOS Master Value Set Catalogue, versioning, and mapping (cross-referencing) semantically equivalent terms or code descriptions in paired member state languages and across coding systems.

It must be noted that even if WP3.5 provides the basis for transcoding and translating, it is the responsibility of the Member States to assure this activity.

WP3.5 aims to provide the epSOS Ontology in a way that enables maintenance, is open to evolution via the functionality of the semantic services. The epSOS Reference Terminology (epSOS Master Value Sets Catalogue) and the epSOS Ontology are living entities, such as the schemas and the schematrons produced in the Implementation and Testing work packages. A general process of maintenance of all these artefacts must be designed, an activity which is outside the scope of this work package.

The entire terminology access services functionality is described as a standard interface, independent of the underlying structure of the ontology, in order to support the rapid development, flexibility and accuracy needed to support the epSOS pivot vocabulary.

5.1 epSOS Terminology Access Services Standards

The terminology access services are based on the HL7 Common Terminology Services (HL7 CTS) specifications. HL7 CTS is an Application Programming Interface (API) specification that is intended to describe the basic functionality that will be needed by HL7 CDA software implementations to query and access terminological content. It is specified as an API rather than a set of data structures. This enables a wide variety of terminological content to be integrated within the HL7 CDA framework without the need for significant migration or rewrite.

Instead of specifying what an external terminology must look like, HL7 has chosen to identify the common functional characteristics that an external terminology must be able to provide. There are two distinct layers between HL7 CDA information processing applications and the target vocabularies. The upper layer, the Message API communicates with in terms of vocabulary domains, realms, coded attributes and other artifacts of the Reference Information Model (RIM) and HL7 messaging model. The lower layer, the Vocabulary API communicates in terms of coding system, concept codes, designations, and other vocabulary related entities.

The CTS 2 specification, a joint effort between HL7 and OMG, is an extension of the original HL7 Common Terminology Services approved standard and includes administration, authoring (curation), mapping (cross-referencing) and versioning of the terminological content.

There are three main functional profiles exposed in the CTS 2 specification: the query profile, the administrative profile, and the terminology authoring profile. These three profiles can be

implemented against three semantic profiles that group together terminologies with similar design or purpose: HL7 profile, mature terminology profile and developing terminology profile. In the implementation of the epSOS TAS, two more profiles were created, namely the Translation and the Request Submission profile.

Within this document reference shall be made to the content that has been defined in:

- ” HL7 Common Terminology Services 2 Service Functional Model (SFM)”. 19.02.2009 at: *http://informatics.mayo.edu/LexGrid/downloads/CTS/cts2/HL7_Common_Terminology_Services_2_Service_Functional_Model_(SFM).htm*

- “HL7 Common Terminology Services” from November 2004 at: *http://informatics.mayo.edu/LexGrid/downloads/CTS/specification/ctsspec/cts.htm*

- “Lexicon Query Service, version 1.0 from 31.06.2000 at: *http://www.omg.org/technology/documents/formal/lexicon_query_service.htm*

- “SNOMED_CT_Technical_Implementation_Guide”, Chapter 6 “Terminology Services Guide” from 31.01.2009 at: *http://www.ihtsdo.org/fileadmin/user_upload/Docs_01/SNOMED_CT_Publications/SNOMED_CT_Technical_Implementation_Guide_20090131.pdf*

5.1.1 Limitations

The epSOS project aims to provide means for communication of data concerning the ePrescription, eDispensation and Patient Summary across state and language borders. The purpose to share data within the epSOS project is to support the health care process within a primary care setting. Another purpose, such as the secondary use of this data (epidemiological studies or research) is out of scope of the epSOS project, even if these areas can be of great interest. . Even if those uses can be of great interest, data to be shared as well as the legal framework need to be defined for this purpose"
The short time lines (nine months) allotted to the semantic services has had a strong influence on the methodology used within the work package.

The data value set is a list of terms chosen from the functional requirements indicated by WP 3.1 and 3.2. The data value set is not an all exhaustive one with regards to all needs for communication of clinical data, nor does it attempt to be. The main purpose of the semantic services is to provide the healthcare provider in a different country with information about the patient within the context of unscheduled care, where little information can mean a lot. The value set shall be seen as an ambition to provide the prerequisites for the epSOS pilots, and not a solution for communication of patient data on a routine basis.

In order to address issues such as patient safety, the original text is always sent, as well as a pdf document, and the original code and the display name is preserved as well (see section 1.2.x - translation code). The pdf content should be constraint for what is defined as the dataset of the patient summary in 3.2 in order to be able to maintain a common understanding of what a patient summary is. From a clinical point of view the aim of the group is not to share as much information as possible but to define what a patient summary has to contain and what should be avoided in order to keep its main use: a summary containing all the important information but being easy and quick to be read by a professional in a short time frame. However, at first, some countries that use one sin-

gle document as a source of information are not able to separate the fields to create the PDF with only the information of the dataset defined. Consequently sometimes at this first step of the project the information will be more than the dataset defined because it will have to be what that entire single coded document contains.

In any case the pdf document will have medical and legal validity and one HCP (in the case of a PS generated and signed by an HCP) or one HCPO (in the case of a PS constructed through different sources of clinical information) will be liable of the data provided.

The standard HL7 Clinical Document Architecture (CDA) was chosen as for the representation of the information presented by the functional work packages due to its wide-spread implementation and the existence of testing tools. WP3.5 provides also a 13606 implementation guide expressing the data elements.

A study of the convergence of a common information representation based on business and concepts models of the clinical reality can prove to be a very fruitful future consideration, such as CDA, EHR-com and EN13940 (Contsys part 1 and working material from Contsys part 2).

6 Definitions and Conventions

6.1 Document Definitions

6.1.1 ePrescription and eDispensation

ePrescribing is defined as prescribing of medicines in software by a healthcare professional legally authorized to do so, for dispensing, once it has been electronically transmitted, at the pharmacy. The epSOS ePrescription is the electronic document resulting from prescribing medicine using software.

eDispensing is defined as the act of electronically retrieving a prescription and giving out the medicine to the patient as indicated in the corresponding ePrescription. Once the medicine is dispensed, the dispenser shall report via software the information of the dispensed medicine(s). The epSOS *eDispensation* is the result of a dispense act (if there is a single document produced for all the medicines dispensed at that moment), or the result of dispensing a item included in an eP (this can be valid for eP and for eP item if the eP contains several items).
These definitions were inferred from the context of the deliverable produced by the WP3.1.

6.1.2 Patient Summary

The epSOS Patient Summary is an electronic document that provides health care professionals with a dataset of essential and understandable health information in order to be able to deliver safe patient care during unscheduled and planned care. The Patient Summary's impact is maximal in the settings of unscheduled care.

It must be noted that the documents referred to in WP3.5 are electronic documents and not classical paper documents. The purpose of the PS information is to support the coordination and continuity of health care in a pan-European mobility of citizens. In the context of patient care it is important to know whether the Patient Summary was generated by an automatic process or created manually by a health care professional. In cases where the Patient Summary is a mixture of an automatic process and completed by a health care professional, from a technical point of view, the Patient Summary will fall into the category of manually created by a health care professional since it will be the latter who will take the responsibility for the information present.

The decision to indicate whether or not the document was created manually or automatically was taken in order to accommodate various manners in creating documents. Some documents are created by a physical person (manually), and in some places the medical data is gathered automatically and hence there has to be an entity who takes responsibility for the accuracy of that information at the point in time when the document was automatically created. Since it is not possible in CDA to represent a mixture of automatically and manually created document, a mixed document is deemed to be created by a person who will take responsibility for the accuracy of the information.

The **Medication Summary** is defined as part of the Patient Summary and it describes the list of the current medications (all prescribed medicine whose period of time indicated for the treatment has not yet expired whether it has been dispensed or not). The Medication Summary is not necessarily related to the prescription/dispensation process. Although Medication Summary is considered as part of the PS, in some Member States it is accessed separately by the pharmacists as they are not allowed to access any other information contained in the Patient Summary. This is part of each country's implementation process.

These definitions are based on the information present in the deliverable produced by WP3.2.

6.2 Syntax Terms Definitions

6.2.1 Data Set Definition

A data set (or dataset) is a collection of data elements, usually presented in tabular form[9]. Data elements are the individual pieces of data within data sets. For example, the patient information data set is made up of the patients name, address, and phone number data elements.

A data element is a unit of data that has as precise meaning/semantics as possible. A data element definition is a human readable phrase or sentence associated with a data element within a data dictionary that describes the meaning or semantics of a data element.

Data element definitions are critical for external users of any data system. Good definitions can dramatically ease the process of mapping one set of data into another set of data[10].

Some example of data elements used in epSOS:

Patient's general information:

- demographics
- contact information
- insurance data

Medical information:

- existing conditions (allergies, current illness or disease, health state, etc)
- medical history i.e. information on previous or current health care
- information about the medication prescribed or dispensed such as the route of administration or the strength of the medication

As mentioned, a collection of data elements is called a **data set.**

6.2.2 Null flavor

In a medical environment the absence of information is just as important as the presence of information. The expression of the missing information and possibly the reason why the information is missing is done via the usage of *null Flavor.*

Every data element has either a proper value or it is considered NULL. If and only if it is NULL, a "nullFlavor" provides more detail as to in what way or why no proper value is supplied.

[9] Wikipedia. http://en.wikipedia.org/wiki/Data_set. Consulted July 21, 2009.

[10] Wikipedia. http://en.wikipedia.org/wiki/Data_element_definition. Consulted July 21, 2009.

The following codes for the nullFlavor were referenced from the "*Data Types - Abstract Specification*", November 29th, 2004, HL7 International, section 1.11.4 Exceptional Value Detail: CS.

For more information please read the referenced material.

Code	Name	Definition
NI	NoInformation	No information whatsoever can be inferred from this exceptional value. This is the most general exceptional value. It is also the default exceptional value.
OTH	Other	The actual value is not an element in the value domain of a variable. (e.g., concept not provided by required code system).
NINF	Negative infinity	Negative infinity of numbers.
PINF	Positive infinity	Positive infinity of numbers.
UNK	Unknown	A proper value is applicable, but not known.
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.
NASK	Not asked	This information has not been sought (e.g., patient was not asked)
TRC	Trace	The content is greater than zero, but too small to be quantified.
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. Note: using this nullFlavordoes provide information that may be a breach of confidentiality, even though no detail data is provided. Its primary purpose is for those circumstances where it is necessary to inform the receiver that the information does exist without providing any detail.
NA	Not applicable	No proper value is applicable in this context (e.g., last menstrual period for a male).
NP	Not present	Value is not present in a message. This is only defined in messages, never in application data! All values not present in the message must be replaced by the applicable default, or no-information (NI) as the default of all defaults.

***Table 2** - Possible values for expressing nullFlavour.*

6.2.3 Minimal and Maximal Data Sets

The ePrescription, eDispensation, and the Patient Summary specifications define the content or the "payload" of the three documents. Particular definitions apply to this context and are described below.

WP 3.1 - Final definition of functional service requirements – ePrescription defines the **minimum data set** that are considered essential from the pharmaceutical point of view to identify the medicine, those that must be present in a prescription by law and those needed to update the relevant prescription once the medicine has been dispensed. The **maximum data set** is considered as additional, and deemed not to have an impact on safely dispense. . The maximum data set provides ex-

tra information for the healthcare provider, but in their absence the dispenser can still safely dispense the medication, or once the medicine has been dispensed, the related prescription can be accordingly identified and updated. The maximum data set must be understood by the receiver.

WP3.2 - Final definition of functional service requirements - Patient Summary defines the minimum data set as the agreed set of essential health information (basic data) that is clinically needed for delivery of safe patient health care (with focus on unscheduled care). A further differentiation is made within the minimum data set between the "***mandatory***" and the "***basic***".

Based on the above definitions, all pivot document data elements follow these rules:

Mandatory indicates that both the data field as well as the value of the data must be present. The data field cannot be empty under any circumstances (not nullable). If this happens the document is not valid and will be rejected. This is equivalent to the minimum definition of WP3.1. In the WP3.5 this is indicated as R, no nullFlavor allowed.

Basic data indicate that the data field must be present but the field can be empty, with a nullFlavorindicating why the information is missing (the country does not track this information, unknown, not applicable etc.). This is expressed as R, nullFlavor allowed in WP3.5.

Extended data refers to information that is desirable to be exchanged between the epSOS participants. The fields and the values of this type of data are optional and therefore can but do not have to be sent. However, the field must be understood by the receiver. In WP3.5 this is addressed as optional elements. In some cases some elements present in WP3.1 such as the social insurance number can be interpreted as being optional.

6.2.4 Optionality (R/O)

These definitions are referenced from the PCC TF:2-6.1, version 5 and from the PCC CDA Content modules section 6.1 Conventions, with the omission of the R2 element.

R

A "Required" data element is one that shall always be provided. If there is information available, the data element must be present. If there is no information available, or it cannot be transmitted, the data element must contain a value indicating the reason for omission of the data. In the epSOS specifications the R data element will branch in two: *mandatory* (R with no *nullFlavor*allowed) and basic (R with *nullFlavor*allowed). Within this document R shall indicate a required data element with *nullFlavor*not allowed. Where *nullFlavor* is permitted, this shall be indicated.

O

An optional data element is one that may be provided, irrespective of whether the information is available or not. Data elements that are marked (O) may be sent at the choice of the sending application. These elements are defined as the extended data set and their expression although optional is necessary so that there is correct semantic interpretation of the sent information. Thus, an optional element need not be sent, but when it is sent, the meaning of that data element is defined so that the receiver can always be assured of what that data element represents when it is present. Senders should not send an optional data element with an unknown value. If the value is not known it is best that the element is not sent.

For more information please read the references mentioned.

RNFA
A required element, with null flavour allowed is a required element that for some reason has an unknown value for some reason. This field is allowed to contain no information, but it is required to indicate why the value is missing (please see section 6.2.2 – Null flavour).

6.2.5 CDA Receiver and Sender Responsibilities

The sender (originator) and the receiver responsibilities are briefly described. They are based on the CDA Release 2.0 Normative Web Edition, May, 2005 and the IHE Patient Care Coordination (PCC) Technical Framework Volume 2, Revision 5.0, Final Text, August 10, 2009.

Each content module within epSOS has a list of data elements that are either required (R) required or optional (O). The presentation of this information varies with the type of content module, and is described in the document. Additional data elements may be provided by the sender and they may not be defined by a specific content module, but the receiver is not required to interpret them.

Required data elements must always be sent. Data elements that are required may under exceptional circumstances have an unknown value (e.g., the allergies of an unconscious patient). In these cases the sending application is required to indicate the reason why the data is not available (basic, not mandatory, therefore Required, nullflavor allowed - RNFA).

Data elements that are marked optional (O) may be sent at the choice of the sending application. Since a content module may include data elements not specified by the profile, some might ask why these are specified in a content module. **The reason for specifying the optional data elements is to ensure that both sender and receiver use the appropriate semantic interpretation of these elements.** Thus, an optional element need not be sent, but when it is sent, the content module defines the meaning of that data element, and a receiver can always be assured of what that data element represents when it is present.

Senders should not send an optional data element with an unknown value. If the value is not known, simply do not send the data element.

Other data elements may be included in an instance of a content module over what is defined by the epSOS specifications. Receivers are not required to process these elements, and if they do not understand them, just ignore them. Thus, it is not an error to include more than is asked for, but it is an error to reject a content module because it contains more than is defined by the epSOS specifications.
A conformant CDA document is supposed to validate its syntax against the CDA Schema, and to insure that used coded terms are allowed within the specified vocabulary domains. However a computer cannot validate every aspect of conformance, particularly those related to the CDA human readability requirements. The purpose of this section is to define the receiver's responsibilities towards a CDA-conformant document.

A document receiver (or document recipient) is an actor that receives documents from a sender (or document originator). The document receiver is responsible for ensuring that received CDA documents are rendered in accordance to HL7 V3 Medical Record specifications.

1. **Default values:** default values defined by CDA have to be taken as defined in the event that no value is contained in a CDA instance.

2. **CDA Header:** A receiver of a CDA document must be able to parse and interpret the complete CDA header. The rendering of its contents is however at his discretion.

3. **CDA Body** rendering constraints: A receiver of a CDA document must be able to parse and interpret the body of a CDA document. Its rendering must conform at least to the following constraints:

   - A non-XML body must be rendered accordingly to its MIME type
   - XML body's section/title labels must be rendered. If not, the section will be considered as unlabeled.
   - XML body's section/text fields must be rendered accordingly to rules defined in section narrative block (see CDA Normative edition section 4.3.5)

4. CDA Body constraints limitations: there is no obligation for a receiver of a CDA document to parse and interpret the complete set of CDA entries contained within the CDA body. Conversely, local regulation or implementation may add constraints that would in this case involve the receiver's responsibility to conform to these rules. Within the epSOS project, the receiver is required to interpret the minimum dataset. For the maximum dataset there is no obligation.

5. A receiver of a CDA document is not required to validate a CDA document against referenced templates unless local regulation or implementation recommends it.

6. Additional data elements may be provided by the sender that are not defined by a specific content module, but in this particular case, the receiver is not required to parse or to interpret them.

The originator (or the sender) of the document must adhere to the rules established with the receiver. The parts of the document that were agreed to be send as structured parts must be sent as such, so that the receiver can render them properly. The responsibilities of the originator, in this case, as quoted by CDA normative edition are:

1. If the CDA Body is structured, the label of a section must be conveyed in the Section.title component. The absence of the Section.title component signifies an unlabeled section.

2. If the CDA Body is structured, the attested narrative contents of a section must be placed in the Section.text field, regardless of whether information is also conveyed in CDA entries.

3. If the CDA Body is structured, the contents of the Section.text field must be created per the rules defined in section 4.3.5 - Section Narrative Block of the CDA

An originator of a CDA document is not required to fully encode all narrative into CDA entries within the CDA body. Within a local implementation, trading partners may ascribe additional originator responsibilities to create various entries.

6.2.6 Cardinality

Cardinality literally means the number of the elements present in a set of element, illustrating many-to-many, many-to-one, one-to-many or one-to-one relationships. In the semantic context, cardinality gives information about the possible number of times an element can exist (instantiations of an entity). For example, a patient can have only one date of birth, but s/he can have more than one address or telephone number.

Cardinality is expressed by two numbers in square brackets: [1..1], for example. The number is the least number of valuesan element can have, while the second number is the maximal number of values for that element (possible instantiations of the object).

If we take for example, **p** and **q** as integer numbers, and if the entity X has a cardinality **[p..q]**, indicating that there are **p** to **q** instantiations of **X**, or **X** can exit minimally **p** times, and maximally **q** times.

Cardinality also gives information about the optionality of an element (the element must be present or not). Table X below shows a few examples of the use of cardinality. The most commonly used values for cardinality are [0..*], [0..1], [1..1], and [1..*]

Cardinality	O/R	Rep	Meaning for X
[0..p]	O	Y	0 to p: X is optional, with maximal p instantiations of X possible.
[1..1]	R	N	1 to 1: X is required, but only 1 instantiations of X is possible. This is the case of a family name, where we are supposed to have only one legal name.
[1..p]	R	Y	1 to p: X is required, with maximal p instantiations of X possible. For example in France a given name is required, with a maximum of four given names, leading to an expression of [1..4].
[0..*]	R	Y	0 to many: X is optional, but the number of instantiations of X is not restricted. For example, not everybody has a nickname, but if they do, the number of nicknames is not limited.
[0..1]	O	N	0 to 1 : X is optional, but only one instantiations of X is allowed.
[1..*]	R	Y	1 to many (infinite): X is required, but the number of instantiations of X is not restricted.
[p..q]	R	Y	p to q: p instanciations of X are required while q instantiations are allowed

***Table 3** - Different Expressions of Cardinality*

6.3 epSOS Value Sets Catalogue and epSOS Ontology Definitions

The terminology used in the epSOS Semantic Services contains terms from different code systems. The meaning of the terms is rooted in a human understanding of natural languages, and there are implicit assumptions about the relations between concepts..

A code system may contain hundreds of thousands of terms. However, for the timelines of the epSOS project, and the limited human resources, only the most commonly used medical terms among the MS are collected and presented in the *Appendix D - epSOS Master Value Sets Catalogue.* It must be kept in mind that if it were not for the translation/transcoding of the terms present in the

epSOS Master Value Sets Catalogue (epSOS MVC), a whole code system can be recommended for one coded system. However, due to the need of translation and/or transcoding, only a limited number of terms were chosen. The choice of the terms present in the epSOS Master Value Set Catalogue was based individual bases for each coded element. Each coded element was allotted a value set based on its characteristics and implication in health care. For example, for the coded element "Active Ingredient", the whole code system was included since this was deemed necessary for patient's safety. Translations and/or transcoding in the national language and the national code system in use must be performed. For other coded elements such as the Illnesses, the Route of Administration or the Package, only the most commonly employed terms were used (for example Chapter XX from ICD-10 External causes of morbidity and mortality. Terms from code systems were chosen based on the criteria from various European health projects and recommendations such as: the European emergency health card, the Czech and Slovak proposal of Emergency Data Set (EDS), the ISO 21549-3 (Patient Health Card Data – Limited Clinical Data), and The Hospital Data Project data set just to name a few examples.
The epSOS Value Set Catalogue is a collection of the mostly used terms from different national and international code systems based on definite criteria presented in the methodology section. The epSOS Value Set Catalogue is the basis for the epSOS Ontology which can be used by the NCPs. Since the terms are already collected from the participating MS, the cross-referencing between the national terminology and the epSOS Ontology is considerably reduced, increasing the semantic computable interoperability. The epSOS ontology is the representational artifact providing reference (in the linguistic sense of the word[11]) for the terminologies used in epSOS.

6.4 Terminology Access Services Definitions

The epSOS Semantic Services define the functional requirements and specifications of a set of service interfaces to allow 'ad-hoc' accurate translation and transcoding of data elements contained in the epSOS pivot documents between paired epSOS MS without distortion or loss of meaning as much as possible. The epSOS Semantic Services also specify functionality for accessing, maintaining, validating, and versioning the underlying content of the epSOS Value Sets Catalogue that enables the translations. The process of the content of the Reference Terminology present in the epSOS Value Sets Catalogue does not enter within the scope of the work package 3.5, but it is part of the implementation and testing activities. Only the services used to access and manage the content of the epSOS MVC are described.

6.5 Wording conventions

6.5.1 SHALL/SHOULD/MAY

Any element[12] that has the description **SHALL** indicate an obligation (mandatory) meaning:

- is required to
- it is required that
- has to

[11] In general as well as in computational linguistics "reference" is the term used for the relation between a term and its referent, viz. the set of things named by the term.

[12] These definitions were taken out of the ISO document "Rules for the structure and drafting of International Standards", Directives ISO/CEI, Partie 2, Annex H.

- only … is permitted
- it is necessary

The verbal forms shown in *Table 4* shall be used to indicate requirements strictly to be followed in order to conform to the document and from which no deviation is permitted.

The ISO document indicates that a "*must*" shall not be an alternative for "*shall*". (This will avoid any confusion between the requirements of a document and external statutory obligations.) Furthermore, it is recommended not to use "*may not*" instead of "*shall not*" to express a prohibition. To express a direct instruction, for example referring to steps to be taken in a test method, use the imperative mood in English (example: "Switch on the recorder").

Any element that has the description **MAY** indicates an option (not mandatory but if present could be sent). *Table 4* indicates some of the wording recommendations:

Expression	Meaning	Conveyed Sense
Shall	is to	Required/Mandatory
Shall not	is not allowed/permitted/acceptable/permissible is required to be not is required that … be not is not to be...	
Should	it is recommend that ought to	Best Practice /Recommendation
Should not	is not recommended ought not to	
May	option, but not mandatory, should be sent if present	Acceptable/Permitted
Need not	it is not required that no … is required	

***Table 4** - Wording conventions (referenced from "Rules for the structure and drafting of International Standards", Directives ISO/CEI, Partie 2, Annex H and from HL7 Version 3 Publishing Facilitator's Guide (http://www.hl7.org/v3ballot/html/help/pfg/pfg.htm).*

7 Methodology

7.1 General methodology

The general methodology is illustrated in *Figure 6.* The functional work packages WP3.1 and WP3.2 have identified certain data elements and their importance (*basic*, *mandatory* or *extended*) with regards to **ePrescription, eDispensation** and the **Patient Summary.** The data elements were validated from a medical point of view and clarification was obtained when needed from the functional work packages. WP3.1 and WP3.2 defined three distinct documents: **ePrescription**, **eDispensation**, and **Patient Summary**.

The data elements as defined by WP3.1 and WP3.2 were separated into two parts: the belonging to the header and the parts that belong to the body of each respective document. An alignment was done between the data elements as to avoid implementation efforts.

The data elements were expressed examined one by one and then mapped onto CDA (Clinical Data Architecture) elements, namely PCC (Patient Care Coordination) content modules. The PCC content modules have representations both for the header and for the body.

Some elements in the header and in the body of the epSOS pivot documents can be coded, such as the data elements "gender" with values such as: "male, female or undifferentiated". These coded terms or values originate from various code systems such as SNOMED CT, ICD-9, ICD-10, LOINC, ATC, HL7 etc. WP3.5 identified the code systems that are used in the epSOS LSP, resulting in the epSOS Master Value Sets Catalogue.

The epSOS Master Value Sets Catalogue provides the basis for the epSOS Master Translation/TranscodingCatalogue (epSOS MTC). The epSOS MTC needs to be accessed and maintained, because each country might use different code system or national extensions of the code systems used. The display name will be naturally different, based on the local language.

The epSOS Master Value Sets Catalogue includes the most employed common terms within the header and the body identified within the content of the documents. The epSOS Ontology offers basis for the relations between the various terms.

The terminology access services describe implementation of functionalities needed for the access and maintenance of the epSOS Ontology.

Issues such as security, patient and HCP authentication are out of the scope of work of WP 3.5.

Recommendations for the articulation with EN13606 are made and care must be exhibited so that the representation of the data elements in either format does not diverge.

It is out of the scope of this deliverable to write the mapping between CDA and EN13606 within the context of producing these documents.

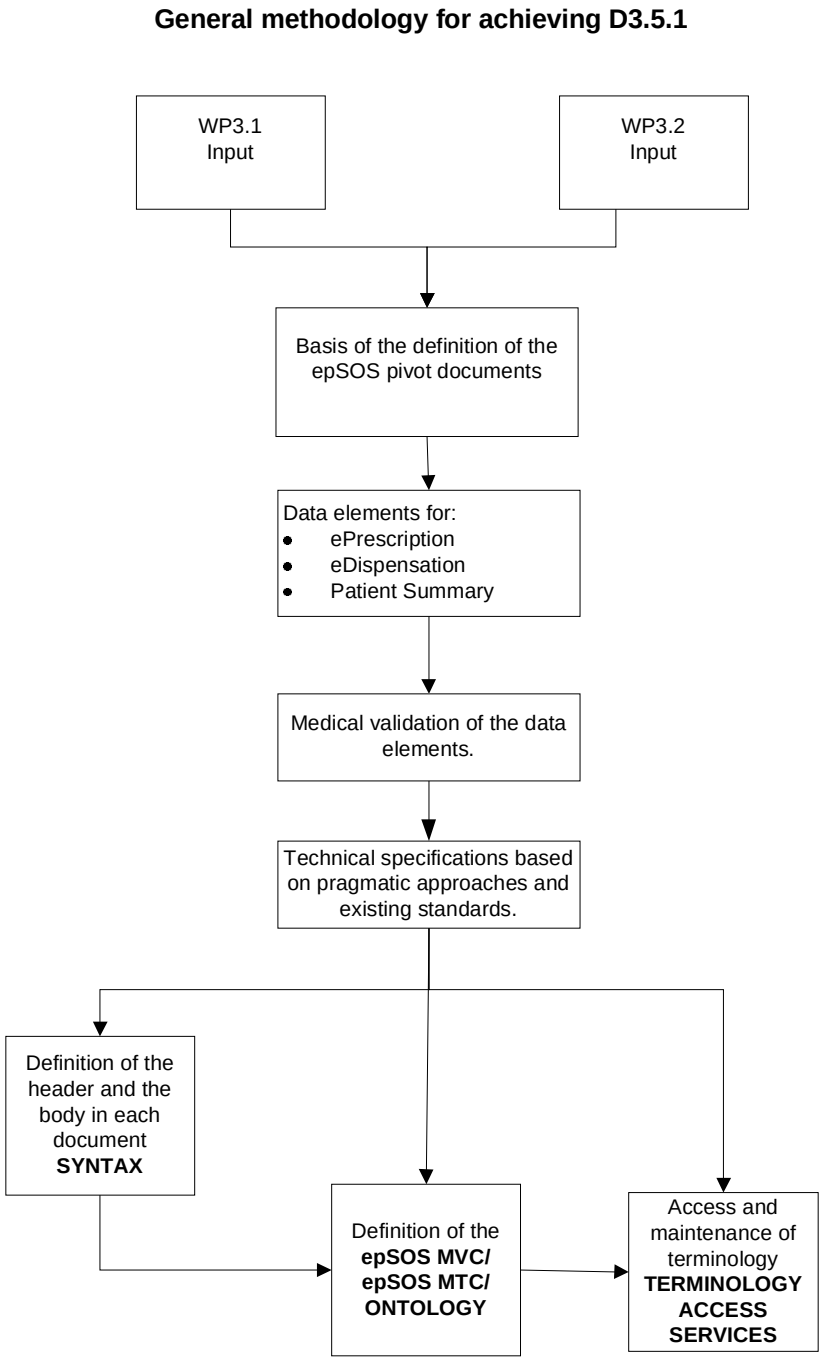

***Figure 6** - The general methodology for drafting the specification of the semantic services.*

7.1.1 Syntax

All the data elements indicated by the functional working groups WP3.1 and WP3.2 were divided up into header and body elements. The header elements were aligned in order to obtain a more uniform epSOS header. The optionality is indicated for all three of them as well a proposition for their cardinality.

The data elements present in the body of the three pivot documents are mapped onto the PCC sections. The mapping was based on the definitions given to each data element by WP3.1 and WP3.2, which were compared to the official definition given by PCC.

Whenever an appropriate definition or section could not be found, a section and/or an entry was created using the official epSOS object identifier or OID (*Figure 7)*

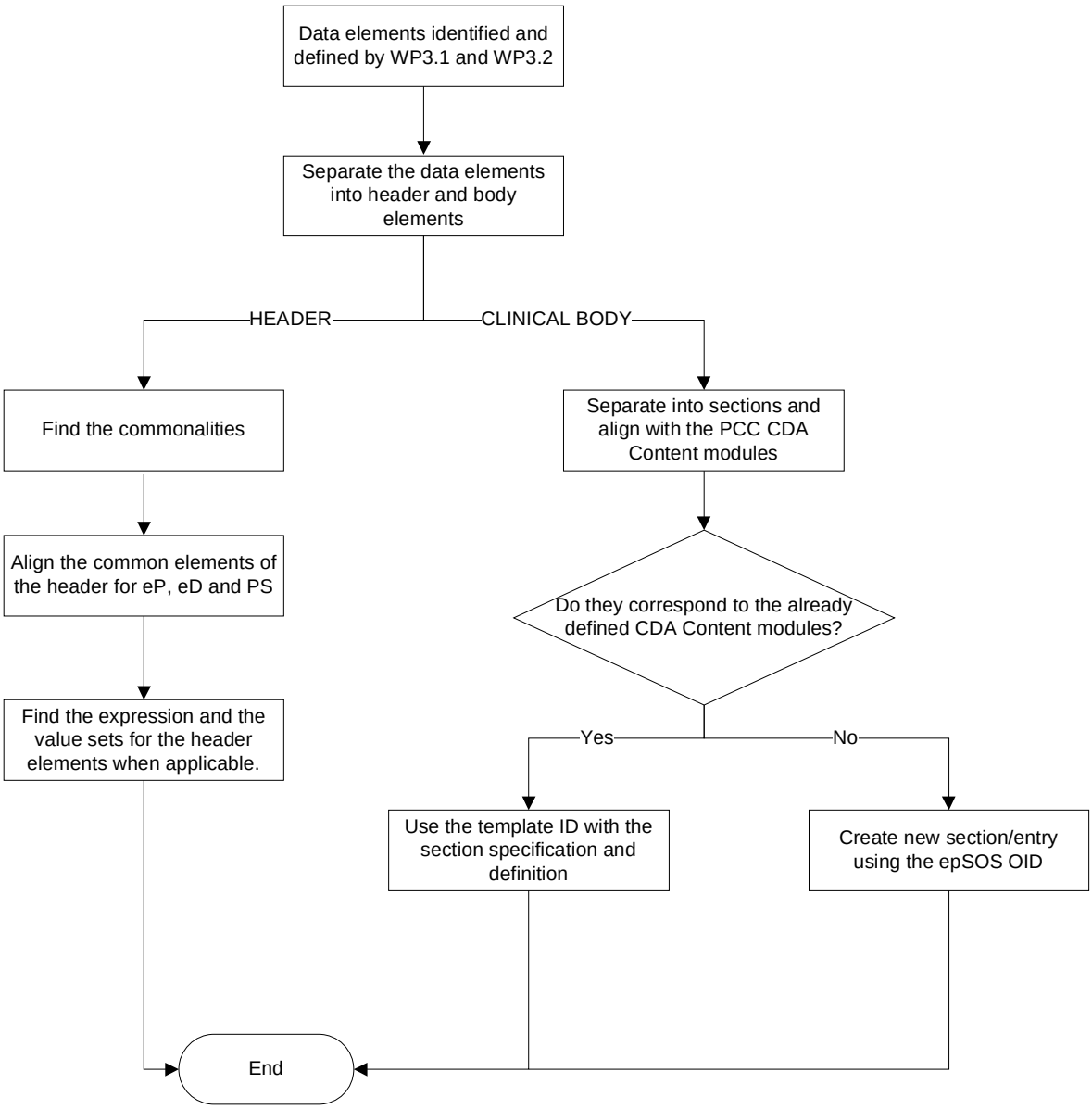

Figure 7** - Methodology used in establishing the **syntax of the pivot documents

7.1.2 epSOS Value Sets

The epSOS Master Value Sets describes the code systems or the value sets originating from codes systems to be used within the framework provided by CDA.

Each coded element whether in the header or in the body is examined for a suitable value set. If the coded element has a close match with an already existing CDA Content Modules, then the code system recommended is studied to see if it responds to the functional requirements. If the functional requirements are met, then the coded element must be further studied conceptually, from a medical point of view and a patient safety point of view, in order to determine whether a full code system is needed or just a part of one.

The methodology of choosing a value set can be seen in ***Figure 8***.

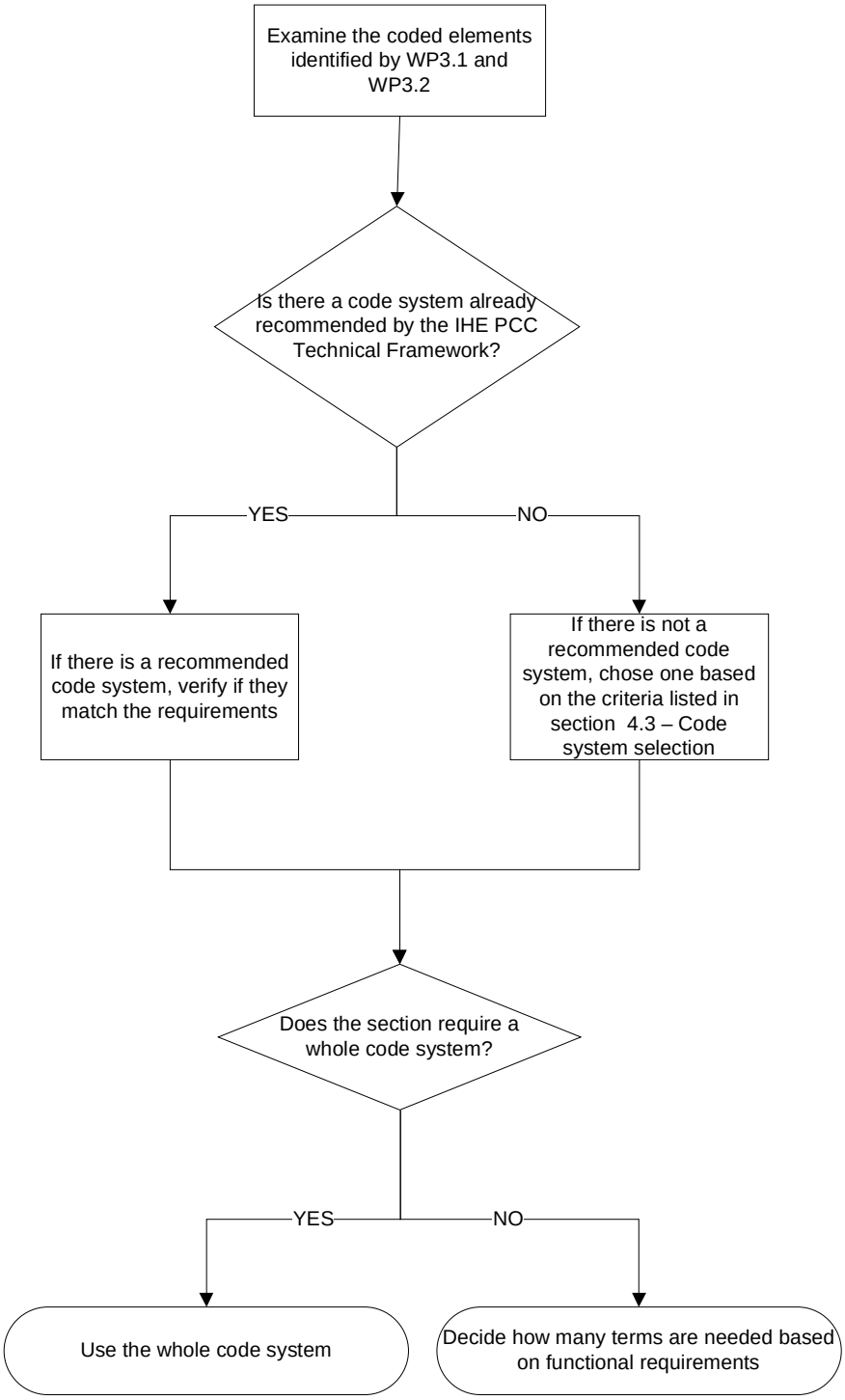

***Figure 8** - Methodology used in establishing the **epSOS Master Value Sets Catalogue's** content.*

7.1.3 epSOS Ontology

The epSOS Ontology is the semantic backbone of the epSOS project. It is based on the MVC and MTC and is aimed to provide the necessary granularity to be the basis of the semantic services in epSOS. The rationale behind the ontology is the opportunity to evolve the semantic basis in a multi-centric way in order to achieve an ever-growing depth of semantic representation. In the future the latter will foster semantic services which are enriched with knowledge management and

decision support functionalities (checking the consistency of transformations, checking relevance of information). The multi-centric possibilities to maintain the semantic foundation of the epSOS services is the main reason to provide an OWL ontologies, since this format has been proved to support such a process very well.

The tool used to cross-reference or map between different code systems at run-time is called the "demonstrator". This tool was created in the scope of work of epSOS WP3.5. The purpose of the demonstrator application was to validate the concept of "on-the-fly" translation service and definitions of terminology access, and to elicit further requirements based on experiences from its implementation. The aim of the demonstrator is to proof that medical information can be transmitted from one language/coding schema to another in a medical useful way (human and machine understandable). The demonstrator offers a strategy for seamless communication of medical content over borders and will translate a medical term/code from one language/coding scheme to another one. For example, if two languages are used such as German and Spanish, the English language will be used as "pivot language" in order to provide a correspondence between the two.

The detailed specifications of these services, the description of the demonstrator as well as the accompanying OWL-file are presented in *Appendix E - Ontology Specifications.*

Figure 9 below illustrates an example of structure modelled using the epSOS Ontology. It presents just a small fraction of the ontology containing instances of few concepts from one branch and their labels and relationships to coding systems.

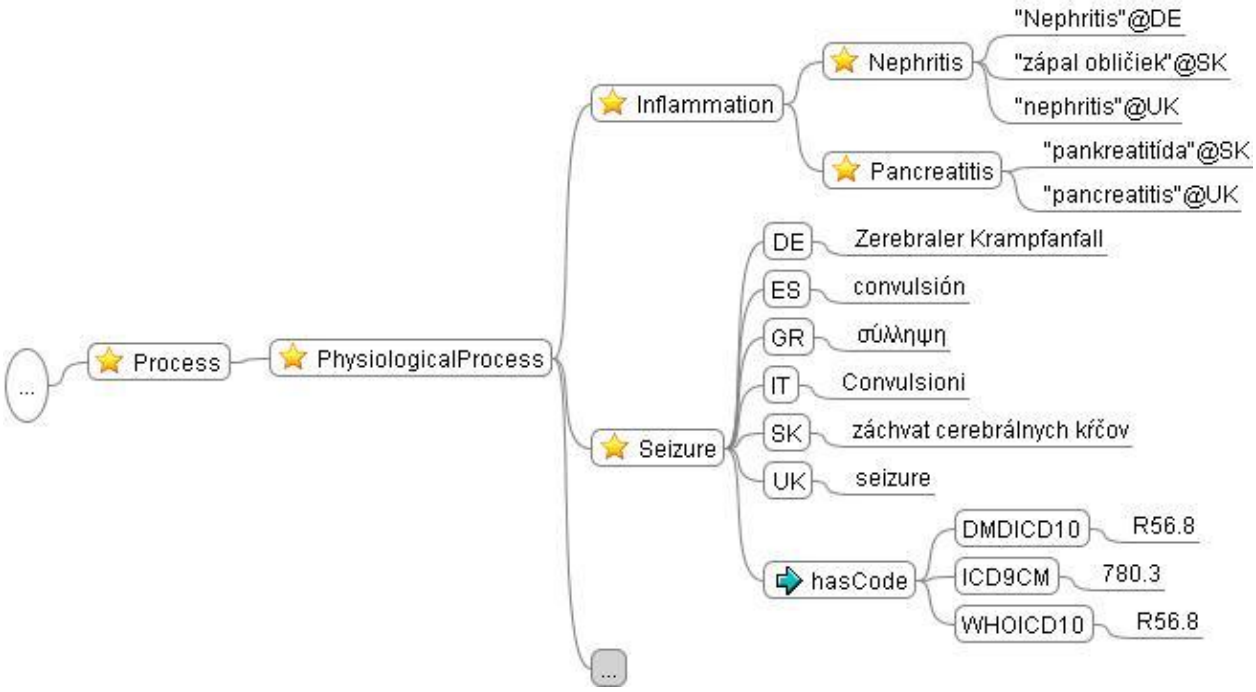

Figure 9 –An example of structure modeled by the epSOS Ontology.

The aim of the epSOS Ontology is to be the linguistic reference of the terms in the epSOS value sets. As a reference system it guarantees the quality of the transcodings/transformations, which mean the preservation of meaning in this process.

In order to assure the high quality of the epSOS Master Value Set Catalogue (epSOS MVC) there is a particular process that must be followed. The epSOS MVC, completed with all the necessary terms, is subjected to one last Quality Review before being sent out to the Member States. Instructuions will be provided as to how to fill it (the translated display names or the transcoded terms according to their used in MS. A procedure for recording errors is sent out as well with the excel file. Thus the epSOS MVC becomes the epSOS Master Translation/TranscodingCatalogue (epSOS MTC). The epSOS MTC is formed by adding transcoding and translation columns for each Member State. Filling out the epSOS MTC is the responsibility of each Member State's National Linguistic Competency Centre. Each Member State will also receive a sheet for documenting the eventual errors and/or omissions. The epSOS MTC serves as the basis for the epSOS Ontology. This will serve as an additional step for the Quality Review of the epSOS MTC.. The work packages 3.8, 3.9 and 3.10[13] are working jointly and have a Semantic Services subgroup whose one of its tasks is the supervision of the epSOS MTC and the impact of the Ontology on the Quality Review/Assurance.

The epSOS MTC (and implicitly the epSOS MVC) are subject to constant development and evolution. It is vitally important the epSOS Ontology stays synchronized with these two resources. In order to achieve that two possible scenarios are possible:

1) After a specified period of time the epSOS Ontology is enriched with all changes that occurred in either, MVC and MTC.
2)
3) Every change in the MVC and MTC is communicated by the curator of the Excel sheets to the curator of the owl file at a certain period of time defined by the semantic implementation group For an in-depth definition of a "curator" please see Appendix F – Terminology Access Services, section 1.2.6.

For the sake of a quick migration of changes and additions, the second strategy should be adopted by epSOS. Hence, once a new version of the MVC/MTC exists, the ontology will be updated. In order to facilitate that task, a workflow has to be specified that provides the ontology curator with means to identify changes and additions.

Another pressing issue is the possible utilization the maintenance process to represent more detailed semantic information than provided in the initial version of the ontology. Our proposal is to run the process of proposals of changes in and additions to the MVC/MTC in parallel to the curator of the former and the curator of the ontology. Thus, the ontology curator can model specifications and definitions related to reference of the term that might not be present in the representation of the excel sheets containing the Reference Terminology.

At the moment, CDA expression of the data elements contains bindings to the various epSOS value sets present in the epSOS MVC. Since each value set is used at the moment as a **flat list of terms within the CDA document**, the granularity within the ontology is not a current issue. The process of asking for a change or correction of the content of the epSOS MVC is centralized. There is only

[13] Work Package (WP) 3.8 is the Integration and Customization WP, WP3.9 is the Development of Proof of Concept System for the Pilot Phase WP, and WP3.10 is The Proof of Concept Testing WP.

one master version of the epSOS MVC, and the processes of requesting a change or a correction by each MS is done through excel sheets. The CDA bindings assure that the terms are part of the value set in question and that they are used in the right context. The excel file, for the epSOS TAS, can be fed directly into an SQL server or an Oracle data base.

In terms of maintenance, WP 3.5 has suggested that a European entity should take care of the maintenance of the epSOS MVC and epSOS MTC, for cases as such as when a new version of a code system is created and/or a Member State needs a new term added to the epSOS MVC and epSOS MTC. The European entity has not yet been identified and this is listed in the Open Issues chapter.

7.1.4 Terminology Access Services Methodology

The terminology access services methodology is based on international standards for interfacing reference terminologies using a service oriented approach elaborated by two main communities: Health Level 7 (HL7) and the Object Management Group (OMG).

The epSOS methodological approach to terminology access services includes a careful study of the released Common Terminology Services (CTS) version 1.2 (HL7 CTS 1.2) and of the CTS 2.0 in preparation (co-operation between the HL7 group and the Object Management Group). The two published standards adopt a service oriented architecture and design, specifying business processes, services and elementary operations for accessing and managing terminologies, independent of the underlying repository implementation.

The terminology access services methodology used to define the functionality needed for accessing and managing the epSOS Master Value Sets Catalogue consists of the following steps:

1. Identify the actors and their roles that participate in the information exchange of pivot documents and therein contained data elements, and roles that are directly implied in the management of the epSOS MTC.

2. Describe the various scenarios of the identified actors and the informational flow between them.

3. Identify and extract processes, commonly used services and operations described by the use cases involved.

4. Compare the above isolated functional elements with the two mentioned standards.

5. Adapt the common service descriptions of CTS for the translational payload, administrative and mapping needed for the access and maintenance of the epSOS Master Value Sets Catalogue/epSOS Ontology.

The epSOS terminology access services specification does not intend to replace the CTS specifications. Instead, the specific findings of the epSOS project are presented as enhancement requirements to the HL7 CTS2 specification.

Other main processes, services and operations that should be supported by the epSOS semantic services, apart from the accurate ‘ad-hoc’ translation of semantically equivalent concepts, include: accessing, querying, navigation, authoring and content versioning of the common epSOS

MTC/epSOS Ontology. These are described in detail in Appendix F – Terminology Access Services.

8 WP3.5 Semantic Services Specifications' Perimeter

The documents exchanged between the NCPs are the pivot documents and the original documents in a *pdf* format as defined by the functional requirements from WP3.1 and WP3.2.

WP3.5 defines the specification for three pivot documents: **ePrescription**, **eDispensation**, and **Patient Summary**. Mapping from the national schemas onto the pivot schema is out of scope of WP3.5. The perimeter of the work achieved in WP3.5 with regards to syntax and terminology can be seen in *Figure 10* and *Figure 11.*

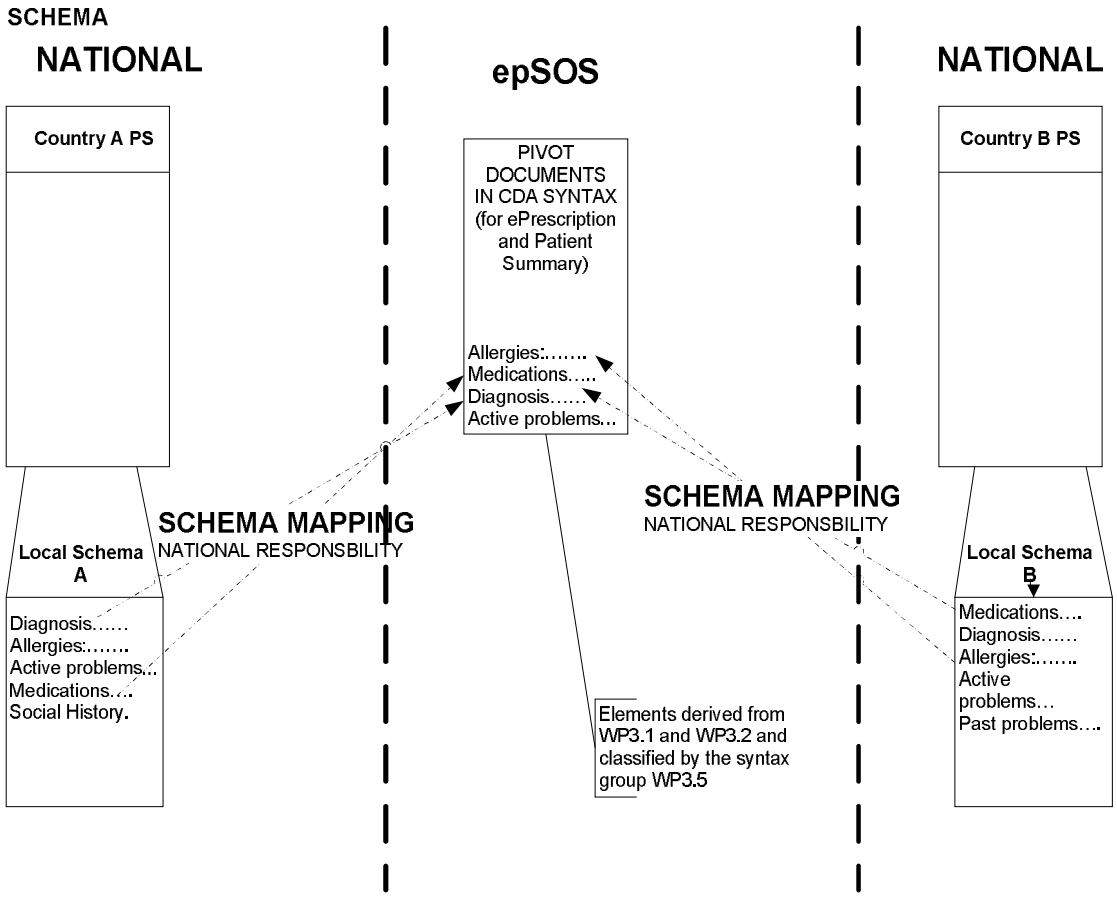

***Figure 10** - The perimeter of work of WP3.5 with regards to the structure of the three documents specifications, namely, ePrescription, eDispensation, and Patient Summary.*

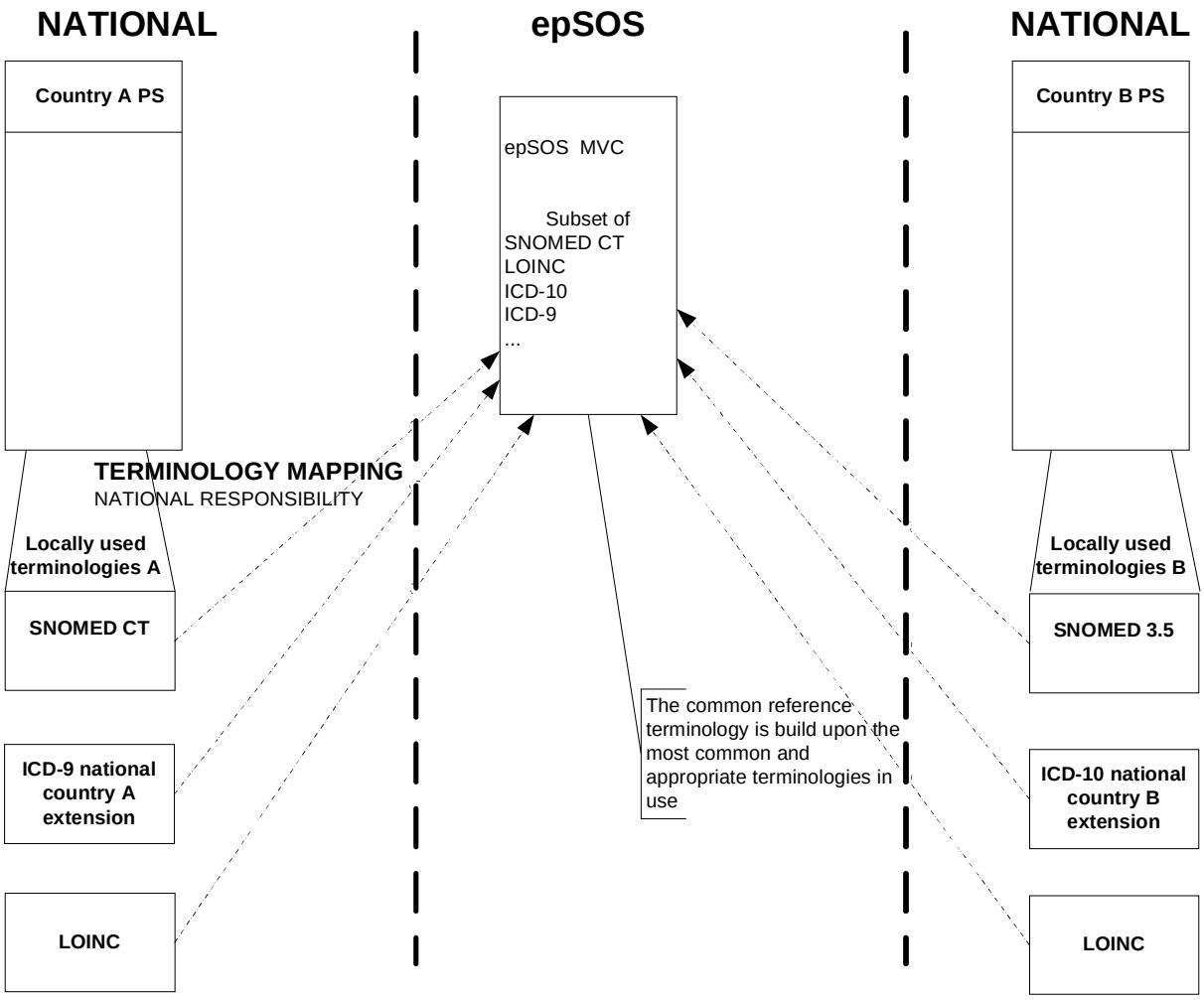

***Figure 11** - The perimeter of work of WP3.5 with regards to the value sets comprising the terminology used in the three documents specifications, namely, ePrescription, eDispensation, and Patient Summary*

WP3.5 also defines the content of the epSOS MVC which is defined based on the following principles:

- As much information as possible should be coded, **while recognizing that not all information will be coded.**
- The terms present in the epSOS MVC are based on international existing code systems.
- The epSOS MVC fits into the framework provided by CDA coded data
- The content of the epSOS MVC is based on various European projects and data, as mentioned in section 4.4.1.

9 Pivot documents and 13606

EN13606 is another standard that defines how data and information should be documented and archivedEN13606 is based on an ISO document 18308 “Requirements for EHR architectures”.

EN13606 is provides a complete separation between the responsibilities for on one hand the IT providers and on the other hand the healthcare knowledge domain through its feature the Two Level Modelling Approach.

EN13606 EHR-com contains five parts. For sake of completeness, the standard EN13606 is described in this chapter.

9.1 Description of the 13606 Standard

This section described shortly the component parts of the EN13606.

9.1.1 Reference Model[14]

The Reference Model describes how clinical facts can be documented taking into consideration patient safety and privacy.

9.1.2 Archetype Model[15]

This model describes how the production of archetypes. Archetypes allow healthcare providers to define the type of information and its way of documenting it, for instance a blood pressure observation. Healthcare professionals will have to produce libraries of archetypes defining the information content of their field of expertise.

A unique feature of the EN13606 is that systems that conform to this standard can implement seamlessly any archetype already defined within a very short period of time.

9.1.3 Terminology[16]

This part contains several internal classifications used by the standard.

9.1.4 Patient Mandate[17]

This part describes how the patient is able to express who has access to what data and information.

[14] ISO 13606-1:2008 Health informatics -- Electronic health record communication -- Part 1: Reference model http://www.iso.org/iso/catalogue_detail.htm?csnumber=40784

[15] ISO 13606-2:2008 Health informatics -- Electronic health record communication -- Part 2: Archetype interchange specification http://www.iso.org/iso/iso_catalogue/catalogue_tc/catalogue_detail.htm?csnumber=50119

[16] ISO 13606-3:2009 Health informatics -- Electronic health record communication -- Part 3: Reference archetypes and term lists http://www.iso.org/iso/iso_catalogue/catalogue_tc/catalogue_detail.htm?csnumber=50120

[17] ISO/TS 13606-4:2009 Health informatics -- Electronic health record communication -- Part 4: Security http://www.iso.org/iso/iso_catalogue/catalogue_tc/catalogue_detail.htm?csnumber=50121

9.1.5 Implementation Guide[18]

This part describes how the standard can be implemented in order to send and receive between systems.

9.2 Semantic Interoperability and the EN13606 in general

9.2.1 Exchange between EN13606 systems

In case of exchange between Member States using the epSOS archetypes developed no transformation application needs to be generated and deployed. Only language translation is needed for the data and information (see *Figure 12* below)

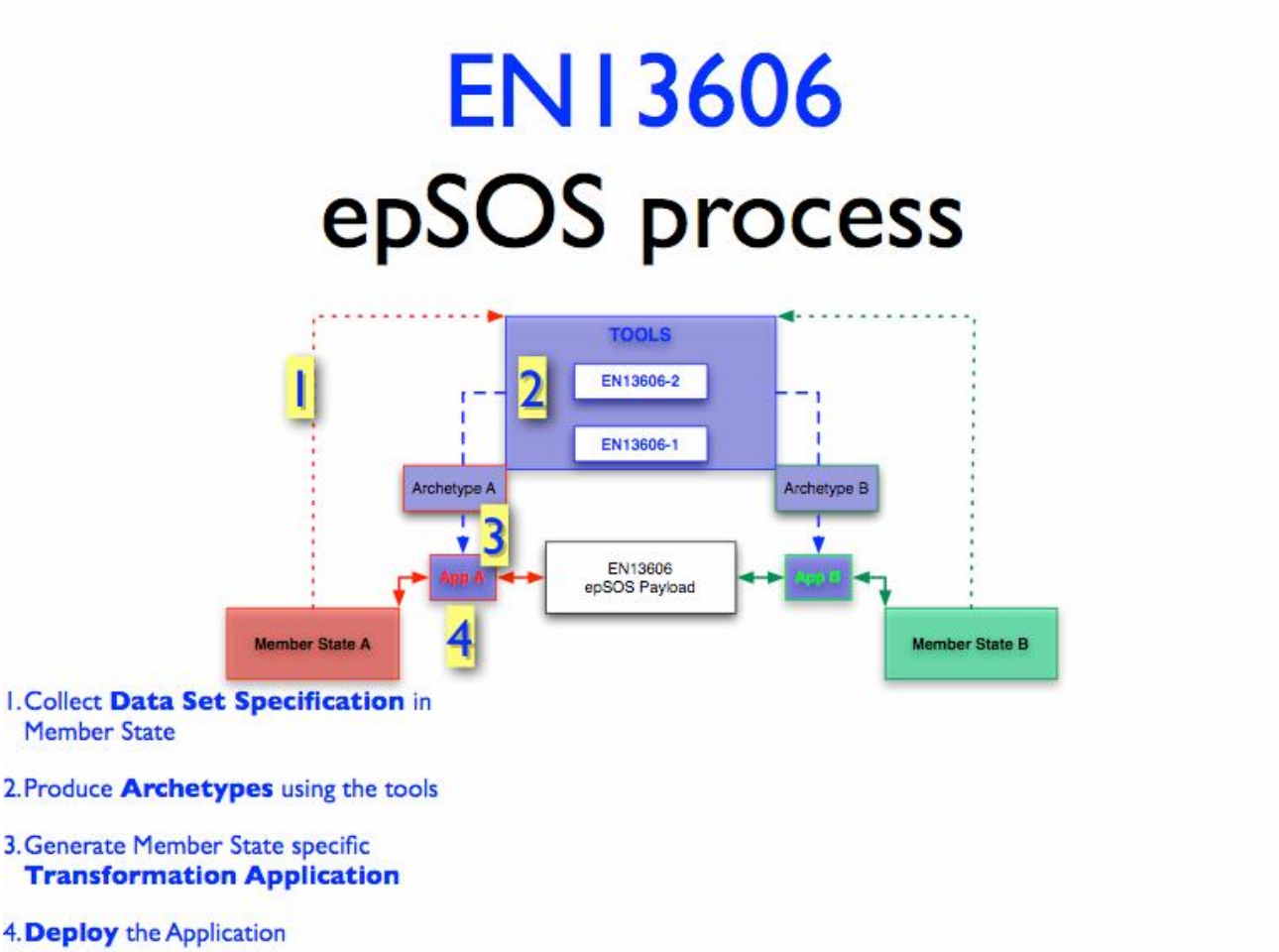

***Figure 12** - The EN13606 epSOS process for two Member States who have chosen to communicate between themselves using 13606. Please note that this is not the official epSOS format.*

[18] CEN pr13606:2007 Health informatics - Electronic health record communication - Part 5: Interface Specification
Under approval

9.2.2 Exchange CDA/CCD

Mapping efforts between HL7 CDA and EN13606 are underway. However, this mapping is out of scope for the WP 3.5 short timelines, and it is a matter of national responsibility. An EN13606 implementation guide is provided in the *Appendix G - CEN EN13606 Technical Specifications* without the mapping present.

10 Issues

10.1 Open Issues

1. The material produced in WP3.5 such as technical appendices and the supporting material needs to be maintained. A further requirement is needed to manage the test tools to be developed by WP3.9. There are two types of maintenance needed: a functional process as well as a physical storage space.

2. Slovakia has proposed a physical storage space for the epSOS Master Translation/Transcoding Catalogue (epSOS MTC). This proposal was deemed as politically sensitive by the group, and was brought to the attention of the TPM. The point whether or not a country can be a host for content concerning the whole European community was left open.

3. The maintenance of the epSOS MVC and epSOS MTC, on which is based the epSOS Ontology needs to be officially maintained by a European entity. This includes a quality assurance process. For the time being this activity has been assigned to the WP3.9. This must also include a legal disclaimers with regards to the document, the implementation guides and the Master Value Sets Catalogue and the Master Translation/TranscodingCatalogue' content.

10.2 Closed issues

1. The Medication Summary is part of the Patient Summary but it is not necessarily related to the ePrescription or eDispensation. The way the information is gathered in the Medication Summary is out of the epSOS functional scope.

2. The fact that substitution of a medication while dispensing must be documented with a "yes" or "no" value; however the substitution itself is a human action. The human action is performed by the pharmacist after consulting/talking to the patient.

3. There are some countries where the patient summaries are created in an ad-hoc manner. This document will only be visualized and not imported. The question of the accuracy and the imputability of the data visualized falls within the realm of the national authorities.

4. The cross-reference between the code systems does not exist officially, except between the code systems ICD-9 and SNOMED CT. The cross-mapping between the code systems with regards to the terms employed in the epSOS Master Translation/Transcoding Catalogue is done with the contribution of the medical and semantic specialist

5. Social Organization Insurance Identifier was removed from the data elements defined by the functional work packages since it was removed from D.3.2.1 and D3.2.2.

6. The dispensed item ID was removed since it was not specified anywhere. Only the eP item ID will be used to make the reconciliation and the traceability between the two.

7. The Medication Summary is not to be described as a special, separate document. This is an issue of the implementing Member States.

8. Since it was not clear what legal responsibility the patient's contact (guardian) has in each country with regards to the patient, information on the participation type and the personal relationship roles are possible is given. (ParticipationTypePatientContact and PersonalRelationshipRoleType. These designations indicate what type of contact this is such as an informant (source of information), a person to call urgently etc. Also the relationship to the patient indicates if it is a relative, a neighbor etc. This is extra information that might be needed in accordance to the legislative procedures in the Member State where the patient receives care.

11 Data elements mapping onto the CDA Content Modules

The data elements identified by the WP3.1 and WP3.2 were mapped onto the CDA content modules. The data elements were numbered so that they can be more easily located. Although there is a hierarchy within the same attributes of the data elements, they are purposely numbered separately so that they can be more easily identified when mapped.

For a detailed implementer's specifications please see *Appendix C - Pivot Documents Specification.*

11.1 Mapping on the CDA templates

The header specifications apply to all three documents. If special elements are needed for a particular type of document (such as ePrescription, eDispensation or Patient Summary), this shall be indicated or presented in a respectively separate section.

The first column contains the data elements as described by the functional work packages WP3.1 and WP3.2. The label in blue denotes the way the data element should be displayed by the software application. A clear indication must be given when grouping elements (family name, given name) as to whether this belong to the patient or to the contact information for example. The way of displaying this information is left at the implementer'

The data elements specified by the functional work packages mapped to different parts of the CDA document structure. The first column contains the number of the functional requirement for traceability purposes. The reader must note that a particular element is first presented as an entity such as the patient's address, and then split into the most granular components so that it can be expressed individually, according to the xml expression. The CDA header contains discrete information about the patient and the context of the document. Document sections and their entries contain the relevant clinical data represented in the document and are represented in section 4 of this appendix.

Although a reference to implementation was indicated, a mapping between the data elements presented by the functional groups ePrescription (WP3.1) and Patient Summary (WP3.2) onto to the corresponding CDA templates is present. The purpose of this exercise is to align the data elements that are deemed to be part of the header in order to provide a more coherent approach in terms of the epSOS pivot documents and to reduce implementers' discretion.

In the absence of an official OID a temporary OID is assigned as the root OID **1.3.6.1.4.1.12559.11.10.1.3** for the WP3.5. Branch 1 was allocated to WP3.5; therefore the OID for object belonging to WP3.5 is 1.3.6.1.4.1.12559.11.10.1.3.1.

The optionality is listed right underneath the data elements.

- **R**- means required, with no null flavor
- **NS**- means not specified. Whenever not specified by a functional work-package WP3.5 made the decision to render it "O".
- **RNFA** - means Required, Null Flavor Allowed. This will be expressed as "R" with the recommended nullFlavor indicated.
- **O** - means optional

- **NA** – means "not applicable" since the data element is not applicable in the respective document.

The data elements that are to be present in each document are documented in the tables below, for the header and for the body. The optionality indicated if the element is needed or not for the respective document. The cardinality was indicated only according to the strongest value for optionality.

The following table maps the data elements present in *Appendix B - Data Elements Correspondence* onto the corresponding CDA/CCD/PCC content modules.

The CDA expression is given, as well as the template ID for the sections and the entries present. When a particular vocabulary is required, it is listed in the column "Required Vocabulary", referencing a Value Set with its own OID and its Value Set Name. The Value Sets are present in the epSOS Master Value Set Catalogue (epSOS MVC).

Editor's note: The following technical specifications are meant to be input for the implementation work package, WP3.9. This in turn will be tested in the work package 3.10, requiring data from the Member States. The Member States are required to provide real data, as it is to be used in the pilot sites. In the case in which the Member States are not in the position of providing structured and coded fields for the items considered R with no null flavour allowed an issue will be raised to the Technical Project Manager in order to find a viable solution.

The elements that are indicated as "optional" by the functional work packages will be rendered as R null flavour allowed in order to approach as much as possible the existing implementation guides. The Member States are not required of adding this element if it is not present, it shall be added by the transformation manager, with the null flavour "NI" or no information. If the Member State wishes to change the null flavour, it can and it will override the "NI" value given by the Member State.

As a closing statement, as the implementation progresses, and the testing starts, there will be need for final tuning. The way in which this will be done is a matter to be dealt with by the Technical Project Manager.

The specifications from the functional work packages 3.1 and 3.2, as well as the ones from the semantic work package 3.5 are combined to result in different implementation specifications for the work package 3.9 (implementation). It is important to recognize that WP 3.1 and WP 3.2 worked at the concept level, WP transformed these concepts into two parts:

- Syntax to enable the representation of the components
- Value sets to be used within the syntax in order to give the content to the concepts expressed.

As a continuation, WP 3.9 will define the precise combination of syntax and the corresponding as an implementation guide.

The goal of the 3.5 specification was to show that the representation of the concepts from 3.1 and 3.2 possible, and to allow 3.9 to provide the exact implementable specifications.

11.1.1 Common Header Data Elements

Require-ment no.	Data element CDA / IHE PCC (WP3.1/WP3.2 label)	PCC Template CDA XPath expression	Optionality/ Cardinality (eP/eD /PS)	HL7 V3 Data Type	Required Vocabulary: Value Set Name and Value Set OID)
R1	**Patient Information**	1.3.6.1.4.1.19376.1.5.3.1.1.1 /ClinicalDocument/recordTarget/patientRole			
R1.1	**Patient Name**	1.3.6.1.4.1.19376.1.5.3.1.1.1 /ClinicalDocument/recordTarget/patientRole/patient/name			
R1.1.1	**Family Name/Surname** **(Family Name/Surname)**	1.3.6.1.4.1.19376.1.5.3.1.1.1 /ClinicalDocument/recordTarget/patientRole/patient/name/family	R / R / R [1..*]	PN	
R1.1.2	**Prefix**	/ClinicalDocument/recordTarget/patientRole/patient/name/prefix/	O / O / O [0..*]	PN	HL7:EntityNamePartQualifier 2.16.840.1.113883.5.1122
R1.1.3	**Given Name** **(Given Name)**	1.3.6.1.4.1.19376.1.5.3.1.1.1 /ClinicalDocument/recordTarget/patientRole/patient/name/given	R / R / R [1..*]	PN	
R1.2	**Gender** **(Gender)**	1.3.6.1.4.1.19376.1.5.3.1.1.1 /ClinicalDocument/recordTarget/patientRole/patient/ administrativeGenderCode	R/ R/R use nullFlavor = UNK [1..1]	CE	HL7:AdministrativeGender 2.16.840.1.113883.5.1
R1.3	**Date of Birth** **(Birth Date)**	1.3.6.1.4.1.19376.1.5.3.1.1.1 /ClinicalDocument/recordTarget/patientRole/patient/birthtime	R / R / R [1..1] The patient DOB may be a partial date such as only the year.	TS	

Require-ment no.	Data element CDA / IHE PCC (WP3.1/WP3.2 label)	PCC Template CDA XPath expression	Optionality/ Cardinality (eP/eD /PS)	HL7 V3 Data Type	Required Vocabulary: Value Set Name and Value Set OID)
R1.4	**Patient Identifiers**	1.3.6.1.4.1.19376.1.5.3.1.1.1 /ClinicalDocument/recordTarget/patientRole/id			
R1.4.1	**Primary Patient Identifier** **(Regional/National Health Id)**	1.3.6.1.4.1.19376.1.5.3.1.1.1 /ClinicalDocument/recordTarget/patientRole/id	R / R / R [1..1]	II	
R1.4.2	**Secondary Patient Identifier** **(Social/Insurance Number)**	1.3.6.1.4.1.19376.1.5.3.1.1.1 /ClinicalDocument/recordTarget/patientRole//id	O / O / O [0..*]	II	
R1.5	**Patient Address** **(Address)**	1.3.6.1.4.1.19376.1.5.3.1.1.1 /ClinicalDocument/recordTarget/patientRole/addr The patient address <addr> element is required. If there is no information, the nullFlavor attribute shall have a value of 'NI' and no address parts shall be present, otherwise there shall be no nullFlavor attribute, and at least one of the address parts listed below shall be present			
R1.5.1	**Patient's Street** **(Street)**	1.3.6.1.4.1.19376.1.5.3.1.1.1 /ClinicalDocument/recordTarget/patientRole/addr/streetAddressLine	R / R / R[19] use nullFlavor [1..*]	AD	
R1.5.2	**Patient's Number of Street**	1.3.6.1.4.1.19376.1.5.3.1.1.1 /ClinicalDocument/recordTarget/patientRole/addr/streetAddressLine	R / R / R use	AD	

[19] This element although indicated as optional by the functional work packages, will be left as R with null flavour allowed in order following as closely as possible the most common Implementation Guides, The R null flavour allowed will be added by the Transformation Manager.

Require-ment no.	Data element CDA / IHE PCC (WP3.1/WP3.2 label)	PCC Template CDA XPath expression	Optionality/ Cardinality (eP/eD /PS)	HL7 V3 Data Type	Required Vocabulary: Value Set Name and Value Set OID)
	(Number of Street)		nullFlavor [1..*]		
R1.5.3	**Patient's City** **(City)**	1.3.6.1.4.1.19376.1.5.3.1.1.1 /ClinicalDocument/recordTarget/patientRole/addr/city	R / R / R use nullFlavor [1..*]	AD	
R1.5.4	**Patient's Postal Code** **(Postal Code)**	1.3.6.1.4.1.19376.1.5.3.1.1.1 /ClinicalDocument/recordTarget/patientRole/addr/postalCode	R / R / R use nullFlavor [1..*]	AD	
R1.5.5	**Patient's State or Province** **(State or Province)**	1.3.6.1.4.1.19376.1.5.3.1.1.1 /ClinicalDocument/recordTarget/patientRole/addr/state	R / R / R use nullFlavor [1..*]	AD	
R1.5.6	**Patient's Country** **(Country)**	1.3.6.1.4.1.19376.1.5.3.1.1.1 /ClinicalDocument/recordTarget/patientRole/addr/country	R / R / R use nullFlavor [1..*]	AD	epSOSCountry 1.3.6.1.4.1.12559.11.10.1.3.1.42.4
R1.6	**Patient's Telecommunication**	1.3.6.1.4.1.19376.1.5.3.1.1.1 /ClinicalDocument/recordTarget/patientRole/telecom The patient telephone or e-mail <telecom> element is required. If there is no information, the nullFlavor attribute shall have a value of 'NI' and the "value" and "use" attributes shall be omitted, otherwise the nullFlavor attribute shall not be present, and the "value" and "use" attributes shall be present			
R1.6.1	**Patient's telephone number**	1.3.6.1.4.1.19376.1.5.3.1.1.1 /ClinicalDocument/recordTarget/patientRole/telecom/@value	R / R / R use	TEL	HL7: URLScheme 2.16.840.1.113883.5.143

Require-ment no.	Data element CDA / IHE PCC (WP3.1/WP3.2 label)	PCC Template CDA XPath expression	Optionality/ Cardinality (eP/eD /PS)	HL7 V3 Data Type	Required Vocabulary: Value Set Name and Value Set OID)
	(Telephone)	/ClinicalDocument/recordTarget/patientRole/telecom/@use	nullFlavor [1..*]		HL7:TelecommunicationAddressUse 2.16.840.1.113883.11.201
R1.6.2	**Patient's e-mail address** **(E-mail)**	1.3.6.1.4.1.19376.1.5.3.1.1.1 /ClinicalDocument/recordTarget/patientRole/telecom/@value /ClinicalDocument/recordTarget/patientRole/telecom/@use	R / R / R use nullFlavor [1..*]	TEL	HL7: URLScheme 2.16.840.1.113883.5.143 HL7:TelecommunicationAddressUse 2.16.840.1.113883.11.201
R1.7	**Patient's preferred language** **(Preferred Language)**	1.3.6.1.4.1.19376.1.5.3.1.2.1 /ClinicalDocument/recordTarget/patientRole/patient/languageCommunication/languageCode	R / R / R use nullFlavor [1..*]	CS	epSOSCountry 1.3.6.1.4.1.12559.11.10.1.3.1.42.4 epSOSLanguage 1.3.6.1.4.1.12559.11.10.1.3.1.42.6
R1.7.A	**Patient's Guardian**	**1.3.6.1.4.1.19376.1.5.3.1.2.4 /ClinicalDocument/recordTarget/patientRole/patient/guardian**	**R / R / R use nullFlavor [1..*]**	**PN**	
R1.7.A.1	**Guardian's Family Name/Surname**	1.3.6.1.4.1.19376.1.5.3.1.2.4 /ClinicalDocument/recordTarget/patientRole/patient/guardian/name/family	R / R / R use nullFlavor [1..*]	PN	
R1.7.A.2	**Guardian's Given Name**	1.3.6.1.4.1.19376.1.5.3.1.2.4 /ClinicalDocument/recordTarget/patientRole/patient/guardian/name/given	R / R / R use nullFlavor [1..*]	PN	

Require-ment no.	Data element CDA / IHE PCC (WP3.1/WP3.2 label)	PCC Template CDA XPath expression	Optionality/ Cardinality (eP/eD /PS)	HL7 V3 Data Type	Required Vocabulary: Value Set Name and Value Set OID)
R1.7.A.3	**Guardian's Address**	1.3.6.1.4.1.19376.1.5.3.1.2.4 /ClinicalDocument/recordTarget/patientRole/patient/guardian/addr The guardian's address <addr> element is required. If there is no information, the nullFlavor attribute shall have a value of 'UNK' and no address parts shall be present, otherwise there shall be no nullFlavor attribute, and at least one of the address parts listed below shall be present			
R1.7.A.3.1	**Guardian's Street (Street)**	1.3.6.1.4.1.19376.1.5.3.1.2.4 /ClinicalDocument/recordTarget/patientRole/patient/guardian/addr/streetAddressLine	R / R / R use nullFlavor [1..*]	AD	
R1.7.A.3.2	**Guradian's Number of Street (Number of Street)**	1.3.6.1.4.1.19376.1.5.3.1.2.4 /ClinicalDocument/recordTarget/patientRole/patient/guardian/addr/streetAddressLine	R / R / R use nullFlavor [1..*]	AD	
R1.7.A.3.3	**Guradian's City (City)**	1.3.6.1.4.1.19376.1.5.3.1.2.4 /ClinicalDocument/recordTarget/patientRole/patient/guardian/addr/city	R / R / R use nullFlavor [1..*]	AD	
R1.7.A.3.4	**Guardian's Postal Code (Postal Code)**	1.3.6.1.4.1.19376.1.5.3.1.2.4 /ClinicalDocument/recordTarget/patientRole/patient/guardian/addr/postalCode	R / R / R use nullFlavor [1..*]	AD	
R1.7.A.3.5	**Guardian's State or Province (State or Province)**	1.3.6.1.4.1.19376.1.5.3.1.2.4 /ClinicalDocument/recordTarget/patientRole/patient/guardian/addr/state	R / R / R use nullFlavor [1..*]	AD	
R1.7.A.3.6	**Guardian's Country (Country)**	1.3.6.1.4.1.19376.1.5.3.1.2.4 /ClinicalDocument/recordTarget/patientRole/patient/guardian/addr/cou	R / R / R use	AD	epSOSCountry 1.3.6.1.4.1.12559.11.10.1.3.1.42.4

Require-ment no.	Data element CDA / IHE PCC (WP3.1/WP3.2 label)	PCC Template CDA XPath expression	Optionality/ Cardinality (eP/eD /PS)	HL7 V3 Data Type	Required Vocabulary: Value Set Name and Value Set OID)
		ntry	nullFlavor [1..*]		
R1.7.A.4	**Guardian's Telecommunication**	1.3.6.1.4.1.19376.1.5.3.1.2.4 /ClinicalDocument/recordTarget/patientRole/patient/guardian/telecom The guardian's telecommunication <telecom> element is required. If there is no information, the nullFlavor attribute shall have a value of 'NI' and no address parts shall be present, otherwise there shall be no nullFlavor attribute, and at least one of the address parts listed below shall be present			
R1.7.A.4.1	**Guardian's Telephone**	1.3.6.1.4.1.19376.1.5.3.1.2.4 /ClinicalDocument/recordTarget/patientRole/patient/guardian/ telecom/@value /ClinicalDocument/recordTarget/patientRole/patient/guardian/ telecom/@use	R / R / R use nullFlavor [1..*]	TEL	HL7: URLScheme 2.16.840.1.113883.5.143 HL7:TelecommunicationAddressUse 2.16.840.1.113883.11.201
R1.7.A.4.2	**Guardian's e-mail addresss**	1.3.6.1.4.1.19376.1.5.3.1.2.4 /ClinicalDocument/recordTarget/patientRole/patient/guardian/ telecom/@value /ClinicalDocument/recordTarget/patientRole/patient/guardian/ telecom/@use	R / R / R use nullFlavor [1..*]	TEL	HL7: URLScheme 2.16.840.1.113883.5.143 HL7:TelecommunicationAddressUse 2.16.840.1.113883.11.201
R1.8	**Contact Person (Patient Contact Information)**	1.3.6.1.4.1.19376.1.5.3.1.2.4 /ClinicalDocument/participant/associatedEntity/associatedPerson			
R1.8.1	**Patient Contact's Family Name/ Surname** **(Family Name/Surname)**	1.3.6.1.4.1.19376.1.5.3.1.2.4 /ClinicalDocument/participant/associatedEntity/associatedPerson/name /family	R / R / R use nullFlavor [1..*]	PN	
R1.8.2	**Patient Contact's Given Name** **(Given Name)**	1.3.6.1.4.1.19376.1.5.3.1.2.4 /ClinicalDocument/participant/associatedEntity/associatedPerson/name /given	R / R / R use nullFlavor [1..*]	PN	

Require-ment no.	Data element CDA / IHE PCC (WP3.1/WP3.2 label)	PCC Template CDA XPath expression	Optionality/ Cardinality (eP/eD /PS)	HL7 V3 Data Type	Required Vocabulary: Value Set Name and Value Set OID)
R1.8.3	**Patient Contact's Address** **(Address)**	1.3.6.1.4.1.19376.1.5.3.1.2.4 /ClinicalDocument/participant/associatedEntity/associatedPerson/addr			
R1.8.3.1	**Patient Contact's Street** **(Street)**	/ClinicalDocument/participant/associatedEntity/associatedPerson/addr /streetAddressLine	R / R / R use nullFlavor [1..*]	AD	
R1.8.3.2	**Patient Contact's Number of Street** **(Number of Street)**	/ClinicalDocument/participant/associatedEntity/associatedPerson/addr /streetAddressLine	R / R / R use nullFlavor [1..*]	AD	
R1.8.3.3	**Patient Contact's City** **(City)**	/ClinicalDocument/participant/associatedEntity/associatedPerson/addr city	R / R / R use nullFlavor [1..*]	AD	
R1.8.3.4	**Patient Contact's Postal Code** **(Postal Code)**	/ClinicalDocument/participant/associatedEntity/associatedPerson/addr /postalCode	R / R / R use nullFlavor [1..*]	AD	
R1.8.3.5	**Patient Contact's State or Province** **(State or Province)**	/ClinicalDocument/participant/associatedEntity/associatedPerson/addr /state	R / R / R use nullFlavor [1..*]	AD	
R1.8.3.6	**Patient Contact's Country** **(Country)**	/ClinicalDocument/participant/associatedEntity/associatedPerson/addr /country	R / R / R use nullFlavor [1..*]	AD	

Require-ment no.	Data element CDA / IHE PCC (WP3.1/WP3.2 label)	PCC Template CDA XPath expression	Optionality/ Cardinality (eP/eD /PS)	HL7 V3 Data Type	Required Vocabulary: Value Set Name and Value Set OID)
R1.8.4	**Patient Contact's Telecommunication**	1.3.6.1.4.1.19376.1.5.3.1.2.4 /ClinicalDocument/participant/associatedEntity/associatedPerson/telecom The patient contact's telephone or e-mail <telecom> element is required. If there is no information, the nullFlavor attribute shall have a value of 'UNK' and the "value" and "use" attributes shall be omitted, otherwise the nullFlavor attribute shall not be present, and the "value" and "use" attributes shall be present			
R1.8.4.1	**Patient Contact's Telephone** **(Telephone)**	1.3.6.1.4.1.19376.1.5.3.1.2.4 /ClinicalDocument/participant/associatedEntity/associatedPerson/telecom/@value /ClinicalDocument/participant/associatedEntity/associatedPerson/telecom/@use	R / R / R use nullFlavor [1..*]	TEL	HL7: URLScheme 2.16.840.1.113883.5.143 HL7:TelecommunicationAddressUse 2.16.840.1.113883.11.201
R1.8.4.2	**Patient Contact's Email** **(E-mail)**	1.3.6.1.4.1.19376.1.5.3.1.2.4 /ClinicalDocument/participant/associatedEntity/associatedPerson/telecom/@value /ClinicalDocument/participant/associatedEntity/associatedPerson/telecom/@use	R / R / R use nullFlavor [1..*]	TEL	HL7: URLScheme 2.16.840.1.113883.5.143 HL7:TelecommunicationAddressUse 2.16.840.1.113883.11.201
R1.8.5	**Participant typeCode** **= added by WP3.5** **(Type of contact)**	1.3.6.1.4.1.19376.1.5.3.1.2.4 /ClinicalDocument/participant/[@typeCode=**'IND']/associatedEntity@ classCode='NOK'|'ECON'|...**	O / O / O [0..*]	CS	HL7 : ParticipationType 2.16.840.1.113883.5.90 HL7: RoleClassAssociative 2.16.840.1.113883.1.11.19313
R1.8.6	**Contact Relationship Type** **= added by WP3.5** **(Contact Relationship)**	1.3.6.1.4.1.19376.1.5.3.1.2.4 /ClinicalDocument/participant/assignedEntity/code	O / O / O [0..*]	CE	HL7:PersonalRelationshipRoleType 2.16.840.1.113883.11.19563

Require-ment no.	Data element CDA / IHE PCC (WP3.1/WP3.2 label)	PCC Template CDA XPath expression	Optionality/ Cardinality (eP/eD /PS)	HL7 V3 Data Type	Required Vocabulary: Value Set Name and Value Set OID)
R1.9	**Prefered HCP/ Legal Organization**[20] **(Prefered HCP/ Legal Organization to contact)**	1.3.6.1.4.1.19376.1.5.3.1.2.4 /ClinicalDocument/participant[functionCode/@code="PCP" and functionCode/@codeSystem='2.16.840.1.113883.5.88']/associatedEntity[@classCode="CAREGIVER"]/scopingOrganization /ClinicalDocument/participant[functionCode/@code="PCP" and functionCode/@codeSystem='2.16.840.1.113883.5.88']/associatedEntity[@classCode="CAREGIVER"]/associatedPerson/			
R1.9.1	**Name of the prefered Legal Organization/HCP (Contact Organization Name)**	1.3.6.1.4.1.19376.1.5.3.1.2.4 /ClinicalDocument/participant/associatedEntity/scopingOrganization/name /ClinicalDocument/participant/associatedEntity/associatedPerson//name	R / R / R use nullFlavor [1..1]	ON/PN	
R1.9.1.1	**Family Name/Surname of the prefered HCP (Family Name/Surname)**	1.3.6.1.4.1.19376.1.5.3.1.2.4 /ClinicalDocument/participant/associatedEntity/associatedPerson//name/family	R / R / R use nullFlavor [1..1]	PN	
R1.9.1.2	**Given Name of the prefered HCP (Given Name)**	1.3.6.1.4.1.19376.1.5.3.1.2.4 /ClinicalDocument/participant/associatedEntity/associatedPerson/name/given	R / R / R use nullFlavor [1..1]	PN	
R1.9.2	**Prefered HCP/ Legal Organization Address**	1.3.6.1.4.1.19376.1.5.3.1.2.4 /ClinicalDocument/participant/associatedEntity/associatedPerson /addr			

[20] A foreign HCP may need a contact (HCP/legal organization) who knows the patient

Require-ment no.	Data element CDA / IHE PCC (WP3.1/WP3.2 label)	PCC Template CDA XPath expression	Optionality/ Cardinality (eP/eD /PS)	HL7 V3 Data Type	Required Vocabulary: Value Set Name and Value Set OID)
	(Prefered HCP/ Legal Organization Address)	/ClinicalDocument/participant/associatedEntity/scopingOrganization/addr			
R1.9.2.1	**Prefered HCP/ Legal Organization Street** **(Street)**	1.3.6.1.4.1.19376.1.5.3.1.2.4 /ClinicalDocument/participant/associatedEntityassociatedPerson / /addr /streetAddressLine /ClinicalDocument/participant/associatedEntity/scopingOrganization//addr /streetAddressLine	R / R / R use nullFlavor [1..*]	AD	
R1.9.2.2	**Prefered HCP/ Legal Organization Number of Street** **(Number of Street)**	1.3.6.1.4.1.19376.1.5.3.1.2.4 /ClinicalDocument/participant/associatedEntity/associatedPerson /addr /streetAddressLine /ClinicalDocument/participant/associatedEntity/scopingOrganization//addr /streetAddressLine	R / R / R use nullFlavor [1..*]	AD	
R1.9.2.3	**Prefered HCP/ Legal Organization City** **(City)**	1.3.6.1.4.1.19376.1.5.3.1.2.4 /ClinicalDocument/participant/associatedEntity/associatedPerson /addr city /ClinicalDocument/participant/associatedEntity/scopingOrganization//addr /city	R / R / R use nullFlavor [1..*]	AD	
R1.9.2.4	**Prefered HCP/ Legal Organization Postal Code** **(Postal Code)**	1.3.6.1.4.1.19376.1.5.3.1.2.4 /ClinicalDocument/participant/associatedEntity/associatedPerson /addr /postalCode /ClinicalDocument/participant/associatedEntity/scopingOrganization//addr /postalCode	R / R / R use nullFlavor [1..*]	AD	
R1.9.2.5	**Prefered HCP/ Legal Organization State or Province** **(State or Province)**	/ClinicalDocument/participant/associatedEntity/associatedPerson / /addr /state /ClinicalDocument/participant/associatedEntity/scopingOrganization//addr /state	R / R / R use nullFlavor [1..*]	AD	

Require-ment no.	Data element CDA / IHE PCC (WP3.1/WP3.2 label)	PCC Template CDA XPath expression	Optionality/ Cardinality (eP/eD /PS)	HL7 V3 Data Type	Required Vocabulary: Value Set Name and Value Set OID)
R1.9.2.6	**Prefered HCP/ Legal Organization Country** **(Country)**	/ClinicalDocument/participant/associatedEntity/associatedPerson / /addr /country /ClinicalDocument/participant/associatedEntity/scopingOrganization//addr /country	R / R / R use nullFlavor [1..*]	AD	epSOSCountry 1.3.6.1.4.1.12559.11.10.1.3.1.42.4
R1.9.3	**Prefered HCP/ Legal Organization Telecommunication**	1.3.6.1.4.1.19376.1.5.3.1.2.4 /ClinicalDocument/participant/associatedEntity/scopingOrganization/telecom /ClinicalDocument/participant/associatedEntity/associatedPerson/telecom The Prefered HCP/Legal Organization telephone or e-mail <telecom> element is required. If there is no information, the nullFlavor attribute shall have a value of 'UNK' and the "value" and "use" attributes shall be omitted, otherwise the nullFlavor attribute shall not be present, and the "value" and "use" attributes shall be present			
R1.9.3.1	**Preferred contact HCP/Legal Organization Telephone** **(Preferred Organization Telephone)**	1.3.6.1.4.1.19376.1.5.3.1.2.4 /ClinicalDocument/participant/associatedEntity/scopingOrganization/telecom/@value /ClinicalDocument/participant/associatedEntity/scopingOrganization/telecom/@use /ClinicalDocument/participant/associatedEntity/ associatedPerson /telecom@value /ClinicalDocument/participant/associatedEntity/associatedPerson /telecom@use	R / R / R use nullFlavor [1..*]	TEL	HL7: URLScheme 2.16.840.1.113883.5.143 HL7:TelecommunicationAddressUse 2.16.840.1.113883.11.201
R1.9.3.2	**Preferred contact HCP/Legal Organization e-mail** **(Preferred Organization E-mail)**	1.3.6.1.4.1.19376.1.5.3.1.2.4 /ClinicalDocument/participant/associatedEntity/scopingOrganization/telecom/@value /ClinicalDocument/participant/associatedEntity/scopingOrganization/telecom/@use /ClinicalDocument/participant/associatedEntity/associatedPerson /telecom@value /ClinicalDocument/participant/associatedEntity/associatedPerson /telecom@use	R / R / R use nullFlavor [1..*]	TEL	HL7: URLScheme 2.16.840.1.113883.5.143 HL7:TelecommunicationAddressUse 2.16.840.1.113883.11.201

Require-ment no.	Data element CDA / IHE PCC (WP3.1/WP3.2 label)	PCC Template CDA XPath expression	Optionality/ Cardinality (eP/eD /PS)	HL7 V3 Data Type	Required Vocabulary: Value Set Name and Value Set OID)
R1.10	**HCP Identification** ***See also body for eP and eD*** **(Health Care Professional)**	1.3.6.1.4.1.19376.1.5.3.1.2.3 /ClinicalDocument/author/assignedAuthor /ClinicalDocument/documentationOf/serviceEvent/performer (this applies to the prescriber and the dispenser). The template ID referenced here refers to HCP information in the /ClinicalDocument/documentationOf/serviceEvent/performer structure. In this document, the same requriements apply to the person author of the document (if there is one), and to the prescrober and dispenser (see body). When there is no HCP but we have the method of assembly of data by a device, such as the "spider" method, we have the following expression; ClinicalDocument/author/assignedAuthor/assignedAuthoringDevice. When When the data is collected from different sources & pre-existing documents that are part of a bigger system. In that case the organization responsible of that collection "signed" the PS as responsible. ClinicalDocument/author/assignedAuthor/representedOrganization			
R1.10.1	**HCP Family Name/Surname** **(Family Name/Surname)**	1.3.6.1.4.1.19376.1.5.3.1.2.3 /ClinicalDocument/author/assignedAuthor/assignedPerson/name/family /ClinicalDocument/documentationOf/serviceEvent/performer/assignedEntity/assignedPerson/name/family	R / R / R [1..*]	PN	
R1.10.2	**HCP Given Name** **(Given Name)**	1.3.6.1.4.1.19376.1.5.3.1.2.3 /ClinicalDocument/author/assignedAuthor/assignedPerson/name/given /ClinicalDocument/documentationOf/serviceEvent/performer/assignedEntity/assignedPerson/name/given	R / R / R [1..*]	PN	
R1.10.3	**HCP Prefix**	1.3.6.1.4.1.19376.1.5.3.1.2.3 /ClinicalDocument/author/assignedAuthor/assignedPerson/name/prefix /ClinicalDocument/documentationOf/serviceEvent/performer/assignedEntity/assignedPerson/name/prefix	O / O / O [0..*]	PN	

Require-ment no.	Data element CDA / IHE PCC (WP3.1/WP3.2 label)	PCC Template CDA XPath expression	Optionality/ Cardinality (eP/eD /PS)	HL7 V3 Data Type	Required Vocabulary: Value Set Name and Value Set OID)
R1.10.4	**HCP Suffix**	1.3.6.1.4.1.19376.1.5.3.1.2.3 /ClinicalDocument/author/assignedAuthor/assignedPerson/name/suffix /ClinicalDocument/documentationOf/serviceEvent/performer/assignedEntity/assignedPerson/name/suffix	O / O / O [0..*]	PN	
R1.10.5	**HCP ID number** **(Identification)**	1.3.6.1.4.1.19376.1.5.3.1.2.3 /ClinicalDocument/author/assignedAuthor/id /ClinicalDocument/documentationOf/serviceEvent/performer/assignedEntity/id	R / R / R [1..]	II	
R1.10.6	**Profession** **(Health Care Professional's Profession)**	1.3.6.1.4.1.19376.1.5.3.1.2.3 /ClinicalDocument/author/functionCode /ClinicalDocument/documentationOf/serviceEvent/performer/functionCode	R / O / O [1..*]	CWE	epSOS : HealthcareProfessionalRoles 1.3.6.1.4.1.12559.11.10.1.3.1.42.1
R1.10.7	**Specialty** **(Health Care Professional's Specialty)**	1.3.6.1.4.1.19376.1.5.3.1.2.3 /ClinicalDocument/author/assignedAuthor/code /ClinicalDocument/documentationOf/serviceEvent/performer/assignedEntity/code	O / O / O [0..*]	CWE	
R1.10.8	**HCP Telecom**	1.3.6.1.4.1.19376.1.5.3.1.2.3 /ClinicalDocument/author/assignedAuthor/telecom /ClinicalDocument/documentationOf/serviceEvent/performer/assignedEntity/telecom			
R1.10.8.1	**HCP Telphone No** **(Health Care Professional's Telephone)**	1.3.6.1.4.1.19376.1.5.3.1.2.3 /ClinicalDocument/author/assignedAuthor/telecom/@value /ClinicalDocument/author/assignedAuthor/telecom/@use /ClinicalDocument/documentationOf/serviceEvent/performer/assignedEntity/telecom/@value /ClinicalDocument/documentationOf/serviceEvent/performer/assigned	O / O / O [0..*]	TEL	HL7: URLScheme 2.16.840.1.113883.5.143 HL7:TelecommunicationAddressUse 2.16.840.1.113883.11.201

Require-ment no.	Data element CDA / IHE PCC (WP3.1/WP3.2 label)	PCC Template CDA XPath expression	Optionality/ Cardinality (eP/eD /PS)	HL7 V3 Data Type	Required Vocabulary: Value Set Name and Value Set OID)
		Entity/telecom@use			
R1.10.8.2	**HCP E-mail** **(Health Care Professional's e-mail)**	1.3.6.1.4.1.19376.1.5.3.1.2.3 /ClinicalDocument/author/assignedAuthor/telecom/@value /ClinicalDocument/author/assignedAuthor/telecom/@use /ClinicalDocument/documentationOf/serviceEvent/performer/assignedEntity/telecom/@value /ClinicalDocument/documentationOf/serviceEvent/performer/assignedEntity/telecom@use	O / O / O [0..*]	TEL	HL7: URLScheme 2.16.840.1.113883.5.143 HL7:TelecommunicationAddressUse 2.16.840.1.113883.11.201
R1.10.9	**Healthcare Facility** ***(This is the Healthcare Facility that is responsible for the HCP)***	1.3.6.1.4.1.19376.1.5.3.1.2.3 /ClinicalDocument/author/assignedAuthor/representedOrganization /ClinicalDocument/documentationOf/serviceEvent/performer/assignedEntity/representedOrganization			
R1.10.9.1	**Healthcare Facility's name** **(Health Care Facility's Name)**	1.3.6.1.4.1.19376.1.5.3.1.2.3 /ClinicalDocument/author//assignedAuthor/representedOrganization/name /ClinicalDocument/documentationOf/serviceEvent/performer/assignedEntity/representedOrganization/name	R null flavor / R / R null flavor [1..1]	ON	
R1.10.9.2	**Healthcare Facility's identifier** **(Health Care Facility's Identifier)**	1.3.6.1.4.1.19376.1.5.3.1.2.3 /ClinicalDocument/author//assignedAuthor/representedOrganization/id /ClinicalDocument/documentationOf/serviceEvent/performer/assignedEntity/representedOrganization/id	R null flavor / R / R null flavor [1..1]	II	
R1.10.9.3	**Healthcare Facility's Address**	1.3.6.1.4.1.19376.1.5.3.1.2.3 /ClinicalDocument/author//assignedAuthor/representedOrganization/addr			

Require-ment no.	Data element CDA / IHE PCC (WP3.1/WP3.2 label)	PCC Template CDA XPath expression	Optionality/ Cardinality (eP/eD /PS)	HL7 V3 Data Type	Required Vocabulary: Value Set Name and Value Set OID)
		/ClinicalDocument/documentationOf/serviceEvent/performer/assignedEntity/representedOrganization/addr			
R1.10.9.3.1	**Healthcare Facility's Street** **(Street)**	1.3.6.1.4.1.19376.1.5.3.1.2.3 /ClinicalDocument/author//assignedAuthor/representedOrganization/addr/streetAddressLine /ClinicalDocument/documentationOf/serviceEvent/performer/assignedEntity/representedOrganization/addr/streetAddressLine	R null flavor / R / R null flavor [1..1]	AD	
R1.10.9.3.2	**Healthcare Facility's City** **(City)**	1.3.6.1.4.1.19376.1.5.3.1.2.3 /ClinicalDocument/author//assignedAuthor/representedOrganization/addr/city /ClinicalDocument/documentationOf/serviceEvent/performer/assignedEntity/representedOrganization/addr/city	R null flavor / R / R null flavor [1..1]	AD	
R1.10.9.3.3	**Healthcare Facility's State or Province** **(State or Province)**	1.3.6.1.4.1.19376.1.5.3.1.2.3 /ClinicalDocument/author//assignedAuthor/representedOrganization/addr/state /ClinicalDocument/documentationOf/serviceEvent/performer/assignedEntity/representedOrganization/addr/state	R null flavor / R / R null flavor [1..1]	AD	
R1.10.9.3.4	**Healthcare Facility's Zip or Postal Code** **(Postal Code)**	1.3.6.1.4.1.19376.1.5.3.1.2.3 /ClinicalDocument/author//assignedAuthor/representedOrganization/addr/postalCode /ClinicalDocument/documentationOf/serviceEvent/performer/assignedEntity/representedOrganization/addr/postalCode	R null flavor / R / R null flavor [1..1]	AD	
R1.10.9.3.5	**Healthcare Facility's Country** **(Country)**	1.3.6.1.4.1.19376.1.5.3.1.2.3 /ClinicalDocument/author//assignedAuthor/representedOrganization/addr/country /ClinicalDocument/documentationOf/serviceEvent/performer/assignedEntity/representedOrganization/addr/country	R / R / R [1..1]	AD	epSOSCountry 1.3.6.1.4.1.12559.11.10.1.3.1.42.4

Require-ment no.	Data element CDA / IHE PCC (WP3.1/WP3.2 label)	PCC Template CDA XPath expression	Optionality/ Cardinality (eP/eD /PS)	HL7 V3 Data Type	Required Vocabulary: Value Set Name and Value Set OID)
R1.10.9.4	**Healthcare Facilities's Telecom**	1.3.6.1.4.1.19376.1.5.3.1.2.3 /ClinicalDocument/author//assignedAuthor/representedOrganization/telecom/ /ClinicalDocument/documentationOf/serviceEvent/performer/assignedEntity/representedOrganization/telecom			
R1.10.9.4.1	**Healthcare Facility's telephone** **(Telephone)**	1.3.6.1.4.1.19376.1.5.3.1.2.3 /ClinicalDocument/author//assignedAuthor/representedOrganization/telecom/@value /ClinicalDocument/author//assignedAuthor/representedOrganization/telecom/@use /ClinicalDocument/documentationOf/serviceEvent/performer/assignedEntity/representedOrganization/telecom/@value /ClinicalDocument/documentationOf/serviceEvent/performer/assignedEntity/representedOrganization/telecom/@use	O / R / O [0..*]	TEL	
R1.10.9.4.2	**Healthcare Facility's e-mail address** **(E-mail)**	1.3.6.1.4.1.19376.1.5.3.1.2.3 /ClinicalDocument/author//assignedAuthor/representedOrganization/telecom/@value /ClinicalDocument/author//assignedAuthor/representedOrganization/telecom/@use /ClinicalDocument/documentationOf/serviceEvent/performer/assignedEntity/representedOrganization/telecom/@value /ClinicalDocument/documentationOf/serviceEvent/performer/assignedEntity/representedOrganization/telecom/@use	O / R / O [0..*]	TEL	
R1.11	**Document identification**	/ClinicalDocument/			
R1.11.1	**Date of creation** **(Document Creation date)**	1.3.6.1.4.1.19376.1.5.3.1.1.1 /ClinicalDocument/effectiveTime	R / R / R [1..1]	TS	

Require-ment no.	Data element CDA / IHE PCC (WP3.1/WP3.2 label)	PCC Template CDA XPath expression	Optionality/ Cardinality (eP/eD /PS)	HL7 V3 Data Type	Required Vocabulary: Value Set Name and Value Set OID)
R1.11.2	**Date of last update** **(Date of last update of document)**	1.3.6.1.4.1.19376.1.5.3.1.1.1 ClinicalDocument/documentationOf/serviceEvent/effectiveTime/high	O / O / R [1..1]	II	
R1.11.3	**Document ID** **(Document ID)**	1.3.6.1.4.1.19376.1.5.3.1.1.1 /ClinicalDocument/id	R / R / R [1..1]	II	
R1.11.5	**Author organization** **(Author organization)**	Same as R1.10.9			
R1.11.6	**Clinical document code** =added by WP3.5	1.3.6.1.4.1.19376.1.5.3.1.1.1 /ClinicalDocument/code	R / R / R [1..1]	CE	LOINC: Document Type 2.16.840.1.113883.6.1
R1.11.7	**Clinial document title** =added by WP3.5	1.3.6.1.4.1.19376.1.5.3.1.1.1 /ClinicalDocument/title	R / R / R [1..1]	ST	
R1.11.8	**Confidentiality code** =added by WP3.5	1.3.6.1.4.1.19376.1.5.3.1.1.1 /ClinicalDocument/confidentialityCode/@code	R null flavor / R null flavor / R null flavor [1..1]	CE	HL7: Confidentiality 2.16.840.1.113883.5.25
R1.11.9	**Legal Authenticator**	1.3.6.1.4.1.19376.1.5.3.1.1.1 The person taking responsibility for the medical content of the document. In Spain this is the regional authority in healthcare. This regional authority healthcare organization will send this to the NCP. The definition of the legal authenticator may vary accoriding to the rules set up in the framework agreement particular to each state. It may	R / R / R [1..*]	PN	

Require-ment no.	Data element CDA / IHE PCC (WP3.1/WP3.2 label)	PCC Template CDA XPath expression	Optionality/ Cardinality (eP/eD /PS)	HL7 V3 Data Type	Required Vocabulary: Value Set Name and Value Set OID)
		be a person or a regional authority, or an NCP. If the legal authetnicator is a person, the same elements as in **R1.10.1 to R1.10.8.2 must be represented within the context of the legal autehnticator.** /ClinicalDocument/legalAuthenticator/assignedEntity/assignedPerson			
R1.11.9	**Legal Authenticator**	1.3.6.1.4.1.19376.1.5.3.1.1.1 If the legal authenticator is a regional authority or another entitty, such as an NCP, the same elements as in **R1.10.9.1 to R1.10.9.4.2 must be represented within the context of the legal authenticator.** /ClinicalDocument/legalAuthenticator/assignedEntity/representedOrganization	R / R / R [1..*]	ON	
R.11.10	**Dcoument Language Code**	1.3.6.1.4.1.19376.1.5.3.1.1.1 /ClinicalDocument/Language	R / R / R [1..1]	CS	epSOSCountry 1.3.6.1.4.1.12559.11.10.1.3.1.42.4 epSOSLanguage 1.3.6.1.4.1.12559.11.10.1.3.1.42.6

11.1.2 Body Data Elements

95 The data elements present in the body concerning the prescriber and the dispenser DO belong in the body. The numbers are kept in the same order as they were listed in Appendix B.

Require-ment no.	Data element CDA / IHE PCC (WP3.1/WP3.2 label)	PCC Section Template CDA XPath expression	PCC Entry content modules CDA XPath expression	Optionality/ Cardinality (eP/eD /PS)	HL7 V3 Data Type	Required Vocabulary: Value Set Name and Value Set OID)
R2	**Prescription**	**Prescription Document 1.3.6.1.4.1.12559.11.10.1.3.1.1.1**				
R2.1	**Prescription ID (Prescription ID)**	**Prescription Section**[21] **1.3.6.1.4.1.12559.11.10.1.3.1.2.1** /ClinicalDocument/component/structuredBody/component/section[templateId@root='1.3.6.1.4.1.12559.11.10.1.3.1.2.1']/id		R / R / NA [1..1]	II	
R.2.2	**Prescriber (Prescriber)**	**Prescription Section 1.3.6.1.4.1.12559.11.10.1.3.1.2.1** /ClinicalDocument/component/structuredBody/component/section[templateId@root='1.3.6.1.4.1.12559.11.10.1.3.1.2.1']/author		R / R / NA [1..1]	PN	
		Please see section R1.10 in the Header for the other Prescriber Attributes while follwing the /ClinicalDocument/component/structuredBody/component/section/author XML element.				

[21] Prescription section, Dispensation section and Medication section instructions of coding are used within the epSOS namespace. For sake of clarity, their Xpath expression are not shown with the mention of it.

Require-ment no.	Data element CDA / IHE PCC (WP3.1/WP3.2 label)	PCC Section Template CDA XPath expression	PCC Entry content modules CDA XPath expression	Optionality/ Cardinality (eP/eD /PS)	HL7 V3 Data Type	Required Vocabulary: Value Set Name and Value Set OID)
R.2.3	**Prescriber Credentialing Organization (College) Identification** **(Prescriber Credentialing Organization)**	**Prescription Section** **1.3.6.1.4.1.12559.11.10.1.3.1.2.1**				
R2.3.1	**Prescriber Credentialing Organization (College) Name** **(Name)**		**Prescription item entry content module** **1.3.6.1.4.1.12559.11.10.1.3.1.3.2** entry/substanceAdministration[templateId/@root='1.3.6.1.4.1.12559.11.10.1.3.1.3.2']/participant[@typeCode='AUT']/participantRole[@classCode='CRED']/scopingEntity[@classCode='ORG']/desc	O / NA / NA [0..1]	ST	
R2.3.2	**Prescribing Credentialing Organization's (College) Identifier** **(Identifier)**		**Prescription item entry content module** **1.3.6.1.4.1.12559.11.10.1.3.1.3.2** entry/substanceAdministration[templateId/@root='1.3.6.1.4.1.12559.11.10.1.3.1.3.2']/participant[@typeCode='AUT']/participantRole[@classCode='CRED']/scopingEntity[@classCode='ORG']/id	O / NA / NA [0..1]	II	
R2.4	**Prescription Item ID** **(Prescription Item ID)**	**Prescription Section** **1.3.6.1.4.1.12559.11.10.1.3.1.2.1**	**Prescription Item Entry Content Module** **1.3.6.1.4.1.12559.11.10.1.3.1.3.2** entry/substanceAdministration[templateId/@root='1.3.6.1.4.1.12559.11.10.1.3.1.3.2']/id	R / R / NA [1..*]	II	

Require-ment no.	Data element CDA / IHE PCC (WP3.1/WP3.2 label)	PCC Section Template CDA XPath expression	PCC Entry content modules CDA XPath expression	Optionality/ Cardinality (eP/eD /PS)	HL7 V3 Data Type	Required Vocabulary: Value Set Name and Value Set OID)
R3	**Dispense**	**Dispensation Document** **1.3.6.1.4.1.12559.11.10.1.3.1.2**				
R3.1	**Dispenser** **(Dispenser)**	**Dispensation Section** **1.3.6.1.4.1.12559.11.10.1.3.1.2.2**	**Dispensed Medicine Entry Content Module** **1.3.6.1.4.1.12559.11.10.1.3.1.3.3** entry/supply[templateId/@root= '1.3.6.1.4.1.12559.11.10.1.3.1.3.3']/performer	NA / R / NA [1..1]	PN	
		Please see section R1.10 in the **Header** for the other **Dispenser Attributes** while follwing the /ClinicalDocument/component/structuredBody/component/section/ entry/supply/performer XML element.				
R3.2	**Dispenser Credentialing Organization** **(Dispenser Credentialing Organization)**	**Dispensation Section** **1.3.6.1.4.1.12559.11.10.1.3.1.2.2**				
R3.2.1	**Dispenser Credentialing Organization (College) Name** **Name**		**Dispensed Medicine Entry Content Module** **1.3.6.1.4.1.12559.11.10.1.3.1.3.3** entry/supply[templateId/@root='1.3.6.1.4.1.12559.11.10.1.3.1.3.3']/participant[@typeCode='PRF"]/participantRole[@classCode="CRED"]/scopingEntity[@classCode="ORG"]/desc	NA / O / NA [0..1]	ST	
R3.2.2	**Dispenser Credentialing Organization's (College)**		**Dispensed Medicine Entry Content Module** **1.3.6.1.4.1.12559.11.10.1.3.1.3.3** entry/supply[templateId/@root= '1.3.6.1.4.	NA / O / NA [0..1]	II	

Require-ment no.	Data element CDA / IHE PCC (WP3.1/WP3.2 label)	PCC Section Template CDA XPath expression	PCC Entry content modules CDA XPath expression	Optionality/ Cardinality (eP/eD /PS)	HL7 V3 Data Type	Required Vocabulary: Value Set Name and Value Set OID)
	Identifier		1.12559.11.10.1.3.1.3.3']/ participant[@typeCode="PRF"]/participant Role[@classCode="CRED"]/scopingEntity [@classCode="ORG"]/id			
R3.2.3	**Dispensed Medicine Id** **(Dispensed Medicine Id)**	**Dispensation Section** **1.3.6.1.4.1.12559.11.10.1.3.1.2.2**	**Dispensed Medicine Entry Content Module** **1.3.6.1.4.1.12559.11.10.1.3.1.3.3** entry/supply[templateId/@root='1.3.6.1.4.1 .12559.11.10.1.3.1.3.3']/product/medication /administerableMedicine/id	NA / R / NA [1..*]	II	
R4	**Medication description**					
R4.1	**Country A Cross-border/regional/n ational medicinal product code** **(National medicinal product code)**	**Prescription Section** **1.3.6.1.4.1.12559.11.10.1.3.1.2.1**	**Prescription Item Entry Content Module** **1.3.6.1.4.1.12559.11.10.1.3.1.3.2** entry/substanceAdministration[templateId/[@root='1.3.6.1.4.1.12559.11.10.1.3.1.3.2']/ consumable/medication/admninisterableMe dicine/code	O / NA / NA	TXT	
R4.2	**Brand name of the medicinal product prescribed in country A** **(Brand Name)**	**Prescription Section** **1.3.6.1.4.1.12559.11.10.1.3.1.2.1**	**Prescription Item Entry Content Module** **1.3.6.1.4.1.12559.11.10.1.3.1.3.2** entry/substanceAdministration[templateId/[@root='1.3.6.1.4.1.12559.11.10.1.3.1.3.2']/ consumable/medication/admninisterableMe dicine/name	R / NA / NA	TXT	
R4.3	**Active ingredient (Active Ingredient)**	**Medication Summary Section** **1.3.6.1.4.1.12559.11.10.1.3.1.2.3**	**Medication Item Entry Content Module** **1.3.6.1.4.1.12559.11.10.1.3.1.3.4** entry/substanceAdministration[templateId/[@root= '1.3.6.1.4.1.12559.11.10.1.3.1.3.4']/	RNFA [1..1]	CD	WHO ATC 2.16.840.1.113883.6.73

Require-ment no.	Data element CDA / IHE PCC (WP3.1/WP3.2 label)	PCC Section Template CDA XPath expression	PCC Entry content modules CDA XPath expression	Optionality/ Cardinality (eP/eD /PS)	HL7 V3 Data Type	Required Vocabulary: Value Set Name and Value Set OID)
			consumable/medication/admninisterableMedicine/ingredient/[@classCode='ACTI']/ingredient/code			
		Prescription Section **1.3.6.1.4.1.12559.11.10.1.3.1.2.1**	**Prescription Item Entry Content Module** **1.3.6.1.4.1.12559.11.10.1.3.1.3.2** entry/substanceAdministration[templateId/[@root= '1.3.6.1.4.1.12559.11.10.1.3.1.3.2']/consumable/medication/admninisterableMedicine/ingredient/[@classCode='ACTI']/ingredient/code	R [1..1]		
		Dispensation Section **1.3.6.1.4.1.12559.11.10.1.3.1.2.2**	**Dispensed Medicine Entry Content Module** **1.3.6.1.4.1.12559.11.10.1.3.1.3.3** entry/supply[templateId/@root= '1.3.6.1.4.1.12559.11.10.1.3.1.3.3']/product/medication/admninisterableMedicine/ingredient/[@classCode='ACTI']/ingredient/code	O [0..1]		
R4.4	**Strength of the medicinal product** **(Strength of the medicinal product)**	**Medication Summary Section** **1.3.6.1.4.1.12559.11.10.1.3.1.2.3**	**Medication Item Entry Content Module** **1.3.6.1.4.1.12559.11.10.1.3.1.3.4** entry/substanceAdministration[templateId/[@root= '1.3.6.1.4.1.12559.11.10.1.3.1.3.4']/consumable/medication/admninisterableMedicine/ingredient/[@classCode='ACTI']/quantity	RNFA [1..1]	PQ, PQ	
		Prescription Section **1.3.6.1.4.1.12559.11.10.1.3.1.2.1**	**Prescription Item Entry Content Module** **1.3.6.1.4.1.12559.11.10.1.3.1.3.2** entry/substanceAdministration[templateId/[@root= '1.3.6.1.4.1.12559.11.10.1.3.1.3.2']/consumable/medication/admninisterableMe	R [1..1]		

Require-ment no.	Data element CDA / IHE PCC (WP3.1/WP3.2 label)	PCC Section Template CDA XPath expression	PCC Entry content modules CDA XPath expression	Optionality/ Cardinality (eP/eD /PS)	HL7 V3 Data Type	Required Vocabulary: Value Set Name and Value Set OID)
			dicine/ingredient/[@classCode='ACTI']/quantity			
		Dispensation Section 1.3.6.1.4.1.12559.11.10.1.3.1.2.2	**Dispensed Medicine Entry Content Module 1.3.6.1.4.1.12559.11.10.1.3.1.3.3** entry/supply[templateId/@root= '1.3.6.1.4.1.12559.11.10.1.3.1.3.3']/product/medication/admninisterableMedicine/ingredient/[@classCode='ACTI']/quantity	R [1..1]		
R4.5	**Medicinal product package (Medicinal product package)**	**Medication Summary Section 1.3.6.1.4.1.12559.11.10.1.3.1.2.3**	**Medication Item Entry Content Module 1.3.6.1.4.1.12559.11.10.1.3.1.3.4** entry/substanceAdministration[templateId/[@root= '1.3.6.1.4.1.12559.11.10.1.3.1.3.4']/consumable//medication/admninisterableMedicine/ingredient/[@classCode='ACTI']/asContent/containerPackageMedicine/formCode	O [0..1]	CD	epSOS:Package 1.3.6.1.4.1.12559.11.10.1.3.1.42.3
		Prescription Section 1.3.6.1.4.1.12559.11.10.1.3.1.2.1	**Prescription Item Entry Content Module 1.3.6.1.4.1.12559.11.10.1.3.1.3.2** entry/substanceAdministration[templateId/[@root= '1.3.6.1.4.1.12559.11.10.1.3.1.3.2']/consumable/medication/admninisterableMedicine/ingredient/[@classCode='ACTI']/asContent/containerPackageMedicine/formCode	R [1..1]		
		Dispensation Section 1.3.6.1.4.1.12559.11.10.1.3.1.2.2	**Dispensed Medicine Entry Content Module 1.3.6.1.4.1.12559.11.10.1.3.1.3.3** entry/supply[templateId/@root= '1.3.6.1.4.1.12559.11.10.1.3.1.3.3']/product/medication/admninisterableMedicine/ingredient/[@cl	R [1..1]		

Require-ment no.	Data element CDA / IHE PCC (WP3.1/WP3.2 label)	PCC Section Template CDA XPath expression	PCC Entry content modules CDA XPath expression	Optionality/ Cardinality (eP/eD /PS)	HL7 V3 Data Type	Required Vocabulary: Value Set Name and Value Set OID)
			assCode='ACTI']/asContent/containerPackageMedicine/formCode			
R4.6	**Pharmaceutical dose form** **(Pharmaceutical dose form)**	**Medication Summary Section** **1.3.6.1.4.1.12559.11.10.1.3.1.2.3**	**Medication Item Entry Content Module** **1.3.6.1.4.1.12559.11.10.1.3.1.3.4** entry/substanceAdministration[templateId/[@root= '1.3.6.1.4.1.12559.11.10.1.3.1.3.4']/consumable/medication/admnisterableMedicine/formCode	O [0..1]	CD	epSOS:DoseForm 1.3.6.1.4.1.12559.11.10.1.3.1.42.2
		Prescription Section **1.3.6.1.4.1.12559.11.10.1.3.1.2.1**	**Prescription Item Entry Content Module** **1.3.6.1.4.1.12559.11.10.1.3.1.3.2** entry/substanceAdministration[templateId/[@root= '1.3.6.1.4.1.12559.11.10.1.3.1.3.2']/consumable/medication/admnisterableMedicine/formCode	R [1..1]		
		Dispensation Section **1.3.6.1.4.1.12559.11.10.1.3.1.2.2**	**Dispensed Medicine Entry Content Module** **1.3.6.1.4.1.12559.11.10.1.3.1.3.3** entry/supply[templateId/@root= '1.3.6.1.4.1.12559.11.10.1.3.1.3.3']/product/medication/admnisterableMedicine/formCode	R [1..1]	CD	epSOS:DoseForm 1.3.6.1.4.1.12559.11.10.1.3.1.42.2
R4.7	**Route of Administration** **(Route of Administration)**	**Medication Summary Section** **1.3.6.1.4.1.12559.11.10.1.3.1.2.3**	**Medication Item Entry Content Module** **1.3.6.1.4.1.12559.11.10.1.3.1.3.4** entry/substanceAdministration[templateId/[@root='1.3.6.1.4.1.12559.11.10.1.3.1.3.4']/routeCode	O	CD	epSOSRoutesofAdministration 1.3.6.1.4.1.12559.11.10.1.3.1.42.12
		Prescription Section **1.3.6.1.4.1.12559.11.10.1.3.1.2.1**	**Prescription Item Entry Content Module** **1.3.6.1.4.1.12559.11.10.1.3.1.3.2**	O		

Require-ment no.	Data element CDA / IHE PCC (WP3.1/WP3.2 label)	PCC Section Template CDA XPath expression	PCC Entry content modules CDA XPath expression	Optionality/ Cardinality (eP/eD /PS)	HL7 V3 Data Type	Required Vocabulary: Value Set Name and Value Set OID)
			entry/substanceAdministration[templateId/ [@root='1.3.6.1.4.1.12559.11.10.1.3.1.3.2']/routeCode			
		Dispensation Section 1.3.6.1.4.1.12559.11.10.1.3.1.2.2	**Dispensed Medicine Entry Content Module 1.3.6.1.4.1.12559.11.10.1.3.1.3.3** entry/supply[templateId/@root= '1.3.6.1.4. 1.12559.11.10.1.3.1.3.3']/entryRelationship [@typeCode='REFR']/substanceAdministra tion/routeCode	O		
R4.8	**Number of packages (Number of Packages)**	**Prescription Section 1.3.6.1.4.1.12559.11.10.1.3.1.2.1**	**Prescription Item Entry Content Module 1.3.6.1.4.1.12559.11.10.1.3.1.3.2** entry/substanceAdministration[templateId/ [@root='1.3.6.1.4.1.12559.11.10.1.3.1.3.2']/ /consumable/medication/admninisterable Medicine/asContent/quantity/numerator	R	PQ	
		Dispensation Section 1.3.6.1.4.1.12559.11.10.1.3.1.2.2	**Dispensed Medicine Entry Content Module 1.3.6.1.4.1.12559.11.10.1.3.1.3.3** entry/supply[templateId/@root= '1.3.6.1.4. 1.12559.11.10.1.3.1.3.3']/quantity	R		
R4.9	**Number of units per intake[22]**	**Medication Summary Section 1.3.6.1.4.1.12559.11.10.1.3.1.2.3**	**Medication Item Entry Content Module**	RNFA	INT	

[22] Posology has been defined from the functional point of view as containing these three components: number of units per intake, frequency of intakes and duration of treatment:(example: 1 unit/intake every 24 hours for a duration of 14 days

Require-ment no.	Data element CDA / IHE PCC (WP3.1/WP3.2 label)	PCC Section Template CDA XPath expression	PCC Entry content modules CDA XPath expression	Optionality/ Cardinality (eP/eD /PS)	HL7 V3 Data Type	Required Vocabulary: Value Set Name and Value Set OID)
	(Number of units per intake)		**1.3.6.1.4.1.12559.11.10.1.3.1.3.4** entry/substanceAdministration[templateId/ [@root='1.3.6.1.4.1.12559.11.10.1.3.1.3.4']/doseQuantity/@value			
		Prescription Section 1.3.6.1.4.1.12559.11.10.1.3.1.2.1	**Prescription Item Entry Content Module 1.3.6.1.4.1.12559.11.10.1.3.1.3.2** entry/substanceAdministration[templateId/ [@root='1.3.6.1.4.1.12559.11.10.1.3.1.3.2']/doseQuantity/@value	RNFA	INT	
R4.10	**Frequency of intakes**[21] (Frequency of intakes)	**Medication Summary Section 1.3.6.1.4.1.12559.11.10.1.3.1.2.3**	**Medication Item Entry Content Module 1.3.6.1.4.1.12559.11.10.1.3.1.3.4** entry/substanceAdministration[templateId/ [@root='1.3.6.1.4.1.12559.11.10.1.3.1.3.4'] /effectiveTime[2]	RNFA	TS IVL_TS PIVL_TS EIVL_TS	If EIVL_TS mode is used, HL7 TimingEvent vocabulary (2.16.840.1.113883.5.139) SHALL be used.
		Prescription Section 1.3.6.1.4.1.12559.11.10.1.3.1.2.1	**Prescription Item Entry Content Module 1.3.6.1.4.1.12559.11.10.1.3.1.3.2** entry/substanceAdministration[templateId/ [@root='1.3.6.1.4.1.12559.11.10.1.3.1.3.2'] /effectiveTime[2]	RNFA	TS IVL_TS PIVL_TS EIVL_TS	If EIVL_TS mode is used, HL7 TimingEvent vocabulary (2.16.840.1.113883.5.139) SHALL be used.

Require-ment no.	Data element CDA / IHE PCC (WP3.1/WP3.2 label)	PCC Section Template CDA XPath expression	PCC Entry content modules CDA XPath expression	Optionality/ Cardinality (eP/eD /PS)	HL7 V3 Data Type	Required Vocabulary: Value Set Name and Value Set OID)
R4.11	**Duration of treatment**[23] **(Duration of treament)**	**Medication Summary Section 1.3.6.1.4.1.12559.11.10.1.3.1.2.3**	**Medication Item Entry Content Module 1.3.6.1.4.1.12559.11.10.1.3.1.3.4** entry/substanceAdministration[templateId/ @root='1.3.6.1.4.1.12559.11.10.1.3.1.3.4'] /effectiveTime[1][@ xsi:type='IVL_TS']/low/@value[24] entry/substanceAdministration[templateId/ @root='1.3.6.1.4.1.12559.11.10.1.3.1.3.4'] /effectiveTime[1][@ xsi:type='IVL_TS']/high/@value[25]	RNFA	IVL_TS	
		Prescription Section 1.3.6.1.4.1.12559.11.10.1.3.1.2.1	**Prescription Item Entry Content Module 1.3.6.1.4.1.12559.11.10.1.3.1.3.2** entry/substanceAdministration[templateId/[@root='1.3.6.1.4.1.12559.11.10.1.3.1.3.4']/ effectiveTime[1][@	RNFA	IVL_TS	

[23] The width of an interval may have to be calculated as the difference between the high and the low values for ePrescription in order to express posology. This does mean the validity of the prescription, this is a time indication about the onset and the end of the treatment. Variations are allowed according to the Member States.

Require-ment no.	Data element CDA / IHE PCC (WP3.1/WP3.2 label)	PCC Section Template CDA XPath expression	PCC Entry content modules CDA XPath expression	Optionality/ Cardinality (eP/eD /PS)	HL7 V3 Data Type	Required Vocabulary: Value Set Name and Value Set OID)
			xsi:type='IVL_TS']/low/@value[26] entry/substanceAdministration[templateId/[@root='1.3.6.1.4.1.12559.11.10.1.3.1.3.4']/effectiveTime[1][@ xsi:type='IVL_TS']/high/@value[27]			
R4.12	**Date of onset of treatment** **(Date of onset of treatment)**	**Medication Summary Section** **1.3.6.1.4.1.12559.11.10.1.3.1.2.3**	**Medication Item Entry Content Module** **1.3.6.1.4.1.12559.11.10.1.3.1.3.4** entry/substanceAdministration[templateId/[@root='1.3.6.1.4.1.12559.11.10.1.3.1.3.4']/effectiveTime[1][@ xsi:type='IVL_TS']/low	RNFA	TS	
		Prescription Section **1.3.6.1.4.1.12559.11.10.1.3.1.2.1**	**Prescription Item Entry Content Module** **1.3.6.1.4.1.12559.11.10.1.3.1.3.2** entry/substanceAdministration[templateId/	O	TS	

Require-ment no.	Data element CDA / IHE PCC (WP3.1/WP3.2 label)	PCC Section Template CDA XPath expression	PCC Entry content modules CDA XPath expression	Optionality/ Cardinality (eP/eD /PS)	HL7 V3 Data Type	Required Vocabulary: Value Set Name and Value Set OID)
			[@root='1.3.6.1.4.1.12559.11.10.1.3.1.3.2']/effectiveTime[1][@ xsi:type='IVL_TS']/low			
R4.13	**Date of end of treatment** **(Date of end of treatment)**	**Medication Summary Section** **1.3.6.1.4.1.12559.11.10.1.3.1.2.3**	**Medication Item Entry Content Module** **1.3.6.1.4.1.12559.11.10.1.3.1.3.4** entry/substanceAdministration[templateId/ [@root='1.3.6.1.4.1.12559.11.10.1.3.1.3.4']/effectiveTime[1][@ xsi:type='IVL_TS']/high	RNFA	TS	
		Prescription Section **1.3.6.1.4.1.12559.11.10.1.3.1.2.1**	**Prescription Item Entry Content Module** **1.3.6.1.4.1.12559.11.10.1.3.1.3.2** entry/substanceAdministration[templateId/ [@root='1.3.6.1.4.1.12559.11.10.1.3.1.3.2']/effectiveTime[1][@ xsi:type='IVL_TS']/high	O	TS	
R4.14	**Instructions to patient** **(Instructions to patient)**	**Prescription Section** **1.3.6.1.4.1.12559.11.10.1.3.1.2.1**	**Prescription Item Entry Content Module** **1.3.6.1.4.1.12559.11.10.1.3.1.3.2** entry/substanceAdministration[templateId/[@root='1.3.6.1.4.1.12559.11.10.1.3.1.3.2']/ entryRelationship[@typeCode='SUBJ']/act[templateId/@root='1.3.6.1.4.1.19376.1.5 .3.1.4.3']/text	O	TXT	
R4.15	**Advise to the dispenser** **(Advise to the dispenser)**	**Prescription Section** **1.3.6.1.4.1.12559.11.10.1.3.1.2.1**	**Prescription Item Entry Content Module** **1.3.6.1.4.1.12559.11.10.1.3.1.3.2** /entry/substanceAdministration[templateId/ [@root='1.3.6.1.4.1.12559.11.10.1.3.1.3.2'] / entryRelationship[@typeCode='SUBJ']/act[templateId/@root='1.3.6.1.4.1.19376.1.5	O	TXT	

Require-ment no.	Data element CDA / IHE PCC (WP3.1/WP3.2 label)	PCC Section Template CDA XPath expression	PCC Entry content modules CDA XPath expression	Optionality/ Cardinality (eP/eD /PS)	HL7 V3 Data Type	Required Vocabulary: Value Set Name and Value Set OID)
			.3.1.4.3.1']/text			
R4.16	**Substitution** **(Substitution)**	**Prescription Section** **1.3.6.1.4.1.12559.11.10.1.3.1.2.1**	**Prescription Item Entry Content Module** **1.3.6.1.4.1.12559.11.10.1.3.1.3.2** entry/substanceAdministration[templateId/[@root='1.3.6.1.4.1.12559.11.10.1.3.1.3.2']/entryRelationship[@typeCode='SUBJ'][@inversionInd='true']/observation[@classCode ='OBS']/value	O	BL	
		Dispensation Section **1.3.6.1.4.1.12559.11.10.1.3.1.2.2**	**Dispensed Medicine Entry Content Module** **1.3.6.1.4.1.12559.11.10.1.3.1.3.3** entry/supply[templateId/[@root='1.3.6.1.4.1.12559.11.10.1.3.1.3.3']/entryRelationship[@typeCode='SUBJ'][@inversionInd='true']/observation[@classCode ='OBS']/value	O	BL	
R5	**Allergy – the following data elements apply only the the Patient Summary.** The field "alerts" was originally defined to include all the important and objective medical information that should be highlighted (such as allergies, thrombosis risk, immune deficit …etc). When defining the content only allergies and intolerance to drugs appear to be the common understanding and the easiest to be transferred. A lot of surveys are being made in different countries (not only in Europe) to make a more evidence-based definition of what should represented and should not byt the concept "alerts", hence not enough information could be provided to take a further decision. As epSOS's intention is not to duplicate information, this shall not be repeated. Alerts are diffucult to represent since they are contextual. Alerts may be represented as severe or life-threatening allergies or other adverse reactions. Another area are certain selected procedures and implanted devivces. The section Allergies and Other Adverse Reactions contains the medical alerts as well, based on the serverity, and their representation becomes a Country B choice.					
R5.1	**Allergy Display Name** **(Allergy Description)**	**Allergies and Other Adverse Reactions Section** **1.3.6.1.4.1.19376.1.5.3.1.3.13**	**Allergy & Intolerance Concern Entry** **1.3.6.1.4.1.19376.1.5.3.1.4.5.3** entry/act[templateId/@root= '2.16.840.1.11	RNFA	CD	epSOSReactionAllergy 1.3.6.1.4.1.12559.11.10.1.3.1.42.11

Require-ment no.	Data element CDA / IHE PCC (WP3.1/WP3.2 label)	PCC Section Template CDA XPath expression	PCC Entry content modules CDA XPath expression	Optionality/ Cardinality (eP/eD /PS)	HL7 V3 Data Type	Required Vocabulary: Value Set Name and Value Set OID)
			3883.10.20.27']/entryRelationship[@typeCode='SUBJ']/observation[templateId/@root='2.16.840.1.113883.10.20.1.18']/entryRelationship[@typeCode='MFST']/observation[templateId/@root='2.16.840.1.113883.10.20.1.54']/code@displayName			
R5.2	**Allergy id code** **(Allergy description id code)**	**Allergies and Other Adverse Reactions Section** **1.3.6.1.4.1.19376.1.5.3.1.3.13**	**Allergy & Intolerance Concern Entry** **1.3.6.1.4.1.19376.1.5.3.1.4.5.3** entry/act[templateId/@root= '2.16.840.1.113883.10.20.27']/entryRelationship[@typeCode='SUBJ']/observation[templateId/@root='2.16.840.1.113883.10.20.1.18']/code@code	RNFA	CD	
R5.3	**Allergy Onset Date** **(Allergy Onset Date)**	**Allergies and Other Adverse Reactions Section and Alerts** **1.3.6.1.4.1.19376.1.5.3.1.3.13**	**Allergy & Intolerance Concern Entry** **1.3.6.1.4.1.19376.1.5.3.1.4.5.3** entry/act[templateId/@root= '2.16.840.1.113883.10.20.27']/entryRelationship[@typeCode='SUBJ']/observation[templateId/@root='2.16.840.1.113883.10.20.1.18']/effectiveTime/low@value	O	IVL_TS	
R5.4	**Allergy Agent Description** **(Allergy Agent)**	**Allergies and Other Adverse Reactions Section** **1.3.6.1.4.1.19376.1.5.3.1.3.13**	**Allergy & Intolerance Concern Entry** **1.3.6.1.4.1.19376.1.5.3.1.4.5.3** entry/act[templateId/@root= '2.16.840.1.113883.10.20.27']/entryRelationship[@typeCode='SUBJ']/observation[templateId/@root='2.16.840.1.113883.10.20.1.18']/participant[@typeCode='CSM']/participantRole[@classCode='MANU']/playingEntity[@classCode='MMAT]/code@displayName	RNFA	CD	If the allergenic agent is a medicament: WHO ATC 2.16.840.1.113883.6.73 If not: epSOSAllergenNoDrugs 1.3.6.1.4.1.12559.11.10.1.3.1.42.19

Require-ment no.	Data element CDA / IHE PCC (WP3.1/WP3.2 label)	PCC Section Template CDA XPath expression	PCC Entry content modules CDA XPath expression	Optionality/ Cardinality (eP/eD /PS)	HL7 V3 Data Type	Required Vocabulary: Value Set Name and Value Set OID)
R5.5	**Allergy Agent Code** **(Allergy Agent Code)**	**Allergies and Other Adverse Reactions Section** **1.3.6.1.4.1.19376.1.5.3.1.3.13**	**Allergy & Intolerance Concern Entry** **1.3.6.1.4.1.19376.1.5.3.1.4.5.3** entry/act[templateId/@root= '2.16.840.1.113883.10.20.27']/entryRelationship[@typeCode='SUBJ']/observation[templateId/@root='2.16.840.1.113883.10.20.1.18']/participant[@typeCode='CSM']/participantRole[@classCode='MANU']/playingEntity[@classCode='MMAT]/code@code	RNFA	II	If the allergenic agent is a medicament: WHO ATC 2.16.840.1.113883.6.73 If not: epSOSAllergennoDrugs 1.3.6.1.4.1.12559.11.10.1.3.1.42.19
R7	**History of past illness and disorders** **(History of past illness)** (note *"disorders"* was added by WP3.5 due to medical concerns).	**1.3.6.1.4.1.19376.1.5.3.1.3.8** **History of Past Illness Section**				
R7.1	**Problem**		**Problem Concern Entry**	O	TXT	

Require-ment no.	Data element CDA / IHE PCC (WP3.1/WP3.2 label)	PCC Section Template CDA XPath expression	PCC Entry content modules CDA XPath expression	Optionality/ Cardinality (eP/eD /PS)	HL7 V3 Data Type	Required Vocabulary: Value Set Name and Value Set OID)
	Description **(Problem Description)**		**1.3.6.1.4.1.19376.1.5.3.1.4.5.2** entry/act[templateId/@root='2.16.840.1.113883.10.20.1.27']/entryRelationship[@type='SUBJ']/observation[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.4.5']/text			
R7.2	**Problem Code** **(Problem Id code)**		**Problem Concern Entry** **1.3.6.1.4.1.19376.1.5.3.1.4.5.2** entry/act[templateId/@root='2.16.840.1.113883.10.20.1.27']/entryRelationship[@type='SUBJ']/observation[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.4.5']/value@code	O	CD	
R7.3	**Problem Onset time** **(Problem Onset Date)** Corrected from "*time*" to "*date*"		**Problem Concern Entry** **1.3.6.1.4.1.19376.1.5.3.1.4.5.2** entry/act[templateId/@root='2.16.840.1.113883.10.20.1.27']/ effectiveTime[@xsi:type='IVL_TS']/low	O	IVL_TS	
R7.4	**Problem End Date** **(Problem End Date)**		**Problem Concern Entry** **1.3.6.1.4.1.19376.1.5.3.1.4.5.2** entry/act[templateId/@root='2.16.840.1.113883.10.20.1.27']/ effectiveTime[@xsi:type='IVL_TS']/high	O	IVL_TS	

Require-ment no.	Data element CDA / IHE PCC (WP3.1/WP3.2 label)	PCC Section Template CDA XPath expression	PCC Entry content modules CDA XPath expression	Optionality/ Cardinality (eP/eD /PS)	HL7 V3 Data Type	Required Vocabulary: Value Set Name and Value Set OID)
R7.5	**Resolution Circumstances** **(Resolution Cicumstances)**		**Problem Concern Entry** **1.3.6.1.4.1.19376.1.5.3.1.4.5.2** entry/act[templateId/@root='2.16.840.1.113883.10.20.1.27']/entryRelationship[@type='REFR']/observation[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.4.1.2']/text	O	TXT[28]	
			Problem Concern Entry **1.3.6.1.4.1.19376.1.5.3.1.4.5.2** entry/act[templateId/@root='2.16.840.1.113883.10.20.1.27']/entryRelationship[@type='REFR']/observation[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.4.1.2']/value@code	O	CD	epSOSResolutionOutcome 1.3.6.1.4.1.12559.11.10.1.3.1.42.24
R8	**Vaccinations**	**1.3.6.1.4.1.19376.1.5.3.1.3.23** **Immunizations Section**				
R8.1	**Vaccinations Brand name[29]** **(Vaccinations Brand Name)**		**Immunization Entry** **1.3.6.1.4.1.19376.1.5.3.1.4.12** entry/substanceAdministration[templateId/@root= '2.16.840.1.113883.10.20.1.24']/	O	TXT	

[28] This represents narrative form, which describes the resolution circumstances. At the same level of information, <value> is of type CD, will code the observed resolution circumstances using codes within the epSOSResolutionCircumstances value set. If this needs to be linked to another entry in the body, you could use template such as 1.3.6.1.4.1.19376.1.5.3.1.4.4., it would look like: entry/act[templateId/@root='2.16.840.1.113883.10.20.1.27']/entryRelationship[@type='REFR']/observation[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.4.1.2']/entryRelationship[@type='REFR']/act[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.4.4]/id, where the id is the same id as the procedure which was used to resolve the problem.

[29] The vaccination brand name SHALL appear in a <translation> element while the coded product name SHALL appear in the code attribute of the <code> element (R8.2)

Require-ment no.	Data element CDA / IHE PCC (WP3.1/WP3.2 label)	PCC Section Template CDA XPath expression	PCC Entry content modules CDA XPath expression	Optionality/ Cardinality (eP/eD /PS)	HL7 V3 Data Type	Required Vocabulary: Value Set Name and Value Set OID)
			consumable/ manufacturedProduct/ manufacturedMaterial/code/translation@displayName			
R8.2	**Vaccination Description (Vaccinations)**		**Immunization Entry** **1.3.6.1.4.1.19376.1.5.3.1.4.12** entry/substanceAdministration[templateId/ @root= '2.16.840.1.113883.10.20.1.24']/ consumable/ manufacturedProduct/ manufacturedMaterial/code	O	CD	epSOSVaccine 1.3.6.1.4.1.12559.11.10.1.3.1.42.18
R8.2	**Vaccinations Code** **(Vaccination id code)**		**Immunization Entry** **1.3.6.1.4.1.19376.1.5.3.1.4.12** entry/substanceAdministration[templateId/ @root= '2.16.840.1.113883.10.20.1.24']/ consumable/ manufacturedProduct/ manufacturedMaterial/code@code	O	II	
R8.3	**Vaccinations Date** **(Vaccinations Date)**		**Immunization Entry** **1.3.6.1.4.1.19376.1.5.3.1.4.12** entry/substanceAdministration[templateId/ @root= '2.16.840.1.113883.10.20.1.24']/effectiveTime	O	TS	
R9	**Surgical Procedures prior past six months**	**1.3.6.1.4.1.19376.1.5.3.1.3.12** **Coded List of Surgeries Section**				
R9.1	**Procedure description** **(Procedure Description)**		**Procedure Entry** **1.3.6.1.4.1.19376.1.5.3.1.4.19** entry/procedure[templateId/@root= '1.3.6.1.4.1.19376.1.5.3.1.4.19']/code/@displayName	O	TXT	

Require-ment no.	Data element CDA / IHE PCC (WP3.1/WP3.2 label)	PCC Section Template CDA XPath expression	PCC Entry content modules CDA XPath expression	Optionality/ Cardinality (eP/eD /PS)	HL7 V3 Data Type	Required Vocabulary: Value Set Name and Value Set OID)
R9.2	**Procedure Code** **(Procedure Id Code)**		**Procedure Entry** **1.3.6.1.4.1.19376.1.5.3.1.4.19** entry/procedure[templateId/@root= '1.3.6.1.4.1.19376.1.5.3.1.4.19']/code/@code	O	CD	epSOSProcedures 1.3.6.1.4.1.12559.11.10.1.3.1.42.10
R9.3	**Procedure date** **(Procedure Date)**		**Procedure Entry** **1.3.6.1.4.1.19376.1.5.3.1.4.19** entry/procedure[templateId/@root= '1.3.6.1.4.1.19376.1.5.3.1.4.29']/effectiveTime	O	IVL_TS	
R10	**Major Surgical Procedures past 6 months**[30]	**1.3.6.1.4.1.19376.1.5.3.1.3.12** **Coded List of Surgeries Section**				
R10.1	**Procedure description** **(Procedure Description)**		**Procedure Entry** **1.3.6.1.4.1.19376.1.5.3.1.4.19** entry/procedure[templateId/@root= '1.3.6.1.4.1.19376.1.5.3.1.4.19']/code/@displayName	RNFA	CD	
R10.2	**Procedure Code** **(Procedure Id Code)**		**Procedure Entry** **1.3.6.1.4.1.19376.1.5.3.1.4.19** entry/procedure[templateId/@root= '1.3.6.1.4.1.19376.1.5.3.1.4.19']/code/@code	RNFA	II	epSOSProcedures 1.3.6.1.4.1.12559.11.10.1.3.1.42.10

[30] As there is subjectivity in the term 'relevant', the date of the procedure will be used as to delineate. As the date can be seen from the procedure, the two have the same expression. It is up to the implementers of the system to display it in a different way.

Require-ment no.	Data element CDA / IHE PCC (WP3.1/WP3.2 label)	PCC Section Template CDA XPath expression	PCC Entry content modules CDA XPath expression	Optionality/ Cardinality (eP/eD /PS)	HL7 V3 Data Type	Required Vocabulary: Value Set Name and Value Set OID)
R10.3	**Procedure date** **(Procedure Date)**		**Procedure Entry** **1.3.6.1.4.1.19376.1.5.3.1.4.19** entry/procedure[templateId/@root= '1.3.6.1.4.1.19376.1.5.3.1.4.29']/effectiveTime	RNFA	IVL_TS	
R11	**List of Current Problems/Diagnosis**					
R11.1	**Problem/diagnosis description** **(Problem/diagnosis description)**	**1.3.6.1.4.1.19376.1.5.3.1.3.4** **History of Present Illness Section** Narrative section section[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.3.4']/text		RNFA	TXT	
		1.3.6.1.4.1.19376.1.5.3.1.3.6 **Active Problems Section**	**1.3.6.1.4.1.19376.1.5.3.1.4.5.2** **Problem Concern Entry** entry/act[templateId/@root='2.16.840.1.113883.10.20.1.27']/ entryRelationship[@type='SUBJ']/ observation[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.4.5']/value/@displayName		TXT	
R11.2	**Problem Code** **(Problem Id code)**	**1.3.6.1.4.1.19376.1.5.3.1.3.6** **Active Problems Section**	**1.3.6.1.4.1.19376.1.5.3.1.4.5.2** **Problem Concern Entry** entry/act[templateId/@root='2.16.840.1.113883.10.20.1.27']/ entryRelationship[@type='SUBJ']/ observation[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.4.5']/value/@code	RNFA	CD	ICD10 2.16.840.1.113883.6.3
		1.3.6.1.4.1.19376.1.5.3.1.3.4 **History of Present Illness Section**				

Require-ment no.	Data element CDA / IHE PCC (WP3.1/WP3.2 label)	PCC Section Template CDA XPath expression	PCC Entry content modules CDA XPath expression	Optionality/ Cardinality (eP/eD /PS)	HL7 V3 Data Type	Required Vocabulary: Value Set Name and Value Set OID)
R11.3	**Problem onset time** **(Problem Onset Time)**	**1.3.6.1.4.1.19376.1.5.3.1.3.6** **Active Problems Section**	**1.3.6.1.4.1.19376.1.5.3.1.4.5.2** **Problem Concern Entry** entry/act[templateId/@root='2.16.840.1.113883.10.20.1.27']/effectiveTime/low	RNFA	IVL_TS	
R12	**Medical Devices and implants**	**1.3.6.1.4.1.12559.11.10.1.3.1.2.4** **Medical Devices Coded Section**				
R12.1	**Device and Implant Description** **(Device and Implant Description)**	**Medical Devices Coded Section** **1.3.6.1.4.1.12559.11.10.1.3.1.2.4**	**Medical Device Entry Content Module** **1.3.6.1.4.1.12559.11.10.1.3.1.3.5** entry/supply[templateId/@root='1.3.6.1.4.1.12559.11.10.1.3.1.3.5']/participant[@typeCode='DEV']/participantRole/playingDevice/code/@displayName	RNFA	TXT	
R12.2	**Device Code** **(Device Id Code)**	**Medical Devices Coded Section** **1.3.6.1.4.1.12559.11.10.1.3.1.2.4**	**Medical Device Entry Content Module** **1.3.6.1.4.1.12559.11.10.1.3.1.3.5** entry/supply[templateId/@root='1.3.6.1.4.1.12559.11.10.1.3.1.3.5']/participant[@typeCode='DEV']/participantRole/playingDevice/code/@code	RNFA	CE	epSOSMedicalDevices 1.3.6.1.4.1.12559.11.10.1.3.1.42.8
R12.3	**Device Implant Date**	**Medical Devices Coded Section** **1.3.6.1.4.1.12559.11.10.1.3.1.2.4**	**Medical Device Entry Content Module**	RNFA	TS	

Require-ment no.	Data element CDA / IHE PCC (WP3.1/WP3.2 label)	PCC Section Template CDA XPath expression	PCC Entry content modules CDA XPath expression	Optionality/ Cardinality (eP/eD /PS)	HL7 V3 Data Type	Required Vocabulary: Value Set Name and Value Set OID)
	(Device Implant Date)		**1.3.6.1.4.1.12559.11.10.1.3.1.3.5** entry/supply[templateId/@root='1.3.6.1.4.1.12559.11.10.1.3.1.3.5']/effectiveTime/@value			
R13	**Treatment Recommendations**	**1.3.6.1.4.1.19376.1.5.3.1.1.9.50Health Maintenance Care Plan Section** **This is a narrative section as the codes that exists with regards to diet, exercise, and other therapeutic recommendations that do not include drugs.**				
R14	**Autonomy/Invalidity**	**1.3.6.1.4.1.19376.1.5.3.1.3.17** **Functional Status Section**				
R14.1	**Invalidity Description** **(Invalidity Description)**	Narrative section section[templateId[@root='1.3.6.1.4.1.19376.1.5.3.1.3.17']/text		O	TXT	
R14.2	**Invalidity Id code** **(Invalidity Id**	section[templateId/[@root='1.3.6.1.4.1.19376.1.5.3.1.3.17']/text		O	TXT	

Require-ment no.	Data element CDA / IHE PCC (WP3.1/WP3.2 label)	PCC Section Template CDA XPath expression	PCC Entry content modules CDA XPath expression	Optionality/ Cardinality (eP/eD /PS)	HL7 V3 Data Type	Required Vocabulary: Value Set Name and Value Set OID)
	code)					
R15	**Social History**	**1.3.6.1.4.1.19376.1.5.3.1.3.16.1** **Coded Social History Section**				
R15.1	**Social History Observations related to: smoke, alcohol and diet.** **(Social History Observations)**	**1.3.6.1.4.1.19376.1.5.3.1.3.16.1** **Coded Social History Section**	**1.3.6.1.4.1.19376.1.5.3.1.4.13.4** **Smoke** Social History Observation entry/observation[templateId/@root= '1.3.6.1.4.1.19376.1.5.3.1.4.13.4'][code@code='229819007]/value/@code	O	PQ	entry/observation[templateId/@root= '1.3.6.1.4.1.19376.1.5.3.1.4.13.4']/code@code value is using epSOSSocialHistory value set 1.3.6.1.4.1.12559.11.10.1.3.1.42.14
			1.3.6.1.4.1.19376.1.5.3.1.4.13.4 **Alcohol** Social History Observation entry/observation[templateId/@root= '1.3.6.1.4.1.19376.1.5.3.1.4.13.4'][code@code='160573003]/value/@code	O	PQ	entry/observation[templateId/@root= '1.3.6.1.4.1.19376.1.5.3.1.4.13.4']/code@code value is using epSOSSocialHistory value set 1.3.6.1.4.1.12559.11.10.1.3.1.42.14
			1.3.6.1.4.1.19376.1.5.3.1.4.13.4 **Diet** Social History Observation entry/observation[templateId/@root= '1.3.6.1.4.1.19376.1.5.3.1.4.13.4'][code@code='364393001]/value/@code	O	CD	entry/observation[templateId/@root= '1.3.6.1.4.1.19376.1.5.3.1.4.13.4']/code@code value is using epSOSSocialHistory value set 1.3.6.1.4.1.12559.11.10.1.3.1.42.14

Require-ment no.	Data element CDA / IHE PCC (WP3.1/WP3.2 label)	PCC Section Template CDA XPath expression	PCC Entry content modules CDA XPath expression	Optionality/ Cardinality (eP/eD /PS)	HL7 V3 Data Type	Required Vocabulary: Value Set Name and Value Set OID)
R15.2	**Social History Reference date range** **(Social History Reference date range)**	**1.3.6.1.4.1.19376.1.5.3.1.3.16.1** **Coded Social History Section**	**1.3.6.1.4.1.19376.1.5.3.1.4.13.4** **Smoke** Social History Observation entry/observation[templateId/@root= '1.3.6.1.4.1.19376.1.5.3.1.4.13.4'][code@code='229819007']/effectiveTime[@type='IVL_TS']/low/value entry/observation[templateId/@root= '1.3.6.1.4.1.19376.1.5.3.1.4.13.4'][code@code='229819007']/effectiveTime[@type='IVL_TS']/high/value	O	IVL_TS	entry/observation[templateId/@root= '1.3.6.1.4.1.19376.1.5.3.1.4.13.4']/code@code value is using epSOSSocialHistory value set 1.3.6.1.4.1.12559.11.10.1.3.1.42.14
			1.3.6.1.4.1.19376.1.5.3.1.4.13.4 **Alcohol** Social History Observation entry/observation[templateId/@root= '1.3.6.1.4.1.19376.1.5.3.1.4.13.4'][code@code='229819007']/effectiveTime[@type='IVL_TS']/low/value entry/observation[templateId/@root= '1.3.6.1.4.1.19376.1.5.3.1.4.13.4'][code@code='229819007']/effectiveTime[@type='IVL_TS']/high/value	O	IVL_TS	entry/observation[templateId/@root= '1.3.6.1.4.1.19376.1.5.3.1.4.13.4']/code@code value is using epSOSSocialHistory value set 1.3.6.1.4.1.12559.11.10.1.3.1.42.14
			1.3.6.1.4.1.19376.1.5.3.1.4.13.4 **Diet** Social History Observation entry/observation[templateId/@root= '1.3.6.1.4.1.19376.1.5.3.1.4.13.4'][code@code='364393001']/effectiveTime[@type='IVL_TS']/low/value entry/observation[templateId/@root= '1.3.6.1.4.1.19376.1.5.3.1.4.13.4'][code@code='229819007']/effectiveTime[@type='IVL_TS']/high/value	O	IVL_TS	entry/observation[templateId/@root= '1.3.6.1.4.1.19376.1.5.3.1.4.13.4']/code@code value is using epSOSSocialHistory value set 1.3.6.1.4.1.12559.11.10.1.3.1.42.14

Require-ment no.	Data element CDA / IHE PCC (WP3.1/WP3.2 label)	PCC Section Template CDA XPath expression	PCC Entry content modules CDA XPath expression	Optionality/ Cardinality (eP/eD /PS)	HL7 V3 Data Type	Required Vocabulary: Value Set Name and Value Set OID)
R16	**Pregnancy History**	**1.3.6.1.4.1.19376.1.5.3.1.1.5.3.4** **Pregnancy History Section**				
R16.1	**Expected Date of Delivery**		**1.3.6.1.4.1.19376.1.5.3.1.4.13.5** **Pregnancy Observation** entry/observation[templateId/@root= '1.3.6.1.4.1.19376.1.5.3.1.4.13.5'][code@code=' 11778-8']/value	O	TS	
R17	**Physical findings**					
R17.1	**Vital Signs Observations** **(Vital Signs Observations)**	**1.3.6.1.4.1.19376.1.5.3.1.1.5.3.2** **Coded Vital Signs Section**				
R17.1.1	**Blood pressure** **(Blood pressure)**		**1.3.6.1.4.1.19376.1.5.3.1.4.13.1** **Vital Sign Organizer** **Systolic** entry/organizer[templateId/@root= '1.3.6.1.4.1.19376.1.5.3.1.4.13.1']/component/observation[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.4.13.2'][code@code='8480-6']/value **Diastolic** entry/organizer[templateId/@root= '1.3.6.1.4.1.19376.1.5.3.1.4.13.1']/component/observation[templateId/@root='1.3.6.1.4.1	O	PQ	entry/organizer[templateId/@root= '1.3.6.1.4.1.19376.1.5.3.1.4.13.1']/component/observation[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.4.13.2']/code@code SHALL use : epSOSBloodPressure 1.3.6.1.4.1.12559.11.10.1.3.1.42.21 Value unit SHALL use epSOSUnits 1.3.6.1.4.1.12559.11.10.1.3.1.42.16

Require-ment no.	Data element CDA / IHE PCC (WP3.1/WP3.2 label)	PCC Section Template CDA XPath expression	PCC Entry content modules CDA XPath expression	Optionality/ Cardinality (eP/eD /PS)	HL7 V3 Data Type	Required Vocabulary: Value Set Name and Value Set OID)
			.19376.1.5.3.1.4.13.2'][code@code='8462-4']/value			
R17.2	**Date** **(Date when blood pressure was measured)**		**1.3.6.1.4.1.19376.1.5.3.1.4.13.1** **Vital Sign Organizer** entry/organizer[templateId/@root= '1.3.6.1.4.1.19376.1.5.3.1.4.13.1']/effectiveTime	O		
R18	**Diagnostic tests**					
R18.1	**Value of blood group observation** **(Result of blood group)**	**1.3.6.1.4.1.19376.1.5.3.1.3.28** **Coded Results Section**	**1.3.6.1.4.1.19376.1.5.3.1.4.13** **Simple observation Entry** entry/observation[templateId/@root= '1.3.6.1.4.1.19376.1.5.3.1.4.13.6'][code/@code='34530-6 ']/value@code	O	CE	epSOSBloodGroup 1.3.6.1.4.1.12559.11.10.1.3.1.42.20
R18.2	**Date of observation** **(Date when blood group was determined)**		**1.3.6.1.4.1.19376.1.5.3.1.4.13** **Simple observation Entry** entry/observation[templateId/@root= '1.3.6.1.4.1.19376.1.5.3.1.4.13.6'][code/@code=' 34530-6 ']/effectiveTime	O	TS	
R19	**Medication Summary** **(Medication Summary)**	**Medication Summary Section** **1.3.6.1.4.1.12559.11.10.1.3.1.2.3**				
R19.1	**Medication Summary Active ingredient description** **(Active**		**Medication Item Entry Content Module** **1.3.6.1.4.1.12559.11.10.1.3.1.3.4** entry/substanceAdministration[templateId/[@root= '1.3.6.1.4.1.12559.11.10.1.3.1.3.4']/	O		

Require-ment no.	Data element CDA / IHE PCC (WP3.1/WP3.2 label)	PCC Section Template CDA XPath expression	PCC Entry content modules CDA XPath expression	Optionality/ Cardinality (eP/eD /PS)	HL7 V3 Data Type	Required Vocabulary: Value Set Name and Value Set OID)
	ingredient)		consumable/medication/admninisterableMedicine/ingredient/[@classCode='ACTI']/ingredient			
R19.2	**Medication Summary Active ingredient code** **(Active ingredient id code)**		**Medication Item Entry Content Module** **1.3.6.1.4.1.12559.11.10.1.3.1.3.4** entry/substanceAdministration[templateId/[@root= '1.3.6.1.4.1.12559.11.10.1.3.1.3.4']/consumable/medication/admninisterableMedicine/ingredient/[@classCode='ACTI']/ingredient@code	O	CD	WHO ATC 2.16.840.1.113883.6.73
R19.3	**Medication Summary Strenght**		**Medication Item Entry Content Module** **1.3.6.1.4.1.12559.11.10.1.3.1.3.4** entry/substanceAdministration[templateId/[@root= '1.3.6.1.4.1.12559.11.10.1.3.1.3.4']/consumable/medication/admninisterableMedicine/ingredient/[@classCode='ACTI']/quantity	O	PQ ,PQ	
R19.4	**Medication Summary Number of units per intake**		**Medication Item Entry Content Module** **1.3.6.1.4.1.12559.11.10.1.3.1.3.4** entry/substanceAdministration[templateId/[@root= '1.3.6.1.4.1.12559.11.10.1.3.1.3.4']/doseQuantity/@value	O	INT	
R19.5	**Medication Summary Frequency of intake**		**Medication Item Entry Content Module** **1.3.6.1.4.1.12559.11.10.1.3.1.3.4** entry/substanceAdministration[templateId/[@root= '1.3.6.1.4.1.12559.11.10.1.3.1.3.4']/effectiveTime[2]	O	TS IVL_TS PIVL_TS EIVL_TS	If EIVL_TS mode is used, HL7 TimingEvent vocabulary (2.16.840.1.113883.5.139) SHALL be used.

Require-ment no.	Data element CDA / IHE PCC (WP3.1/WP3.2 label)	PCC Section Template CDA XPath expression	PCC Entry content modules CDA XPath expression	Optionality/ Cardinality (eP/eD /PS)	HL7 V3 Data Type	Required Vocabulary: Value Set Name and Value Set OID)
R19.6	**Medication Summary Duration of treatment**		**Medication Item Entry Content Module** **1.3.6.1.4.1.12559.11.10.1.3.1.3.4** entry/substanceAdministration[templateId/ @root='1.3.6.1.4.1.12559.11.10.1.3.1.3.4'] /effectiveTime[1][@ xsi:type='IVL_TS']/low/@value entry/substanceAdministration[templateId/ @root='1.3.6.1.4.1.12559.11.10.1.3.1.3.4']/ effectiveTime[1][@ xsi:type='IVL_TS']/high/@value	O	IVL_TS	
R19.7	**Medication Summary Date of onset of treatment**		**Medication Item Entry Content Module** **1.3.6.1.4.1.12559.11.10.1.3.1.3.4** entry/substanceAdministration[templateId/[@root= '1.3.6.1.4.1.12559.11.10.1.3.1.3.4']/ effectiveTime[1][@ xsi:type='IVL_TS']/low	O	TS	
R19.8	**Medication Summary Pharmaceutical Dose Form**		**Medication Item Entry Content Module** **1.3.6.1.4.1.12559.11.10.1.3.1.3.4** entry/substanceAdministration[templateId/ [@root= '1.3.6.1.4.1.12559.11.10.1.3.1.3.4 ']/consumable/medication/admninisterable Medicine/formCode	O	CD	epSOS:DoseForm 1.3.6.1.4.1.12559.11.10.1.3.1.42.2