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WP6 Software and extensions for CEF eHDSI

D6.4: eHDSI semantic components enhancements for IDMP

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[1] Dissemination level: PU: Public; CO: Confidential, only for members of the consortium (including the Commission Services); EU-RES: Classified Information: RESTREINT UE (Commission Decision 2005/444/EC); EU-CON: Classified Information: CONFIDENTIEL UE (Commission Decision 2005/444/EC); EU-SEC Classified Information: SECRET UE (Commission Decision 2005/444/EC)

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Deliverable abstract

The Deliverable 6.4 (D6.4) aims at pursuing the objective of illustrating the required extensions to the semantic components of the eHDSI architecture so to enable a proper transcoding and translation cross border. The semantic components will focus particularly on the Transformation manager, the Terminology Server Access Manager (TSAM) and the Local Terminology Repository (LTR) and might require formulating architectural specifications that modify the component to MCV/MTC from terminology servers such as the Central Terminology Server, the EMA SPOR database or other Medicinal Product Databases

Key words: ISO IDMP; EMA; eHealth, ePrescription, Patient Summary,UNICOM, CDA Implementation Guide, ValueSets.

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List of abbreviations

Abbreviation	Complete form [1]
ADE	Adverse Drug Event
API	Active Pharmaceutical Ingredients
ATC	Anatomical Therapeutic Chemical Code
CEF	Connecting Europe Facility
CEN	European Committee for Standardization
eD	eDispensation
DSS	Decision Support System
EPF	European Patients' Forum
eHDSI	Health Digital Service Infrastructure
EHR	Electronic Health Record
EMA	European Medicines Agency
eP	ePrescription
epSOS	Smart Open Services for European Patients
EU	European Union
FDA	USA Federal Drug Agency
GDPR	General Data Protection Regulation
GP	General Practitioner
GS1	Global Standards One
HCPO	Healthcare Provider Organisation
HL7	Health Level Seven
HP	Health Professional
ICD-10	International Statistical Classification of Diseases and Related Health Problems, 10th revision
IDMP	Identification of Medicinal Products
IHE	Integrating the Healthcare Enterprise
ISO	International Organization for Standardization
LTF	Legal Task Force
MPD	Medicinal Product Dictionary
MS	Member State
MVC	Master Value Catalogue
NCA	National Competent Authority (for human medicines)
NCP	National Contact Point
NCPeH	National Contact Point eHealth
NIA	National Identification Authority
Ophelia	OPtimising HEalth LIterAcy
OrCD	Original Clinical Document
OTC	Over the Counter

[1] See 9.1 for the explanation of some of these terms

PhP	Pharmaceutical Product
PhPID	Pharmaceutical Product identifier
PS	Patient Summary
SDO	Standards Developing Organisation
SPOR	Substance, Product, Organisation and Referential
SubID	Identification of the (active) substance
TBD	To be done
UNICOM	Up-scaling the global univocal identification of medicines
WP	Work Package
WHO	World Health Organisation

Table 1: List of abbreviations

1 Executive summary

The IDMP standards are a set of guidelines and requirements developed by the International Organization for Standardization (ISO) and the European Medicines Agency (EMA) for the identification and classification of medicinal products.

This set of five standards (Substance, Product, Organization, Clinical trial identification and reference information) aims to ensure the consistent and accurate identification of medicinal products across different countries and regions, and to facilitate the exchange of information about these products between regulatory authorities, manufacturers, and other stakeholders. Eventually, this supports the ePrescription and eDispensation cross border guaranteeing higher standards of safety for patients.

The document fulfills the objective of illustrating the required extensions to the semantic components of the eHDSI architecture so to enable a proper transcoding and translation cross border. The semantic components will focus particularly on the Transformation manager, the Terminology Server Access Manager (TSAM) and the Local Terminology Repository (LTR) and might require formulating architectural specifications that modify the component to MCV/MTC from terminology servers such as the Central Terminology Server, the EMA SPOR database or other Medicinal Product Databases.

2 Introduction

2.1 Background

UNICOM leverages the ISO IDMP set of internationally agreed standards for univocal identification of medicines to support the semantic interoperability in the medicinal products domain.

In particular, the UNICOM consortium gathers stakeholders ranging from all medically relevant fields such as National Competent Authorities for Medical Products, National eHealth Centres, Standard Development Organisations (SDOs), Health-IT vendors, producers of pharmaceutical dictionaries as well as clinicians and patients.

This ecosystem collaborates with participating EU Member States healthcare services (eHealth Digital Services Infrastructure - eHDSI) to facilitate the implementation of the standards and terminologies particularly in the emerging cross-border ePrescription and eDispensation services.

The correct identification of medications is pivotal to ensure patient care, reduce the risk of errors and adverse effects, guarantee an efficient pharmacovigilance and to foster innovation in the provision of international digital health services.

2.2 Introduction to D6.4

The document identifies the enhancements that can be realized in the Identification of Medical Products (IDMP) with particular regard to the eHDSI semantic components.

The work assumes the CEF eHDSI Technical Specifications as starting point and builds on that by mapping the requirements and constraints from the countries participating in the action. This procedure allows to tailor the definition of the ePrescription and Patient Summary solutions ultimately supporting patients in cross border care pathways

Configuring as input for WP6 eHDSI cross border/national eHealth services piloting, the document assess the possibility to maintain backward compatibility with the current solution but also provides a set of Change Proposals (eg. CEF eHDSI Change Proposal)

2.3 Methodological approach

The definition of the Change Proposals results from a joint effort among all stakeholders from WP5 IDMP adoption by eHealth Services, WP6 Software and extensions for CEF eHDSI and WP7 eHDSI cross-border/national eHealth services piloting. Nonetheless, the development of the change proposals results also from the contribution of the eHMSEG Communities with particular regard to the eHMSEG ePrescription Cluster, the Semantic Task Force (STF) and Business Requirements Workgroup.

This collaboration translates in a consequent effective contribution to the:

- Definition of the business requirements in the eHDSI Requirements Workgroup;
- Implementation of the software specifications in the eHDSI Technical working group;
- Extension of the Art Décor Implementation Guide and CDA Display tool in the Semantic Task Force - Architecture;

- Development of the Master Value Set Catalogue (MVC) in the STF Semantic.

2.4 Scope of the document

The scope of the document embraces the identification of the updates in the semantic components which impact on services in eHDSI.

In order to cover the aforementioned topic, the present document is structured as follows:

- Chapter 1, an Executive summary;
- Chapter 2, introducing the task and deliverable in the context if the Unicom project and the CEF eHDSI Specifications;
- Chapter 3, defining and describing in detail the various Semantic components in the eHealth Digital Service Infrastructure;
- Chapter 4, focusing on the description of the Information Flow;
- Chapter 5, concerning the Clinical Document Architecture (CDA) description, including the Art Décor Implementation Guide;
- Chapter 6, describing the Minimum Attribute List for eHealth;
- Chapter 7, introducing the Wave 6 Change Proposals, related to medicinal products and further described in D7.2.
- Chapter 8, providing final remarks
- Chapter 9 – Annex, including eHDSI Concepts and Definitions, and the eHDSI Change Proposal Management procedures

3 Semantic components in the eHealth Digital Service Infrastructure

3.1 Overall architecture of eHealth Digital Service Infrastructure

The overall architecture of the eHealth Digital Service Infrastructure allows the cross-border interchange of clinical documents, translated in the requested language, while keeping the legal-medical value.

From a high-level viewpoint, (see figure X) it is possible to distinguish between Core / Central Services, used for the configuration of the network and the handling of the terminologies, and the network of the National Contact Points for eHealth (NCPeH), which perform the real time exchange of the documents, to provide the eHealth cross-border services.[2]

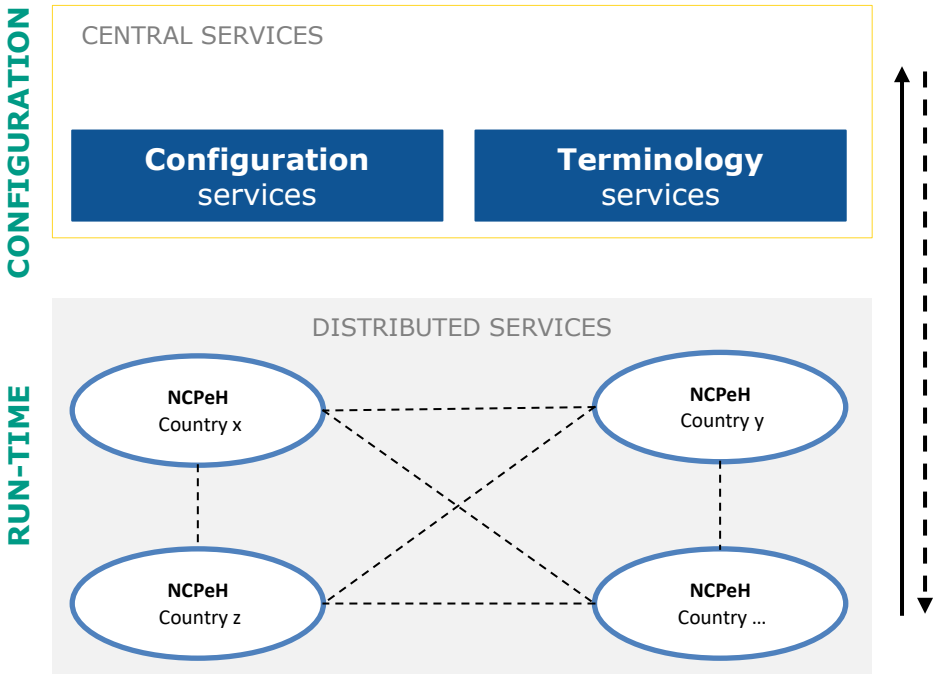

Figure 1: eHDSI System Architecture

The OpenNCP is the reference implementation of the NCPeH, provided by EC DG Santé Solution Provider, is composed by element provided as Core Service (the yellow ones in the following figure), mainly to assure the cross-border communication from a secured technical and trusted semantic standpoints, and Generic Services, to be implemented by the single Member States, to connect the NCPeH to the National Infrastructure.

[2] The following pictures are derived from the EC DG Santé, Solution Provider presentation on eHDSI, 2016-12-07

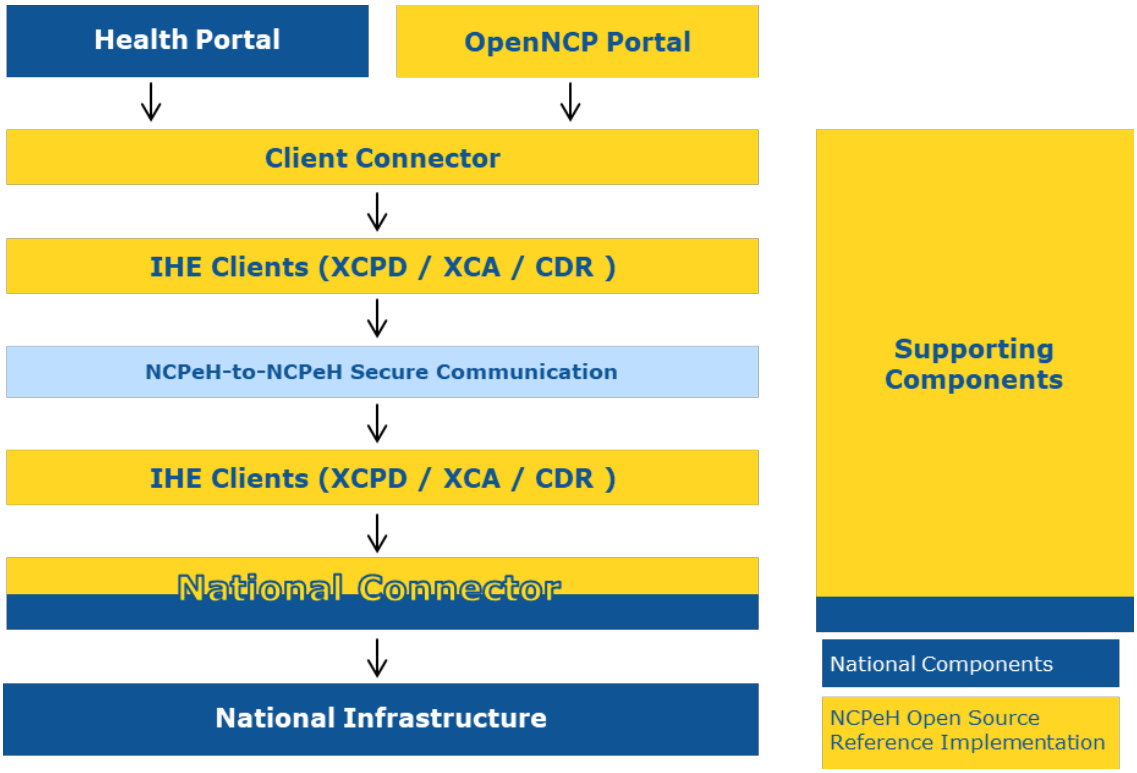

Figure 2: NCPeH – OpenNCP High level architecture

In the following figure, the OpenNCP components are exploded, to distinguish among the IHE Protocol Terminators (XCPD, XCA, XDR), the trust and security components (Security manager, Audit manager, Automatic Data Collector (eADC), and the local semantic components (TM, TSAM, LTR, Terminology sync.) and the Central Configuration Services.

The semantic components will be described in detail in the following sections.

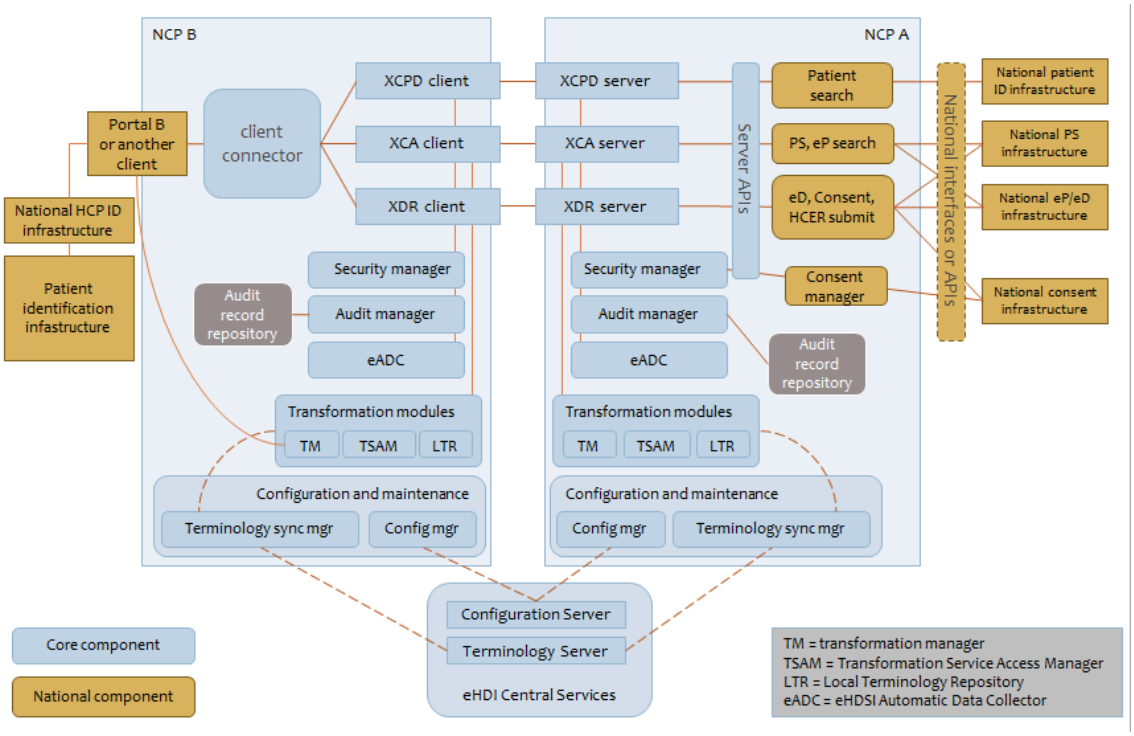

Figure 3: OpenNCP, Central Configuration and components.

3.2 Central Terminology Service: The Master Value Set Catalogue

The Central Terminology Service (CTS) is a service provided by the EC DG Santé Solution Provider, to develop and curate the terminologies used for the clinical documents exchanged through the eHealth Digital Service Infrastructure (eHDSI).

The CTS is connected to the NCPeH, through a secure TESTA NG connection, and has a user interface exposed on internet, to allow authorized users' access.

The CTS contains the Master Value Set Catalogue (MVC) and its translation/transcoding (MTC) of the Member States.

The eHealth DSI Master Value Sets Catalogue is a resource that provides a standardized list of terms, codes and definitions to be used within the CDA to facilitate the exchange of healthcare information between different systems.

The Master Value Sets Catalogue is a key component of the eHealth DSI's efforts to promote the use of standardized terminologies as it provides one or more suitable value sets for each coded element present in the header or in the body of the document.

To ensure the correct attribution of the coded element to the proper value set, the recommendation of the suitable value set is double checked. Given a coded element, a prerequisite for the value set is that it satisfies the functional requirements. Hence, if a coded element already has an existing CDA Content Modules, the code system is checked to ensure that it responds to functional requirements. Then, if these are met, the element is further assessed from a medical and patient safety point of view to evaluate the possibility of attributing multiple code system (partially or entirely). This possibility should apply only to the clinical content as the other information should follow the standards.

The MVC is created and curated by the EC DG Santé Solution Provider, in application of the adopted Change Proposals. The MTC is creating by clinical semantic specialist of every Member States, by translating the MVC or defining mapping between nationally used code systems and the MVC Value Sets. The MTC, before its use in the NCPeH, must be formally verified and approved.

In case of a new version of the MVC, with the addition of new Value Sets. In the Central Terminology Service it will be enough to upload the new code system, if not present yet, and select the terms of the new Value Sets.

Different is the creation of new version of the CTS, with the addition of new services. It is currently in use CTS v2. It is foreseen the creation of a new release to allow the management of different versions of the code system, to share among other Member States translations/transcoding performed centrally (e.g. the mapping from EMA SPOR code system and EDQM), or performed by other Member States (e.g. to provide to a citizen access to his documents in a language different from his Country of Affiliation one.

Some of the functional requirements of these CTS extension related to EMA SPOR will be a joint activity between eHMEG Semantic Task Force and UNICOM.

At the following link the semantic workpage can be found: SEMANTIC Home - My Health @ EU - eHealth Digital Service Infrastructure (eHDSI) - EC Extranet Wiki (europa.eu)

At the following link eHDSI assets can be found: LINK ASSET Assets - My Health @ EU - eHealth Digital Service Infrastructure (eHDSI) - EC Extranet Wiki (europa.eu)

At the following link all Master Value Sets Catalogue versions can be found, with particular attention to the ones updated in Wave 6: MVC (Master Value Sets Catalogue) - My Health @ EU - eHealth Digital Service Infrastructure (eHDSI) - EC Extranet Wiki (europa.eu)

3.2.1 Value Sets

A Value Set is a collection of uniquely identifiable valid concept representations hence, given any concept representation, the value set allows to determine whether this belongs to a value set providing important information for the use and implementation of the semantic services.

The value sets represent a list of valid concept codes (ie. Identifiers and names) and this set can be flat, if the concepts are drawn from a single code system, or hierarchical, if it the concepts are drawn from multiple code systems. For example, considering the value set “Colors of the Rainbow”, “yellow” would be a valid concept as it is a concept that is logically representative of the value set that it belongs to and there is a unique definition of the possible set of colours for a rainbow. Instead, considering the value set “Contact of a person” there is not a flat list of valid concepts but instead several set possibilities depending on the means of contact, if the mean is “phone” then the set can be cellphone or telephone and the related values.

Note that the Value Sets are not mutually exclusive and that each code system in the header or body of a document can be mapped to even an entire code system or just to a portion of the terminology, particularly targeted toward a specific audience.

The eHealth DSI Value Sets Catalogue refers to the use cases mentioned in the [PS Functional requirements], the [eP Functional requirements], the [eD Functional requirements] and the [OrCD Functional requirements].

MVC for pharma components
eHDSIActiveIngredient
eHDSICountry
eHDSIDisplayLabel
eHDSIDocumentCode
eHDSIDoseForm
eHDSILanguage
eHDSINullFlavor
eHDSIPackage
eHDSIQuantityUnit
eHDSIRouteofAdministration
eHDSISubstance
eHDSISubstitutionCode
eHDSITimingEvent
eHDSIUnit

Table 2: List of MVC considered relevant for the pharmaceutical part

3.2.2 Translating/Transcoding

The eHealth DSI Master Value Sets Catalogue consists of commonly agreed-upon concepts used to represent the value for each data element as defined by the users’ functional requirements and consists of internationally used concepts such as those from ICD-10, SNOMED CT, LOINC, ATC, and EDQM Standard Terms, with an English display name. However, these code systems need then to be translated in the relevant country language. In this perspective, the eHealth DSI Master Translation/Transcoding Catalogue (eHealth DSI MTC) builds on the eHealth DSI Master Value Set Catalogue and acts as bridge between translated coding systems.

Each deploying country contributes to the eHealth DSI Master Value Set Catalogue integrating it with the display name(s) in the national language(s) corresponding to the eHealth DSI term. Alternatively, especially when an alternative international code system has been adopted, it can employ the English designation.

As a result, the semantic allows to map the national terminology to the eHealth DSI Master Translation/Transcoding Catalogue (eHealth DSI MTC). The same mapping to the eHealth DSI MVC is not part of the Semantic Services Specification

3.2.3 Code systems selection

The selection of the code systems to be used in the MVC is based on the application of the following selection rules agreed by the Member States and the European Commission:

- The code system must be an International Standard, defined and maintained by an officially recognized Standards Development Organisation (SDO)
- The maintenance and update process of the code system shall be defined and applied.
- The use of the code system shall not be blocked by copyrights. If Licenses for using the code system are required, they shall be provided at reasonable cost.
- The code system shall be adopted and in use in most of the Member States,
- The translation of the code system in the Member State national languages should be available

The selection of the code system, on the basis of the listed selection rules, in eHDSI is performed by the eHMSEG Semantic Task Force, with the Change Proposal procedure. Change proposals are approved by the Member States and adopted by MyHealth@EU governance boards.

Starting from the eHealth Network Guidelines Release 3, preferred code systems are already indicated for each data element of the clinical document. In that case the selection for application in MyHealth@EU is bound by that indication.

3.2.4 Terms selection of the Value Sets

Each Value Set of the MVC is associated to one or more specific code systems.

In general, not the full code system is associated to a single Value Set: a subset of terms must be identified as those included in a Value Set.

An example is EDQM: disjoint subsets of it are used for Dose Form, Route of Administration, Quantity Unit, Package.

The selection of terms is performed by the eHMSEG Semantic Task Force, always keeping in mind the clinical relevance (for the clinical Value Sets) or the coherence with standards (for the technical Value Sets, e.g. related to the HL7 CDA structure):

- Adopt the Value Set indicated in an International Standard (e.g. HL7 ePharmacy standard, HL7 International Patient Summary Guidelines)
- Define business rules to automatically select terms (e.g. EDQM Dose Forms for Human Use, excluding Veterinary Use)
- Perform a term-by-term selection (e.g. starting from SNOMED CT Global Patient Summary Set, select first the Procedures, then consider those related to relevant Surgical Procedures).

In the past, each created/updated ValueSet was included in a Change Proposal for formal approval.

Recently, some Value Sets, based on WHO ATC Classification for active ingredients, EDQM Standards Terms, EMA SMS Substance data, and ORPHAnet nomenclature for Rare Diseases, are automatically updated on a yearly basis[3], by applying the defined business rules,

[3] Specific “hot-fix” are also allowed, when it is urgent to update a Value Set, as it happened for the COVID vaccines

to assure alignment with the current version of the code systems.

Others, like WHO ICD-10, UCUM and the Value Sets based on SNOMED GPS continue to undergo a term-by-term update, because it is considered relevant the decision of clinical and semantic experts of the Semantic Task Force.

3.3 OpenNCP Semantic Components

3.3.1 Transformation Manager and its configuration XML file

The Transformation Manager is a module that interacts with the CDA XML files to enable the bidirectional conversion of the eHealth DSI Reference Terminology with the national terminology. In detail, the transcoding refers to the data transformation from a national language to the eHealth DSI Reference Terminology whereas the translation stands for the other way around (I.e., the data transformation from the eHealth DSI Reference Terminology to a national language). These are the two main scenarios where the TM module serves its purpose but it can do so only on two conditions. The first is that the input data needs to be compliant with the eHealth DSI specification of CDA documents for Patient Summary, ePrescription and eDispensations. The second is that to successfully execute the data transformation it needs to integrate with libraries for XML processing as well as the TSAM and AuditService modules. The TM is controlled by the XML Configuration file, which data elements of the CDA shall be processed.

In most of the cases, when a new version of the CDA is release, it is sufficient to update the XML Configuration File.

3.3.2 Terminology Access Manager (TSAM)

Similarly to the TM, the Terminology Services Access Manager (TSAM) is a module that performs a data transformation of a given concept designation. In particular, the TSAM exploits the information present in the Local Terminology Repository to perform two main actions: translating the concept into the requested target language in a country and transcoding a given "local" coded concept into the appropriate eHealth DSI coded concept.

The former action refers to the association of a display name expressed in the country's language to the appropriate eHealth DSI coded concept. This operation is symmetric hence the module translates from local language to English (the eHealth DSI reference language) but also the other way around (i.e., Reference language to local language).

Instead, the latter consists in the association of a concept coded in a country's specific classification system to a common standard eHealth DSI coded concept. This action is performed when bringing local documents to the eHealth DSI pivot document format and this transcoding result in the integration of the eHealth DSI concept code and designation with the local code and designation. When doing so, if the attributed standard concept is not a synonymous then it needs to be a specification of the more general eHealth DSI concept. As a result, it can occur that one local concept is associated with exactly one eHealth DSI concept.

In principle, when a new version of a CDA or of the MVC are released, the TSAM does not need any change.

3.3.3 Local Terminology Server (LTR) and TSAMSync

The Local Terminology Server is the database, internal to the OpenNCP, where the Master Translation/Transcoding Catalogue (MTC) of that Member State, is stored. The TSAM fetches the MTC data directly from the LTR, in real time, while processing the data for

translation/transcoding. The buffering of the MTC in the LTR allows avoiding the real time access to the Central Terminology Service.
The TSAMSync is the components that allows to download the MTC Value Sets from the Central Terminology Service to the LTR.
The development of the new TSAMSync component tries do decouple as much as possible the terminology server (and the relative services chosen) from the actual data handling and insert into the LTR db.
When a new version of the MVC is released, if a new Value Set was added, the LTR db shall be recreated, adding the new Value Sets.
If the existing Value Sets are updated, no changes are needed to the LTR db structure.

The TSAMSync is designed for not requiring changes in case a new MVC is created.

However, if structural changes are implemented to the Central Terminology Service, it may happen the TSAMSync should be updated, too.

3.4 The National Connector

3.4.1 The political and semantic role of the National Connector

The National Connector is the element that connects the national eHealth infrastructure of a Country with the NCPeH.

It can be also considered the element to decouple the national infrastructure from the NCPeH and the MyHealth@EU specifications and requirements.

If a Member States decides to adopt the OpenNCP as reference implementation of the NCPeH, the only constraint is to provide as input to the OpenNCP a document compliant to the specification of the eHDSI Friendly CDA:

- the eHDSI Friendly CDA MUST be compliant to the structure of the eHDSI Pivot CDA (i.e., the document exchanged cross-border between two NCPeH): the OpenNCP semantic components do not transform the CDA structure;
- the eHDSI Friendly CDA MAY use display labels of the concepts of the MVC Value Sets in a language different from English designation: the translation is performed by the OpenNCP semantic components;
- the eHDSI Friendly CDA MAY use code systems (or just concepts[4]) different from those of MVC Value Sets: the transcoding is performed by the OpenNCP semantic components, by exploiting the MTC.

These degrees of freedom allow a Member State to decide if the clinical documents in use in that eHealth System are fully, partially compliant to the MyHealth@EU specifications or largely different from them.

The National Connector can be designed to totally filling the structural gaps, by creating a eHDSI Friendly CDA structure.
A significative example is the creation of the Patient Summary “on-the-fly”, upon a request coming from the Country of Treatment. The National Connector retrieves the clinical information related to the specified patient, from the selected sources of clinical data, according to defined search rules.
Other examples are the transformation from a different standard, like EN13606 OpenEHR, or the HL7 FHIR Patient Summary, into the eHDSI Friendly CDA, or the transformation of specific sections.

[4] An example of this is the case in which a Member State has decided to adopt the full set of SNOMED CT concepts for Procedure, and a mapping to the eHDSIProcedures Value Set must be performed.

Another freedom is to decide to use the OpenNCP semantic components and the MVC/MTC to translate or transcode the concepts, or to do it in the National Connector, providing as input to the OpenNCP already an eHDSI Pivot document.

Each Member State may take political decisions on when and how to adopt the MyHealth@EU specifications at national level.
The same freedom is applicable in the context of ISO IDMP adoption in the eHealth national service. The following section will consider this case.

3.4.2 Creating IDMP enriched medicinal products description

Even before the adoption of ISO IDMP attributes in eHDSI Wave 6, several Member States (Italy among the others), used to create MyHealth@EU compliant ePrescription and the Medication Summary of the Patient Summary within the National Connectors.

When the national ePrescription does not contain all the eHDSI data elements to describe the medicinal product to be dispense, but just, e.g., the national Market Authorisation Number, or the Group of Equivalence Code (for generic products), these data were (and still are) used by the National Connector as entry to the extended medicinal product data base, to retrieve all the data elements required in the eHDSI ePrescription. The same for the Medication Summary. The same approach was adopted to integrate missing data or convert data elements from the national coding into the eHDSI code systems / Value Sets.

This is a practical example on how the National Connector allows Member States to decouple the national well established ePrescription system (and related political decisions, organisational procedures, semantic assets) from the annually changing MyHealth@EU mandatory specifications.

4 Information Flow

4.1 Semantic Document Workflow

The information workflow triggers with a request from the Health Professional (HP) of Country B to the NCPeH of that same country to access the medical information needed to handle patient care.
The request is forwarded to the NCPeH of the patient's country of affiliation (ie. Country A) which retrieves the medical information for the relevant patient and process it according to the pivot document syntax and vocabulary. This process results in NCP-A outputting the pivot document (inclusive of the original code, the original display name, the pivot code and the pivot display name) and a PDF version of the original document. Further details can be deepened in Section 2.2.
Next, the pivot and the PDF are sent to NCPeH-B where it undergoes two processes. The first consists in the rendering of the information in the local data format and language. The second process maps the content to a national schema and code system. Although being an optional processing, the document provides some guidelines for terminology Translation/Transcoding through the eHealth DSI Master Translation/Transcoding Catalogue (eHealth DSI MTC) and the Terminology Access Services.
Eventually, the Terminology Access Services interface ensures the correspondence between the terminology in the original document and that of its interoperable counterpart. This terminology is accessed by runtime components, fulfilling the translational requirements, but also by terminology curators, fulfilling the terminology maintenance requirements. Such runtime components can be embedded in the NCPeH architecture or offered as a web service by the NCPeH locally to the HP depending on whether the data privacy and security policies forbid the direct handling of patient information without being encrypted and signed.
Overall, the document defines the standard interfaces to the eHealth DSI MTC, as well as the indications for creating, maintaining and augmenting its contents.

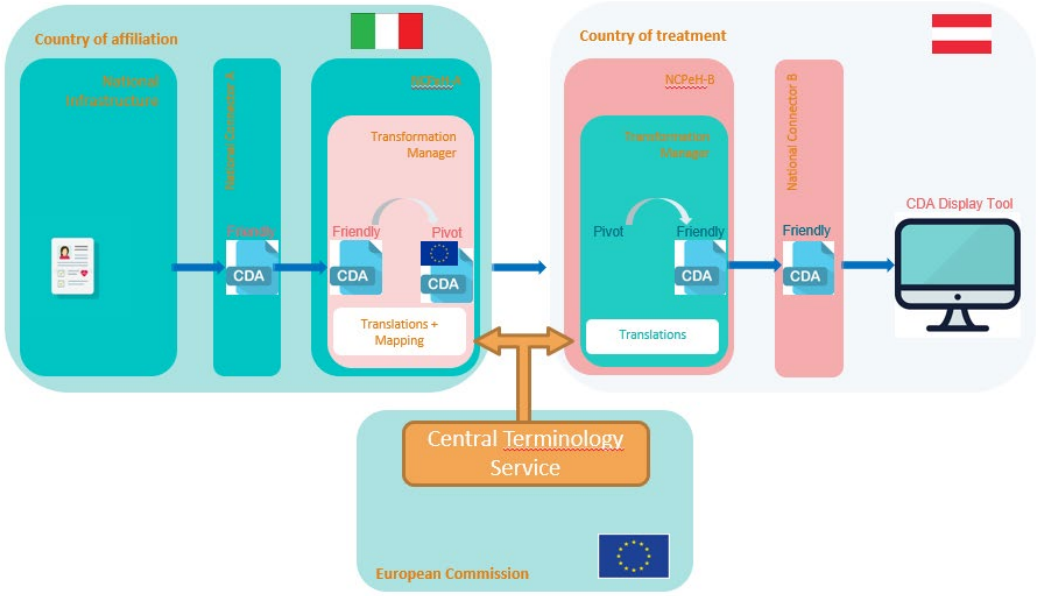

Figure 4: Representation of a generic semantic workflow document between a country of affiliation and a country of treatment.

4.2 Exception to the Semantic processing of documents

There are two exceptions to the semantic processing of documents, and these are represented by the Change Proposals 28 and 67.

Regarding the Change Proposal 28, this Change Proposal seeks to alter the Semantic Services Specification document in order to make it easier for countries exchanging documents to understand and utilize them without requiring the receiving countries to translate the entire code system into their national language. This proposal is being presented alongside another proposal to adopt multiple code systems for clinical data elements. Both proposals are related because adopting multiple code systems for MVC requires countries B to display English designations, which can be a significant effort for deploying countries whose healthcare professionals are already proficient in scientific English.

As for the Change Proposal 67, this modification impacts the CDA Display Tool requiring the addition of a new component that displays the original text description. In detail, if a national-level code system is not considered adequate for inclusion in the MVC (e.g. not using an International Code System), information can still be exchanged and used by healthcare professionals in the country of treatment if it is provided in English. The CDA Display Tool and tools for displaying patient summaries will need to be updated to show the original textual description, code system, and version of the information in its original form. It is also recommended to display a message indicating that the information is being presented as it was originally sourced. In the future, a language tag may be added to allow the receiving member state to decide whether or not to display the information if it is provided in English.
However, this decision should be supported by a legal assessment on the responsibility of a Member State to hide received medical information.
Currently the Country of Treatment may disregard the clinical information provided by the Country of Affiliation, if those data do not belong to the Maximum/Extended Data Set.

For the time being, only the patient is allowed to hide clinical information in his EHR, e.g. hiding specific prescription, or specific data in his Patient Summary.

5 Clinical Document Architecture

5.1 CDA Basics

The Clinical Document Architecture (CDA) with the Health Level 7 (HL7) standard is a markup language for exchanging electronic health records (EHRs) by encoding clinical documents in a way that is both human-readable and machine-readable. It is designed to standardize the content of EHRs, enabling interoperability and data exchange between healthcare systems and organizations.

The *HL7 CDA standard* together with the *HL7 Continuity of Care Document (CCD)* and the *IHE Patient Care Coordination (IHE PCC)* are used to express the data elements defined by:

- the Patient Summary Functional requirements
- the ePrescription Functional requirements
- the eDispensation Functional requirements
- the OrCD Functionla requirements

The expression of these data elements according to the three standards is due to:

- the wide adoption of the CDA implementation in the majority of the countries
- the ease of implementation
- the standards currently adopted in the industry

The information in the document needs to be read by humans as well as processed by software hence the information must be coded with coding systems such as SNOMED-CT, ICD-10 or LOINC among others. To further structure the information, each document consist of a header defining general information about the episode of care (eg. patient, healthcare professional in charge of the patient, type of document) and the body containing the specific clinical content.

5.2 eHDSI Art Décor Implementation Guide

ART-DECOR® – the open-source tool suite that aims at interoperability solutions in the healthcare sector and that fosters collaboration between all stakeholders involved in the process of making real interoperability come true**.**

5.2.1 About eHDSI

The eHealth Digital Service Infrastructure (eHDSI or eHealth DSI) is the initial deployment and operation of services for cross-border health data exchange under the Connecting Europe Facility (CEF). eHDSI sets up and starts deploying the core and generic services, as defined in the CEF, for Patient Summary and ePrescription. The generic services are the necessary implementation of data exchange at country level, the core services at EU level. These together enable the provision of Cross Border eHealth Information Services (CBeHIS).

5.2.2 Use cases

Within the eHDSI project, two main use cases are defined:

- Patient Summary: access to important medical data for patient treatment.
- ePrescription/eDispensation: cross-border use of electronic prescriptions.

Release notes of the CDA Implementation guides can be found at the following location: https://ec.europa.eu/cefdigital/wiki/x/rYDuAw

The value sets that are used inside the project are combined in a master value set catalogue (MVC): https://ec.europa.eu/cefdigital/wiki/x/yT4ZAg

5.3 Building on eHDSI Art Décor Implementation Guide

Art decor is mainly used for creating CDAs and as a testing tool. For the creation of CDA art decor it allows you to use a template within which it is possible to implement the different levels (header, section and entry) for the different use cases.

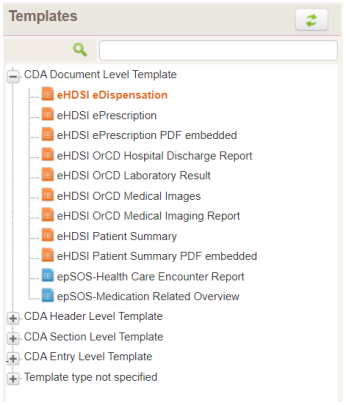

Figure 5: Screenshot of the structure of a CDA template implemented on ART-DÉCOR

The Panel offers the list of all Value Sets of the Project, sorted alphabetically and indicating whether they are in-project Value Sets (plain colored icons) or references from a Building Block Repository BBR (chain symbol).

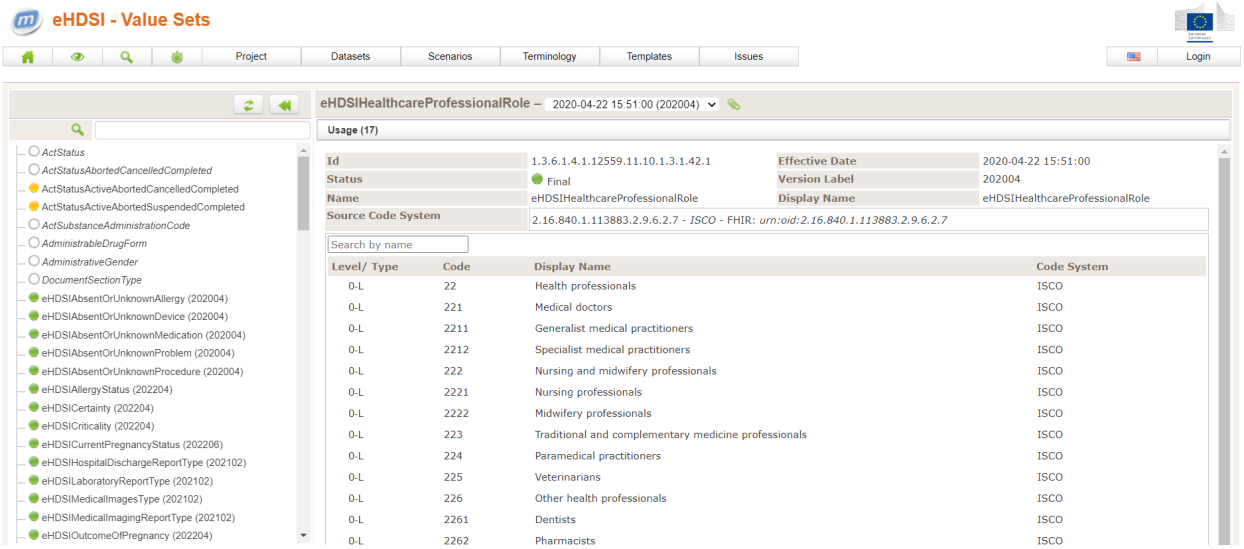

Figure 6: eHDSI value sets screenshot that shows how values set to art decor are displayed

At the following link it is possible to view the overall architecture of the valuesets used for the aforementioned use cases *eHDSI - Datasets*

Datasets are mounted inside the template which is nothing more than a CDA, and based on the level they are inserted.

The figure below represents how a CDA in art decor is implemented. In particular, the value sets and the codesystems and the attribute are inserted within the template.

An explanatory example in xml format is also presented in the section.

These CDAs are then used for testing.

Another function of Art decor is also to create xml which are then used and processed by the transformer manager whose function was previously described in paragraph 3.3.1.

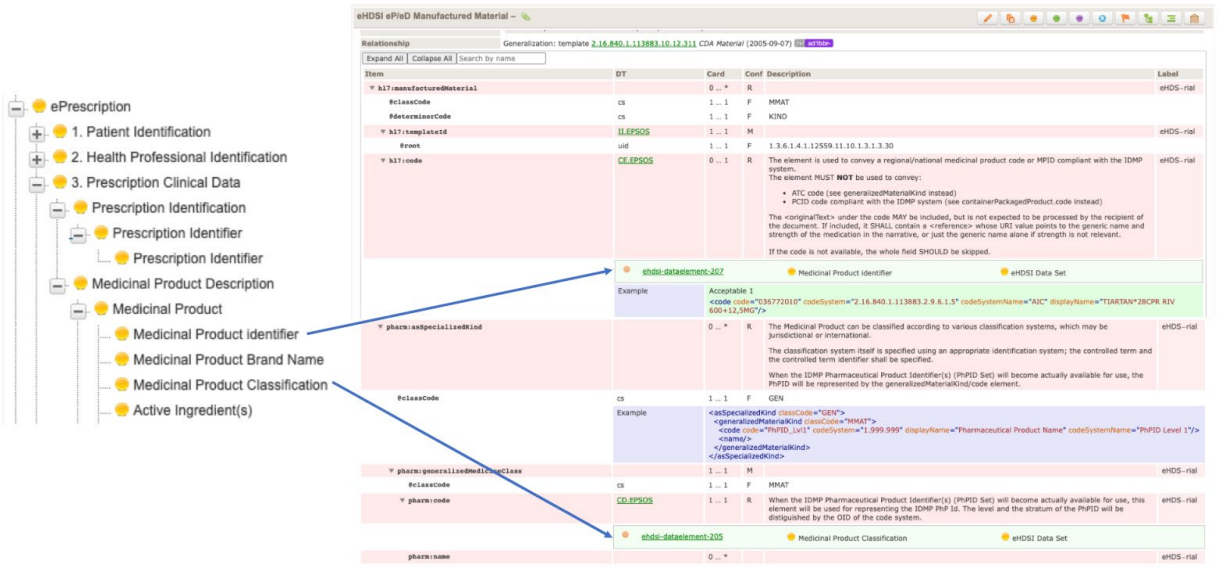

Figure 7: example of how a CDA template is implemented on ART DECOR

6 MINIMUM ATTRIBUTE LIST for eHealth

6.1 SPOR as coding system

SPOR data management services support the collection, storage, and analysis of data generated through patient-oriented research projects. These services may include the development of data management plans, the provision of secure data storage and backup solutions, the creation of data dictionaries and study documentation, and the development of data analysis pipelines. The goal of this coding system is to facilitate the sharing of data among researchers, while also ensuring the privacy and confidentiality of the data supporting the EU regulatory process.

In detail, the four SPOR data management services are:

- Substance Management Services (SMS)
- Product Management Services (PMS)
- Organisation Management Services (OMS)
- Referentials Management Services (RMS)

6.2 SPOR RMS

Referential Management Services (RMS) are one of the two types of service of the SPOR data management services to go live. Together with OMS (Organisation Management Services), these services provide the data foundations for the two other types of SPOR data management services that are the Product Management Services (PMS) and the Substance Management Services (SMS) which still need to be activated.

RMS referentials replace the European Union Telematics Controlled Terms (EUTCT) system in providing referentials lists and terms such as route of administration and dosage forms within a particular region or healthcare system.

In detail, the RMS allow users to:

- Navigate and export referentials lists and terms;
- Modify, update and translate referentials lists and terms
- Subscribe to notifications of new and updated lists
- Subset terms identifying them with tags

7 eHDSI Wave 6 Changes to enhance ePrescription & Patient Summary

7.1 eHDSI Communities

The work at the basis of this and other WP5, WP6 and WP7 Deliverables stems from the collaboration of various entities and workgroups, which have contributed to the development of the current status.

In particular, it is important to mention the eP Cluster and the Semantic Task Force, the Change Management and Business Requirements Work Group and Technical Work Group.

UNICOM co-operated with these eHMSEG Communities, to support the preparation of the

Change proposals related to the Medicinal Products and the alignment of eHDSI assets to Wave 6 specifications.

7.2 eHDSI Change Management process

The procedure describing the Change Proposal Management used within the eHDSI framework, and in particular its workflow, can be read below, in Chapter 8 Annex Section. Its objective is to "assess and approve the integration of the change requests which can impact the policy, technical and/or operational activities of eHDSI". It applies to requirements, specifications and frameworks and can have policy, operational or technical impact on eHDSI activities. The actors involved in the process are the requester, the eHDSI change manager, the eHDSI solution provider, the eHDSI owner and co-owner, the e-Health Operational Management Board (eHOMB) (which oversees the provision of service and) and the stakeholders, including eHMSEG, the Communities and the Standards Development Organizations.

The main steps of the aforementioned process are:

- Draft CP Preparation
- CP Generation
- CP Registration
- CP Distribution
- CP Impact Assessment by Solution Provider, Owner and eHMSEG
- Inputs merging
- Prepare consultations
- Provide clarifications and advice
- Share the outcome with eHMSEG
- CP Decision by eHOMB
- Publish CP

7.3 eHDSI Change proposals for Wave 6, related to medicinal products

The present section provides the list, title and description of the Change proposals for Wave 6, related to medicinal products, which are the following:

- CP-061, which comprises a collection of independent CDA IG improvements, such as Change Cardinality of the eHDSI Allergy And Intolerance Concern, Change cardinality of hl7:entryRelationship that links to an observation within the Allergies and Intolerance concern, Fix code element definition in eHDSI Problem Status Observation, Remove negationInd and replace by the use of statusCode in eHDSI Immunization, Wrong determinerCode used for epsos:containerPackagedMedicine in eHDSI Material and various more;
- CP-062, focusing on Medication Information representation improvements through splitting eHDSI Manufactured Product template between PS and ePeD;
- CP-063, including five Improvements to medication information representation through the representation of the medicinal product packaging;

- CP-066, regarding the preparation of Business Requirements for the ISO IDMP Adoption by eHDSI;
- CP-068, which concerns the extension of the Value Set for Timing Events in order to include in the HL7 v3-TimingEvent code list some missing codes of events which are frequently used in dosage information in many countries, i.e. Morning, Noon, Evening and Night;
- CP-070, concerning the update of the Value Sets in the MVC based on the newest versions of ICD-10 and Common UCUM Units;
- CP-071, related to the Automatic update of the Value Sets in the MVC based on ATC Classification, EDQM Standards Terms, EMA SMS Substance data, and ORPHAnet nomenclature.

The modifications and integrations of the semantic components described above, as well as the semantic assets updates for Wave 6, will be described in detail in Deliverable 7.2.

7.4 eHDSI Wave 6 eHDSI semantic components enhancements for IDMP

Wave 6 introduced changes in semantic assets that have been reported in the tables below and mapped according to the releases. In particular, the first table contains the MVCs considered essential for the pharmacological components and have been implemented by indicating an x where changes to the MVCs have been introduced.

The second table instead represents the semantic architectural assets.

A significant change performed in the HL7 CDA for ePrescription/eDispensation and Patient Sumary for Wave 6 is the adoption of HL7 ePharmacy Profile for Medicinal Products, in spite of the old proprietary epSOS specifications: this is really relevant evolution towards the adoption of International Standards.

For further details relating to the releases, please refer to the links inserted in the title of the columns.

MCV Value Set	Rel. 5.2	Rel. 6.0	Rel. 6.1	Rel. 6.2
eHDSIActiveIngredient	✓			
eHDSIDisplayLabel			✓	
eHDSIDocumentCode				
eHDSIDoseForm	✓	✓		x
eHDSINullFlavor		✓		
eHDSIPackage	✓			x
eHDSIQuantityUnit		✓		x
eHDSIRouteofAdministration	✓			x
eHDSISubstance		✓	✓	
eHDSISubstitutionCode				
eHDSITimingEvent				

eHDSIUnit				x

Table 3: Table identifying the MVC changes for the respective releases.

First Wave 6 asset release was in June 2022, next will be in January 2023.

Asset	*WAVE 6*
Implementation guide	*6.5.0*
Central terminology server	*2.1.3*
OpenNCP	*6.2.0*
Configuration-manager	
e-sens-non-repudiation	
Security-manager	
Audit-manager	
Data-model	
Assertion-validator	
cda-display-tool	xsltransformer tsam-exporter
Default-policy-manager	
Trc-sts	
Trc-sts-client	
Tsam	
Tsam-sync	
Transformation-manager	
eadc	
Consent-manager	
Protocol-terminators	openncp-interface openncp-client-connector openncp-xdr-ws-client openncp-xdr-ws-server-impl openncp-nc-mock-it openncp-ncp-pt-utils openncp-ws-server
openatna	
Openncp-common-components	
openstork	
Openncp-gateway	

Table 4: Table identifying the technology assets changes for the respective versions.

7.5 Creating IDMP enriched medication descriptions

The implementation of the Wave 6 Change Proposal will allow to have the complete reliable description of medicinal products.

However, UNICOM WP4[5] has made evident that the Member States and the National Competent Authorities have different plans for implementing EMA SPOR.

The adoption of ISO IDMP in the normal ePrecribing services will be probably, necessarily implemented several years later.

Hopefully, several elements introduced by the mentioned Change Proposal are left optional, to allow Member States to decide when and how to adopt them.

[5] UNICOM WP4: IDMP implementation at National Drug Agencies

The National Connector features (cfr. section 3.4) can be the basis for a gradual implementation, without affecting the national prescribing services.

As indicated in section 3.4.2, the National Connector may be connected to the Medicinal Product Database which will contain the data associated to the IDMP attributes to be included in the eHDSI Friendly ePrescriptions.

Member states may decide to develop their own Medicinal Products Database or get the data from the NCAs or MPD providers.

WP6 Task 6.1 medicinal product db is developed to be EMA FHIR Guidelines / ISO IDMP SPOR implementation.

The inclusion of IDMP Attributes data can be incremental both per medicinal product and per attribute, allowing an incremental piloting, starting from a subset of medicinal products (e.g. some products of the Pilot Product List from UNICOM WP4, WP8[6] and WP9[7], and the eHDSI Critical Test Data, and some attribute provided by the NCA.

Feeding these data in the Medicinal Product Data Base could start in the eHDSI Pre-Production Environment and lately transferred in the Operation Ready Environment.

Transcoding from the nationally used code systems, or from the EMA RMS coding to the eHDSI Value Sets can be performed either in the national medicinal product data base, or in the National Connector medicinal product db or in the NCPeH, using the MTC. However, official mapping should be provided directly by EMA; through European Commission, or through the NCAs.

The implementation of the National Connector is not a centralised activity. Each Member State will take its own decisions and roadmap for adoption.

UNICOM Deliverable D7.1 “Piloting Strategy definition“, and D7.2 “Proof of Concept demonstrator report” will provide further details.

[6] UNICOM WP8: Clinical Care, Patients, Pharmacies, Research and Pharmacovigilance

[7] UNICOM WP9: Medicinal Product Dictionaries and Clinical System Software

8 Final considerations

The Deliverable D6.4, after a thorough analysis of the eHDSI architecture and components, addresses the process of defining the changes to be implemented in the eHDSI assets (the specifications, the Master Value Sets Catalogue and the Art Décor Implementation Guide) and the software assets (the OpenNCP and the portal CDA Display Tool, as reference implementation of the NCPeH). The Semantic Components are included in the one listed above.

However, the mere implementation of the NCPeH Semantic Components and eHDSi semantic assets it is not enough to achieve the alignment with eHDSI Wave 6 specifications.

The relevance of the National Connector, as the element to connect, and at the same time, to decouple, the National Infrastructure and the NCPeH, as the gateway toward Europe, has been discussed, highlighting the flexibility in term policies, clinical, organisational, semantic, and technical solutions to run national services and to exchange clinical documents, cross-borders.

This level of freedom may allow a gradual adoption of eHDSI requirements and specifications, without highly impacting on the national eHealth services, while respecting the MyHealth@EU specifications.

Furthermore, the adoption of appropriate means to get the Minimal IDMP Attribute set, from the National Competent Authorities, is basic to implement the currently optional ePrescription data elements is a step toward the extensive IDMP adoption.

The three elements together (eHDSI core semantic components, the MS generic component, including the National Connector and the adequate Medicinal Product Database, like the one developed in UNICOM T6.1, the coded IDMP Minimal Attribute data elements), even progressively, will be the path Member State should follow in order the achieve highly probable and safe dispensation abroad.

These concepts will be further discussed in WP7 as the roadmap to implement and operate MyHealth@EU IDMP enriched eHealth cross-border (and national) services.

9 Annex

9.1 Concepts and Definitions

This chapter intends to present the definition of the terms and the main concepts that are used on this document in order to ensure the correct understanding of the text. The source of all definitions used can be found in the table below and come from CEF eHDSI glossary[3].

Concept	Definition
Active substance/ Active ingredient/ Active pharmaceutical ingredient	Any substance or mixture of substances intended to be used in the manufacture of a medicinal product and that, when used in its production, becomes an active ingredient of that product intended to exert a pharmacological, immunological or metabolic action with a view to restoring, correcting or modifying physiological functions or to make a medical diagnosis.
Actors	► Actors may represent roles played by human users, external hardware, or other subjects. ► Actors do not necessarily represent specific physical entities but merely particular facets (i.e., "roles") of some entities that are relevant to the specification of its associated use cases. ► A single physical instance may play the role of several different actors and a given actor may be played by multiple different instances. ► Types of actors include: Users, database systems, clients and servers, cloud platforms, devices
Adverse Drug Event	A response to a medicinal product which is noxious and unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis, or therapy of disease or for the restoration, correction or modification of physiological function.
Allergen	A usually harmless substance capable of triggering a response that starts in the immune system and results in an allergic reaction. Example of allergens: pollen, dust mites, animal dander, mould, medications, insect venoms and various foods.
Attribute	A property or a characteristic of an entity. eHDSI use: Identity Management Specification
Available prescriptions	The prescriptions that can be retrieved for the patient in the act of dispensing (at that specific or particular moment). This implicitly means that it is a time valid prescription.
Brand name or Name of the medicinal product	The name, which may be either an invented name not liable to confusion with the common name, or a common or scientific name accompanied by a trademark or the name of the marketing authorization holder.
Business actor	Business Actors perform business processes or functions in an organisation. Business Actors are humans working in departments, and business units. Business Actors may be individuals or groups such as healthcare professionals.
Connecting Europe Facility eHealth Digital Service Infrastructure	The initial deployment and operation of services for cross-border health data exchange under the Connecting Europe Facility (CEF). eHDSI sets up and starts deploying the core and generic services, as defined in the CEF, for Patient Summary and ePrescription. EU financial mechanism (based on call for proposals) that was launched by November 2015 and used by MS to support CBeHIS provision (preparation, deployment and operation of NCPeH - meaning generic services in CEF).
Clinical Information System	Solutions of Primary Care Centres, General Practitioner's for documentation and Prescription.
Coding System	A scheme for representing concepts using (usually) short concept identifiers to denote the concepts that are members of the system; defines a set of unique concept codes. Examples of coding systems are ICD-9, LOINC and SNOMED.
Concept	Unit of knowledge constructed through combining characteristics.

[3] https://ec.europa.eu/cefdigital/wiki/display/EHOPERATIONS/eHDSI+Glossary#eHDSIGlossary-C

Concept	Definition
Connecting Europe Facility	A key EU funding instrument supporting the development of high performing, sustainable and efficiently interconnected trans-European networks in the fields of transport, energy and digital services (telecom).
Dispensed Medicine	The medicine given to a patient as indicated in the prescription ordered by a prescriber.
Dispenser	Healthcare professional who provides the order of a prescription. The professional person must be authorized to do so.
Pharmaceutical Dose Form	The physical manifestation (“entity”) that contains the active and/or inactive ingredients that deliver a dose of the medicinal product. The key defining characteristics of the Dose Form can be the state of matter, delivery method, release characteristics and the administration site or route for which the product is formulated. A term for the physical characteristics of a drug product - e.g., tablet, capsule or solution - which contains the drug substance and almost invariably other ingredients, such as excipient, fillers, flavours, preservatives or emulsifiers. The form in which a pharmaceutical product is presented in the medicinal product package as supplied by the marketing authorization holder/manufacturer/distributor (e.g. tablets, syrup).
e-Dispensing/ eDispensation	The act of electronically retrieving a prescription and giving the medicine to the patient. Once the medicine has been dispensed, a report on the items dispensed is sent to the prescribing Member State in a structured format.
Electronic Health Record	A comprehensive, structured set of clinical, demographic, environmental and social data information in electronic form, documenting the Health Care given to a single individual. Comprehensive medical record or similar documentation of the past and present physical and mental state of health of an individual in electronic form, and providing for ready availability of these data for medical treatment and other closely related purposes. A comprehensive, structured set of clinical, demographic, environmental and social data information in electronic form, documenting the Health Care given to a single individual.
Electronic Health Record System	System for recording, retrieving and manipulating information in electronic health records.
European Medicines Agency	A decentralised agency of the European Union (EU). It began operating in 1995. The Agency is responsible for the scientific evaluation, supervision and safety monitoring of medicines in the EU.
ePrescription	A medicinal prescription issued and transmitted electronically. The concept of the ePrescription service is understood as the ordering of a prescriptionin software, the electronic transmission of that prescription from the Prescription provider to a Dispense provider, the electronic dispensing of the medicine and the electronic transmission of the dispensed medicine information from the dispenser provider to the prescription provider. The ePrescription service is made up of electronic prescribing and electronic dispensing: ePrescribing is defined as prescribing of medicines in software by a health care professional legally authorized to do so, for dispensing once it has been electronically transmitted, at the pharmacy. 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 about the dispensed medicine(s).
General Practitioner	A physician who provides primary care. A general practitioner treats acute and chronic illnesses and provides preventive care and health education for all ages and both sexes.
Generic medicinal product	Shall mean a medicinal product which has the same qualitative and quantitative composition in active substances and the same pharmaceutical form as the reference medicinal product, and whose bioequivalence with the reference medicinal product had been demonstrated by appropriate bioavailability studies. The different salts, esters, ethers, isomers, mixtures of isomers, complexes or derivatives or an active substance shall be considered to be the same active substance, unless they differ significantly in

Concept	Definition
	properties with regard to safety and/or efficacy. In such cases, additional information providing proof of the safety and/or efficacy or the various salts, esters or derivatives of an authorised active substance must be supplied by the applicant. The various immediate-release oral pharmaceutical forms shall be considered to be one and the same pharmaceutical form. Bioavailability studies need not be required of the applicant if he can demonstrate that the generic medicinal product meets the relevant criteria as defined in the appropriated detailed guidelines.
Guideline	A suggested way of compliance when doing something. It is visible to those using or supporting the use of a particular service, but there are no sanctions if it is not followed.
Healthcare	Health services provided by health professionals to patients to assess, maintain or restore their state of health, including the prescription, dispensation and provision of medicinal products and medical devices.
Health Professional	A doctor of medicine, a nurse responsible for general care, a dental practitioner, a midwife or a pharmacist within the meaning of Directive 2005/36/EC, or another professional exercising activities in the healthcare sector which are restricted to a regulated profession as defined in Article 3(1)(a) of Directive 2005/36/EC, or a person considered to be a health professional according to the legislation of the Member State of treatment; In some documents, the acronym HCP is used. Doctor of medicine or a nurse responsible for general care or a dental practitioner or amidwife or a pharmacist within the meaning of Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications or another professional exercising activities in the healthcare sector whichare restricted to a regulated profession as defined in Article 3(1)(a) of Directive2005/36/EC . This means that a Health Care Professional is a person who delivers health care or care products professionally to any individual in need of health care services, in order to prevent, relieve or treat a medical problem. A Health Care Professional must be related to at least one HCPO.
Hospital Information System	Implemented Solutions in Hospitals for documentation, accounting, etc. HIS delivers PS, eP for eHealth DSI.
Identifier	Non-empty set of attribute values that uniquely characterize an entity in a specific domain of applicability.
Medical (Health) Record	A systematic documentation of a patient's medical history and care. The term 'Medical record' is used both for the physical folder for each individual patient and for the body of information which comprises the total of each patient's health history. Medical records are highly personal documents and there are many ethical and legal issues surrounding them such as the degree of third-party access and appropriate storage and disposal. Although medical records are traditionally compiled and stored by healthcare providers (HP) personal health records maintained by individual patients have become more popular in recent years.
Medication Summary	All prescribed medicine which period of time indicated for the treatment has not yet expired, whether they have been dispensed or not. It is a synonymous of current medication. It contains the following information of each one: active ingredient, strength, posology (number of units per intake, frequency of intakes (per day/month or week) and duration of treatment) and onset date of treatment. At least, a list of current prescriptions with the following information of each one: brand name, active ingredient, pharmaceutical dose form, strength, package size, posology, onset date of treatment and end date of treatment.
Medicinal Prescription	Any medicinal dispensation issued by a professional person qualified to do so.
Medicinal Product	Any substance or combination of substances that may be administered to human beings (or animals) for treating or preventing disease, with the view to making a medical diagnosis or to restore, correct or modify physiological functions. NOTE 1: A medicinal product may contain one or more manufactured items and one or more pharmaceutical products. NOTE 2: In certain jurisdictions a medicinal product may also be defined as any substance or combination of substances

Concept	Definition
	which may be used to make a medical diagnosis. NOTE 3: Adapted from ENV 13607 and ENV 12610.
Medicinal Product Dictionary	A systematic and accurate listing, description and identification of medicinal products designed to support the use (prescription, dispensing and administration of medications) in clinical care or other purposes (adapted from ISO 19256)
Medicinal Product Package/ Package Type	Delivery unit of a medicinal product in an outer container.
Medicine	(a) Any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or (b) Any substance or combination of substances which may be used in or administered to human or veterinary beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis. For UNICOM scope, only medicinal products for human use will be considered.
Member States	In the domain of application of the EU DIR 2011/24, Cross-Border Health, and in particular of Article 14: eHealth, with the term Member States are identified the Central Institutions (Ministries, eHealth Agencies) and the Regional Institution governing the National and Regional Healthcare systems, the Healthcare Provider Organisations and and the ensemble of healthcare services. Member States National Regulatory Competent Authorities (NCA) and EMA marginally falls under the EU DIR 2011/24. In the context of this deliverable, the term “Member States” is used in relation to the Health Care Services, under the domain of application of Article 14. This could be extended or altered by the adoption of the Regulation on the European Health Data Space. When NCA are referred to, explicit reference will be made.
Master Value Sets Catalogue	A collection of terms used within certain parts of the eHDSI pivot documents (either parts describing the patient demographics or the clinical problems for example) based on International Standard code system such as ICD-10, SNOMED CT, ATC classification, EDQM Standard Terms, and UCUM.
Original prescription	The minimum data set defined but as prescribed in the origin country (e.g. the brand name of country A that it will probably be different than the one dispensed in country B).
Patient Summary	An identifiable “data set of essential and understandable health information” that is made available “at the point of care to deliver safe patient care during unscheduled care [and planned care] with its maximal impact in the unscheduled care”; it can also be defined at a high level as: “the minimum set of information need to assure Health Care Coordination and the continuity of care”.
Pharmaceutical Product	Qualitative and quantitative composition of a medicinal product in the dose form approved for administration in line with the regulated product information
Posology	Instruction on number of units per intake, frequency of intakes (per day/month or week) and duration of treatment.
Prescriber	Health Care Professional who issues a prescription.
Prescription	A prescription for a medicinal product or a medical device issued by a member of a regulated health profession within the meaning of Article 3 (1) (a) of Directive 2005/36/EC, who is legally entitled to do so in the Member State in which the prescription is issued.
Route of administration	Indicates the part of the body through or into which, or the way in which, the medicinal product is intended to be introduced. In some cases, a medicinal product can be intended for more than one route and/or method of administration.

Substance	Any matter irrespective of origin which may be: human, e.g. human blood and human blood products; animal, e.g. micro-organisms, whole animals, parts of organs, animal secretions, toxins, extracts, blood products; vegetable, e.g. micro-organisms, plants, parts of plants, vegetable secretions, extracts; chemical, e.g. elements, naturally occurring chemical materials and chemical products obtained by chemical change or synthesis.
System actor	System Actors also known as technical actors include the non-human actors, for instance information system or provides conveying information across borders.
Time valid prescription	It is the time during which the prescription can be dispensed (see Terminology in section 11). E.g. In Andalusia the time validity means that the patient can withdraw the medicine from the pharmacy until the date of the end of treatment while in other countries, like the UK, the patient can withdraw the medicine up to a maximum number of days from the date of issue, e.g. 6 months.

Concept	Definition
Valid prescription	An ‘’official!’’’ prescription, i.e., a prescription made fulfilling the legislation and the procedures defined in that country.

9.2 eHDSI Change Proposal Management Procedure Workflow