D6.1 Preparation and background for a roadmap on future eHDSI use cases and features

Draft for discussion

WP6 Enhancing continuity of care

26-10-2018

Revision 0.2

Grant Agreement nº 801558

To prepare construction and maintenance of an eHDSI Roadmap on future use cases and features of the NCPeH this documents proposes a collaborative way forward and an Annex with quotes and summaries from relevant previous work. The roadmap will be based on the current use cases and its timing.

CONTROL PAGE OF DOCUMENT	
Document name	D6.1 Roadmap on future eHDSI use cases and features
Work Package	WP6 Enhancing continuity of care
Status	Draft for discussion at 14th eHealth Network meeting of 13th Nov 2018
Revision	0.2
Date	26-10-2018
Author(s)	Christof Gessner
Beneficiary(ies)	Gematik

REVISION HISTORY				
Revision	**Date**	**Author**	**Organization**	**Description**
0.1	30-08-2018	Christof Gessner Beatrice Streit	gematik	First version of the document
0.1a	04-09-2018	Christof Gessner	gematik	Suggestions from QM applied
0.2	26-10-2018	Christof Gessner	gematik	Incorporating comments and additional input

Ref. n.	**Document**
	eHAction Grant Agreement n. 801558
	Annex I – eHealth Action Proposal
	eHAction Consortium Agreement (pending)
	MWP 2018-2021

Table of Content

Table of Figures

Acronyms

Acronym	Description
AGREEMENT	Agreement between National Authorities or National Organisations responsible for National Contact Points for eHealth on the Criteria required for the participation in Cross-Border eHealth Information Services (JAseHN D6.2)
ART-DECOR	DECOR (Data Elements, Codes, OIDs and Rules) is a methodology to capture the data needs of caregivers in terms of datasets and scenarios and use it to generate various artefacts: documentation, value sets, XML instance validation, generation and processing support, and test tools etc. ART (Advanced Requirement Tooling) is the DECOR user interface to create and adapt DECOR files, and to generate artefacts from DECOR files.
AUTH	Authentication
BgZ	Basisgegevensset Zorg (Basic Data Set for Care) – Patient Summary in the Netherlands
CDA	HL7 Clinical Document Architecture
CEN IPS	International Patient Summary project by CEN/TC 251
CTS	Common Terminology Services
DICOM	Digital Imaging and Communications in Medicine
DSI	Digital Service Infrastructure under the “Connecting Europe Facility” (CEF)
eIDAS	electronic IDentification, Authentication and trust Services – eIDAS is an EU regulation on a set of standards for electronic identification and trust services for electronic transactions in the European Single Market.
eHAction	eHealthAction – 3rd Joint Action to support the eHealth Network
eHDSI	eHealth Digital Service Infrastructure
eHMSEG	eHealth Member States Experts Group
eHDSI Owner	The eHDSI Owner, DG SANTE Unit B3, ensures the liaison between the various Commission services and the eHealth Network
eHDSI Solution Provider	The eHDSI Solution Provider is the European Commission, DG SANTE Unit A4 (supported by DG DIGIT Units A3, B4). The eHDSI Solution Provider is responsible for building eHDSI specific software and services, advises and assists Member States on setting up the generic services and provides the core services.
EED	epSOS Evolving Document
EHIC	European Health Insurance Card
eHN	eHealth Network
EHR	Electronic Health Record
EHRxF	Electronic Health Record exchage Format
EMA	European Medicines Agency - a European Union agency for the evaluation of medicinal products.
eP/eD	electronic Prescription / electronic Dispense record
ERN	European Reference Network - European Reference Networks (ERNs) are virtual networks involving healthcare providers across Europe. They aim to facilitate discussion on complex or rare diseases and conditions that require highly specialised treatment, and concentrated knowledge and resources.
ERN CPMS	ERN Cinical Patient Management System
EU	European Union
FHIR	Fast Healthcare Interoperability Resources - a standard for exchanging healthcare information electronically.
GDPR	General Data Protection Regulation (EU) 2016/679 - a regulation in EU law on data protection and privacy for all individuals within the European Union (EU) and the European Economic Area (EEA).

Acronym	Description
ID	Identification
IHE	Integrating the Healthcare Enterprise - a non-profit organization that aims at improving the way computer systems share information
HCER	Healthcare Encounter Report
HCIM	Health and Care Informatioon Models, (in Dutch: Zorg Informatie Bouwstenen - ZIBs)
HL7	Health Level Seven International - a not-for-profit, ANSI-accredited standards developing organization dedicated to providing a comprehensive framework and related standards for the exchange, integration, sharing, and retrieval of electronic health information that supports clinical practice and the management, delivery and evaluation of health services.
HP	Health Professional
MS	Member State
NCC	National Competence Center
NCPeH	National Contact Point for eHealth for the Cross Border eHealth Information Services (CBeHIS).
MRO	Medication related overview - a document for informational purposes only that supports all possible information that might be needed in the process of prescribing, dispensing (and possibly even administering) medication to the patient in a foreign country.
MWP	Multi-Annual Work Plan
ONC	The Office of the National Coordinator for Health Information Technology (ONC) is a staff division of the Office of the Secretary, within the U.S. Department of Health and Human Services.
openEHR	openEHR is a standard specification in health informatics that describes the management and storage, retrieval and exchange of health data in electronic health records (EHRs).
OpenNCP	eHDSI NCP software publicly available under Open Source licensing.
PAC	eHDSI Use Case, enabling the patient to access and understand what the Health Professional has recorded in the PS or eP, in order to participate in his or her own care, and/or to improve the information he or she gives to another Health Professional
PCHA	Personal Connected Health Alliance a non-profit organization formed by HIMSS. PCHAlliance is a HIMSS Innovation Company.
PS	Patient Summary
R&D	Research and Development
RD	Rare Diseases
ReEIF	Refined eHealth European Interoperability Framework
PRSB	The Professional Record Standards Body (PRSB) is an organisation in UK that was established in 2013 to ensure that there are consistent standards for care records. The aim of the organisation, which is funded by NHS Digital, is to develop clinical standards for health and care records, as approved by the Academy of Royal Medical Colleges.
SAML	Security Assertion Markup Language
SDO	Standard Developing Organisation
SNOMED CT	SNOMED CT or SNOMED Clinical Terms is a systematically organized computer processable collection of medical terms providing codes, terms, synonyms and definitions used in clinical documentation and reporting.
TESTA-ng	Trans European Services for Telematics between Administrations. TESTA-ng is the fourth generation of TESTA since 2013.
TM/TSAM	Transformation Manager and Terminology Service Access Manager – components of OpenNCP
UCAT	Use case Authoring Tool
UCR	Use Case Requirements
WP	Work Plan

1. Introduction

In its 12th meeting the eHealth Network adopted its Multi-Annual Work Plan (MWP) for the years 2018 to 2021. The MWP is in line with the objectives of the eHealth Network as outlined in article 14 of Directive 2011/24/EU and includes four priority areas with several topics each. The Joint Action eHealthAction is in charge to deliver proposals, recommendations and methodologies on how to proceed with already undergoing activities and to scope and initiate new ones in the defined priority areas and topics. However, the eHealthAction might not be the only contributor to the MWP of the eHealth Network[1].

As one of the eHealthAction Work Packages, WP6 - Enhancing Continuity of Care builds on the priority areas C.2, C.3 and C.4 as well as on D.2 of the MWP. Grouping of the topics into Work Packages and Tasks of the eHealthAction was the duty of the Leadership Council of the eHealthAction and done in alignment with the eHealth Network chair and MS co-chair.

Work Package	Tasks	Deliverables	MWP 2018-2021
WP.6 Enhancing continuity of care	T6.1 Support of the eHDSI uptake	D6.1 Roadmap on future eHDSI use cases and features (M12)	Combination of C.2 New Cases for eHDSI and C.4 European Reference Network eHealth Services
	T6.2 Support of the legal eHDSI matters	D6.2 eHDSI legal report (M18)	C.3 Legal challenges
	T6.3 eSkills for Professionals	D6.3 Report on eSkills for Professionals (M24)	D.2 eSkills for Professionals

Task 6.1, Support of the eHDSI update, aims at commitment on sustainable usage of NCPeH among Member States (MS) and Countries and between MS/Cs and central sevices provided by the European commission. Besides member states of the European Union also EFTA/EEA countries may be included in eHDSI activities (Lugano convention), at present this applies to Iceland, Liechtenstein, Norway and Switzerland. From now on we will use the term “Member States” in this document with the meaning “Member States and Countries”, Ms/Cs). It will deliver an eHDSI roadmap on future use cases and features of components and services including a proposal for a timeline. The task will describe strategies to advance the definition of the interoperable clinical content that is needed to support continuity of care across a portfolio of conditions and use cases. A draft roadmap will be submitted to the eHN in November 2018 for information and feedback. The refinement phase of the roadmap includes

[1] Quotes from eHealth Network Multiannual Work Programme 2018-2021: The MWP is based on the main EU policy documents related to eHealth and builds on the results of work undertaken under the previous MWPs, as well as relevant JAseHN (the previous Joint Action) deliverables. The eHN set up a sub-group for drafting its new Multiannual Work Programme, with participation from member states and chaired by the European Commission.

two workshops and aims at consolidation of the final Deliverable D6.1 for the eHN meeting in May 2019.

The document at hand is a draft version of D6.1 Roadmap on future eHDSI use cases and features, which includes first results of desk research applied to already known potential use cases for eHDSI and recommendations for their implementation in the eHDSI. This work proposes a methodology on how to analyse those use cases and – if applicable – additional use cases and features in order to derive specific activities to be performed in order to enable and support use case implementation. The objective of this work is to provide a roadmap towards future use cases for the European eHealth Digital Services Infrastructure (eHDSI). The scope is therefore not limited to the scope of the current CEF funding period of eHDSI, described in the (amended) CEF work programme 2015. In particular it is not limited to the current support actions for Patient Summary and ePrecription/eDispensation services and the services of the IT platform for European Reference Networks (for details see: DG SANTE, 'Note on the EHDSI Infrastructure'.)

This document suggests the construction and maintenance of an eHDSI Roadmap on future use cases and features of the NCPeH including a proposal for a timeline. The initial version of the roadmap will be based on the current use cases and their timing. The main purpose of this document is to foster discussions of Member States and European Commission on the completeness of already identified activities as well as providing feedback on the methodology laid out to reach the final version of D6.1 Roadmap on future eHDSI use cases and features. The authors believe that in order to efficiently add add new cases ("Combination of C.2 New Cases for eHDSI and C.4 European Reference Network eHealth Services" in the MWP) it is indispensable to identify, specify and prioritze the activities and related governance processes that enable the re-use of knowledge, components, clinical content in a co-ordinated way. Therefore this document proposes such activities, structured in the form of a roadmap. The roadmap is considered to form a bridge between strategy and implementation, it does not by itself define the strategy or prioritize the strategic goals.

The document prepares a collaborative way towards roadmap decisions, based on strategic priorities to be delivered by the eHN. Also contained is an (informal) Annex with quotes and summaries from relevant previous work[2]. Additionally the eHealth Network Members will be asked to discuss on basis of the document at hand, which level of detail for the intended Roadmap for eHDSI may be the most helpful one for an effective and efficient process towards implementation, with a view on the available resources and the need for a coordinated approach across European Member States and European Commission.

[2] Note: **The Annex is not considered to be a logical part of this deliverable**. It is merely added to point the reader at important reference material published elsewhere. It is intented to remove the Annex upon finalization of the document, but retain the information for the time being. For an effective workshop-based development of this document, the participants and co-authors should be familiar with the content quoted in the Annex. (see also: eHealthAction, 'Project Handbook'., ch. 7)

2. Future Roadmap Elements and Activities

2.1. Assumptions and objective

The following assumptions were made with regards to the future Roadmap for eHDSI:

The Roadmap for eHDSI would be adopted by the eHealth Network in May 2019 at the earliest. Given that a certain time period is needed to implement the envisaged Roadmap for eHDSI, it would apply earliest from the beginning of 2020, which corresponds to the current planning of Wave 4 of CEF eHealth.

The reviewed material (see Annex) strongly encourages a two stage approach:

- First, a consistent definition of each new use cases or extension to an existing use case is required as input to the roadmap. It is important to reach consensus on a 5-10 page document for each use case that all stakeholders can understand, the benefits expected, the policy, organizational and semantical challenges that are needed to deploy such a use case. The dependencies, if any with other use cases should be analysed. This should be a robust but focussed functional requirements document upon which a formal consensus of the eHN should be reached. The functional requirements are expressions of stakeholder needs of a system to achieve particular goals. The prioritization of new use cases and extensions is based on strategic decisions of the eHN.
- Second, a roadmap shall be set up and continuously maintained, that provides a realization plan view on required activities (at EU and MS level). This roadmap spans currently supported use cases and a set of new multiple use cases and functionalities. Previous material discourages to view the realization of use-cases in an isolated fashion from functional requirements to implementation. The prioritization of roadmap items should support an iterative approach, improving current use cases, and enabling new use cases at the same time, with small measurable steps.

The roadmap is designed to visualize the elements to be considered when making a given strategy actionable. The roadmap should detail the direction how eHDSI evolves and the work that is required to get there. It should also allow to assess new requests for functionality against planned work in view of available resources. This implies that while the roadmap is a strategic document, it does not by itself define the strategy or prioritize the strategic goals. By identifying actionable and measurable roadmap items, it also serves as a tool to estimate the required resources that are needed to deliver the specified functionality and features.

This led to our concept of a roadmap that comprises activities that are suitable to support a growing set of use-cases, instead of creating simply a prioritized list of use cases. In other words: In order to be positioned for a future wider range of use-cases, preparatory and accompanying activities are necessary that enable the implementation of envisaged use-cases within a reasonable timeframe and with minimum effort. Such activities might include: training for experts in MS, improved access to and use of tooling, establishing governance for feedback from implementers and users, identifying focal areas of clinical content, enhance publishing modular and re-usable specifications, develop migration paths to new specification elements etc. We consider a Roadmap for eHDSI to consist of a collection of suitable activities, prioritized and assigned to a realization timeline. This roadmap will be a document which has

to be constantly maintained and updated after a certain period of time. Therefore a dedicated process and an owner of the Roadmap for eHDSI has to be defined and set up.

A governance and process for this roadmap yet has to be developed and agreed upon, allowing for a careful view on available resources and ongoing specification, implementation, and deployment activities. It is assumed that member states will be actively involved with the roadmap implementation, defining the clinical models, providing input on the decisions etc.

The intention to define and implement a roadmap for eHDSI is to foster the sustainability and uptake of the eHDSI, and to avoid the risk of a gridlocked eHDSI where Solution Provider together with MS have to allocate all available resources to the current use cases PS and EP/eD.

2.2. Vision of the eHDSI Roadmap

2.2.1 Analysis of previous recommendations

The analysis of published material and recommendations spans a wide area of topics and activities. Following a first attempt to use the Refined ehealth European Interoperability Framework (ReEIF) as a guideline to establish a structure and classification, it became apparent that many opportunities to create value lie in combining two or more "interoperability levels", joining forces across a spectrum of professions, methods and expertise. For example, to bring together legal experts with IT experts to identify the (legal and technical) requirements of a specific cross-border data-exchange pattern, and then design solution components as artefacts that can be re-used in mulitiple use-cases that expose similar legal requirements. Or to have clinicians and semantic experts jointly developing re-usable elements of clinical contentthat are suitable for cross-border scenarios. In literature the concept of "clinical building blocks", CBB, is used, also known as "Health and care information models" (not to be confused with "CEF building blocks"). Health and care information models are also referred to as Clinical Building Blocks - They are detailed data specifications of medical concepts in a given context [see for example: Nictiz, 'Registratie Aan de Bron, Architecture, Volume 1'.].

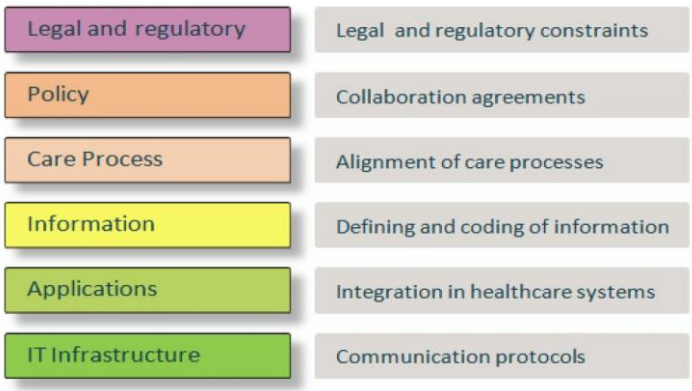

Figure 1*: Interoperability layers of the ReEIF*

Compared to the European Interoperability Framework (EIF), which is another related approach that gives specific guidance for interoperable digital public services, the ReEIF

provides more granularity[3]. This accomodates for the inclusion of additional actors that are specific for the healthcare domain: the patients, the care providers, and their national or regional organizations. This allows to differentiate between those interoperability requirements or activities that are specific to the healthcare domain (i. e. must involve and respect domain-specific knowledge) and others that are of more generic nature. While eHDSI use cases generally aim at domain-specific goals, they usually also include elements or “features” that are less domain-specific.

In trying to separate and classify the various eHDSI-related recommendations in the literature, we identified two useful parameters: Most items, tools, and activities can be assigned a position within a spectrum between a more technical view on one end, and a clinically-oriented asset or approach. As a second "axis", we found it useful to sort items based on their conceptual "attitude": Would the recommendations address work in a sphere of legal, regulatory or business decision-making - or would they rather suggest an "engineering" approach, based on technological infrastructure and tending towards rational, fact-driven, "scientific" decisions.

The following visual scheme shows a preliminary result of such a "mapping", which is somewhat arbitrary and schematic, of course.

[3] Since the creation of ReEIF as a specialization of the EIF for the healthcare domain, the EIF was further developed under the ISA2 programme of the European Commission. Apparently, the contributions from healthcare were not considered in this development. It remains to be investigated if and how the recently developed concepts and tooling for eGovernment could be applied here.

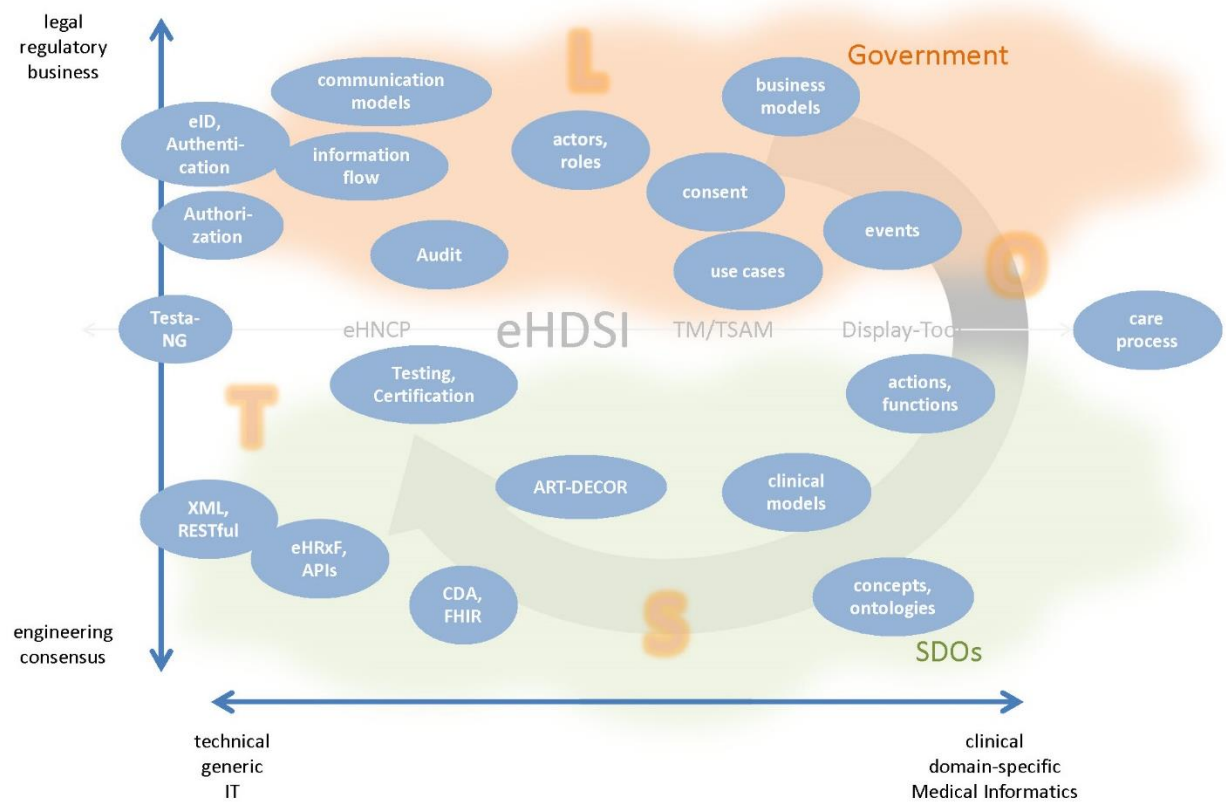

Figure 2 - Roadmap Elements and Activities

As a next step we tried to locate the interoperability aspects of the ReEIF in this coordinate system, this is indicated by the "L-O-S-T" letters (for legal – organizational – semantic – technical).

A number of sources mention and recommend a "use-case-based" methodology for a future eHDSI evolution. However, there seems to be some confusion about what “use cases” are in this context. We may follow an article by Bourquard et. al [Karima Bourquard, Anna Orlova, and Charles Parisot, ‘Understanding User Needs for Interoperability: Defining Use Cases in EHealth’.] arriving at the following hierarchy of concepts for the various levels of requirements specifications:

- Business Cases (“Breakthrough Areas”) – e. g. “IT support for Immunization”
- (Interoperability) Use Cases – e. g. “report immunization information to physician’s EHR system”
- Realization Scenarios – e. g. “document-based structured information exchange (CDA)”
- Technical Use Cases (with implementation options) – e. g. “XDS Cross-enterprise document sharing”

One characteristic aspect of each requirement hierarchy level is the different addressed audience (decision makers, CEOs, Healthcare Professionals, System architects, implementers

etc.). Another characteristic difference is the level of detail concerning legal/organisational/semantic/technical aspects in the expressed requirements. This is where it is helpful to link such concepts to the ReEIF model and it's actors.

Here we investigate the process steps that constitute the typical development path from business cases and use-case specifications to realization scenarios, and finally to technical implementation and deployment steps.

If we consider using the ReEIF to analyze and implement a number of use cases, we can see that there are development steps (i. e. activities) on each ReEIF-level that are repeating across multiple use cases. This is true for legal, organisational, clinical/semantic, and technical steps. One outcome of this recognition is the identification of CBBs, and their potential for re-use. And there are other repeating "patterns" on the other ReEIF levels (identification, authentication, push/pull, consent management, care process integration etc.). The rationale of this roadmap is to identify those patterns, instead of discussing, specifying and implementing them in a "silo-type" again and again for each use-case in isolation. The introduction of the two-dimensional ReIF-landscape is intended to clarify that some steps in analysis, development, implementation can be looked at in a use-case-independent fashion. This approach should enable more efficient solutions that can be re-used across use cases (separation of concerns).

If we follow the sequence of development activities, we can recognize a typical "path", i. e. a sequence of activities. In our two-dimensional view of the ReEIF the general course of the "use-case" approach would lead to some sequence of required development activities and design decisions that roughly follow a clock-wise path, reflecting the hierarchy of requirement specifications mentioned above (indicated by the shaded arrow in the map, starting at business cases and use cases, finally leading to testable implementations). The degree of excursion into the "clinical sector" depends on the use-case. For some use-cases the development path might more directly move to a technical solution, without much impact on the domain-specific "clinical semantics" sectors.

After capturing all legal, organisational, clinical, semantic, and technical requirements, the result is an implemented and deployed technical solution that supports the care process. This final deployed result is indicated as a straight line, connecting the technological infrastructure deployment components (e. g. TESTA-NG, NCP) to those that are serving the care processes on the right-hand side of the spectrum (e. g. TM/TSAM, presentation). The power and capacity of such an implemented solution directly depends on the quality of the development process. If multi-use-case aspects are considered throughout all layers of the design and development process, the same technical architecture should be capable of serving a larger number of use cases with fewer adjustments4.

The indispensable interaction during development with the stakeholders constituting and defining the care process and its actors are summarized in the item "care process" on the very right-hand side. The care process requirements, as expressed by patients, HCPs and their organizations enter the development process here. The deliverables of the eStandards project

[4] While the epSOS architecture was designed with much thought and multiple use cases in mind, the actual OpenNCP implementations were sometimes created under pressure to deliver, which in some cases lead to the introduction of shortcuts, in favor of specific use-cases in the scope of CEF funding.

suggest additional development processes for interactions with stakeholders of the legal and technical sectors (co-creation governance alignment CGA).

2.2.2 Identification of actionable tasks

The currently implemented use-cases PS and eP/eD have their roots and history in the epSOS/EXPAND projects. They successfully proved that a coordinated approach across all levels of interoperability can produce a viable product and a working solution for the given cross-border use-cases. The project-oriented goals and conditions in the given setting under CEF-funding sometimes favored ad-hoc solutions for CEF-specific use-cases over the construction of sustainable and broadly re-usable components. However, along the path to implementation of PS and eP/eD many tools and assets were created or employed, that maintained a broader scope and might well be re-usable beyond those two current CEF-use-cases, let's call them "multi-use-case assets".

Under the assumption that other use-cases would take a similar path to implementation (from business case through technical use cases), it appears worthwhile to analyze a few focal points along this "common development path" in a somewhat isolated way. While recommendations in the literature sometimes seem difficult to translate into actionable tasks in the view of a single additional use-case, in the view of a multi-use-case approach they very often can be assigned to a focal point in the visual "interoperability landscape" shown above, relating to a specific aspect of tooling, standards, design or decision-making.

This leads to the idea of developing and governing different areas of the "ReEIF interoperability landscape" independently, accounting for multiple use-cases. Example: The challenge of cross-border agreement on clinical concepts and (small) clinical models could be approached without looking at the particular "business-use-case" of exchanging patient summaries for unplanned care, instead choosing a broader view that is equally valid for multiple use cases. Also, the communication patterns of information flow and their legal implications can be investigated (almost) without looking at the particular clinical content and data to be exchanged. So the focus on "task areas" instead of use-cases might be a good start for devising a roadmap.

2.2.3 Towards reusable use case components

Built from the US ONC use case approach, the technical report ISO/TR 19669 "Health informatics — Re-usable component strategy for use case development" aims at establishing a catalogue of re-usable assets. It offers a scheme to isolate the steps that lead from business requirements and use-cases to an implemented eHealth-solution. This report ISO/TR 19669 assigns workforce specializations, activities and tools to the individual steps.

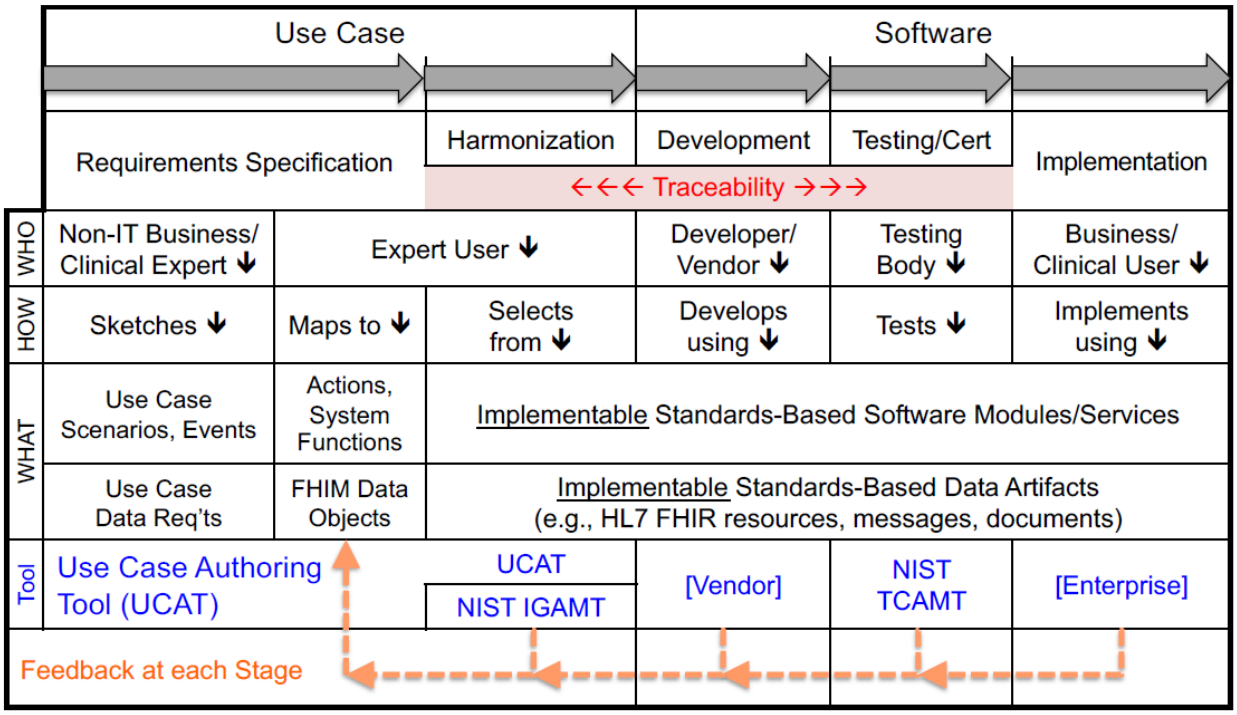

Figure 3*: End-to-end traceability from statement of requirements to fulfillment in live production systems (from ISO/TR 19669).*

Note that the items in the "Tool" row are quoted as an example. For eHDSI they might be translated as follows: UCAT/IGAMT → ART-DECOR, [Vendor] → Solution Provider; TCAMT → IHE Gazelle; [Enterprise] → operation by Member States.

Comparing this model to the current situation in eHDSI, we recognize that most of the tools and workforce specializations are in place already. But currently they are solely committed to the implementation of PS and eP/eD. We have the development of OpenNCP components and of CTS by the eHDSI Solution Provider, we have testing with the IHE Gazelle tools, we have the MS tasked with deployment and operation. We have ART-DECOR as a collaborative tool for capturing and harmonizing data models, importing value sets and terminologies (from CTS), linking everything into rule-based technical specifications (e. g. CDA), enabling automated test generation (e. g. IHE Gazelle). Those tools that are already employed for harmonization, development and testing are use-case-independent and "generic". So it would be easy to re-use the tools, assets and acquired proficiency across multiple use cases.

With this in mind, we can identify one important step that might need more attention: To capture legal/business/clinical requirements of any use-case (business case, interoperability use case, realization scenarion, technical use case) in a more structured way5. This includes identifying actors and roles, formalizing scenarios, events and actions, specifying data objects and elements. The development of a structured catalogue of those "re-usable use case components" is directly linked to the tooling and expertise that is already available in eHDSI.

[5] Note that the audiences of business cases, interoperability use cases, realization scenarios, technical use cases are all different. So it is important to establish views on the specifications that respect the habits of each specific audience.

Such a catalogue would enable traceability of requirements across use-cases and across the implementation path. Also, it would offer a way to capture feedback, improvements and variations. Establishing such a repository of components would greatly increase the flexibility of eHDSI to adopt "new use cases", partly by enabling the re-use of assets already there, partly by providing a sound basis for qualified governance decisions.

A similar argument might hold in another focal area of the landscape: The various patterns of information flow across the border and within the national part of the implementations could probably be described and analyzed in a way that is independent from the particular clinical data that are exchanged. This applies to identification/authentication, consent management, and push/pull or query/response communication types and the related infrastructure. This means that technical solutions (CEF building blocks?) could be identified and selected together with their legal and organizational support, that offer valid and usable transport functionality across many "clinical use cases".

Moving to the challenge of achieving agreement on concepts, terms, terminology systems across European healthcare systems, it might also be useful to separate areas of concepts related to (legal) identification/authentication of persons, organizations and systems, from areas of capturing clinical content or from human-readable presentation of such content. Be aware of complexity when starting with medicinal products, diagnoses and procedures, because those areas have a strong overlap between clinical and legal/business aspects. Instead, start with clearly clinical concepts. Patient summary content modules might offer a good starting point.

Such "separation of concerns" should be mirrored in the bodies of governance and expertise that are required for cross-border decision-making (and their funding, of course).

2.2.4 Governance and stakeholder engagement

The analysis also suggests that two separate “spheres of interest” can be described: On the first hand: the realm of policy decisions and legal considerations (the top half of the interoperability landscape), related responsibilities are rules and agreed policies around privacy, liability, fair and open business models, consent and access control. Actors are less responsible (and knowledgeable) when it comes to clinical information models, codesystems, and (technical) rules of making those concepts usable across system and country borders. On the other hand, there are national and international standards, SDOs and technical experts that are focussing on interoperable solutions for exchanging clinical content and take care of patient safety concerns and concise clinical meaning (the lower half of the landscape). Both communities address IT requirements and solutions, and both are connected to the health care professionals. But traditionally, the two spheres – let’s call them “policy” and “technical” – have little overlap. This is a challenge (and an opportunity) for progress and governance[6]. The proposal of an all-encompassing “SDO-NCC-platform” has not found much support yet in the eHN [eHealth Network Secretary, ‘Discussion Note on EHealth Interoperability and Policy Actions to Improve Semantic Interoperability in the EU’, May 2018.], although there has been significant progress on national level in some countries. However, funding and connecting the

[6] Some MS managed to establish agencies or competence centers that already made progress in bridging the gap (e. g. NICTIZ in the NL) by organizing the dialogue between all actors, including the clinical workforce. We assume that such an approach would also be able to include regional care organisations and patients.

activists in the SDO "technical" area across borders in a well-organized way (similar to the government-driven projects and task-forces) will likely speed up the development of coherent IT-solutions and reliable international standards, without compromising the authority of national decisions in healthcare issues. The coordination between legal requirements and standards would be mediated by the clinical workforce in an active role and supported by using a common technical infrastructure that guarantees fulfilment of the legal non-clinical requirements (ID, Auth, liability, privacy etc.)

2.2.5 Extending the method beyond current use cases

While ERNs and patient registries are very different from PS/eP in terms of communication patterns, business models, legal foundation and privacy rules, there is no apparent reason why clinical content standardisation and technology to share such content across borders should not be tackled in a joint effort[7].

The epSOS use cases of "Healthcare Encounter Report" HCER and "Medication Related Overview" MRO (see epSOS specifications[8]) are again rather different from PS and eP/eD in terms of communication patterns and legal requirements. However, they are probably completely covered concerning the clinical content and exchange formats, once this is solved for PS/eP, because originally they were developed based on common content specifications (CDA, patient summary).

2.3. Roadmap Elements and Activities

2.3.1 Activities

The evolution of the eHDSI aims at supporting new use cases and functionalities, which are specified and prioritized in appropriate governance processes. Also, the currently implemented use cases need further development and improvement. The analysis in the previous sections resulted in the identification of specific activities and work items that are required to enable the current eHDSI to support the given strategic goals, in favor of an approach towards modular components that are efficiently re-usable across multiple use cases. Therefore, the activities listed here are not bound to specific use cases, but focus on identified steps that are suitable and required for the implementation of multiple use cases. The activities are listed in the following table. They typically relate only to a subset of the ReEIF interoperability levels, this is indicated in the right hand column.

In this section, the objective is the identification of separate "work areas", somewhat abstract activities that still have to be bound to specific problems (use cases, functional requirements, clinical specialties etc.) in order to become measurable and actionable roadmap elements or "work items". Prioritization of work items then happens in a separate next step: the assignment of specified activities to resources and a timeline, i. e. the creation of a roadmap

[7] The authors want to express their view that that clinical content is not different between the use-cases. They question the organizational separation between ERNs and PS and eP/eD and support a convergence between the ERNs and PS /eP/eD with respect to cinical content.

[8] Those use cases are already implemented in the current OpenNCP code. However, it was decided to not consider further activity for HCER and MRO in the current CEF-funding phase.

that details the work that is required to reach the strategic goals. An initial arbitrary roadmap example is provided in section 2.3.2 below. An appropriate process of constantly reviewing the roadmap is yet to be defined. This process should capture the strategic prioritization, relate it to available resources and include input/feedback from implementers, users, stakeholders, patients etc.

The following table lists activities that are focused on relatively small areas of the "interoperability landscape" defined above. They were derived from previous recommendations proceeding as described in the previous section.

This compilation of activities is non-exhaustive and should be reviewed and extended during the consolidation phase of this deliverable.

Table 1 – Activities on elements of eHDSI

Activity	ReEIF levels, affected areas
A) identify cross-border communication patterns, information flow	
1) additional patterns (push / pull, query / retrieve)	Applications, IT-Infrastructure
2) ID requirements, eID, consent, liability, trust	Legal, Policy
3) business models, value chains (convergence to ERNs)	Policy, Care Process
B) create and maintain a catalogue of re-usable use case components	
1) common requirements statements	Policy, Care Process
2) common actors and roles	Information
3) common actions, event steps, events	Information
4) common data objects and elements	Information
C) create small information blocks, starting from PS/eP/eD elements	
1) modular Health and Care models	Information, Application, (support from Care Process)
2) demographic data, identification	Policy, Applications, IT-Infrastructure
3) metadata (for queries, also for access control and consent)	Care Process, Information, Legal
4) capture data elements and relations (may use ART-DECOR)	Policy, Care Process, Information
5) specify formalized and testable components (may use ART-DECOR)	Information, Applications
D) refine and adapt the information elements	
1) terminology binding, mapping	Information, Applications
2) mostly MS activity (because of exisiting national solutions)	Policy, Information, (support from Care Process)

E) separate different modes of terminology use	
1) legal vocabulary: roles, consent, identification	Legal, Policy, Information
2) presentation, user interface (labels for data fields, section and table headings, error messages)	Applications, Care Process
3) clinical content, medical documentation	Care Process, Information
F) support local / national system integration	
1) presentation of documents	Applications, Care Process
2) re-use of data (import into national system)	Applications, Information
3) generation of data, assembly (export from national system)	Applications, Information
G) review OpenNCP implementation	
1) enable transport of new document types	Policy, IT-Infrastructure
2) review aspects of configuration, scalability	Applications, IT-Infrastructure
3) consider using DECOR output for generation of code and configuration (already there for test creation)	Applications, Information
H) Review quality assurance processes of services implementation (taking into account the existing quality assurance method for eHDSI, e.g. testing, auditing)	
1) model for more flexible (modular) quality assurance methods	All
2) tools to be used, improve ease of use and testing automation	Applications, Information
I) assign/delegate Governance, Ownership, Maintenance	
1) of Roadmap and its elements	**All**
2) of Building Blocks	Applications, IT-Infrastructure
3) of Implementable Specifications (data formats, testable)	Applications, Information
4) of Terminologies and Value Sets	Care Process, Information

2.3.2 Draft Roadmap "Version zero"

This section maps out a possible roadmap of actionable work items as an example, based on the results presented above and the current status of eHDSI as perceived by the authors. Building the actual roadmap requires more input, it should be compiled and prioritized by a dedicated team, using appropriate input and decision-making procedures (governance). More work and discussion is needed to arrive at a viable selection of relevant roadmap elements (work items), and their prioritization. **In the scope of this deliverable an initial version should be built during the consolidation phase of this deliverable.**

It is suggested to use a simple non-linear timeline of "now", "next" and "later". Progress can be monitored and adjustments to available ressources[9] can be reflected in updated versions

[9] It is to be discussed if responsibilites could be assigned on the level of Activities (2.3.1), or resource assignment should be decided on the roadmap level (2.3.2) where available resources could be assigned on a case-by-case basis. Some activities could be performed by the solution

of the roadmap. While short term activities must be described in much detail and have appropriate workforce and funding assigned (on EU and MS level), this requirement can be relaxed for the "next" section, and even more for the "later" section.

short term (#now):

- [G1] Enable transport of a "new" document type, re-using the PS use-case for all other use-case components (suggestions: immunization record or HL7-IPS CDA)
- [B1] Capture and catalogue common requirements statements from PS and eP/eD use cases
- [E1] Agree on concepts and vocabulary for "Treatment Relationship Confirmation", i. e. SAML assertion.
- [E2] Agree on concepts and vocabulary for presentation of PS demographic data, data field names (table headings), and section headings.
- [C1] create clinical model for Allergies and Intolerances
- [H4] define governance for Terminologies and Value sets for Allergies and Intolerances

medium term (#next):

- [C4] capture data elements for Allergies and Intolerances in ART-DECOR
- [C5] specify CDA representation of Allergies and Intolerances in ART DECOR
- [B1] Capture and catalogue common requirements statements for HCER use case (re-using content that is already in catalogue)
- [A2] Address liability concerns of healthcare professionals, agree on specific requirements for eP/eD use case.

long term (#later):

- [H4] define governance for Terminologies and Value sets for Diagnoses and Procedures
- [C1] review models / data elements used in ERN for Allergies and Intolerances
- [A2] Address liability concerns of healthcare professionals, agree on specific requirements for PS use case.

provider, by national experts, or even third parties. We are leaning towards designing this as part of the prioritization process, assessing the available resources.

Reference List

eHealth Network, 2018. Discussion note on eHealth interoperability and policy actions to improve semantic interoperability in the EU.

eHealth Network, 2017a. Multiannual Work Programme 2018-2021.

eHealth Network, 2017b. Note on the eHDSI Infrastructure: systems developed for European Reference Networks and for the Crossborder exchange of ePrescription and Patient Summary.

eHealth Network, 2015. Refined eHealth European Interoperability Framework.

eHealthAction, 2018. Project Handbook & Rules of Operations.

eStandards Project, 2015. D3.1: The case for formal standardization in large-scale eHealth deployment.

ISO/TR 19669 Health informatics - Re-usable component strategy for use case development, 2017.

Karima Bourquard, Anna Orlova, Charles Parisot, 2017. Understanding User Needs for Interoperability: Defining Use Cases in eHealth. Journal of AHIMA 88, 42–45.

Michiel Sprenger, A.-J.S., 2017. Registratie aan de Bron, Architecture, Volume 1 - Basic Document - The basic principles of health and care information models (HCIMs) and how they can be used.

Appendix – Compilation of previously published recommendations and roadmaps

The following sections contain summaries and selected quoted content from a large number of sources. **They are not being considered a part of the deliverable or the roadmap.** The material is included merely to guide the reader to the valuable work that has been done in past, delivering recommendations and ways forward for the eHDSI. **This material is included in the draft for the readers' convenience, but it is intended to remove it before finalization.**

Reference List of Documents reviewed, that are summarized or quoted in the Appendix:

12th Meeting of eHealth Member States Expert Group, 2018. Agenda Point 12: New features for Wave 3.

ANTILOPE, 2015. D1.1: Refinement Definition document.

eHealth Network, 2018. Discussion note on eHealth interoperability and policy actions to improve semantic interoperability in the EU.

eHealth Network, 2017. Note on the eHDSI Infrastructure: systems developed for European Reference Networks and for the Crossborder exchange of ePrescription and Patient Summary.

epSOS, 2012. D1.4.3 EED SERVICES including specifications for all services.

eStandards, 2017. D3.5 Roadmap for collaborative & sustainable standards development Recommendations for a globally competitive Europe.

eStandards, 2016a. D2.1: Extension of the eEIF: Five new Use Cases.

eStandards, 2016b. D2.2: Guideline: How to harmonise & establish selected clinical content for eEIF use cases.

EXPAND, EUCERD, PARENT, 2015. Exploratory Paper on eHealth Strategies and Roadmaps supporting European Reference Networks and Rare Disease Policies.

JAseHN, 2017a. D.7.1.1: The establishment of a platform for the sharing of national eHealth Strategies.

JAseHN, 2017b. D5.3.3 Report on elements to be taken into consideration for updating the PARENT JA Guidelines for Patient Registries.

JAseHN, 2017c. D5.4.2: Proposing Actions to Promote the Use of Common Standards and Technical Specifications in eHealth Within the EU.

openMedicine, 2015. D1.2 Complementary use cases.

VALUeHEALTH, 2017a. D1.3: Roadmap of consolidated prioritised use cases.

VALUeHEALTH, 2017b. D2.3 Business model report for CEF sustainability up to and beyond 2020.

VALUeHEALTH, 2017c. D4.2: Asset development methodology corresponding to priorised interoperability services.

VALUeHEALTH, 2017d. D5.2 VALUe(HEALTH) Chains: Consensus Statements of key Value Chain participants on sustainability initiatives.

VALUeHEALTH, 2017e. D3.2 Adoption and incentives roadmap.

VALUeHEALTH, 2016. D1.2 Prioritised Use Cases.

VALUeHEALTH, 2015. D5.1 VALUeHEALTH Alliance proposals for stakeholder engagement for cross-border eHealth sustainability beyond CEF.

A. Use Cases and Scenarios

A.1. eHDSI Improvements, New Requirements and Future Use Cases

As part of ongoing eHDSI activities an open list of eHDSI Improvements, New Requirements and Future Use Cases was created. This list is intended to gather in one place the new use cases and candidate requirements needed to evolve eHDSI. This list is maintained on the eHDSI wiki pages and should be updated each time new use cases or new requirements are identified for eHDSI. Input for this list was requested from eHOMB and the Member States.

The list contains three types of items:

1. approved change proposals to be implemented for wave 3
2. additional (candidate) requirements
3. new use cases and extensions of existing use cases

It is expected from eHMSEG to decide upon the next priorities to be implemented for Wave 3, using this list as input and basis for discussions.

The items in this list are subject to acknowledgement and prioritization under the governance rules of eHN and the eHMSEG change management process. ["New features for Wave 3", 12th Meeting of eHealth Member States Expert Group, 23. October 2018, Agenda Point 12]

A.2. Selected eHDSI business use cases

VALUeHEALTH has identified potential use cases based on current knowledge and experience, but the project team does not claim to have developed an exhaustive list. Hence, we expect new use cases to be identified. [VALUeHEALTH, 'D1.2' and 'D1.3']

- Safe prescribing
    - This use case aims to ensure that prescribing decision support algorithms (which already exist) are able to access safety critical information that may be held in the systems of multiple health care providers who are caring for the patient: other current medication, allergies and intolerances, clinical conditions, significant family history, relevant bio-markers etc. It extends the Medication Profile use case, enriching the information content to form a kind of medical summary.
- Integrated care and self-management for long-term conditions
    - Condition-specific, semantically interoperable, information sharing between actors involved in the healthcare and social care and self-care of a patient's portfolio of long-term conditions.
- My care plan
    - This personalised care plan could range in focus from a single condition to the complete portfolio of health issues, care issues and prevention matters relevant to a patient, in each case documenting the problems, goals, and

actors involved and scheduled care activities, with reminders. The goal is to improve quality of care. Patients have access

- Online continuity of care health summary
    - A consolidated online health and care summary that would meet the needs of emergency or unplanned care and also support planned care (continuity of care for a patient's long-term conditions), available to the patient and authorised health and care professionals, anywhere globally, hence nationally and cross-border. Could include medical history.
- Help keep patients at home
    - Primarily targeted at frail individuals, including the elderly, who might either have recently been discharged from hospital or be at risk of deterioration at home. This use case would be achieved through a portfolio of personally tailored sensors and monitoring devices in the home or worn, integrated and monitored through smart algorithms and remote call centres, to ensure early detection and escalation of a health or care need.
- Coordinated cancer care
    - To connect the actors involved in diagnosing, treating and supporting a patient with cancer, providing them with distributed access to detailed (not just summary) cancer records from each care setting and coordinating their activities through an integrated distributed care plan Could be nationally and cross-border..
- Online medication profile
    - Secure online access to the patient's current and recent medication, available to the patient and authorised health and care professionals and carers, anywhere globally.
- Prevention plan
    - This use case focuses on health promotion, illness prevention and health screening programmes that might be developed through multi-stakeholder collaboration at a regional or national level, and delivered to citizens through mobile and wearable applications and personal health systems.
- Care services directory
    - An online searchable directory, at a European scale, of health and care services, including contact information. This might be used to direct the referral of a patient who needs treatment in a location unfamiliar to his or her normal care provider, or to issue an urgent electronic request for background information if the patient is now being seen in an unplanned care setting.
- Population health comparisons
    - European member states very much want to share information about population health characteristics and health status, illness prevalence, comparative effectiveness and optimising clinical outcomes, safety issues

and early detection of outbreaks etc. In order to improve the quality, sensitivity and accuracy of the presently available benchmarks, there is a need to run analysis queries (in a privacy protecting way) on fine-grained electronic health record information, in a standardised way so that the results are compatible across equivalent sub-populations and countries.

- Cross-border pharmacovigilance
    - There is recognised under-reporting of drug safety issues that arise in patients (such as significant adverse reactions), primarily because of the effort involved by clinical practitioners in filing a report, and at times the lack of awareness that a clinical event might be caused by a drug. Decision support systems embedded within EHR systems and clinical applications can be designed to prompt clinicians to consider a drug cause of a clinical observation such as a symptom, and can semi-automatically generate most of the necessary report, for quick review and electronic submission.
- Clinical trial matching
    - It is recognised that more patients would like the opportunity to discover if they may be eligible for a clinical trial to treat their condition, than are given that opportunity. Systems have now been developed that can take the criteria for a new clinical trial and match them to eligible patients within an electronic health record repository. There is a need to scale up such systems across Europe, in a standardised (multi-vendor) way, and also to provide a way in which patients can themselves provide their health history and disease situation into an online environment that can search for relevant trials in their geographic vicinity.
- Key care facts
    - A well-indexed, searchable and user-friendly compendium of the most important clinical care recommendations, cautions and risks for a comprehensive set of clinical conditions, including rare diseases. This is needed, and needs to be frequently updated, because of rapid advances in medical knowledge and because the sheer volume of such information makes it difficult for practitioners to keep up-to-date, especially about conditions they will rarely see. Ideally it should be cross indexed with EHR data so that the most important relevant care facts can be presented to the clinician in a patient specific way. The clinical knowledge should include optimal treatment guidelines, best practices and the potential roles of patients in engaging in the care plan.
- Diagnosis support
    - A pattern matching medical knowledge service that can take the presenting clinical profile of the patient (symptoms, signs, investigation results, past history) and provide a probabilistic differential diagnosis in accordance with therapeutic guidelines. This use case is envisaged to be primarily delivered as a background service to clinicians, to prompt them to consider a diagnosis that appears not to have been made in the patient but is highly likely.

A.3. Selected eHDSI interoperability use cases

eEIF / Antilope / ReEIF, see also https://usecase-repository.ihe-europe.net/ and [eStandards D2.1]

Note: many of the following use-cases are not primarily addressing cross-border scenarios, but relate to in-house or regional/national inter-institutional data exchange.

- e-Prescription and e-Dispensing
- Patient Summary sharing
- Request and results sharing workflow for radiology
- Request and results sharing workflow for laboratory
- Cross-enterprise Referral and Discharge Reporting
- Involvement by chronic patients in electronic documentation of healthcare information
- Remote monitoring and care of people at home or on the move using sensor devices
- Medical Board Review
- Immunization
- Antenatal care

This work suggested a systematic layered approach to link use cases to profiles: “Antilope Use cases” can be realized through “Antilope Realisation Scenarios” that make use of “Functionalities, transactions” which can be implemented using “Profiles” that are based on “Standards”.

In [Antilope D1.1: Refinement Definition document] it is recognized that “In this process, a number of gaps (need to extend an existing profile, lack of profile and gaps in underlying standards) may be identified and an appropriate approach need to be selected (e.g. request the development/extension to a profile and/or standard)”. It is recommended that “A maintenance agreement should be established with the source profiling or standards organization”, with the objective to engage the source organizations for any additional development.

openMedicine D1.2 Complementary use cases

- Ordering and supply
- Product recall
- Product authentication against counterfeiting
- Clinical trials
- Clinical research
- Waste management

epSOS "extension use cases"

- Patient Access to Information PAC
    - https://ec.europa.eu/cefdigital/wiki/display/EHNCP/Patient+Access+to+Information+PAC
- Medication Related Overview
    - https://ec.europa.eu/cefdigital/wiki/display/EHNCP/Medication+Related+Overview
- Health care encounter report
    - https://ec.europa.eu/cefdigital/wiki/display/EHNCP/HCER+Service+for+Patient+Summary+Extension

Also mentioned: Exchange of Laboratory Results, Exchange of Images, Radiology Results

However, in eHDSI Change Proposal CP-12, 01/02/2017, it was decided to "Remove all references to (...) PAC, HCER and MRO services"

eStandards applies the approach it developed to four identified areas of cross-border healthcare:

- Unplanned and Emergency Care – is provided for within Directive 2011/24/EU on Cross-Border Care;
- Chronic Disease Management – is addressed within the European Public Health Programme;
- European Reference Networks for Rare Diseases – are provided for within Directive 2011/24/EU on Cross-Border Care;
- Common Identification of Medication across the above three care areas – as provided for by the EU legislation on Safe Medicinal products, in particular Commission Implementing Regulation (EU) No 520/2012 on Pharmacovigilance.

A.4. Specification of additional services for epSOS (D1.4.3 EED SERVICES)

The epSOS document “D1.4.3 EED SERVICES including specifications for all services” was published in 2012. It describes services for the following use cases:

- extension of the epSOS Core Services - Patient Summary and ePrescription
    - “Patient information will be made available by country B to country A”
    - “medicine newly prescribed in country B” will be an extension to the eP service.
    - “Role specific access to medication related overview”
- Additional Service EHIC to illustrate how to improve coordination between epSOS core services and health administration processes
- Additional Service 112 Emergency
- Additional Service Access for Patients

- "Patient Access to country A information in country B language"

Compared to the specifications of the Patient Summary and eP/eD, those use cases do not require additional content (with the exception of the 112 case, where "extensive work in the semantic services must take place"). However, the address significant variations in the communication patterns. Moreover, they imply that elements of PS and eP/eD might be used in isolation from others, be used in subsets of the full PS/eP/eD, and that translation/transformation sequences are different.

The authors refrain from analysing the methods to produce a valid PS and to analyse different approaches (e. g. automated extraction vs. human intervention). Overall, policies and organizational issues are deferred or delegated to other parts of the epSOS project. Instead, it focusses on the functional service specifications related to the use cases. However, the requirement of testing, verifying compliance to specification, and also functional end-to-end testing is indispensible for each additional use case implementation.

A few selected statements/questions/criteria from the document:

- how existing data can be used in processes defined in new use cases
- avoid defining "new data", only define if unavoidable for added functionality
- coordinate assessment/evaluation with semantic expert group, formalize such interaction
- maintain flexibility of data sets with regard to new requirements
- specify reasonable sets of "exceptional conditions"

A number of analysis results are reported in the document, followed by recommendations. Two focal areas are clearly discernible: security-related (identification of actors, authentication, authorization) and clinical-semantic-related (alignment processes around "conceptual" and "implementable" information models, consistency of terminologies used, ongoing revision and monitoring of specifications, clinical/organizational support at MS level)

B. Results of the project and activity driven Analysis

B.1. eStandards

eStandards addresses the people and organizations concerned with development of standards (governance, procurement, technical artefacts, clinical models etc.) for health care systems. The work aims at greater collaboration across the healthcare spectrum, bringing in the views of all users – citizens, healthcare workforce, researchers, vendors and health systems (purchasers). The ultimate goal are health systems that deliver effective care to meet the needs of individual patients and populations. Four core concepts are identified to make this happen:

- the flow of trusted data
- respect for differing perspectives of the stakeholders
- a reusable set of standardised eHealth artefacts
- co-create, govern and align eStandards along the life-cycle

The early deliverables of eStandards focussed on the existing standards artefacts and reflected on how they met the demands of the Refined eHealth European Interoperability Framework (ReEIF).

eStandards proposed a methodology for standards development - and for the creation of a specific roadmap for adopting a specific set of standards – that is based on the idea of a continuous flow between three acts of design, development, and interaction: Co-creation, Governance and Alignment.

The concept of co-creation is based on acknowledging the difficulties in healthcare to work together across a wide spectrum of players. It has a built-in provision to address conflicts of interests and opinions up front. It does so by having the participants in the process learn to understand each other's perspective in the course of the development of a product, work method, or indeed a standard.

Governance implies that regulators are involved in the standards life cycle activities and standards developers are fully aware of the regulations, which impact upon the use of standards. Finally, governance requires a constant process of monitoring and evaluation to allow alignment to be made with standards or regulatory and governance frameworks.

Alignment ensures the changes in the perceptions of stakeholders or changes in governance are accommodated into projects and initiatives already underway. A key requirement of including alignment activities is to ensure that appropriate monitoring and feedback systems have been set up to make sure that relevant changes can be captured and addressed. Within standards development work, the alignment element requires activity principally on the part of the standards developing organisations which musts remain vigilant to potential changes in governance or stakeholder concerns and needs.

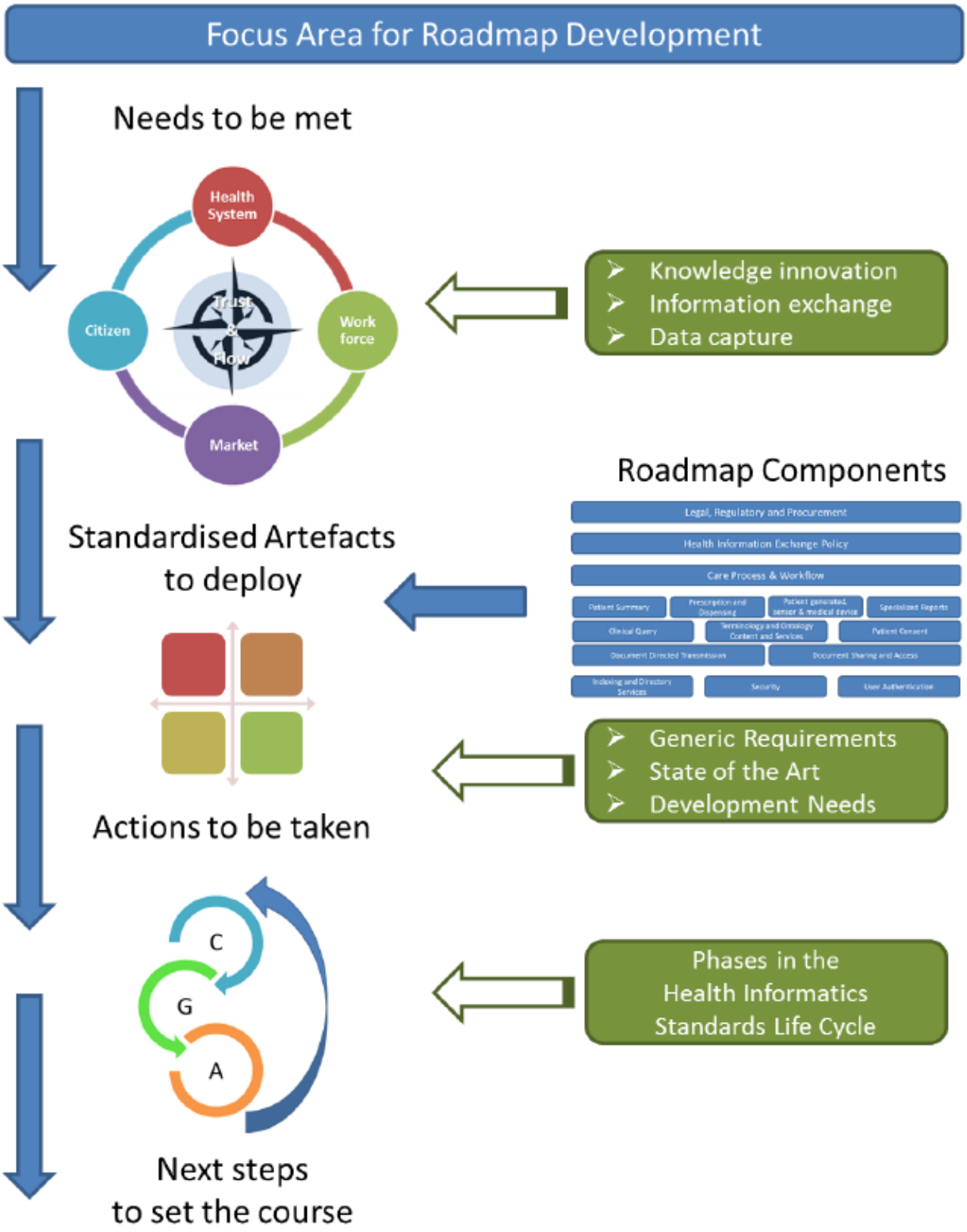

Figure 4 - Focus areas for Roadmap Development

The three core steps of the eStandards Roadmap Methodology are:

- identify the actors from across the healthcare spectrum who may have an interest in the way in which standards-based solutions are used. Develop appropriate ways of

educating them about the value of standards and develop suitable ways of collecting and using their needs.

- Assess the Use Cases, Roadmap Components, and standardised artefacts that already exist and critically assess the extent to which they are able to drive trust and flow of data.
- develop a co-creation-governance-alignment process
    - Develop tools for co-creation
    - Examine the validity of the governance frameworks
    - Engage in a constant flow of alignment

The approach is then applied to four identified areas of cross-border healthcare:

- Unplanned and Emergency Care – is provided for within Directive 2011/24/EU on Cross-Border Care;
- Chronic Disease Management – is addressed within the European Public Health Programme;
- European Reference Networks for Rare Diseases – are provided for within Directive 2011/24/EU on Cross-Border Care;
- Common Identification of Medication across the above three care areas – as provided for by the EU legislation on Safe Medicinal products, in particular Commission Implementing Regulation (EU) No 520/2012 on Pharmacovigilance.

These four areas have been chosen because they have special relevance to healthcare within the European policy setting. It is worth noting here that, with some limited exceptions, the European Union has no legal competence to adopt EU law in the field of healthcare, as healthcare is a matter of national competence according to the EU's founding or 'constitutional' document, the EC Treaty.

Among other recommendations, eStandards proposes to consider the role of a European platform representing the eHealth Standards Developing Organisations and national eHealth competence centres, as identified by the eHealth Network. Such a platform could well play a coordinating role as a guardian of the roadmap components and specific standardised artefacts that are identified across the various eStandards Roadmaps for particular focus areas in health management and healthcare delivery across Europe.

B.2. JAseHN

[D5.4.2] Policy paper proposing actions to promote the use of common standards or technical specifications in eHealth within the EU

The policy paper provides an overview of policy recommendations produced by EU projects related to Cross-Border Services. Based on these existing recommendations a set of recommendations for the eHealth Network are suggested to ensure future actions and initiatives to advance cross-border healthcare. The recommendations were subjected to four selection criteria before being considered in the policy paper. The recommendations are based on existing projects [Agenda point 3, eHN Agenda Nov 2017]

Task 5.4 did a thorough literature review of the current EU Policy and Standardisation for interoperability. It summarizes much of the material very well, so the reader is referred to D5.4.2 for more details for some of the work that is also reported in this document.

Selected recommendations from D5.4.2:

- Put more emphasis on clinical information models (recommendation 4)
    - proposed actions: Assess Health and Care information modelling practices and standards; Agree to have an in depth discussion on Health and care information modelling until 2020
- A combined strategy for eHealth and semantic interoperability is a prerequisite for any decision about the adoption and role of terminology resources (recommendation 7)
    - proposed actions: Define and adopt an eHealth and derived semantic strategy; Align eHealth and semantic strategy. Typically it will be Use case based.
- Provide open access tools and testing data for deployment of standards sets, Shaping the way to Certification (rec. 8)
    - proposed actions: Adopt eHealthDSI testing strategy for national use cases; Have an in depth discussion to move from testing to certification – Request a policy paper on testing and certification from JAseHN
- Build a stable governance model for Interoperability (rec. 10)
    - proposed actions: Establish an Interoperability Task force of experts at national level, and also for the eHDSI at a cross border healthcare level, define an acceptable custodian.

(Interestingly, this selection diverges significantly from the prioritization in Figure 3, D5.4.2. One reason is that the authors of eHAction D6.1 have less focus on “top-down” strategies towards interoperability, another reason is that eHDSI in the meantime made some progress that either fulfilled some recommendations or made them appear less important for progressing)

[D5.5] Report on European semantic interoperability in eHealth and recommendations

The report is meant to provide an analysis of the state-of-play on EU semantic interoperability. Based on existing projects and initiatives that deal with semantic interoperability, five recommendations are formulated to achieve a common strategic approach to semantic interoperability in Member States. [Agenda point 3, eHN Agenda Nov 2017]

The report sets out to perform a review of ongoing and past projects, initiatives and strategies both at the EU and Member State level in order to provide the eHN with an updated state of play with regards to semantic interoperability.

A central issue is the development of semantic resources, described as an incremental process consisting of “layers” that necessitates the creation of terminologies, ontologies and meaningful interfaces. Besides the use of controlled terminologies, ontologies, and appropriate mappings, the document notes a separate category of activities, which deals with bringing structure to the information landscape. This is mostly referred to as "Clinical Modeling". The aim of these models is to bring several relevant values together in a small

clinical model describing an entity that is use case and technology neutral but understandable for health professionals.

For Cross-border interoperability the translation of preferred terms or fully specified names only is not sufficient for many use cases that require concept retrieval or machine processing of clinical narratives.

For terminologies, this will best be achieved by starting with areas where there is a high degree of consensus on both the content and the need. Key areas are likely to be sensitivities and adverse drug reactions, translational medicine, and large scale public health and population research initiatives such as bio-banking.

TermInfo challenge: The very same complex information can be represented to different proportions in clinical ontologies and clinical information models which is known to create semantic interoperability problems.

Reusing Semantic Projects' Deliverables: The main issue from all the analysed projects in semantic interoperability (as is arguably the case in other interoperability domains as well) is lack of follow-up and proper alignment both during the project duration and afterwards. The reuse of project deliverables and lessons learned is low and thus provides little value for the overall approach to semantic interoperability.

Building of Expert Semantic Communities: There are some notable examples of establishing a community of semantic experts which would contribute to the overall semantic interoperability such as The European Institute for Innovation through Health Data (i~HD). However, they are quite recent and still need to demonstrate their added value. They are also research oriented which seriously impact their practical applicability in "real-life" situations. The objective to set up a European network of excellence or a network of national centres to facilitate the use of archetypes and use of multilingual terminology resources has not yet materialized. There is a need for collaborative and specialised semantic communities that would contribute significantly to the semantic interoperability effort by standardising terminologies for local purposes.

Based on the analysis performed and with the active support of participating countries, the report proposes a number of recommendations and actions to be undertaken, which are summarized in the following.

RECOMMENDATION #1: Endorse a Common EU-Level Semantic Interoperability Tooling Strategy by Adopting an Implementation Roadmap

- #now Support ongoing EU and MS initiatives that aim at adopting and implementing terminology resources and other semantic standards. Support the use of structured primary documentation by encouraging software vendors and healthcare providers to implement better support for entering coded information ideally entered at the point of care.
- #next Elaborate a shared catalogue of semantic assets used and developed in the EU and abroad and identify user groups and use cases for semantic interoperability in the EU public and private domain.
- #later Support the development of an open source, publicly available service that provides access to the core terminologies

RECOMMENDATION #2: Use the outcomes of previous semantic projects as a key foundation of that strategy.

- #now Collect best practices originating from or described in previous semantic interoperability projects, catalogue their main findings and recommendations and systematically monitor ongoing projects in order to identify best practices regarding the practical use of semantic resources and information models.
- #next Classify and prioritize the use of semantic resources and information models with regards to the use cases defined in the EU semantic interoperability strategy.
- #later ...

RECOMMENDATION #3: Create a reasonably stable ecosystem of terminologies by connecting EU-level aggregation terminologies, reference direct healthcare provision terminologies, and national user interface terminologies

- #now Endorse the creation of MS terminology centres in charge of creating semantic resources and establish mechanisms for EU-wide dissemination in order to ensure the semantic interoperability following a “bottom up” approach to implementation. (There should be no need to create new “bodies” for semantic interoperability as the build-up of national competence centres for semantic resources to act as a single point of contact for EU semantic interoperability issues should suffice.)
- #next Support the creation and evolution of a semantic ecosystem that will maintain semantic resources on the EU level.
- #later Propose and introduce new semantic resources from the “top down” by introducing mechanisms for EU semantic resources management.

RECOMMENDATION #4: Develop content and services for training and education of end users in order to support “Semantic Literacy” on the Member State national level

- #now Establish national education/training services associated with the use of terminologies, ontologies and interfaces. Ensure a transfer of knowledge from Member State terminology experts to other stakeholders involved in the continuum of care such as healthcare decision makers, local authorities and agencies.
- #next Endorse Member State efforts in continuously collecting and analysing user needs in relation to terminologies, ontologies and interfaces. Build-up national competence centres for semantic resources to act as single point of contact and share knowledge with other Member States.
- #later In order to improve semantic consistency with regards to terminology resources, establish common reusable catalogues of interface terms for both natural and clinical languages and share them between Member States.

RECOMMENDATION #5: Start by doing - Select a Promising Use Case/Set and achieve Tangible Semantic Interoperability for that Use Case/Set.

- #now Select the most promising use case set/information model/value set to achieve MS semantic interoperability in practical terms. (Be aware of the pitfalls attributed to drugs, diagnoses and procedures as these may require an in-depth analysis, beyond

the use of aggregation classifications for representing direct care data in individual patients!)

- #now **Agree to use clinical modelling for representing and sharing clinical data structures across the EU, select an approach out of the several that exist.**
- #next Acquire rights from SNOMED International to use the required value sets across the whole EU and harmonize/translate the value sets in national languages.
- #later ...

As final considerations, the deliverable reports: Regardless of their significance, standards and semantic assets from EU projects are not organized to support easy finding and re-use.

"What is missing is a clear global vision on the future of semantic interoperability in eHealth, and the strategy to convincingly describe the crucial use cases and services that need to be implemented in order to establish interoperable systems."

Both papers were presented at the eHN November 2017, the policy paper and the recommendations were presented for adoption by the eHN.

The discussion is summarized in the minutes: "Several Member States mentioned that they could not adopt the recommendations due to the fact that there were still many open issues on the content and also because some of the recommendations do not provide or are not clear on a way forward. However, they have acknowledged that these topics are important and progress is needed."

eHN in Nov 2017 noted that the recommendations try to find a way forward, and stated: "There are many recommendations made, and thus, it is necessary to make a prioritization but it also requires a **roadmap** on how to move them forward." The eHN concluded "that both deliverables presented were considered as not mature for adoption."

Members of the eHMSEG Semantic Task Force have recently expressed the need to support a longer term vision which goes beyond the more incremental adaptation of the epSOS/EXPAND legacy, but to build up on the results of epSOS/EXPAND [D5.4.2].

B.3. GDPR and eHealth DSI Legal Task Force

This section will be added in a next version, explaining the relevance of GDPR for eHDSI, and potential impact on the roadmap.The authors anticipate that this section will highlight arguments that are in favor of (or against) a more modular approach to development and implementation.

B.4. eHealth DSI Semantic Community

The Semantic Task Force was established by the eHMSEG as a first step towards building the "eHDSI Semantic Community" to support the adoption of the results and assets from epSOS/EXPAND for eHDSI. In close collaboration with the eHDSI Solution Provider the three working groups of the Sematic Task Force (Organizational, Semantic, Architecture) contribute expertise from the MS in preparing and assessing change proposals, adapting and fine-tuning the specifications, applying technical corrections.

The eHealth DSI Semantic Community uses ART-DECOR (Data Elements, Codesystems, OIDs, and Rules) as their platform for the collaboration with (national) non-technical clinical experts, terminologists and implementers of eHDSI for Patient Summary and ePrescription.

While the assets from epSOS/EXPAND were based on international standards (HL7 CDA) and profiles (IHE), many refinements and constraints were applied, in order to fulfill the implementation requirements of the epSOS use cases PS and eP/eD and to satisfy needs of participating countries. Support and participation of profiling and standards organisations is present, but until today without formal and sustainable agreements concerning the governance of the semantic assets.

B.5. CEN IPS

The CEN IPS Standards Project proposal "SA/CEN/GROW/EFTA/000/2015-6 International Patient Summary" was funded with eHN and EC approval; the aim of this agreement was to "participate in the creation of an International Patient Summary specification, at a global level, and turn this into a European Standard, in line with the Guidelines on Minimum/Non-exhaustive Patient Summary Dataset for Electronic Exchange as adopted by the eHN".

The CEN IPS project formally began in May 2016 and was targeted for completion in March 2019.

The strategic goal is to provide a harmonised specification i.e., a formal, coherent and consistent, specification that builds upon existing European work, contributes to the global activity and benefits the on-going European efforts to establish better continuity and coordination of care.

The tactical aim is to support this strategy by realising two main objectives:

- 'Participation', recognising that an International Patient Summary necessarily requires working closely with a global community, and
- 'Assurance', requiring that any international deliverable will be both faithful to existing European work and refined such that it is relevant to the rich European context and culture but capable of satisfying emerging requirements.

The outputs or deliverables of CEN IPS map the objectives by producing two consensus-driven, open standards:

The first standard is a data-centric, formal representation of the eHN dataset that adheres to the principles of being a minimal or core dataset that is both non-exhaustive and extensible. This standard is intended to be global; its' content is condition-independent and specialty-agnostic yet still clinically relevant to any attending clinician. Furthermore, it has been designed to be implementation independent, recognising that myriad patient summaries already exist and are endemic to the fabric of healthcare workflows. The standard used a 'progressive approach' permitting extensibility and providing rules as to how required data can be added. The IPS use case also uses ISO 13940, Systems of Concepts for Continuity of Care (2016), which was originally created by Europe before being adopted by ISO, as an underlying support for interoperability through the use of its concepts and terminology. This standard, draft prEN 17269, was submitted for ballot in February and the ballot closes end of September.

The second standard is a technical specification that provides implementation guidance for the European stakeholder or customer. Its design taking into consideration the different jurisdictions' needs that cross-boundary activities in Europe are required to address, and the reality that the different, pre-existing implementation models should be able to derive and deliver conformant patient summary content and requirements from the framework that EN17269 provides. Whereas prEN17269 is 'International', emphasizing the need to provide generic solutions for global application beyond a particular region or country, prTS17288 capitalises on the fact that the domain model of the former standard permits efficient and effective use both at the local and regional level, so as to maximise its applicability and benefit. Furthermore, the prTS17288 document uses the Refined European eHealth Interoperability Framework (ReEIF) to structure and present its guidance material in a way that is intended to be familiar to a European Audience. This standard, draft prEN 17269, was submitted to CEN on July 23rd to be translated for ballot.

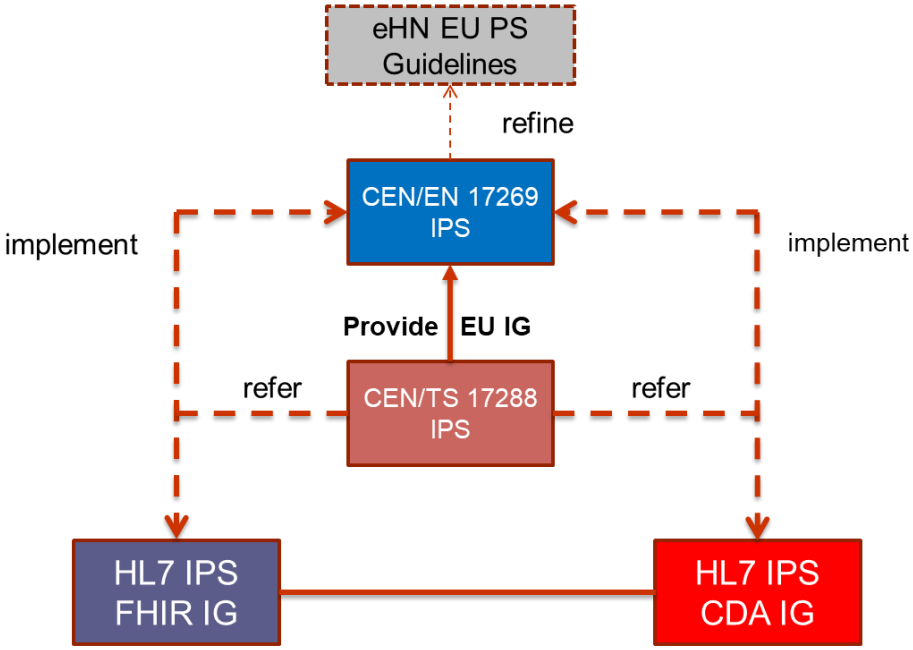

Figure 5: Dependencies between CEN IPS standards and HL7 Implementation Guides (IG)

CEN and HL7 cooperated closely, sharing team members. The active and close participation led to a harmonized approach. Four standards, two from CEN and two from HL7, were drafted in just two years, which is exceptionally fast for SDO processes. The standards are:

- EN 17269: Domain Model (CEN IPS)
- CDA Implementation Guide (HL7 IPS)
- FHIR Implementation Guide (HL7 IPS)
- TS 17288: European Implementaion guide of IPS (CEN IPS)

Furthermore, the CDA version of IPS is heavily based on the eHDSI work and efforts have been made to ensure that eHDSI is also conformant to EN17269.

B.6. European Reference Networks

The 2015 work programme of CEF defines Patient Summary and ePrescription/eDispensation as the scope of the eHDSI, the amendment added the core services of European Reference Networks. The duration of action is 4 years (2015–2019). Future calls are expected in 2017 and possibly later during the duration of the CEF programme until 2020.

The European Reference Networks (ERN) will have their governance structures. However, the CEF financing will be under the umbrella of the eHDSI. Many legal, organisational, semantic and technical issues of eHDSI will be the same. The ERNs are in the building phase and the links of eHDSI-ERN to the eHDSI-PS/eP are still unclear and needs to be considered in the near future. At national level the NCPeH may have a role, and at EU level the eHealth Network may get involved in policy decisions.

Formally the eHealth DSI under the CEF consists of two parts. The system enabling the cross-border exchange of ePrescriptions and Patient Summaries for unscheduled care is commonly referred to as the eHDSI. The second part consists of IT tools enabling the co-operation and clinical work of the European Reference Networks of highly specialised clinical centres. This ERN IT Platform allows pooling of knowledge, improvement of diagnosis and care in medical domains where expertise is rare, and helps Member States with low number of patients to provide highly specialised care. [Note on the eHDSI infrastructure: systems developed for European Reference Networks and for the Cross-border exchange of ePrescription and Patient Summary, presented at Agenda point 2b, eHN November 2017, Brussels, 14 November 2017]

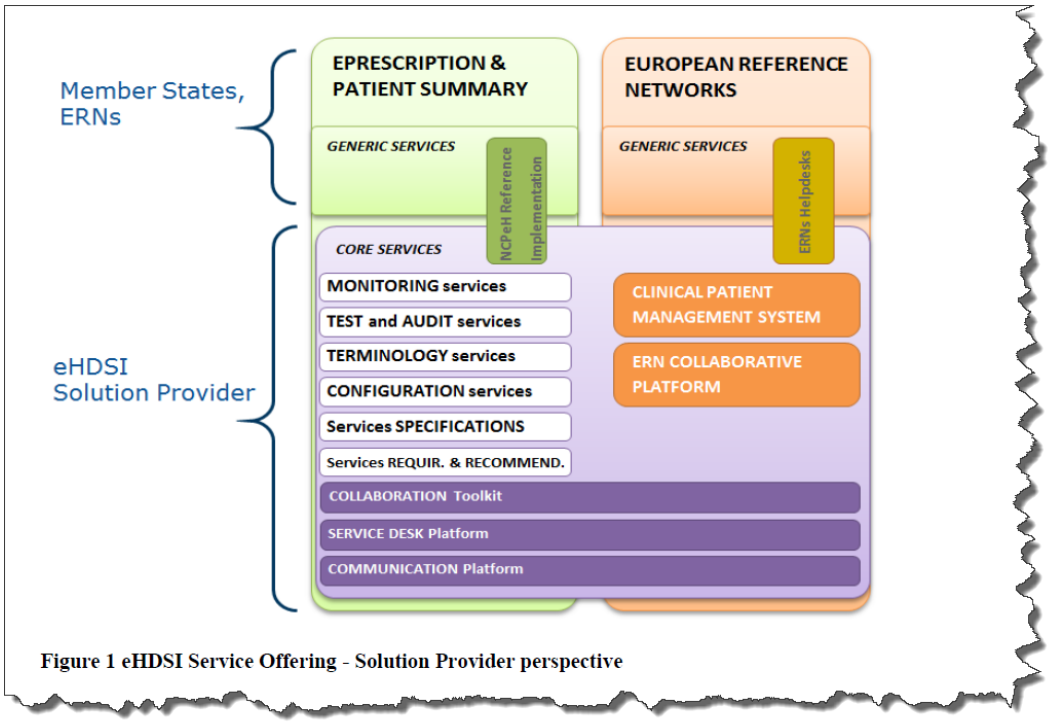

Figure 6 - eHDSI Service Offering from Solution Provider Perspective

[Note on the eHDSI infrastructure, page 2, Brussels, 14 November 2017]

The CPMS is the tool to be used by ERN multidisciplinary healthcare team on daily basis. The main high-level use cases are:

- Treating healthcare provider requires support to diagnose or treat a patient,
- Treating healthcare provider enrols patient in the CPMS and creates a new Panel,
- The Panel Lead invites other specialists to the panel to make their contribution,
- Panel members can collaborate effectively using the CPMS,
- Treating healthcare provider can attach DICOM images from their local disk and from the healthcare provider organization to the Panel,
- Treating healthcare provider can attach CDA files from their local disk and from the healthcare provider organization to the Panel,
- Data can be shared with research participants (invited panel members),
- The system monitors participation and reports against Key Performance Indicators,
- The System Administrator manages the system,
- The ERN Coordinator manages the data.

[Note on the eHDSI infrastructure, page 5, Brussels, 14 November 2017]

B.7. Patient Registries

In the context of eHDSI, patient registries have been considered a relevant asset for cross-border data-exchange concerning clinical research and HTA, especially in the context of rare diseases.

PARENT defined a patient registry as “an organised system that collects, analyses, and disseminates the data and information on a group of people defined by a particular disease, condition, exposure, or health-related service, and that serves a predetermined scientific, clinical or/and public health (policy) purposes. “ [JAseHN D5.3.3]

Jointly EXPAND/EUCERD/PARENT published a strategy paper in 2015 with a number of specific recommendations for future eHDSI use cases around rare diseases (RD). This includes

- extension of the Patient Summary with RD-related information
- supporting planned care through shared care records, possibly based on Health Care Encounter Report services (HCER)
- extending eID services to include identifiers for patients/research participants that enable linking of genome data with phenotypic information

The paper considers a strategic roadmap of activities supporting convergence between the eHealth domain and the relevant RD, ERN and Registry related activities, focussing on extensions of existing CEF eHealth DSI, as intermediate steps towards a unified conformant approach. [Exploratory Paper on eHealth Strategies and Roadmaps supporting European Reference Networks and Rare Disease Policies, EXPAND/EUCERD/PARENT, 2015]

A recent joint workshop RD-ACTION / EMA / DG SANTE workshop explored how to work together with the European Reference Networks (ERNs) in the field of complex and rare

diseases. The relevance of patient registries was mentioned in some contributions [European Medicines Agency, London, UK, 29/05/2018 - 30/05/2018].

C. Results of the topic and role driven Analysis

C.1. ReEIF

The Refined eHealth European Interoperability Framework [JAseHN D5.4.4] defines a model using six "levels" to describe the aspects of interoperability within large-scale projects.

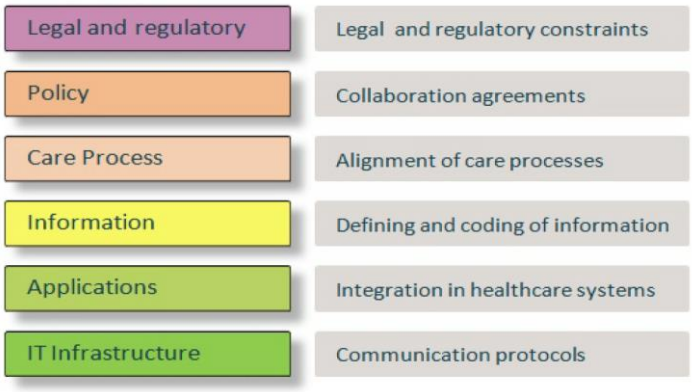

Figure 7- ReEIF levels

It also provides a Template for the description of high-level Use Cases and Realisation Scenarios so that all use cases can be described in the same manner. Besides the the functional description of the process (Use Case), the template requires a translation into technical process steps (Realisation Scenario). It aims at assigning existing profiles (e. g. IHE, PCHA) to the identified technical process steps of the use case. The ReEIF and this template look at the information content only at a relatively high level. Specification of information "units" that are exchanged is mentioned as a part of the technical process flow. No reference is made to the re-usability of artefacts across use cases.

C.2. Clinical content standards

[ch 3, VeH D4.2]

describes functional requirements of information flow for three selected scenarios. It states that the key investments will be semantic, but legal, organisational, technical aspects will also be implied. In general it is needed to: define the interoperable clinical content that is needed to support continuity of care for a portfolio of long term conditions.

[ch 4 VeH D4.2]

reports on methods for defining clinical content standards. As an example, the SemanticHealthNet project focused specifically on marshalling clinical and Informatics expertise (...), in part in order to better understand how domain experts and technical experts can best work together to develop specific semantic interoperability standards (see also eStandards D2.2). That methodology focuses on the development of clinical lead specifications and is deliberately agnostic about which of the presently used interoperability standards might be the “carrier” for the corresponding clinical information. In order to maximally align with good clinical practice, guidelines defined by professional societies must be used. It is recommended to represent the content in more than one of the main interoperability standards in use internationally. A similar approach should be taken to the terminology bindings,

preferably by centralising the definition of cross mappings and language translations so as to assure the quality of the health information being shared across Europe. However, for the time being, no central entity is taking the legal and medical responsibility of defining and sharing centrally defined cross-mapping.

Workflow steps in the good practice development of clinical semantic interoperability standards, described in eStandards D2.2

Due to overlap of content between disease areas, clinical model development should occur in parallel across health conditions. The development of clinical models and terminology bindings and language translations for a set of semantic interoperability asset bundles therefore needs to be undertaken in a coordinated and well-managed way.

Examples for this method are: HCIM, BgZ in the Netherlands (see ch. 9 in eStandards D2.2: Guideline: How to harmonise & establish selected clinical content)

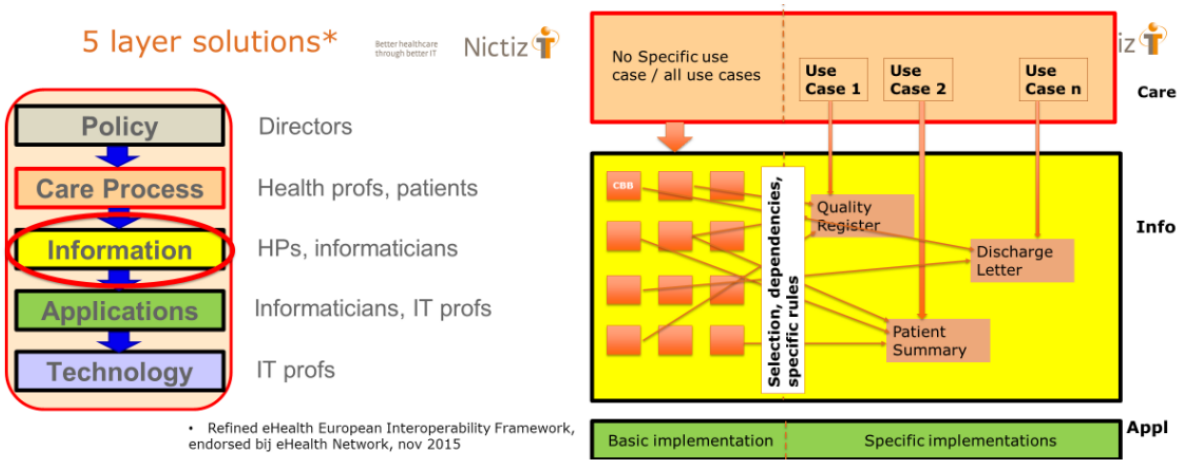

Figure 8 - Exemplary ReEIF usage

[eStandards D2.2] describes good practices in the specification of clinical content. It gives an overview of the clinical content specification methods used by selected relevant organisations in the field (IHE, SNOMED International, HL7, openEHR, PRSB)

C.3. (Technical) Gaps to be filled to run the User Stories over the CEF eHDSI

[ch 5 Gaps to be filled to run the User Stories over the CEF eHDSI., VeH D4.2] CEF eHDSI is de facto a technological infrastructure, enriched by semantic services, to allow the transformation and the interchange of clinical documents, while respecting the legal and organisational requirements, and the EC Regulations and Directives. **The infrastructure is intrinsically able to transfer any type of clinical document, being the transport mechanism independent and unaware of the transported document**: the translation metadata only contains the (..) code identifying the (type of the) transferred document.

The infrastructure and the support services include the Central (core) services which span from service provision to the change management process to keep specifications and implementations up-to-date.

The services fully specified and operationalised as CBeHIS by the CEF call 2015 and 2017 are:

- Patient Summary for unplanned care
- ePrescription / eDispensation

No other services, although specified and implemented in epSOS, like the Health Care Encounter Report (HCER), the Medication Related Overview (MRO) are, for the time being, included in the CEF eHDSI. The epSOS specifications of HCER and MRO have been removed from the Operation Ready Semantic Specifications.

The process to perform the change management under the CEF eHDSI is strictly governed by a procedure which fixes several steps to go from the initial change proposal, to a first high level governance approval, to Member States approval, with the support of the National Competence Centres, to the adoption at core level, by aligning the specifications, implementing the technical and semantic adaptation, releasing the updated version of the affected assets (i.e. the NCPeH, the MVC, or other core components), updating the testing tools.

Other epSOS use cases (HCER, MRO) also introduce other communication modes (push, pull), with legal impact and challenges related to identification of non-resident patients (“country B”).

There is the need to extend the clinical documents, e. g. for content from specialist encounters. As stated, this is not a problem for the CEF eHDSI. The challenge is to achieve an agreement among Member States for extending the specifications. Therefore, the authors consider a governing body that should assign to the International SDOs the task of standardising the contents of these documents.

The CEN Project on International Patient Summary might be the correct standardisation activity which will define the contents that will be adopted by the appropriate EU level governing body (bodies) and implemented both centrally and locally by Member States.

C.4. Re-usable component strategy for use case development

ISO/TR 19669 "Health informatics — Re-usable component strategy for use case development" This technical report is based on work of US ONC, Standards and Interoperability Framework.

Most Use Cases in healthcare informatics focus on information processes and flows, step-wise and integral to health care/business processes, often tightly interwoven with patient flows and provider/practitioner work flows [10.3]. Four basic categories of Use Case Components are evident: 1) Requirements, 2) Actors and Roles, 3) Scenarios, Events and Actions, 4) Data Objects and Elements [11]. These components can be catalogued and re-used. During Use case development, some components will be selected and re-used from the component catalog, other components will be selected from the component catalog and modified to fulfill new Use Case requirements, and still others will be new to this Use Case.

The completed and approved Clinical/Business Case Requirements serve as the basis for end-to-end traceability from statement of requirements to fulfillment in live production systems through the following phases:

a) Harmonization: selection of standards, implementation guides, implementable standards-based software modules and data objects, based on Use Case Requirements (UCRs)

b) Software design/development: building software solutions based on (to fulfill) Use Case Requirements;

c) Software testing and certification

d) Software deployment and implementation

e) Software in production use

To the extent that subsequent phases maintain continuity to the base Clinical/Business Case, it is possible to update the original Use Case Requirements as new discoveries are made or Scenarios conceived. The updates may be captured in a document or spreadsheet or be facilitated by a Use Case Authoring Tool (UCAT).

Table 13 End-to-End Progression Anchored at Use Case Requirements (example)

	Use Case			Software		
	Requirements Specification		Harmonization	Development	Testing/Cert	Implementation
			←←← Traceability →→→			
WHO	Non-IT Business/ Clinical Expert ↓	Expert User ↓		Developer/ Vendor ↓	Testing Body ↓	Business/ Clinical User ↓
HOW	Sketches ↓	Maps to ↓	Selects from ↓	Develops using ↓	Tests ↓	Implements using ↓
WHAT	Use Case Scenarios, Events	Actions, System Functions	Implementable Standards-Based Software Modules/Services			
	Use Case Data Req'ts	FHIM Data Objects	Implementable Standards-Based Data Artifacts (e.g., HL7 FHIR resources, messages, documents)			
Tool	Use Case Authoring Tool (UCAT)		UCAT NIST IGAMT	[Vendor]	NIST TCAMT	[Enterprise]
	Feedback at each Stage					

Figure 9 - Exemplary End-to-End Progression anchored at Use Case Requirements

Note that the items in the "Tool" row are quoted as an example. For eHDSI they might be translated as follows: Harmonization = ART-DECOR, [Vendor] = Solution Provider; NIST TCAMT = IHE Gazelle; [Enterprise] = operation by Member States.

C.5. Improve semantic interoperability in the EU

[Discussion note on eHealth Interoperability and policy actions to improve semantic interoperability in the EU through eHealth standards from the European Commission (DG SANTE)]

Proposes a way forward to achieve enhanced eHealth interoperability. Achieving health policy ambitions requires interoperability specifically through standards. However, when addressing

health policy ambitions health data interoperability is often presumed, rather than addressed explicitly as an integral part to attaining these ambitions

Recommendation: Create a permanent cooperation between national interoperability and semantic experts as a subgroup of the eHealth Network. The national interoperability and semantic experts (typically members of the National Competence Centres) should have a national mandate to work on interoperability and standards at EU-level. This group should have the mandate to strive for better semantic interoperability in the EU through the alignment of eHealth standards. It should also address the need to exchange on common semantic challenges. This involves deciding which use-cases are of high priority and promising for the coming 3 years and are at the same time in line with the ambitions of the European Commission (i. e. developing and maintaining a roadmap). It is stated that use-cases can be de-composed in "technical and semantical terms". The platform can serve to align semantic needs from all other health projects established by the EU (for instance on rare diseases) and by doing so minimize the overall effort and resources while maximizing the effect not only for specific projects but for the overall EU health care enhancement. In a stepwise approach they should pick up the challenges in cooperation towards alignment or convergence between the ways Member States document clinical processes.

The paper also mentions the possibility to facilitate the storage and dissemination of reports/studies/project results concerning eHealth interoperability and standards, e. g. as a follow-up to JAseHN D7.1.1 concerning a "Report on the establishment of a platform for the sharing of national eHealth strategies" (as part of eHealthAction).

C.6. Adoption challenges and success strategies

[ch 3 Investigating adoption challenges and success strategies, VeH D3.2]

The document investigates adoption challenges and success strategies. It elaborates on four items – governance, financial management, organisational culture, and non-financial incentives – as a list of challenges that need to be overcome in order to ensure the on-going sustainability of CEF-related systems and services.

Governance and regulation: MSs collaborate in three roles: eHN, JAseHN/eHAction, eHNCP. In this context the role of the CEF could be further specified in relation to the eHealth domain, and in terms of the tasks that it can “own” (i.e., for which it is responsible or accountable), so as to drive forward the development of interoperable assets and the implementation of interoperable services. [p 31] Regulation: majority of these needs are recognised and on-going efforts are made by the EC or eHN to deal with such needs, but much more support documentation is needed. Recommendation to support commissioning and procurement on national and local level (single GP). The uptake of guidelines and profiles could certainly benefit from being accompanied by relevant financial incentives. There is a need for technical education amongst procurers. Shifting influence to procurers and users.

Further topics are investigated in the chapter, such as:

- Care process interoperability and organisational culture (respect national autonomy)
- Non-financial incentives
- Barriers and Success factors

C.7. Business Model, Value Chains

VeH D2.3 "Business model report for CEF sustainability up to and beyond 2020" presents a business model that focuses on the sustainability of the European eHealth Digital Services Infrastructure (eHDSI). It suggests the need to define a general approach to the kinds of cross-border use cases to be supported. **The report assumes that National eHealth projects have so far focused more on establishing the infrastructure than on sharing clinical content and sees this as a business opportunity.** The proposed key activities include "Update and evolve centralised knowledge services and interoperability assets", "Develop and maintain extensions to new cross-border eHealth services, Develop conformity assessment services"

In ValueHealth D5.2 "VALUe(HEALTH) Chains: Consensus Statements of key Value Chain participants on sustainability initiatives" the authors analyze a selection of "value chains" in the continuum of EU cross-border services. In each case they assign the roles of funders, providers, users and beneficiaries.

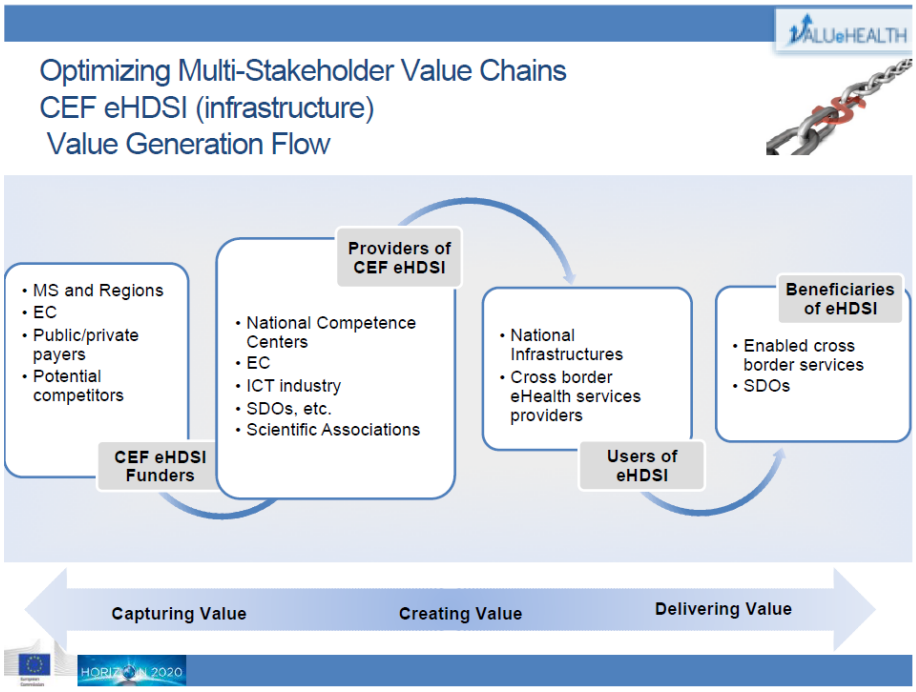

Figure 10 - Value chains and value generation flow of eHDSI

VeH D5.3 elaborated a two-year Business Plan for a proposed EU eHealth Business Unit. Activities are proposed to support cross border eHealth Services for current and future use cases.

C.8. Recommendations for adoption and incentives roadmap

[ch 6 VeH D3.2]

The final section of the deliverable highlights the importance of three strategic areas for the future work of the CEF. The three areas are as follows:

- Strategic area 1) Foster innovative use of health data
- Strategic area 2) Reinforce clinical engagement

- Strategic area 3) Evidence and promote the value of interoperable eHealth solutions

Each strategic area lists either what it does (the "how") or what its issues are; a set of objectives; specific tasks / measures; a set of activities (about three); and the relevant instruments that could be suggested to support these activities.

C.9. Stakeholders, Alliances, SDOs

The need to reach out to and interact with other groups is mentioned in various publications. As an example, the creation of a platform where focused dialogue and exchange amongst stakeholders can take place is addressed in [VeH D5.1].

Also the project eStandards arrived at detailed recommendations for allowing greater collaboration across the healthcare spectrum, bringing in the views of all users – citizens, healthcare workforce, researchers, vendors and health systems (purchasers). [eStd D3.5 Recommendations on SDO on ways of working in harmonization of information structures and clinical content]

C.10. Engaging with health professionals

[ch 4 Engaging with health professionals, VeH D3.2] The chapter highlights the concerns that continue to be expressed by healthcare professionals vis-a-vis receiving and dealing with patient summary data that comes from across borders and from other countries, professions, and occupations.

Liability issues relating to eHealth: While some European-level legislation has an impact on eHealth, there is no specific European legislation dedicated to the liability for (eHealth-related) products and services or (data) that are supplied through such applications.

The authors suggest that examples for potential action could include, e.g.:

- New concepts in liability, e.g., multiplayer liability.
- The adoption of EU level standard contract guidelines seeking to identify the various parties involved in delivering eHealth services; they could also establish the various liabilities that each party should accept.
- Whether specific guidelines on eHealth services could be drafted under provisions for a Code of Conduct based on Directive 2000/31 (The Electronic Commerce Directive).

The authors quote work from Andoulsi & Wilson (2012), that in summary ended their survey of EU-level legislation oriented towards liability by encouraging the establishment of a much firmer legal basis for the sale of eHealth goods and provision of eHealth services. The express intention would be to create the necessary legal certainty on the part of healthcare professionals and patients that would drive market confidence in eHealth across the EU.

More specifically, the Healthcare professionals' role in relation to the eHDSI patient summary is investigated. It is imperative that healthcare professionals understand that the primary application of this patient summary is to provide them with a dataset of essential and understandable health information to deliver safer patient care. Furthermore, healthcare

professionals also need to understand the value of the summary as a clinical tool i.e., more precisely, what the Patient Summary is and what it is not, and how it was created.

After reviewing how liability issues were tackled in epSOS, they discuss patient summaries being extracted automatically vs. being "signed off" by a medical practitioner. As a result, health professionals in each country will require to receive clear statements

- How to use information that comes from another country / other countries, and how to act on that data.
- Professional guidance, including formal assurances about medico-legal liability, when it comes to both the communication of patient summary information and the receipt and use of summary data originating from elsewhere.
- Legal and professional accountability liabilities if they use cross-border information in decision making and it proves to have been incomplete (such as in a partial medication list), inaccurate, or to have been wholly in error (such as if information is provided for the wrong patient).
- How to face workload challenges i.e., reducing duplication of data entry.

As a result, with specific reference to future CEF and post-CEF related work, it is important to:

- Include professional associations as stakeholders in the work of the CEF 2018-2021 and post-CEF.
- Professional accountability in the contexts of use of cross-border patient data.
- Contribute relevant details in professional codes of conduct, behaviour, and ethics.
- Reach a specific cooperation agreement on e.g., the diabetes use case and on temporarily held data.