eHAction

Joint Action supporting the eHealth Network

D6.1 Roadmap on future eHDSI use cases and features

WP 6 Enhancing continuity of care

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For Discussion

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To prepare construction and maintenance of an eHDSI Roadmap on future use cases and features of the NCPeH, this document proposes a collaborative way forward. The roadmap is based on the current use cases and their timing.

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Acronyms and Abbreviations

Acronym	Description
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
CBeHIS	Cross-Border eHealth Information Services
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)
ESO	European Standardisation Organisations (CEN, CENELEC, ETSI and their members)
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	eHAction – 3rd Joint Action supporting the eHealth Network
eHDSI	eHealth Digital Service Infrastructure
eHMSEG	eHealth Member State Expert 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
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 Dispensing 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 Clinical 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).
ID	Identification
IHE	Integrating the Healthcare Enterprise - a non-profit organisation that aims at improving the way computer systems share information

HCER	Healthcare Encounter Report
HL7	Health Level Seven International - a not-for-profit, ANSI-accredited standards developing organisation 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 Programme
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.
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
PCP	Pre-Commercial Procurement
PPI	Public Procurement of Innovation
PS	Patient Summary
RD	Rare Diseases
ReEIF	Refined eHealth European Interoperability Framework
SDO	Standards Developing Organisation
SNOMED CT	SNOMED CT or SNOMED Clinical Terms is a systematically organised computer processable collection of medical terms providing codes, terms, synonyms and definitions used in clinical documentation and reporting
UCAT	Use case Authoring Tool
UCR	Use Case Requirements
WP	Work Plan, Work Package

Executive Summary

This document, eHAction deliverable D6.1, contributes to an eHDSI Roadmap on future use cases and features components and services including a proposal for a timeline. The document provides guidance and recommendations for activities on European, national and regional levels. A draft methodology for the roadmap was submitted to the eHN in November 2018 for information and feedback [1]. The refinement phase of the roadmap included two workshops; a final consolidated Deliverable D6.1 will be submitted for the eHN meeting in June 2019.

The envisaged roadmap comprises activities centred around reusable "features" or interoperability assets. In order to be positioned for a future wider range of use cases, preparatory and accompanying activities are necessary that enable the implementation of future use cases within a reasonable timeframe and with minimum effort. It is necessary to start with activities that enable the reuse of knowledge, components, and clinical content definitions – preferably building on solutions and governance processes that are already established and have proven useful within and between MS/C. This document proposes such activities. The roadmap forms a bridge between strategy and implementation, it does not by itself define the strategy or prioritise the strategic goals.

The European eHealth DSI, like other large-scale eHealth projects, requires a multi-stakeholder governance. In a joint coordination process, involving actors on European, national, and regional level, each stakeholder should be able to intervene at the appropriate level: healthcare professional organisations, national competence centres, industry actors and patient groups, as well as other authorities with competence in relevant areas.

Identification and Prioritisation of Use Cases

Objective:
Develop and support strategies and activities to foster exchange and innovative use of health data.

Recommendations:

- Create business models around the EHRxF recommendation, considering new use cases that benefit from using the recommended formats.
- Extend the current use cases (PS and eP/eD) with Laboratory and Imaging data, also consider inclusion or referencing of such data within Hospital Discharge reports.
- Align the planning of new use cases with the availability of corresponding national or regional data services and service consumers.
- Demonstrate the value of interoperable solutions by generating and disseminating new and robust evidence of value for cross-border eHealth services [2].
- Incentivise national initiatives, including funding of cross-border collaboration of NCCs, and leverage of established internationally connected communities (e. g. ESOs).
- Address semantic interoperability for cross-border networks for public health and research (e. g. registries, networks for rare diseases) as an integral part of eHDSI service provision.
- MS/C should consider the added value of reusing cross-border clinical data within national projects, for example: supporting research and public health use cases.

- Encourage, inspire and promote solutions to use EHR to support preventing unnecessary treatment and expenditure.
- Develop and implement specific measures at national and cross-border levels to foster public and private stakeholders to prepare and open or participate in procurement processes, especially PCP and PPI of cross-border solutions.

Communication, Community and User Engagement

Objective:
Stimulate the building and uptake of interoperable healthcare solutions by creating awareness and enthusiasm.

Recommendations:

- Provide knowledge on used and recommended standards, their history, together with tools for development, improvement, profiling, and adoption for new use cases and solutions.
- Enable healthcare providers and clinical experts to work with semantic and IT experts in order to co-create solutions for new use cases.
- Create visibility of cross-border use-cases to health IT implementers, including access to specifications and tools for testing and development.
- Offer training and certification for implementers, whenever standards and profiles are published or updated during implementation of a new use case.
- Connect initiatives on national level, e.g. by publishing information about national stakeholder and standardisation organisations in eHealth, and their contacts at EU and national level. This could be jointly created by eHAction and stakeholder organisations.
- Identify or establish national centres for terminology, coordinating and participating in collaboration between EU member states, including providing peer support, joint multi-national projects, etc.

Policy, Governance and Strategy Definition

Objective:
Develop a collaborative European eHealth governance.

Recommendations:

- Establish processes for joint coordinated, multi-stakeholder-development of eHealth solutions, involving healthcare ICT competence centres (NCCs) and SDOs, employing available expertise and established consensus processes on national and international levels. Follow successful examples on national and regional level.
- Provide documentation of available standards and the history of their creation.
- Plan progress towards interoperability, creating and maintaining a roadmap with achievable milestones. Monitor progress independently, through periodic review of outcomes.

- Provide means for electronic identification and authentication of patients and care providers, to support authorisation including patient consent.
- Develop guidelines and/or regulations to encourage healthcare providers to digitally capture and reuse structured health data.
- Consider regulatory requirements to enhance the use of standardised concepts along the value chain, e. g. for laboratory and radiology reports.
- Identify bottlenecks to provide focused intervention areas where different EU, national, regional and local funds can be utilised in the optimal combination through actions and calls.
- Foster agreement between MS/C on legislation to enable access to cross-border eHealth services.
- A joint coordination process towards new use cases and features should take into account the operational requirements of currently established solutions under the CEF eHDSI project.

Interoperability Assets and Solutions

Objective:
Enhance interoperability with existing and emerging health IT systems in member states

Recommendations:

- Create and maintain a growing catalogue of re-usable solutions that support multiple use cases and their requirements.
- Specify consented building blocks of clinical information. Utilise results based on the eHN guidelines (e. g. CEN-IPS) as building block repository, based on eHN guidelines. Provide tooling for collaborative development and endorsement.
- Technically enable the cross-border transport of new clinical content, beyond the currently supported PS and eP/eD document types.
- Extend scope of secure cross-border exchange beyond direct patient care use cases (e. g. for research, public health), including consideration of legal implications.
- Agree on common terminology system for administrative data and metadata, to establish common understanding, trust, and integration. Required are translations of data item names in the information models, definitions, section headings, text display labels, etc.
- Agree on structures for imaging reports.
- Make presentation of clinical information to users consistent across use cases.
- Provide modular tools for testing and/or assessment, to enhance the quality assurance of the various artefacts.

Introduction

In its 12th meeting the eHealth Network adopted its Multi-Annual Work Programme (MWP) for the years 2018 to 2021 [3]. 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 eHAction is in charge to deliver proposals, recommendations and methodologies on how to proceed with already ongoing activities and to scope and initiate new ones in the defined priority areas and topics. However, eHAction might not be the only contributor to the MWP of the eHealth Network[1].

Task 6.1, Support of the eHDSI update, aims at commitment on sustainable usage of NCPeH among and between Member States and other participating Countries, supported by services provided by the European Commission. Besides member states of the European Union, EFTA/EEA countries may also 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” or “MS/C” in this document with the meaning “Member States and other participating Countries”.

This document, eHAction Deliverable D6.1, contributes to an eHDSI Roadmap on future use cases and features of components and services including a proposal for a timeline. The document provides guidance and recommendations for activities on European, national and regional levels. A draft methodology for the roadmap was submitted to the eHN in November 2018 for information and feedback [1]. The refinement phase of the roadmap included two workshops; a final consolidated Deliverable D6.1 will be submitted for the eHN meeting in June 2019.

The envisaged roadmap comprises of activities centred around reusable “features” or interoperability assets. In order to be positioned for a future wider range of use cases, preparatory and accompanying activities are necessary that enable the implementation of future use cases within a reasonable timeframe and with minimum effort. It is necessary to start with activities that enable the reuse of knowledge, components, and clinical content definitions – preferably building on solutions and governance processes that are already established and have proven useful within and between MS/C. This document proposes such activities. The roadmap forms a bridge between strategy and implementation, it does not by itself define the strategy or prioritise the strategic goals.

The scope is not limited to the current CEF funding period of eHDSI, described in the CEF work programme 2018 [4]. The goal is to foster the alignment and development of future use cases and features for eHDSI beyond 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’[5].)

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

Purpose: The goal is to support the digital transformation of health and care in the Digital Single Market: empowering citizens and building a healthier society [6], based upon a well-defined set of rules, agreements, standards and profiles.

[1] Quotes from eHealth Network Multiannual Work Programme 2018-2021 [3]: 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.

The intention to define and implement a roadmap for eHDSI is to foster the sustainability and uptake of the eHDSI across all interoperability levels, involving all stakeholders. The recommendations for the roadmap are designed to identify the activities to be considered when making a given strategy actionable. By identifying and recommending actionable and measurable roadmap activities, it also serves as a tool to estimate the required resources that are needed to deliver new use cases and features.

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

Governance: The European eHealth DSI, like other large-scale eHealth projects, requires a multi-stakeholder governance. In a joint coordination process, involving actors on European, national, and regional levels, each stakeholder should be able to intervene at the appropriate level: healthcare professional organisations, national competence centres, industry actors and patient groups, as well as other authorities with competence in relevant areas.

The recommended activities described in the following sections[2] are based on desk research and incorporate results from two workshops. The workshops investigated selected areas for new use cases, using the ReEIF [8], in order to arrive at specific recommendations for their implementation. The selected areas were: Patient Summary, ePrescription/eDispensation, Laboratory Results, Medical imaging and reports, and Hospital Discharge reports. This selection is based on the recent recommendations for a European Electronic Health Record exchange format [6].

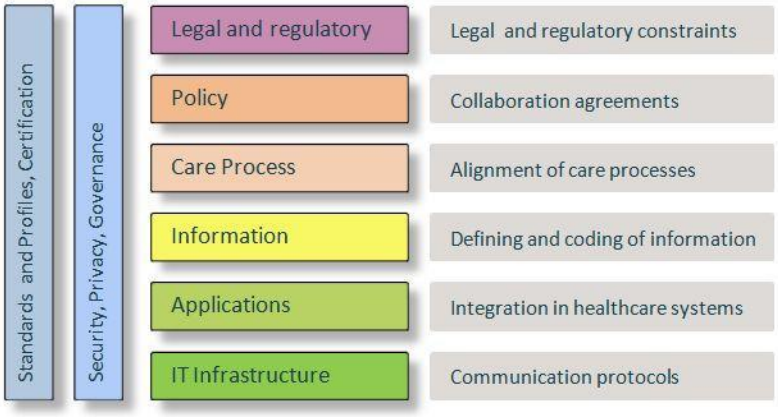

Figure 1*: Interoperability layers of the ReEIF (from Antilope D1.1* [9]

[2] The format of the following sections and recommendations was inspired by other recent publications [7].

Definitions

A number of analysed sources mention and recommend a "use-case-driven" methodology for a future eHDSI evolution [10]–[12]. However, there seems to be some confusion about what "use cases" are in this context. For the purposes of this document, the following terms and definitions apply, specifying a hierarchy of concepts for the various levels of requirements specifications and solutions:

Business Case: Overall description of a need for information sharing within and across healthcare organisations using Health IT, often linked to health objectives. It is written by users in a natural language and may include several **interoperability use cases** [13]. (Example business cases: "Medication Management", "Emergency Response", "Immunisation", "Citizen empowerment", "Clinical research") A business case describes the needs and objectives of stakeholders. Target audience: Decision makers.

Interoperability Use Case: Description of a specific example of Health IT use for information sharing within the **business case**. Several **interoperability use cases** may derive from the **business case**. It includes depiction of business actors (humans) and technical actors (systems), scope, and workflows of tasks performed by health professionals and associated data flows. It is written in a natural language and may include several **realisation scenarios** [13]. (Example interoperability use cases: "ePrescribing and eDispensing", "Exchange of Patient Summary", "Immunisation information sharing") An interoperability use case describes the needs of users interacting with a system, in order to create value within a given business case. Target audience: Health professionals.

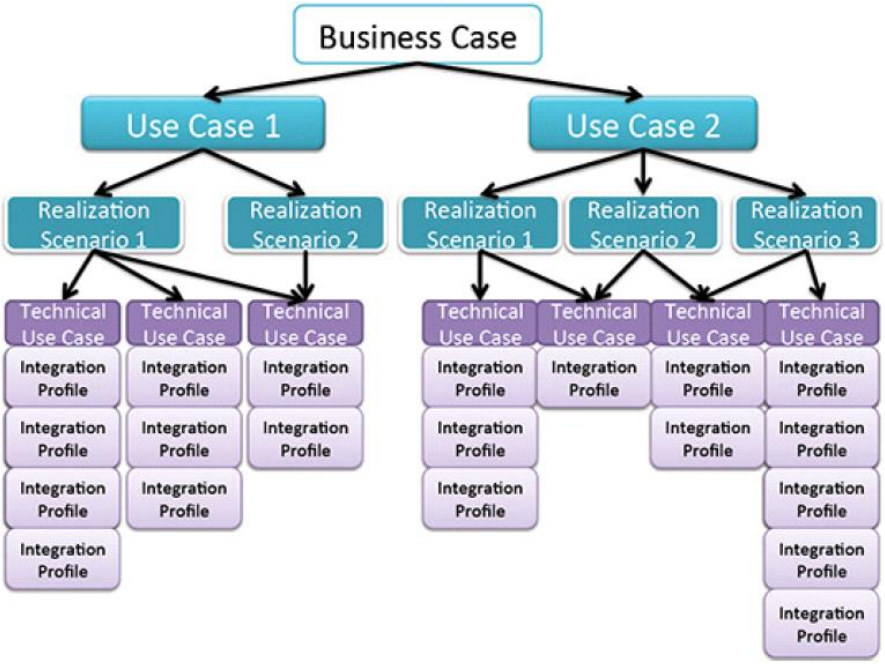

Figure 2*: Hierarchy of concepts* [14]

Realisation Scenario: Description of a subset of workflow steps and data requirements within the interoperability **use case** from the business actors' perspectives as well as specific **transactions** of

technical actors (systems) to support workflow steps and data requirements. It is written in a natural language and may include several **technical use cases** for the selected **transaction** [13]. (Example realisation scenarios: Provider Access to Images) A realisation scenario describes the requirements for those who have to implement a solution. Target audience: Project managers, system architects, and implementers.

Feature: Solution for one or more **realisation scenarios**. A feature contributes to a solution to stakeholder needs (Business case) or user needs (Interoperability use case) within the scope of a realisation scenario. A feature describes high-level functionality, it characterises the behaviour of the system. Target audience: Decision makers.

Transaction: Exchange of specific information (content) between IT-systems that participate in a realisation scenario. (Example transactions: send-receive ePrescription, request-receive authentication data, data query).

Technical Use Case: Description of needs for a specific **transaction** between technical actors (systems, IHE actors) that supports one or more **realisation scenarios**. They are written in technical language and may include several implementation options enabled by individual standards selected for the **transaction** [13]. (Example technical use cases: Provider Directory, Cross-Community Access, Mobile Access to Health Data, Patient Identity Management) Target audience: System architects and implementers.

Roadmap: Realisation plan view on required activities (at EU and MS level) aiming at the implementation of **features** that offer solutions for selected **interoperability use cases**. This roadmap spans currently supported use cases and solutions for multiple new use cases. The prioritisation of new use cases is subject to the strategic decisions of the eHN. This roadmap supports such strategic decisions by delivering a structured view on the conditions and required activities that impact implementation, taking into account all levels of the ReEIF [8]. Target audience: Decision makers and Project managers.

Recommendations for future use cases and features

Opportunities and challenges for future use cases and features of eHDSI are highlighted in the following sections. The material is compiled from desk research, as reported in the Annex of the previously published background document [1], and from results of the two interactive workshops of eHAction Task 6.1. The chapter is organised in four parts, that reflect different subject areas across all ReEIF levels where joint coordination appears necessary and should be organised according to the specific needs of the collaborating parties and stakeholders. Recommendations for moving forward are derived from this analysis, for each part.

1.1 Identification and Prioritisation of Use Cases

Objective:
Develop and support strategies and activities to foster exchange and innovative use of health data.

1.1.1 Introduction

The current use cases for cross-border exchange, ePrescription/eDispensation and Patient Summary, succeeded in establishing governance and solutions, connecting the MS/C. To build on those results, agreement on the steps towards additional use cases is required. Reviewed literature discourages to approach the realisation of each new use-case in an isolated fashion from functional requirements to implementation.

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, organisational and semantic challenges that are needed to deploy such a use case. The dependencies, if any, on other use cases should be analysed.

Reviewing reusable use case components from previous work (European, national or regional), and assessing available resources for implementation and deployment, the eHN can agree on the next steps. The recommendations of the current document contribute criteria for the assessment, prioritisation and selection.

Other EU projects have suggested use cases and business cases; a selection is listed in Appendix A of this document. Additional use cases can be derived from the data exchange formats that were recently recommended by the European Commission [6].

With a view on the ReEIF [8], this section corresponds to the ReEIF “Policy” level, that addresses contracts and agreements between organisations that have to be made. The purpose and value of the collaboration must be set. Trust and responsibilities between the organisations are formalised on the Policy level. In governance documents the governance of collaboration is anchored; as use cases are related to clinical problem descriptions, interactions of “Policy” with the “Care Process” level must be considered.

Use cases for (cross-border) health data sharing are embedded in business models. They support the creation of value chains connecting the participants. The topic of creating value chains in eHealth was extensively investigated by the Horizon 2020 project VALUeHEALTH [2].

As citizens and clinicians are increasingly enabled to securely share medical information, alignment between solutions for broader business models like PS or eP and more specific business models for

smaller groups or specific problems (e. g. networks for patients with rare diseases) becomes an attractive option, reusing the same clinical information elements.

Relevance of new use cases, features, and eHDSI improvements from a citizen perspective, will be judged based on improved medical outcomes and individual benefits as a patient. A high degree of information re-use between national systems, as well as between specialised research and general care will contribute. Re-use of shared information across use cases appears to be essential.

1.1.2 Opportunities

As a step towards use cases around the EHRxF recommendations, extending the current use cases is a promising first step:

Laboratory data: Extend PS by including selected laboratory data. For example: renal diagnostic results provide relevant information in the context of Medication treatment.

Imaging information: Extend PS by image links, consider diagnostic and non-diagnostic images. Add data definitions for reporting relevant observation results in PS (and Discharge Summary). Consider use cases and solution scenarios for cross-border access of images.

Hospital Discharge report: Explore the similarities and differences with Patient Summary and IPS use cases; this promises a high degree of reusing existing data definitions.

ePrescription: Evaluate opportunities for extending ePrescription to support emerging IDMP standards, alignment with corresponding Horizon 2020 projects is an option.

Patient Summary: Investigate options to adopt results of the "International Patient Summary" (IPS) project, consider the IPS FHIR format as a possible pathway to broader adoption.

Uptake of the EHRxF recommendations in existing use cases opens up the possibility to move from mere exchange formats to implementable use cases that employ such formats. There are good practices of solutions to use EHR to support preventing unnecessary treatment and expenditure, e.g. EHR alert helps provider reduce blood transfusion rate and save costs[3].

There is a need for data exchange beyond the immediate care process: cross-border lab services, radiology second opinion, clinical research and public health.

Structured clinical data are valuable for international research projects, quality registries, public health, surveillance, decision support and so forth. This widens the scope of eHDSI beyond immediate patient care.

Solutions for European cross-border use cases focusing on specific diseases, registries, and data for clinical research are not yet coordinated with developments in other areas of eHDSI.

New use cases create additional value by enabling national systems to import clinical data into national infrastructures and using the data for various purposes.

Funding for national eHealth initiatives should favour the development of internationally aligned solutions and cross-border collaboration. This could be coordinated by the national competence centres.

[3] As an example: Cerner EHR alert helps Missouri provider reduce blood transfusion rate, save $1 million [Bill Siwicki, April 01, 2019 Healthcare IT News, www.healthcareitnews.com]

1.1.3 Challenges

Lack of secure positive identification of patients and health professionals across borders.

Heterogeneous regulations across Europe regarding authentication, authorisation and privacy.

A wide variety of incompatible formats and (sub-)standards.

Licence fees for access to some standards.

Procurement of cross-border solutions has not yet arrived at a free market, where innovative IT vendors compete. Various approaches have been tried in the effort to foster co-creation in the frames of Pre-Commercial Procurement (PCP) or Public Procurement of Innovation (PPI) projects co-financed by Horizon 2020.

The service portfolio of Cross-Border eHealth Information Services (CBeHIS) relies on the availability of data on the national or regional level.

The generation/retrieval of information for use cases like PS is implemented in rather different ways, ranging from manual entry to automatic extraction from national EHR systems.

1.1.4 Recommendations

Create business models around the EHRxF recommendation, considering new use cases that benefit from using the recommended formats.

Extend the current use cases (PS and eP/eD) with Laboratory and Imaging data, also consider inclusion or referencing of such data in Hospital Discharge report.

Align the planning of new use cases with the availability of corresponding national or regional data services and service consumers.

Demonstrate the value of interoperable solutions by generating and disseminating new and robust evidence of value for cross-border eHealth services [2].

Incentivise national initiatives, including funding of cross-border collaboration of NCCs, and leverage of established internationally connected communities (e. g. ESOs).

Address semantic interoperability for cross-border networks for public health and research (e. g. registries, networks for rare diseases) as an integral part of eHDSI service provision.

MS/C should consider the added value of reusing cross-border clinical data within national projects, supporting e. g. research and public health use cases.

Encourage, inspire and promote solutions to use EHR to support preventing unnecessary treatment and expenditure.

Develop and implement specific measures at national and cross-border levels to foster public and private stakeholders to prepare and open or participate in procurement processes, especially PCP and PPI of cross-border solutions.

1.2 Communication, Community and User Engagement

Objective:

Stimulate the building and uptake of interoperable healthcare solutions by creating awareness and enthusiasm.

1.2.1 Introduction

The challenge is to align standardisation activities across countries, including stakeholders from the policy level as well as clinical experts.

Engagement with relevant stakeholders is indispensable to identify and review emerging technological and methodological innovation and to identify appropriate steps to achieve progress in the long-term exchange of healthcare information.

Formalised specification of data exchange formats together with international terminologies provide solution elements ("interoperability assets") that are usable for multiple eHealth interoperability use cases. Tools for development and conformance testing are available.

One central aspect is to enable a sustainable collaboration between the ReEIF [8] "Care Process" layer with other aspects of interoperability, as this is the source of specifying the functional and workflow requirements that drive other aspects of use case implementation.

In the case of terminology there are examples of establishing "National Release Centres" that are required to align national activities with international work [15].

Many national stakeholder organisations (payers, providers, patients, industry) also act internationally through their respective European umbrella organisations. International standardisation organisations are connected through the respective international SDOs and their national affiliates or member organisations. Examples are HL7, IHE, SNOMED International, CEN, LOINC and PCHAlliance.

The topic is also related to eHAction WP6 T6.3 (Report on eSkills for Professionals) [16]. This Roadmap could deliver input, and results from T6.3 could support the necessary availability of knowledge, skills and expertise.

The Horizon 2020 project *eStandards* has created valuable deliverables, including analysis of the interoperability challenges in healthcare and a proposal for a workable process to involve multiple stakeholders in jointly creating solutions [17].

The creation or identification of standards for solutions by experts complements the endorsement or enforcement of such standards by regulators. Communication and coordination between the two groups is essential.

1.2.2 Opportunities

Standardisation communities have already produced specifications and solutions for many eHealth use cases. The knowledge, often in the form of implementable specifications, is already there. It is necessary to make these assets known and accessible for future development of cross-border exchange.

For evaluating options for publishing and open access to assets, a collaboration with WP2 should be established. Stakeholders need to be identified and connected, modern platforms for collaborative work should be employed to connect communities.

There is a need to increase availability of expertise concerning recommended standards in order to support rapid implementation and deployment. This includes the decision-making processes for standardised solutions.

Training for implementers (architects, programmers) is required whenever standards and/or profiles are published or updated during implementation of a new use case. Certification programmes could be based on this.

National eHealth competence centres should be involved in targeting the identification of the meaningful medical concepts for each given context. This should be aligned with the long-term strategy developed by the eHN Common Semantic Strategy Task Force.

There is a need for data definition and terminology centres at national level. To build consensus between member states, cooperation between those national centres should be established concerning European cross-border eHealth.

Standards can function as a “memory” of consented solutions, they provide systematic knowledge management.

1.2.3 Challenges

Regulators and governments are not using the established SDO processes in eHealth to create consensus with stakeholders, build on best practices, maintain specifications throughout their lifecycle.

Engagement of domain experts, healthcare professionals, IT vendors, and patients requires incentives, which are rare in the current eHDSI, at least from an industry perspective.

1.2.4 Recommendations

Provide knowledge on used and recommended standards, their history, together with tools for development, improvement, profiling, and adoption for new use cases and solutions.

Enable healthcare providers and clinical experts to work with semantic and IT experts in order to co-create solutions for new use cases.

Create visibility of cross-border use cases to health IT implementers, including access to specifications and tools for testing and development.

Offer training and certification for implementers, whenever standards and profiles are published or updated during implementation of a new use case.

Connect initiatives on national level, e. g. by publishing information about national stakeholder and standardisation organisations in eHealth, and their contacts at EU and national level. This could be jointly created by eHAction and stakeholder organisations.

Identify or establish national centres for terminology, coordinating and participating in collaboration between EU member states, including providing peer support, joint multi-national projects, etc.

1.3 Policy, Governance and Strategy Definition

Objective:
Develop a collaborative European eHealth governance.

1.3.1 Introduction

This section corresponds to the "Legal and regulatory" level of the ReEIF [8], and also its interaction with "Policy" level: Successful implementation of new eHDSI features and use cases requires compatible legislation and regulatory guidelines that define the boundaries for interoperability across borders, but also within a country or region refined.

The task is to appoint governance, ownership and maintenance of eHDSI specifications and regulations on various levels, e. g. within and between the interoperability levels of the ReEIF. One goal is the establishment of a joint coordination process [6], aligning local and international activities, with their respective expertise and stakeholder engagement [18] [19].

The transition towards internationally interoperable solutions faces the fundamental question: How to connect country-specific national activities to the European goal of aligning those developments in order to create an ecosystem that supports local goals of patients and providers as well as the needs of the envisaged digital infrastructure that enables citizens and enterprises to act beyond national borders? eHAction WP8 "Integration in national policies & Sustainability" will contribute to this topic.

Elements for possible alignment of governance and stakeholder involvement were suggested by the eStandards project [17]: Interacting cycles of co-creation, governance, and alignment are suggested to connect the different stakeholders. The *eStandards* project emphasised the role of the standardisation organisations (SDOs) and their consensus-based and expert-driven processes in establishing sustainable governance models for eHealth.

While such joint and coordinated governance of eHealth standardisation plays a central role for establishing interoperable solutions, it must also be recognised that there is a difference between defining standards and endorsing or enforcing them. Taking governmental measures to incentivise or regulate the market involves public procurement, licensing and conformance certification issues, and all kinds of legal requirements to be considered. Future eHDSI use cases and features therefore require coordinated decisions and agreements also beyond the specification of international eHealth standards. Also, cooperating national competence centres for eHealth (NCCs) can contribute to the creation of shared principles, realisation scenarios and implementation guidelines.

In the course of putting the CEF-eHDSI solutions into operation, a dedicated multi-national governance model was agreed and established [20], primarily to ensure and stabilise the establishment of the first operational cross-border services for the two selected CEF-eHDSI use cases, ePrescription and Patient Summary. However, as this governance is tied to the needs of operational decisions, it may not be the best model for a governance that aims at evolving future new use cases.

A central strategic topic, albeit not eHealth-specific, is the establishment of agreed ID requirements, eID, consent, liability, trust: One example is the use of secure electronic identification and authentication means provided for in Regulation (EU) No 910/2014 (eIDAS). This topic may have different requirements for use cases targeting research, public health and health system planning.

Also consider GDPR requirements related to privacy, security. One suggestion is the "privacy-by-design" approach, to be supported by appropriate technical specifications. Requirements of secure sharing and access control have to be met by appropriate technical solutions.

Establishing a common view on clinical concepts, as currently materialised in the MVC (master value set catalogue) requires formal agreement between member states. Building on the results of the epSOS/EXPAND pilot project, this is a task that would benefit from a process that involves stakeholders on the national level. This is closely linked to the work of the "Common semantic strategy" work of eHN.

1.3.2 Opportunities

New use cases lead to new data definitions, requirements for workflow support etc. The new data definitions also need linking to terminologies. Similar challenges have already been met on regional and national levels, where expertise and collaborative processes involving stakeholders have been established and proven to be useful, typically connected to international standardisation processes. This suggests similar approaches on a European level.

Joint coordinated work with SDOs (local and international) should help to establish broad consensus and build on solid experience.

Progress towards interoperability needs to be monitored and feedback from solutions and users recognised, including potential for iterative improvement.

Identifying common priorities in MS/Cs, together with joint coordination of tasks, deliverables and milestones should support progress towards EU-wide interoperability.

Regulations promise measures for cross-border identification of patients and care providers.

In order to capture high quality structured data, healthcare providers must be incentivised and motivated. This can be achieved in a number of ways: fast and user-friendly data entry, decision support based upon the structured information to assist the healthcare professional, automatic reporting (quality registrations, benchmarking and management reports) and scientific research.

Additional players along the value chain may be motivated to contribute to the availability of unified concepts, thereby supporting interoperability (e. g. encourage laboratory suppliers to provide standardised analytics codes, to feed into the representation of clinical data).

Compare national strategies for common priorities and synergies to improve cross-border exchange of electronic health records (with WP8 processes and tools).

The organisational layer of eHealth interoperability needs to be developed, as recommended in a recent study [21]: "for instance supporting the harmonisation of national legislation, more efficient cooperation and coordination mechanism among Member States, and identifying and involving policy-making stakeholders".

The strategic role of standardisation organisations and their members for the development of future European ICT solutions is emphasised in publications of the Commission, addressing a broader scope than healthcare [22], [23], [24].

1.3.3 Challenges

Existing divisions in financing, management structures, and healthcare institutions hinder the transition to new ways of health and care provision.

Major disparities between countries regarding the legal situation are reported in an overview of the current national laws on electronic health records (EHRs) in the EU Member States [25].

Risk of stagnation of eHDSI where the Solution Provider together with MS have to allocate all available resources to implementing the current cross-border use cases PS and EP/eD.

Healthcare providers are not motivated to digital capture and access of routine health data. This is a complex issue with numerous causes, but it impedes development of data sharing.

1.3.4 Recommendations

Establish processes for joint coordinated, multi-stakeholder-development of eHealth solutions, involving healthcare ICT competence centres (NCCs) and SDOs, employing available expertise and established consensus processes on national and international levels. Follow successful examples on national and regional level.

Provide documentation of available standards and the history of their creation.

Plan progress towards interoperability, creating and maintaining a roadmap with achievable milestones. Monitor progress independently, through periodic review of outcomes.

Provide means for electronic identification and authentication of patients and care providers, to support authorisation including patient consent.

Develop guidelines and/or regulations to encourage healthcare providers to digitally capture and reuse structured health data.

Consider regulatory requirements to enhance the use of standardised concepts along the value chain, e. g. for laboratory and radiology reports.

Identify bottlenecks to provide focused intervention areas where different EU, national, regional and local funds can be utilised in the optimal combination through actions and calls.

Foster agreement between MS/C on legislation to enable access to cross-border eHealth services.

A joint coordination process towards new use cases and features should take into account the operational requirements of currently established solutions under the CEF eHDSI project.

1.4 Interoperability Assets and Solutions

Objective:
Enhance interoperability with existing and emerging health IT systems in member states

1.4.1 Introduction

The objective is the identification of separate interoperability assets and their related "activities", which then have to be bound to specific targets (use cases, functional requirements) in order to become measurable “work items” as actionable elements for a roadmap.

Providing an infrastructure for secure sharing of data, common models for the exchanged health information, and a set of mutually agreed definitions of clinical concepts are indispensable elements for an EU-wide sharing of health information. In the context of establishing the roadmap it is important that work on these elements is not repeated for each new use case.

Necessary activities to coordinate the creation of European solution elements and re-use it for new use cases are listed and described in the following sections. Implementation of technical solutions for infrastructure and information exchange involves IT vendors and healthcare information experts, who are typically active on a national level. It should be considered how a joint coordinated cross-border development can leverage their capabilities and competences. The compilation of such "interoperability assets" and related activities is non-exhaustive and should be reviewed and extended regularly.

Secure Exchange and Sharing

The current eHDSI use cases implement the retrieval of a PS or eP from another country and the sending of an eD document. There are a number of additional patterns of communication, that are not yet supported in the current use cases such as: push notifications, queries for specific clinical content, subscription of events, alert notifications.

Legal requirements like patient information, consent, provenance, agreed vocabulary for legal/administrative data elements (professional roles etc.) are implemented by technical solutions and infrastructure.

Methods for secure identification and authentication are essential, and not use-case-specific, usually not even specific for the healthcare domain.

Health and Care Information Models

A successful approach in several MS has been the specification of consented building blocks of clinical information. This is done on a technology-neutral level, in order to create a basis of consensus across participants, regardless of implementation: The goal is a "unified understanding" of clinical concepts (here: across MS/C). While this topic focuses on the structure of clinical information, and its related conditions and context, it has a close linkage to the topic of terminologies (see next section), in order to identify value sets for the data fields in such structures.

Connect national healthcare ICT competence centres for cooperation on the definition of these building blocks.

Since epSOS this approach is followed in sharing models between PS and eP/eD. The recently published CEN-IPS [26] lends itself as a building block repository, based on agreed eHN guidelines. Another example is the Dutch HCIM approach [27]. Utilise such initiatives as the starting point for a multi-use case information building block repository.

Tools for collaborative development and endorsement are available, and partially already in use for eHDSI.

A library of interoperable healthcare "building blocks" will support rapid implementation of new features and use cases. Implementable technical specifications provide reusable service components. Existing platforms should be used, in order to enable development and refinement of interoperable technical components, that can be tested and integrated.

Data may or may not be compatible with what is available or usable within an existing national eHealth infrastructure. Each member state participates in building consensus on cross-border exchange, but is at the same time challenged to organise a "national roadmap" towards making such information usable and retrievable from the national information systems.

Terminologies, Common Semantic Strategy

The "Common Semantic Strategy" Work Group aims at establishing a common semantic strategy for the standardised exchange of health information within the European Union, facilitating convergence of interoperability standards. For the roadmap the strategic alignment with a scope of several years has to be taken into account when identifying necessary work items on a shorter time scale.

In the context of the roadmap, the focus is on mapping from existing systems at national level, and on supporting migration concepts to concepts agreed on a European level for cross-border purposes.

Aside from an emerging joint governance, it appears useful to connect national healthcare terminology centres, following the idea of connecting the expertise of "national release centres" across countries [15] .

Access to the Central Terminology Server (CTS) is currently limited to participants of CEF eHDSI. For realisation of future use cases, access might be extended, and CTS could serve as a platform for the exchange of concepts and translations between MS/C.

Guidelines for the presentation of documents that contain narrative text and structured coded information need to be reviewed and extended to use cases beyond PS and eP/eD.

Re-usable use case components

In order to avoid duplicate work and reduce expenses, there is a need to create and maintain a growing catalogue of re-usable use case components. This should cover a large variety of interoperability assets ranging from specifications to software libraries implementing components. For planning implementations, it is relevant to know, where those interoperability assets are already implemented and in which context they are in use.

Structured capture of use case definitions and requirements enables identification of such components. They should be documented and made accessible in appropriate ways, enabling searching and commenting/feedback, serving as an information platform for a joint coordinated process. A standardised structured template to capture the requirements and elements of a use case (and suitable realisation scenarios) was developed by Antilope [9] and is part of the ReEIF [8].

For each use case the catalogue would include specifications of requirements, actors, roles, and transactions. All of them are potentially applicable beyond one specific use case. This catalogue should also include generic CEF building blocks, that are already employed outside of eHDSI, such as eID or eDelivery.

There already are some attempts to establish a repository for use cases [28] or interoperability assets [29] in existence. These can be used as a starting point for a European repository of interoperability assets.

1.4.2 Opportunities

This section gives an overview of the opportunities that the four domains of this chapter provide, in order to technically support the development of additional use cases and the potential to contribute reusable interoperability assets.

Secure Exchange and Sharing

Various data exchange patterns exist for cross-border communication. The conditions for information flow, the implications for privacy and security, and value propositions of additional data sharing patterns are to be investigated. Technical solutions are needed that are compliant to the legal and regulatory framework for identification, authentication and authorisation. Alternative data flows (eDelivery, mobile access) may be employed.

The existing infrastructure needs to be enabled to transport additional document types – Currently, the reference implementation is operational only for two specific use cases (PS and eP/eD), supporting secure transport of the related document types and data objects. For new use cases additional document types and data objects must be considered.

The scope of secure cross-border exchange could be extended beyond direct patient care, after considering legal implications (GDPR, purpose of use). Example use cases could address research data and public health.

The OpenNCP reference implementation with its “national connector” offers options to interface NCPs to other national systems (e. g. research, public health) to connect systems across borders.

Modules of OpenNCP are usable for testing and for developing other solutions (national or industry), including use of MVC/MTC tables for translation and transcoding.

The OpenNCP reference implementation is based on results of the epSOS pilot, there is the opportunity to review and update the system in view of additional eHDSI requirements. Review aspects of configuration, scalability: The reference implementation as well as the individual connections to national networks may need to be adapted in order to support new use cases.

Cross-border solutions for declaration of consent, access control or retrieval of data require consented high-level concepts that are independent of the actual data payload to be exchanged. Therefore, features for this kind of processing should be developed as a separate layer, that is independent of the clinical content exchange format(s) and specific use cases.

Support various methods of data capture (from primary systems, centralised, de-centralised institutional systems).

Health and Care Information Models

Starting from PS/eP/eD or CEN-IPS elements, small information blocks can be identified, defined and refined. Such processes have already started successfully in some member states, involving a range of stakeholders from healthcare professionals to IT experts. The opportunity to arrive at internationally reusable building blocks relies on establishing similar consensus-based processes also across national borders. This includes the detailed capture of the required semantic information content, as well as ready-to-use implementations for the exchange standards that are used on the technology layer.

Promising first opportunities to apply such agreed “building blocks” of health and care information models are: structured imaging reports and their elements, and hospital discharge reports, reusing elements from Patient Summary and/or IPS. This will directly support the envisaged agreement on interoperable EHR exchange formats.

There is a need for common understanding, trust, and integration. This could be served by translation of data item names in the models, definitions, section headings, text display labels,

including administrative data and metadata. Several initiatives are working on this in parallel: eHDSI-MVC, CEN-IPS and IDMP translations for national standardisation bodies. Such activities provide a good starting point for a joint and coordinated effort.

Shared libraries of data elements must be provided in a structured way, that enables implementers to generate interoperable and testable technical components. Technical platforms exist, that enable collaborative development and refinement of shared data elements (such as ART-DECOR, currently used as a tool for collaboration and publication of HL7 CDA R2 specifications within eHDSI as well as in a significant number of MS/C, or simplifier.net for FHIR specifications).

The availability of the HL7 CDA implementation guides in a machine-readable format is already employed within eHDSI to automatically generate documentation and test tools. Such use of formalised specifications can be further employed in additional ways (code generation, tools for configuration and presentation, code libraries), thereby enhancing functionality and reducing development and maintenance costs.

Terminologies, Common Semantic Strategy

Separate different modes of terminology use:

Clinical content and medical documentation are often related to clinical building blocks, where specific concepts are required. Laymen's views on coded clinical concepts may supplement those of health professionals.

Legal vocabulary (for professional qualifications, roles, consent, identification) can be established and maintained independent of clinical content. Regulations for privacy and security require agreed concepts and specific terminologies. Agreement on such concepts appears necessary to enable secure and GDPR-conformant data access, processing and exchange.

Presentation of clinical and legal information to users should be consistent across use cases. Style guides and dedicated vocabulary for user-interfaces can support usability. Examples are: labels for data fields, section and table headings, error messages.

Re-usable use case components

Requirement statements, if expressed in a use-case neutral way, can be listed and used to create a catalogue of requirements. Different use cases would select (and possibly modify) requirements from such a catalogue, instead of starting from zero for each use case.

Identify the main participants in the process. These can be individuals or organisational units. They are real-world parties. Also, the participating IT systems can be seen as actors that are connecting the participants and other actors. Participants and systems are best described in terms of their functional roles.

Describe the sequence of events and interactions between the participants on a functional level, capturing the different interaction steps of a process. The technical realisation of a process builds on transactions between systems and/or participants, that are potentially reusable across use cases to a high degree.

The information "units" that are exchanged between the actors during the process are to be identified on a functional level. They are typically reusable across different process steps and transactions, so they are process-independent assets.

The catalogue should also identify reusable services and components (starting from eHDSI central services and from NCP concept and implementation).

To enhance the quality assurance of the various artefacts, modular tools for testing and/or assessment are needed. This includes, but is not limited to technical components, clinical content, requirement specifications, legal agreements. Such tools should be accessible by all interested parties.

Generation of validation reports to monitor progress of implementations and reuse of assets. This will also provide feedback to requirement specifications.

1.4.3 Challenges

Health systems are organised differently in the various EU member states. This leads to development of isolated solutions that often result in difficulties exchanging and using data across national (or regional) borders. Incentives to follow EU wide interoperability strategies are limited.

EU wide coordination is often limited to government-driven activities. This may preclude access of regional or national actors to innovative development on an international scale. While SDOs are present and active in practically all member states, they are not perceived and promoted in their role as mediators between local and international activities.

Experts and SMEs are typically involved in only a subset of domains.

While some countries start aligning with international standards, accessibility of suitable and implementable “interoperability assets” is still limited on a European scale.

1.4.4 Recommendations

- Create and maintain a growing catalogue of re-usable solutions that support multiple use cases and their requirements.
- Specify consented building blocks of clinical information. Utilise results based on the eHN guidelines (e. g. CEN-IPS) as a building block repository. Provide tooling for collaborative development and endorsement.
- Technically enable the cross-border transport of new clinical content, beyond the currently supported PS and eP/eD document types.
- Extend the scope of secure cross-border exchange beyond direct patient care use cases (e. g. for research, public health), including consideration of legal implications.
- Agree on a common terminology system for administrative data and metadata, to establish common understanding, trust, and integration. Required are translations of data item names in the information models, definitions, section headings, text display labels, etc.
- Agree on structures for imaging reports.
- Make presentation of clinical information to users consistent across use cases.
- Provide modular tools for testing and/or assessment, to enhance the quality assurance of the various artefacts.

Summary and Discussion

The evolution of the eHDSI aims at supporting new use cases and functionalities, which are specified and prioritised in appropriate governance processes. Also, the currently implemented use cases need further development and improvement. The statements 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 favour of an approach towards modular components that are efficiently re-usable across multiple use cases. Therefore, the recommended 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.

Prioritisation of work items should happen as a separate next step: the assignment of specified activities to resources and a timeline, i. e. the creation of a roadmap that details the work that is required to reach the strategic goals. An appropriate process of constantly reviewing the roadmap is yet to be defined. This process should capture the strategic prioritisation, relate it to available resources and include input/feedback from implementers, users, stakeholders, patients etc.

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Appendix A: Use Cases and Features (Examples)

An extensive review of previously published material was done in the initial phase. Many use cases and business cases were mentioned and described in more or less detail. A comprehensive list was prepared in a submission of eHAction Task 6.1 for the eHN meeting in November 2018, see Appendix A in the previously published "Preparation and Background" document [1]. Other additional use cases were identified during discussions and in the T6.1 workshops. For convenience, a list of selected example use case titles is reproduced here.

- Identify and authenticate Person
- Establish trusted relationship between Health Professional in country B with service in country A
- Raise technical problem from country A to country B
- Understand clinical content from radiology report
- Establish valid translations of clinical concepts (terminology)
- Document patient consent, purpose of use
- Provide register of professional roles, create mapping for authorisation purposes
- Identify medicinal product
- Obtain permission to use clinical data for research purposes
- Authorisation of Health Professional acting on behalf of a patient in country B
- Citizen present in country B wants to access health services in country A
- Cross-border reimbursement
- Evaluate clinical data from multiple countries (for clinical study, for public health/surveillance)
- Safe prescribing [30]
- Integrated care and self-management for long-term conditions [30]
- My care plan [30]
- Online continuity of care health summary [30]
- Help keep patients at home [30]
- Coordinated cancer care [30]
- Online medication profile [30]
- Prevention plan [30]
- Care services directory [30]
- Population health comparisons [30]
- Cross-border pharmacovigilance [30]
- Clinical trial matching [30]

- Key care facts [30]
- Diagnosis support [30]
- Request and results sharing workflow for radiology [28]
- Request and results sharing workflow for laboratory [28]
- Involvement by chronic patients in electronic documentation of healthcare information [28]
- Immunisation [28]
- Medical Board Review [28]
- Antenatal care [28]
- Product recall [31]
- Clinical trials [31]
- Clinical research [31]
- Waste management [31]
- Patient Access to Information (PAC) (epSOS)
- Medication Related Overview (MRO) (epSOS)
- Health care encounter report (HCER) (epSOS)
- Chronic Disease Management [12]
- European Reference Networks for Rare Diseases [12]
- Common Identification of Medication [12]
- Service EHIC (epSOS D1.4.3 EED SERVICES)
- Service 112 (epSOS D1.4.3 EED SERVICES)
- Patient Access to country A information in country B language (epSOS D1.4.3 EED SERVICES)
- Transition of care in transatlantic scenarios [32]
- International Patient Summary [26], [33]