eHAction

Joint Action supporting the eHealth Network

# D8.2 - Policy document about technology report

## WP8 - Integration in National Policies and Sustainability

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Version 1.0

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This document presents the work regarding the policy technology on eHealth. Through the huge level of information and granularity associated with this subject, this deliverable contains four chapters about: Electronic health record exchange format (EHRxF); the Common Semantic strategy (CSS); eHealth reference architecture (eHRA) and Common Strategy for the use of Digital Identification in Health in the European Union (eID).

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# i. Table of Contents

# ii. List of Figures



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# iv. Acronyms and Abbreviations

| Acronym | Description |
|---|---|
| ATC | Anatomical Therapeutic Chemical - medicines classification |
| $C^4ISR$ | Concept of the US Defense Force: *Command, Control, Communications, Computers, Intelligence, Surveillance and Reconnaissance* |
| CALLIOPE | CALL for InterOPErability |
| CBeHIS | Cross-Border eHealth Information Services |
| CHAFEA | Consumers, Health, Agriculture and Food Executive Agency |
| CSA | Coordination and Support Action |
| CSS | Common Semantic Strategy |
| CT | Computed Tomography |
| DICOM | Digital Imaging and Communications in Medicine |
| EA | Enterprise Architecture |
| eD | eDispensation |
| EDQM | European Directorate for the Quality of Medicines |
| eHAction | eHealth Action |
| eHDSI | eHealth Digital Service Infrastructure |
| eHealth | Electronic Health |
| eHMSEG | eHealth Member States Expert Group |
| eHN | eHealth Network |
| EHR | Electronic Health Record |
| EHRxF | Electronic Health Record Exchange Format |
| EIF | European Interoperability Framework |
| EMA | European Medicines Agency |
| eP | ePrescription |
| epSOS | European Patients Smart Open Services |
| EQA | External Quality Assurance |
| EQALM | European Organisation for External Quality Assurance Providers in Laboratory Medicine |
| ERN | European Reference Networks |
| EU | European Union |
| FAIR | Findable, Accessible, Interoperable, and Reusable |
| FEA | Federal Enterprise Architecture |
| GA | Grant Agreement |
| GDPR | General Data Protection Regulation |
| HHS | US Department of Human and Health Services |
| HL7 | Health Level 7 |
| HL7 FHIR | Health Level 7 Fast Healthcare Interoperability Resources Specification |
| HP | Health Professional / Healthcare Professional |
| ICD-10 | International Classification of Diseases – version 10 |
| ICD-10-CM | International Classification of Diseases – version 10 – Clinical Modification |
| ICD-O | International Classification of Diseases for Oncology |
| ICT | Information and Communication Technology |
| ISO | International Organization for Standardization |
| JA | Joint Action |
| JCP | Joint Coordination Process |
| JRC | Joint Research Centre |
| LC | Leadership Council |
| LEAR | Legal Entity Appointed Representative |
| LOINC | Logical Observation Identifiers Names and Codes |
| mHealth | Mobile Health |

| Acronym | Description |
|---|---|
| MoH | Ministry of Health |
| MRI | Magnetic resonance imaging |
| MWP | Multiannual Work Programme |
| NCP(s) | National Contact Point(s) |
| NCPeH | National Contact Point for eHealth |
| NCSP | NOMESCO Classification of Surgical Procedures |
| NPU | Nomenclature for Properties and Units |
| PCS | Procedure Coding System |
| PS | Patient Summary |
| QM | Quality Manager |
| RM | Risk Management |
| RMS | Referentials Management Services |
| SC | Steering Council |
| SDO | Standards Development Organization |
| SNOMED CT | Systematized Nomenclature of Medicine – Clinical Terms |
| STF | Semantic Task Force |
| Tcon | Teleconference |
| WG | Working Group |
| WP | Work Package |
| WPL | Work Package Leader |

# General Executive Summary

During the 13th eHN meeting held on 15 May 2018, eHealth interoperability and policy actions to improve semantic interoperability in the EU were discussed[1]. This was intended to initiate a constructive discussion among members of the eHN with the objective to further improve eHealth interoperability in the EU. As a result of this discussion, it was noted by the participants that an 'Electronic Health Record Exchange Format (EHRXF)' and a 'Common Semantic Strategy (CSS)' was needed in the EU. The proposals for 'European eHealth Reference Architecture proposal (eHRA)' was presented to the EC in Jan. 2020, as a tool to support Member States on the eHealth governance process and the 'Common Strategy for the use of Digital Identification in Health in the European Union (Common eID)' follow the same steps of eHRA (Jan. 2020) and was also considered due to their highly strategic value at European and national levels. A formal invitation to all Member State/country representatives was made, asking each one to nominate an expert for those four working groups. As such, four provisional working group was raised under the eHAction activities (WP 8), to discuss the principles, scope and ambition of the groups.

In view of the huge volume of information and granularity associated with this subject, this document is divided into four parts in order to organise the information and lead the reader towards better understanding of the content:

**Part 1 (D8.2.1): Member States/countries document about Electronic Health Records Exchange Format (EHRxF)**

The main purpose of the EHRxF part is to provide information to all participants involved in the eHAction (Joint Action supporting the eHealth Network) about the tasks related to the support given to the European Commission in the drafting the Commission Recommendation on the Electronic Health Record Exchange Format (EHRxF). It provides an overview of the documents and materials used, workshops and teleconferences conducted, consultations and other related work. This is in view of better preparing partners to support the endorsement of the Commission Recommendation text, if and when such is sought by the Commission, and to better inform eHealth Network (eHN) representatives if the eHN is called upon to endorse the Recommendation on EHRxF.

**Part 2 (D8.2.2): Common Semantic Strategy for Health in the European Union**

This part contains the common semantic strategy (CSS) for health for the EU for the next five years. It was elaborated by the Member State/country representatives who have discussed and aligned a common view of semantic interoperability based on their national reality and the real perspectives for adoption, implementation and operationalisation for the Member States/countries.

**Part 3 (D8.2.3): European eHealth Reference Architecture proposal**

Most of the solutions developed in the eHealth environment depend on each other to survive, or only make total sense when they are interconnected. Through this chapter, eHAction aims to promote the importance of outlining a Reference Architecture, in line with the Health eGovERA framework, for eHealth based on the Enterprise Architecture (EA) framework aiming for the interoperability of regional eHealth, focusing on the governance process.

This requires the setting the principles for using EA to help eHealth programmes in order to reduce duplication, increase shared services, increase common planning of eHealth synergies, close performance gaps, and promote the empowerment of European eHealth strategy and goals.

[1] Cover Note by eHealth Network Secretariat:
https://ec.europa.eu/health/sites/health/files/ehealth/docs/ev_20180515_co02_en.pdf

**Part 4 (D8.2.4): Common eID Approach for Health in the European Union**

There is a need to establish a common strategy for the use of digital identification in health to leverage the building of electronic identification capacity/capabilities in all Member States/countries, leveraging the most recent European legislation, based on sustainable EU policies issued by the high-level authorities of both the eID and eHealth worlds, as well as the European Commission.

The development of a common strategy for digital identification in health will ensure the unequivocal identification of EU citizens and support the Member States to increase and improve their cross-border health services.

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Each of these four parts presents the shared views of Member States/countries about these themes that were elaborated through meetings, teleconferences and email exchanges to guarantee agreement between the authors and their respective countries. In each part, tools and roadmaps are presented to support the integration of new technologies among the Member States and establish new patterns for adoption of new technologies in order to achieve real eHealth interoperability in the European Union.

The parts already included on this deliverable were approved on the previous eHN meetings, namely EHRxF (Part I) and CSS (Part II). The documents regarding the correspondent parts of eHRA and Common eID will be presented for approval on the 19th eHN meeting (June 2021). After their approval, it will be included on this document as Part III (D8.2.3 – eHRA) and Part IV (D8.2.4 – Common eID).

# PART I

# D8.2.1 – Member States/countries document about Electronic Health Record Exchange Format

# I-1 Executive Summary

The EU's Electronic Health Record Exchange Format (EHRxF) initiative aims to make it possible for people to access their health records across EU borders as needed for cross-border healthcare purposes such, as in case of accidents while travelling, or to seek treatment of chronic conditions, or rare diseases. In any situation where a person requires healthcare treatment in another Member State, having access to their personal health records will support and improve the quality of this care, for example by enabling faster, more accurate diagnosis and improved prognosis. The initiative also aims to facilitate the flow of health data across borders to the benefit of citizens, to underpin the digital transformation of health and care. It therefore aims to give further impetus to Member State efforts to develop the interoperability of their systems.

# I-2 Introduction

The access and sharing of Electronic Health Records are very relevant to the political interest of the Member States and European Commission, so the Commission needs to prioritise policies to support Member States' approaches[2]. This necessity came from the eHealth Network (eHN) in May 2018, when it strongly endorsed the creation of a working group about EHRxF to manage and align standards on eHealth; this group worked to reach general agreement on a common set of standards that is needed for EHRxF interoperability.

This work was delivered to eHN by means of a letter of commitment and intention that was presented to the European Parliament by the President of the Commission, in alignment with the Commission's Communication on the Digital Transformation of Health and Care[3] on April 25th, 2018, which emphasises citizens' right to have access to their health data cross-border.

The Commission provided a recommendation at the end of the workshop regarding the initiative and constraints to consider and for what reasons. The approach adopted by the Commission to frame the EHRxF Recommendation comprises the following elements/principles:

Iterative process: 'what' needs to be exchanged and 'how' to exchange it need to be decided progressively. Development and extension can be realised in at least three dimensions:

a) areas of implementation (e.g. 'simple lab', problems/diagnoses, etc.),

b) waves/countries, and

c) depth of implementation (from untranslated PDFs to structured and coded).

All these dimensions may be iterated;

- No change (or minimal) to national systems is mandated. Some changes should be necessary to implement the EHRxF and some extensions in Europe, but the Commission cannot mandate those changes. Each Member State has total autonomy to decide if these changes will be implemented on their systems;
- Based on widely used common frameworks/specifications to interface. (While this is a good practice, there is likely to be limited common use of frameworks and/or specifications. Even if the same specifications and/or terminologies are used, the actual implementation can be significantly different.)

# I-2.1 Background

In order to contribute to the thinking and elaboration of the European Commission recommendation and to contextualise a better analysis of the topic, a list of relevant documentation from previous Commission funded projects (for example Antilope[4], eStandards) and previous Joint Actions such as JAseHN[5], that in some way or another can relate to the EU EHRxF in its principles, its process or its purpose, was identified.

Commission recommendation should include an iterative approach and technical specifications that can be used at national level by Member States. This subject implies the customisation of frameworks in use (document from 2015), according to the content, stakeholders' opinions, exchange formats, IHE profiles to be used in public procurement by Member States, and terms to adopt the proper profiles. The Member States should converg e forces to support exchange formats and to improve the eHealth sector in an interoperable way.

[2] https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:52018DC0233&from=EN
[3] https://ec.europa.eu/digital-single-market/en/news/communication-enabling-digital-transformation-health-and-care-digital-single-market-empowering
[4] https://www.antilope-project.eu/
[5] https://jasehn.eu/

It is clear that the EHRxF cannot be devoid of clinical content and therefore from considerations about semantics. Having recognised this, a format that can be, to the possible extent independent from specific use cases (in a clinical sense) and therefore more possible to be separated from small-scale information blocks/ semantic constraints may be longer lasting.

The relevant documentation regarding some principles to develop and implement the EHRxF could be found in the reference section.

A series of IHE profiles that may be relevant for the EHRxF have already been analysed by the Commission and received, in 2015, endorsement for their usage in procurement processes in UE[6, 7].

## I-2.2 Relevant existing exchange profiles

### I-2.2.1 CALLIOPE (CALL for InterOPErability) [8]

The intention of the European eHealth Interoperability Roadmap prepared by the CALLIOPE Thematic Network was to propose a robust, complete and consistent global view of an interoperability roadmap for eHealth in Europe, describing possible 'highways' and presenting a coherent factual basis for decision making. It built on the stakeholder requirements and consensus (vs expert view only) around a complete view of the working model needed to serve the common aim: Sustainable Healthcare: Sharing Information and knowledge for better health. It does so by bringing together visions, concepts, principles and emerging findings from collaborative European cross–border initiatives.

### I-2.2.2 IHE Profiles analysed by the European Commission

A series of IHE Profiles[9] that may be relevant for the EHRxF have already been analysed by the European Commission and received, in 2015, endorsement for their usage in procurement processes in the EU[10, 11].

These profiles are a excellent model to be a base to develop a complete EHRxF that meets EU expectations and needs.

### I-2.2.3 ELGA (ELektronische GesundheitsAkte)[12]

In Austria, the ELGA system is already in use (observation phase until 2020) as a modern and secure EHR infrastructure. This system is based on use of international uniform standards (required by medical societies) and clear structured data to exchange between IT systems. It is a good example of interoperable infrastructure and structured data and can be used as a model on which to build the strategy in EHRxF.

## I-2.3 Context

The main purpose of this document is to provide information to all participants involved in the eHealth Action (eHAction, Joint Action supporting the eHealth Network) about the task related with supporting the European

[6] https://wiki.ihe.net/index.php/Profiles
[7] https://wiki.ihe.net/index.php/Exchange_of_Personal_Health_Record_Content_Profile
[8] http://www.ehgi.eu/Download/European%20eHealth%20Interoperability%20Roadmap%20[CALLIOPE%20-%20published%20by%20DG%20INFSO].pdf
[9] https://www.ihe.net/resources/profiles/
[10] https://wiki.ihe.net/index.php/Profiles
[11] https://wiki.ihe.net/index.php/Exchange_of_Personal_Health_Record_Content_Profile
[12] https://elga.gv.at/technischer-hintergrund/technische-elga-leitfaeden/index.html

Commission on drafting the Commission Recommendation on the Electronic Health Record Exchange Format (EHRxF). It provides an overview of documents and materials used, workshops and teleconferences conducted, consultation and other related work. This is in view of better preparing partners to support the endorsement of the Commission Recommendation text, if and when such is sought by the Commission, and to better inform eHN representatives if the eHealth Network is called upon to endorse the Commission Recommendation.

In February 2019 the was released the 'Commission Recommendation on a European Electronic Health Record exchange format (C(2019)800)'[13]. Parts of this document was used as basis to the elaboration of the text of the Commission recommendation on EHRxF. As an eHAction deliverable this document supported Member States' expert teams has provide advice to their respective MoH representatives at the eHealth Network, to endorse in an informed and positive manner the Commission Recommendation.

## I-3 Scope and aim of the document

The main scope is related to the choice of 'healthcare information categories' (such as lab results, radiology pictures, discharge reports, etc.), data encoding formats for each category where possible, and specifications for exchange protocol elements. The data encoding formats focus on codifying standards currently in use and the exchange protocols, indicate needs for strong authentication, consent/privacy control and security protocols. It is very important to maintain the proper authentication, privacy (consent) and security monitoring for all transferable data. The proposal from EHRxF is to have everything, which is immediately understandable when accessed cross-border (e.g. between countries with different languages) and patient-centred, with the glossary easier to upgrade.

Members should converge forces to support exchange formats and to leverage interoperability to improve the eHealth sector, which needs to focus on citizens' interests and their rights to access data, respecting the data protection rules.

Healthcare is becoming more and more a networked care, due to ageing population, multi-morbidity, specialisation of care and the increasing role of the patient. To transfer the data, all relevant stakeholders in health and healthcare need to be able to connect in an interoperable way.

- **Different levels of detail**

Member States have different levels of granularity in their EHRs and can provide data based on the levels of granularity that they support. However, the level of granularity to which data is structured and/or standardised will differ. This makes interoperable exchange of information challenging, not just because these differences need to be somehow managed and mapped, but also because it is difficult to ensure the transfer from the point of view of authentication, consent data, and security protocols. It is strongly recommended to reuse the eHDSI, which allows involving healthcare professionals, and to identify different levels of granularity to generate a consensus among the Member States.

The Directive 2011/24/EU provides rules for facilitating the access to safe and high-quality cross-border healthcare and promotes cooperation on healthcare between Member States, in full respect of national competencies in organising and delivering healthcare.

The European Commission Communication on Digital Health in April 2018 announced further work on standards for the exchange of patient records. The 13th meeting of the eHealth Network agreed the formation of a subgroup to progress this. Following two workshops and a number of teleconferences, it is proposed

13 https://ec.europa.eu/digital-single-market/en/news/recommendation-european-electronic-health-record-exchange-format

that the development of the standard be progressed with a step-by-step approach, whereby candidate additions to the standard be reposed as additional guidelines within the structure previously.

Many Electronic Health Record definitions exist, here are some links help inform knowledge about this.

- https://www.healthit.gov/faq/what-electronic-health-record-ehr
- https://www.cms.gov/Medicare/E-Health/EHealthRecords/index.html
- https://www.himss.org/library/ehr
- ISO13606-1 Health informatics - Electronic health record communication - Part 1: Reference model
- ISO13606-2 Health informatics - Electronic health record communication - Part 2: Archetype interchange specification

From discussions so far (eHAction and EHRxF workshops), it is clear that the EHRxF is not the description of a 'local' or even 'national' format for an EHR, but rather the description of how these can interact and exchange parts of the health-related information that each, albeit their structure, may contain differences between there.

## I-3.1 Purpose and Process

On 25th April 2018, the European Commission published the Communication on enabling the digital transformation of health and care in the Digital Single Market – Empowering citizens and building a healthier society, with three priority pillars:

- Pillar 1 - Citizens' secure access to and sharing of health data;
- Pillar 2 - Better data to promote research, prevention and personalised health and care;
- Pillar 3 - Digital tools for citizens' empowerment and for person-centred care.

One of the actions required by the Commission under Pillar 1 is to elaborate a Commission Recommendation on a European Exchange Format for Electronic Health Records in three sections:

1. Invite Member States to promote cross-border electronic access to and use of health data;
2. Recommend technical specifications for a European exchange format of EHRs;
3. Recommend that Member States develop and implement measures to monitor the uptake of the technical specifications of the European EHR exchange format.

In the 13th eHN meeting on 15th May 2018, chaired by Clemens Martin Auer, Director General, Federal Ministry of Health, Austria and Xavier Prats Monné, Director General for Health and Food Safety, DG SANTE, it was decided that a working group on Electronic Health Records Exchange Format would be created with the mission to co-elaborate, or rather contribute to, the creation of the Commission Recommendation regarding the exchange format of EHR between Member States, with the perspective that such joint effort would better support the aim that the Commission Recommendation is not delayed in its publication, but also that its acceptance and adoption by Member States is as fast and easy as possible. It was also decided that this working group would be integrated in the eHAction, where the eHAction coordinator (Henrique Martins - SPMS) was responsible for managing both.

In order to create the working group, the eHAction Coordinator, together with the DG SANTE, DG CONNECT and DG DIGIT, decided that each Member State should formally nominate a person to join the working group. The nominated person should be a person working at national level on interoperability matters,

interoperability connectors and national platforms with an expertise on EHRs and good knowledge of semantics. Additionally, knowledge and experience of the different use cases that would be part of the EHR exchange format (e.g. patient summary, lab results or medical images) and preferably at European level (cross-border/cross-region). The initial material to be considered by the working group was:

- Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on enabling the digital transformation of health and care in the Digital Single Market;

- DigiCare – Communication on enabling the digital transformation of health and care in the Digital Single Market - Empowering citizens and building a healthier society – ppt.

## I-4 Information blocks, IHE profiles and technical standards that could apply to a common exchange format

Typically, five types of standards, with the accompanying implementation specifications, are necessary and used together to achieve interoperability for a given purpose (Figure 1). It has been demonstrated that there is often a challenge to demarcate the scope of terminology and information model standards. Efforts include SemanticHealthNet[14], HL7 Terminfo[15] , and CIMI[16].

| CATEGORIES OF STANDARDS | FUNCTIONS OF STANDARDS | EXAMPLES OF REAL WORLD USE OF THE STANDARDS |
|---|---|---|
| VOCABULARY & CODE SETS (SEMANTICS) | The information is universally understood | SNOMED CT, IDMP LOINC |
| FORMAT, CONTENT & STRUCTURE (SYNTAX) | Information is in the appropriate format | HL7 CDA, HL7 FHIR HL7 v2 |
| TRANSPORT | The information moves from point A to point B | XML, JSON |
| SECURITY | The information is securely accessed and moved | WS3C DSig |
| SERVICES | Provides additional functionality so that information exchange can occur | WS-1, TLS, X509 |

**Figure 1 –** this figure shows the five types of standards to achieve an EHR, their use and some global examples. Source: ONC Interoperability Roadmap, 2015

1) Vocabulary/ terminology standards are sometimes unique to healthcare and use specific case (e.g. codes to represent medications could be (and is often, e.g. CAS) shared, also used for laboratory tests).

[14] http://www.semantichealthnet.eu/
[15] http://www.hl7.org/Special/committees/terminfo/index.cfm
[16] http://www.hl7.org/Special/Committees/cimi/index.cfm

2) Content/ format standards are also often unique to healthcare and may be use specific case for things like data capture or computation within a specific clinical workflow or domain (e.g. the content/ format standard used for a referral to a specialist would not be used to bill for a procedure).

3) Transport standards are typically not unique to healthcare because they are used to connect two or more parties together without a focus on the data that is transported from one party to another.

4) Security standards are not unique to healthcare and often applied in different ways to meet given data protection requirements. However, in healthcare there are legal minimums for functional security outcomes. In any event, a security standard supports achieving those security outcomes prescribed by the Security Rule.

5) Standards for services typically represent technical infrastructure used to connect different systems together to perform actions that support user needs.

To provide further definition for European Commission policies, it is essential to make national efforts and share the best practices on semantics. It is recommended to work cross-border on semantic topics and create converging tracks (Figure 2).

> Most of the Member States agree to create a standard norm for EHR communication, including dependent and non-dependent content. The focus should be: terminologies, semantics, ICT infrastructures, transport layers and use cases.

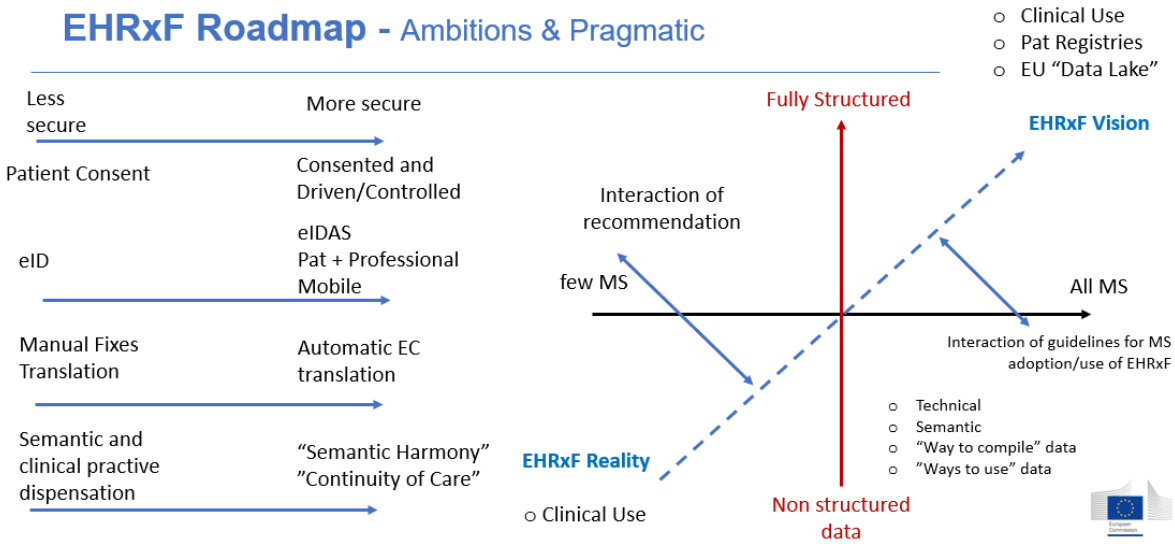


**Figure 2 –** EHRxF Roadmap Ambitions and Pragmatic Way Forward

The figure shows the main necessities of the data structuring (technical, semantic, how to compile, and how to use the data) with all Member States/countries to lead the EHRxF to a unique 'data lake', including clinical use and registers, shared by all EU members.

## I-5 Architecture Exchange

National architecture in countries should follow national prerogatives, and should be auditable, secure, redundant architecture assuring the fluidity of cross-border information exchange. Each Member State is responsible for assuring national infrastructures, legal requirements, operational solutions and technical support, allowing that citizen medical information would be available where needed. This means that, more than specifying how EHRxF will impact internal aspects of national infrastructures and architectures, eHRxF needs to define and codify the 'API-like' block, that allows these national blocks to communicate with each other, and with the citizen at the same time. In light of the GDPR, and for political and societal support, all

exchange architecture will need to ensure total control by the patient (i.e. he/she should receive messages about a request for a data transaction, verify it, and either agree with it or block it).

The technical and semantics standards should be improved in accordance with international strandards. The glossaries of terms and definitions from projects such as Antilope, ValueHealth, eStandards, EXPAND, ASSESS CT and epSOS should be reused. Data should be exchanged for patients and healthcare professionals to provide better care and for research.

## I-6 Semantics (Meaning of Information)

The eHealth Network have the subgroup on semantics, responsible for adress the semantic issues and recommendations at European level. From analysis so far, building broad consensus on semantics may prove to be difficult, but smaller scale (regional, bilateral, or topical/use case) may be possible. This calls for a Common Semantic Strategy for eHealth in EU.

The EHRxF should be agnostic to semantic context, including licensing agreements, allowing the exchange within the 'allowable formats', and fostering open standards as much as possible.

A network of national experts on semantics is a critical governance structure; the cost of its maintenance needs to be considered and sustained. Without its work, no real meaningful clinical exchange will happen in areas like detailed documentation, discharge summaries/letters, and other text-rich clinical/medical documents. Claiming LOINC adoption, for example, with no more detail, is obviously not enough, so the way by which detail as well as consensus is to be fostered and then decided and then adopted is critical.

## I-7 Technical

The EHRxF technical specifications should be released in a 'for discussion' format first, so that mature conceptual and technical teams from Member States with more EHR exchange experience can comment, and clarify; and then only later the specifications may be released in a stable form.

The technical architecture of the data exchange will be supported by eHDSI and NCPeHs, if this is further developed and its maintenance team is stable and funded appropriately. This does not preclude that peer-to-peer organisations cannot exchange using the same format, and other infrastructures. Leaving these degrees of freedom can foster a multiplier effect of the 'format' in many digital services, at national, regional, one-on-one bilateral level, or even between systems within a Member State.

## I-8 Localisation/Implementation of EHR Exchange Format

It will be key to adoption that processes of participation in the creation of the format and its updating exist for Member States. Equally important is the capacity to localise and implement the reference EHRxF.

This means that a capacity building exercise will be needed not just for industry players, but also for national eHealth agencies, either because they need to change/ensure national EHRs are capable of exchanging data using the new format, but also, as many may need to create the incentives for industry as well as healthcare providers, especially in more decentralised health system arrangements.

**Points to be clarified:**

1. How to start an iterative process between two or more countries, with meaningful transfer of data. This needs to take into consideration what ICT is developed, in what context, e.g. FHIR (medical devices and apps), CDA (hospital records);

2. What relevant information from other projects can be used;
3. How to compile the lab information and reuse infrastructures;
4. The level of granularity in different Member States/countries and what should be achieved by all.

Key factors for success in EHRxF adoption by Member States are (this does not aim to be an exhaustive list):

1. Having participated in the creation of this reference approach to exchange;
2. Capacity to contribute to its evolution via an open governance process linked to the current eHealth Network agenda;
3. Mature (or maturing) national exchange architecture and/or national EHR projects;
4. Capacity to implement reference architectures in national settings;
5. Central team with expertise in medical knowledge (healthcare providers), IT architecture, semantics, and technical interoperability;
6. eHealth Strategy supported by political decision makers.

## I-8.1 Investing in eHealth interoperable infrastructures in Member States

If no investment and push for interoperable infrastructures is targeted by the European Commission and in alignment with eHealth network, as was suggested in the Informal Council of Ministers of Health in Vienna, in September 2018, many healthcare providers, where data is collected, stored and used, will not have systems capable of outputting EHRxF-compliant data elements/documents. Such EHRxF-ready IT certificate seals should be classified and managed by the Member States based on requirements coming out of the official EHRxF technical specifications, but its maintenance and verification should happen in each Member State according to its existing processes.

EU funds could potentially be used for exploring a common process for organising the channelling. Likewise, EU funding initiatives could perhaps be used as seed funding for cluster experimentation of the first generation of EHRxF information blocks, such as Imaging, Laboratory and Hospital Discharge Reports.

## I-8.2 Follow up adoption by healthcare providers adoption

The Refined eHealth European Interoperability Framework (ReEIF), as presented here, is general enough in its definition and scope and useful for any cross-border, national, regional or local interoperability project in Europe. Consistently using it will bring unity of concepts, thus providing better and clearer communications between all parties involved: decision-makers, healthcare providers, health professionals, architects, software providers, IT professionals, etc. Its value has been proven by the usage of (parts of) the framework in different national and regional projects all over Europe.

It is strongly recommended that any activity on interoperability starts with the description of the desired outcome in terms of care processes, i.e. in terms of what patients and health professionals want to achieve with the interoperable solution to be created. This is where the use case description template comes into play, it will give a formal description of the use case as the starting point, and the template enforces completeness and homogeneity in the form of the description.

## I-8.3 Preparing and accompanying eHealth industry

It is obvious that, for the Patient Summary and ePrescription/eDispensation, the 10-year long road is understandable; it went through conceptualisation, large-piloting (epSOS), refinement and handover of specifications (EXPAND), creation of communities and processes for implementation (eHN Subgroup on Implementation and CEF eHDSI set-up) and go-live in January 2019. This was a journey that started in 2008.

It is unthinkable that for exchanging imaging reports we will take another 10 years. The length of this road can be shortened if some principles are observed:

a) Not all but some image formats are accepted;

b) Semantic/technical definitions are established;

c) Funding mechanisms used by the Commission are non-bureaucratic and agility is the rule;

d) Focus is maintained in the go-live and real service provision.

The eHealth industry needs to be further involved, not just in a meeting format in Brussels, or via IHE or other representation, but directly activated at the level of each Member State, as most of the eHealth partners are local vendors. This means Member States need to have an industry-directed programme that could benefit from a common EU-wide approach in some respects but should of course be country-specific.

## I-9 Governance of the EHRxF

The adoption of an EHRxF would also mean the adoption of a governance framework to keep the format updated. Like any standardisation exercise, there would need to be a cycle:

- Reach agreement, based on desk research;
- Conceive a concept and adopt it;
- Test/implement;
- Consolidate/write the standard;
- Revise/question and improve;
- Monitor and assess progress;
- Have joint coordination between the European Commission and Member States and a shared roadmap;
- Based on data provided by Member States, the European Commission will publish progress reports;
- The European Commission and Member States should agree the overall priorities and tasks for further specifications to be considered in the years ahead;
- Participation of a network of experts from competent authorities for digital health and of a wider group of stakeholders.

Therefore, the EHRxF should contain a section that details the process, i.e. the meta process by which this format will be maintained in the future, by whom and what resources are to be made available to that function.

**Level of Detail**

The level of detail at which the EHRxF should operate seems to be that which allows national differences in messaging, transition, semantic standards, as well as minimal interference with existing national EHR projects, while allowing exchange of meaningful 'Information Blocks'. So far, consensus has not been reached on whether a 'clinical' use case approach would facilitate the implementation, and if it is at all possible

considering the significant differences of healthcare settings in the EU countries. However, it seems that opportunities may exist in more standardised 'information pieces' like imaging, or lab results. This is not just because industry standards seem more stable, but also because these seem to be elements of healthcare in all countries, that do not provoke immediate different interpretations.

Some, however, defended that the EHRxF should be clinically structured into: summary, cardiological data, torax, etc., imaging reports, lab results, i.e. much like the 'structure' of a local EHR. This seems to be a very interesting avenue for exploration.

In the second workshop it became clear that within each 'information block', i.e. sharing laboratory results, structured and non-structured source data would condition possible exchange, and that the aim should be to strive for structured exchange as much as possible, maintaining, however the capacity to exchange unstructured data, even to the point of a 'PDF- like' scenario.

Below, there is a table with some suggestions on 'what kind of information' and 'what are the information blocks', based in reference models, that should be considered as a possible exchange format for health data, aligned with the discussion of Member States/countries through the workshops, surveys and deliverables.

**Information categories**

| No | Information Blocks (datasets) | Data Reference Models |
|---|---|---|
| 1 | Patient Summary<br>Structured according to Chapter 4 of the 'Guideline on the electronic exchange of health data under Cross-Border Directive 2011/24/EU – Release 2 – Patient Summary for unscheduled care' adopted by the eHealth Network on 21 November 2016 [17] | HL7 Clinical Document Architecture (CDA) Release 2[18]<br>(Level 3 and Level 1) |
| 2 | ePrescriptions<br>Structured according to Chapter 4 of the 'Guideline on the electronic exchange of health data under Cross-Border Directive 2011/24/EU – Release 2 – ePrescriptions and eDispensations', adopted by the eHealth Network on 21 November 2016 [19] | HL7 Clinical Document Architecture (CDA) Release 2[20]<br>(Level 3 and Level 1) |
| 3 | Laboratory results | HL7 Clinical Document Architecture (CDA) Release 2[21]<br>(Level 3 otherwise Level 1 – PDF/A) |
| 4 | Medical imaging reports and images | HL7 Clinical Document Architecture (CDA) Release 2[22]<br>&<br>DICOM© (Digital Imaging and Communications in Medicine)[23] |

[17] https://ec.europa.eu/health/sites/health/files/ehealth/docs/ev_20161121_co10_en.pdf
[18] http://www.hl7.org/implement/standards/product_brief.cfm?product_id=7
[19] https://ec.europa.eu/health/sites/health/files/ehealth/docs/ev_20161121_co091_en.pdf
[20] http://www.hl7.org/implement/standards/product_brief.cfm?product_id=7
[21] http://www.hl7.org/implement/standards/product_brief.cfm?product_id=7
[22] http://www.hl7.org/implement/standards/product_brief.cfm?product_id=7
[23] https://www.dicomstandard.org/

| | | |
|---|---|---|
| 5 | Medical Summaries<br>- *Episode Summary*<br>- *Discharge Summary*<br>- *Transfer Summary* | HL7 Clinical Document Architecture (CDA) Release 2[24]<br>(Level 3 otherwise Level 1 – PDF/A) |

**Exchange specifications**

| No | Purpose | Specifications |
|---|---|---|
| 1 | To locate communities which hold patient-relevant health data and the translation of patient identifiers across communities holding the same patient's data. | IHE XCPD - Cross-Community Patient Discovery[25] |
| 2 | To query and retrieve patient relevant medical data held by other communities. | IHE XCA - Cross-Community Access[26] |
| 3 | To provide document interchange using a reliable messaging system and permit direct document interchange between EHRs, PHRs, and other healthcare IT systems in the absence of a document-sharing infrastructure such as XDS Registry and Repositories. | IHE XDR - Cross-enterprise Document Reliable Interchange[27] |
| 4 | To facilitate the registration, distribution and access, across health enterprises of patient electronic health records. | IHE XDS - Cross-Enterprise Document Sharing[28] |
| 5 | To establish security measures which, together with the Security Policy and Procedures, provide patient information confidentiality, data integrity and user accountability. | IHE ATNA - Audit Trail and Node Authentication[29] |
| 6 | To address the sharing of laboratory reports among a community of healthcare settings and care providers. | IHE XD-LAB - Sharing Laboratory Reports[30] |
| 7 | To provide a mechanism to record the patient privacy consent(s) and a method for Content Consumers to use for enforcing the privacy consent appropriate to the use.<br>This profile complements XDS by describing a mechanism whereby an XDS Affinity Domain can develop and implement multiple privacy policies and describes how that mechanism can be integrated with the access control mechanisms supported by the XDS Actors (e.g. EHR systems). | IHE BPPC - Basic Patient Privacy Consents[31] |
| 8 | To support the means to query and retrieve patient relevant medical imaging data held by other communities.<br>The XCA-I Profile extends the IT Infrastructure XCA Profile. XCA provides access to all medical data including diagnostic reports, imaging manifests and to the images referenced in the imaging manifests. | IHE XCA-I - Cross-Community Access for Imaging[32] |

[24] http://www.hl7.org/implement/standards/product_brief.cfm?product_id=7
[25] https://wiki.ihe.net/index.php/Cross-Community_Patient_Discovery
[26] https://wiki.ihe.net/index.php/Cross-Community_Access
[27] https://wiki.ihe.net/index.php/Cross-enterprise_Document_Reliable_Interchange
[28] https://wiki.ihe.net/index.php/Cross-Enterprise_Document_Sharing
[29] https://wiki.ihe.net/index.php/Audit_Trail_and_Node_Authentication
[30] https://wiki.ihe.net/index.php/Sharing_Laboratory_Reports
[31] https://wiki.ihe.net/index.php/Basic_Patient_Privacy_Consents
[32] https://wiki.ihe.net/index.php/Cross-Community_Access_for_Imaging

| | | |
|---|---|---|
| 9 | To provide a solution for publishing, finding and retrieving imaging documents across a group of affiliated enterprises.<br>It extends XDS in order to share images, diagnostic reports and related information across a group of care sites. | IHE XDS-I.b -Cross-enterprise Document Sharing for Imaging[33] |

| No | Technical Frameworks |
|---|---|
| 1 | IHE Technical frameworks[34] |

**Phased approach**

It seems evident from the complexity of the task and the timing for both Commission and Member State endorsement process that the EHRxF would benefit from a phased approach. Possibly, agreement on a generic exchange mechanism, the processes by which to sustain and enhance it, and the implementation and governance structure would be difficult to achieve in the next few months. More details, technical guidelines and support implementation may need to come in a second phase, while clinical building blocks, detailed structures, and clear semantic agreements may require some more time, a more robust governance, and may or not be desirable, depending on the level of coverage.

# I-9.1 Legal (Legal and Regulatory)

The identification/mapping of European and national legislation on the use of EHR formats leads the need to harmonise some national technical documents, which is predicted to be minimal; the Member States/countries should share the functional definitions to identify what should be harmonised between the countries.

The indication on activities related to the EHRxF should be 'cybersecurity-observant' in a proactive manner. This means that of course the observance of the NIS Directive is paramount, but it is also key in the EHRxF acceptance by Member States. Standards like HL7-FHIR, if incomplete without a definition of minimal security, should always be referred to in accordance with European standards.

Citizen consent is fundamental in all EHRxF transactions. Architecture and supporting infrastructure should ensure a simple and transparent 'real-time' instance. It should be asked for and provided, using SMS-like mechanisms (as an informative way to guarantee the granting of consent by the citizen), and dual-factor authentication mechanisms.

# I-9.2 Organisational (Policy and Care Process)

The creation of a process and governance to adopt new versions of the EHRxF, technical guidelines, and organisational guidance seems critical.

The eHN subgroup on semantics is in line to follow the usage and development of the EHRxF with delegated powers to work with DG CONNECT on phased releases.

Funding for ongoing central effort in standardisation is critical; this could not be supported by eHealth Action since its budget was fixed and this was not included in its mission. Also, this funding needs to be more sustainable than a project of 3 years' duration.

[33] https://wiki.ihe.net/index.php/Cross-enterprise_Document_Sharing_for_Imaging
[34] https://wiki.ihe.net/index.php/Frameworks

# I-10 Final considerations and future processes

## I-10.1 Additional Considerations, Remarks and Concerns

All Member States should be involved in the drafting of the EHRxF functional and technical specifications if they so wish, and the European Commission services should provide and co-fund a participatory process for this.

The CEF eHDSI current roadmap/strategy for phased implementation of PS and eP/eD services needs to be fine tuned, so that additional services can use the same IT infrastructure.

If the IT structure is upgraded according with the processes and governance bodies, it will be adapted as needed, so that reusability of both technology and common processes could results in collective savings and less overall cost.

# PART II

# D8.2.2 – Common Semantic Strategy for Health in the European Union

# II-1 Executive summary

The European Commission has acknowledged the need for eHealth interoperability for more than a decade. Considering this necessity, some projects have aimed to develop the interoperability of electronic health records within the European Union (EU). This has triggered initiatives such as epSOS and CALLIOPE, as well as a subsequent first Joint Action, the eHealth Governance Initiative (eHGI). These were some of the first steps to define and drive a way forward to achieve the best feasible scenario for EU eHealth integration.

In the collaborative project named CALLIOPE (2008-2010), various eHealth experts proposed an interoperability roadmap, which remains, for the most part, amazingly valid, especially with regards to semantic interoperability. Amongst the many useful recommendations in this document, there were also concrete possible steps suggested.

In May 2018 the eHealth Network (eHN) discussed the need for a common semantic approach towards standardised exchange of health information in the EU. In November 2018, the eHN endorsed the work of the Working Group on Common Semantic Strategy (CSS), created within eHAction to come up with a solid proposal for a five-year strategy, that was discussed as a draft in June 2019 and approved in November 2019.

According to the recent Commission Recommendation on European Electronic Health Record Exchange Format[35] (EHRxF, 6th Feb. 2019) the following healthcare information domains have been identified as a source of baseline requirements to establish EU semantic interoperability recommendations:

- Patient Summary
- ePrescription/eDispensation
- Laboratory Results
- Medical Imaging and Reports
- Hospital Discharge reports

In addition to the above, the field of rare diseases has been identified as the one with a high demand for standardisation due to the specific nature of rare diseases, their devastating impact on patients and unique challenges associated with their treatment. Rare diseases are also one of the key domains of the European Reference Networks (ERNs)[36].

To achieve a CSS for health information capture, visualisation, portability, processing, storage, mark-up, annotation, retrieval, accessibility, exchange, secondary use, analytics, reporting, communications, knowledge representation, modelling, decision support and innovative information management, consideration should be given to all semantic requirements that are relevant for health data in the EU or globally. Initial focus should be on cross-border eHealth requirements, but including all other eHealth related subjects as necessary, to support national-level approaches when required and as needed.

It should be noted that the governance structure proposed in the document is the result of shared reflections of the CSS working group, the CSS workshops, the work of subgroups, Member States/countries' internal work around the CSS, and the work of the Semantic Task Force (STF) of the eHealth Member States Expert Group (eHMSEG). This is still to be aligned and streamlined with a global approach under the concept of the Joint Coordination Process[37] and other holistic governance efforts of the eHN and its subgroups, as well as other functional and already existing bodies, including eHMSEG and STF. The CSS proposal of interaction could be seen throughout the document, considering these groups and new ones.

This document intends to formally present to the eHN the work developed by the CSS Working Group, in the form of an elaborated CSS draft proposal to achieve semantic interoperability in selected use cases for healthcare and health management at the EU level in the coming years. The selected information domains

[35] https://ec.europa.eu/digital-single-market/en/news/recommendation-european-electronic-health-record-exchange-format
[36] https://ec.europa.eu/health/ern/networks_en
[37] The first debate between EC and the Member States was on the 6th May 2019, in an eHN subgroup meeting, and is still to be further debated in the eHN meeting in June. Please, see chapter 6 for more information.

represent what the group has considered reasonably feasible within 5 years. Some future domains will need a more precise definition before any strategic proposal can be formulated.

# II-2 Introduction

## II-2.1 Background

The European Commission has acknowledged the need for eHealth interoperability for more than a decade. Considering this necessity, some projects are aimed at developing the interoperability of electronic health records within the European Union (EU). This has triggered initiatives such as epSOS and CALLIOPE, and a subsequent first Joint Action, the eHealth Governance Initiative (eHGI). These were some of the first steps to define and drive a way forward to achieve the best feasible scenario for EU eHealth integration.

The epSOS[38] project (2008-2014) set out to develop, evaluate and pilot some cross-border eHealth services and elaborate recommendations for them. The focus of this initiative was to achieve high quality, secure and safe services for the exchange of Patient Summary and ePrescription/eDispensation data in a European cross-border context.

The Commission expressed the need for enhanced cross-border interoperability of electronic health records through the publication of a Recommendation on 2 July 2008 (2008/594/EC)[39]. The semantics topic was one of the main points to be improved and structured for this proposal. Ten years after this first initiative, the adoption and implementation of a European Electronic Health Record Exchange Format (EHRxF) and interoperability mechanisms is still a strong necessity to be achieved within the EU.

In the collaborative project named CALLIOPE[40] (2008-2010), various eHealth experts proposed an interoperability roadmap which remains, for the most part, amazingly valid, especially with regards to semantic interoperability. Amongst the many useful recommendations in this document, there were also concrete possible steps suggested.

The eHealth interoperability topic gained even more importance through the Directive on the application of patients' rights in cross-border healthcare (2011/24/EU)[41] published on 9 March 2011. Within it, the legal foundation was created to set up the eHealth Network (art. 14) whose main objective is to 'work towards delivering sustainable economic and social benefits of European eHealth systems and services and interoperable applications […]'. Furthermore, the Commission came up with a detailed roadmap to empower patients and healthcare workers, to link up devices and technologies, and to invest in research towards personalised medicine for the future through the eHealth Action Plan 2012-2020[42]. With the Digital Single Market strategy[43], the Commission made eHealth interoperability part of its priorities in order to strengthen EU competitiveness.

According to the recent Commission Recommendation on European Electronic Health Record Exchange Format (EHRxF[44], 6 February 2019) the following healthcare domains have been identified as a source of baseline requirements for technical interoperability standardisation:

- Patient Summary
- ePrescription/eDispensation

[38] https://ec.europa.eu/digital-single-market/en/news/cross-border-health-project-epsos-what-has-it-achieved
[39] https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32008H0594
[40] http://www.ehgi.eu/Download/European%20eHealth%20Interoperability%20Roadmap%20%5bCALLIOPE%20-%20published%20by%20DG%20INFSO%5d.pdf
[41] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32011L0024&from=EN
[42] https://ec.europa.eu/health/sites/health/files/ehealth/docs/com_2012_736_en.pdf
[43] https://ec.europa.eu/commission/priorities/digital-single-market_en
[44] https://ec.europa.eu/digital-single-market/en/news/recommendation-european-electronic-health-record-exchange-format

- Laboratory Results
- Medical Imaging and Reports
- Hospital Discharge Reports

In addition to the above, the field of rare diseases has been identified as one with specific needs and high priority for standardisation. Rare diseases may be debilitating or life threatening and can have devastating impact on patients and their families. Treatment is associated with challenges different and often more serious than from those associated with more prevalent diseases. Due to the unique nature of rare diseases, promising therapies can only be developed through international collaboration based on comprehensive collection and cross-border sharing of clinical data. Standardisation of rare diseases shall be aligned with the above-mentioned domains where appropriate (e.g. adding of rare diseases in Patient Summaries).

As things stand today regarding semantic interoperability, some Member States/countries have set national-level semantic strategies in order to generate and provide data for cross-border patient care, as well as aggregate data from different sources for public health and health management applications.

Additionally, future semantic interoperability may request:

- Adoption of interoperability standards for biomedical research and other secondary uses, such as e.g.: ISO/DIS21393 'Health Informatics - Omics Mark-up Language (OML)'[45];
- Standards and methodologies for promising new uses based on Real World Data, such as Artificial Intelligence and Big Data applications.

## II-2.2 Current context

Achieving genuine interoperability in the EU is key to promoting an effective exchange of health information. Interoperability means the ability of health information systems to work together within and across organisational, regional and national boundaries in order to share information needed to provide healthcare services. In particular, semantic interoperability enables sharing and processing of healthcare data while keeping its relevant context and meaning. Semantic interoperability retains the ubiquity of the information travelling across clinicians, laboratories, hospitals, pharmacies and patients, regardless of the ICT systems applied. It is crucial to make data commonly available and interpretable across the whole healthcare and well-being pathway.

Information modelling and coding standards are the pillars on which technical, syntactic and semantic interoperability are supported. However, there should be uniform guidelines referring not only to the use of standards but also to information exchange formats. The uniformity of coded and structured data, travelling through standardised messages using standardised formats, will allow for the meaningful sharing of information between IT systems.

The overall aim is to facilitate the meaningful sharing of information both internally within a country and across borders. Thus, health information should flow for European citizens along their healthcare pathway, with minimum loss of meaning, or no loss at all.

To achieve this, a meaning-oriented strategy needs to be put in place, encompassing all kinds of health information, potentially including data generated and owned by patients, as well as information used for health and social care, and research.

Cross-border standard specifications have a great potential for usage in national systems. The standardisation of the semantic approach should bring benefits for Member States/countries due to:

- Availability of knowledge for national semantic resources of Member States/countries;
- Common standards as a reference for specifications for other ICT-related projects within Member States/countries;

[45] https://www.iso.org/standard/70855.html

- Use of common semantic standards for setting national standards, minimising burden on national resources;
- Higher acceptance among national users for adoption of a common EU standard (as the legitimacy of such standards would not be questioned by national stakeholders).

The adoption and use of semantic standards for health will bring benefits to all stakeholders: healthcare service providers, health professionals, healthcare system vendors, citizens/patients, public institutions responsible for public healthcare, public payers and many others[46].

The use of commonly adopted standards can therefore ensure better treatment for patients, regardless of their whereabouts, by ensuring the correct and unambiguous exchange of clinical data between Member States/countries and healthcare stakeholders. Additionally, the increase in exchange of health information could have secondary uses, relevant to public health programmes and clinical research, updating national and regional policies to improve citizens' life.

Some initiatives to improve eHealth semantic interoperability among Member States/countries are already being developed, such as the Semantic Task Force (STF)[47] of the eHealth Member States Expert Group (eHMSEG). This group is focused on practical issues regarding the implementation of two cross-border services: Patient Summary (PS) and ePrescription (eP)/eDispensation (eD). They have already made available some recommendations regarding these domains of healthcare. However, as this group is driven by the practical issues of only two of the five EHRxF information domains; a large part of EU semantic necessities is still unexplored and in need of a solid strategy on how to move forward within the sphere of semantic interoperability.

During the 13th eHN meeting held on 15th May 2018, eHealth interoperability and policy actions to improve semantic interoperability in the EU were discussed[48]. This was intended to initiate a constructive discussion among members of the eHN with the objective to further improve semantic interoperability in the EU. As a result of this discussion, it was noted by the participants that a Common Semantic Strategy (CSS) was needed in the EU. As such, a provisional working group was raised under the eHAction activities, to discuss the principles, scope and ambition of such a strategy. A formal invitation to all Member State/country representatives was made, asking each one to nominate an expert for this working group.

This document is the result of the active participation of the nominated representatives from a set of Member States/countries in 14 teleconferences and three workshops: two held in Lisbon (1st & 2nd October 2018 and 18th & 19th March 2019) and one held in Brussels (2nd & 3rd September 2019).

The aim of the Working Group is to set a foundation for the development of a CSS for Health in the EU, whilst addressing some of the relevant needs. It should describe possible steps to achieve a solid basis within five years, while noting that, for a solid semantic strategy, the work cannot stop there and planning for continuity needs to be included in further considerations. It was stated by the semantic experts that such a semantic strategy is a matter for at least 10 years and, once established, needs ongoing maintenance and evaluation. The mission and the vision of the resulting CSS should set and share a 10-year perspective.

[46] https://euhealthcoalition.eu/wp-content/uploads/2019/06/Future-of-Health-recommendations-in-full-new.pdf
[47] https://ec.europa.eu/cefdigital/wiki/display/EHSEMANTIC/eHMSEG+Semantic+Task+Force+documents
[48] Cover Note by eHealth Network Secretariat: https://ec.europa.eu/health/sites/health/files/ehealth/docs/ev_20180515_co02_en.pdf

## II-2.3 Description of the challenge

Due to the lack of regulation on the adoption of semantic standards for health information at EU level, Member States/countries have addressed their needs through the adoption of national standards or divergent international standards. Therefore, the decision on which standard to adopt has been taken in Member States/countries according to their internal exchange and analysis needs, and not according to any alignment with any criteria from other European authorities. So far, Member States/countries have achieved different levels of adoption and implementation of modelling and semantic standards that enable semantic interoperability of health data. Many national-level decisions are trying to cope with internal interoperability issues, lack of national semantic resources and conflicting interests among national stakeholders. Existing standards-based solutions and systems may be aimed to address immediate priorities but often tend to have limited applicability outside each national environment and are not easily sustainable in the long term. This causes a situation of high heterogeneity of semantic standards adopted and in use in the EU, and consequently low alignment between Member States/countries for the exchange of information.

To solve this, it may not be realistic to force Member States/countries to implement a retrospective adoption of standards, or to impose standards prospectively in the short term. This situation of high heterogeneity of semantic standards in use, and low alignment between Member States/countries represents a challenge that must be resolved to achieve genuine semantic interoperability among the Member States of the EU. One possible way is by evolving and maintain semantic assets and capacity building aligned with universities, and foster the national terminology/semantic centres in order to ensure the use of the updated semantic artefacts.

# II-3 Mission and Vision

## II-3.1 Mission

Establish a Common Semantic Strategy for the adoption of standards facilitating large-scale exchange of health information in the European Union, by facilitating convergence on interoperability standards for all Member States/countries. This adoption should be based on sustainable EU policies, information exchange flows between countries, conditions of availability of data, and the national standards that countries have adopted in the absence of previous European regulation. The governance process for semantic interoperability efforts shall be interlinked with the governance of projects and services for eHealth in Europe, within the framework of the Joint Coordination Process.

## II-3.2 Vision

The EU and its partners will achieve genuine semantic interoperability that allows the effective exchange and use of electronic health data.

# II-4 Goals

In order to make it feasible to effectively align to the Common Semantic Strategy by 2025, three strategic goals are set for the upcoming period of five years (Table 1):

**G1 – Structure a common approach on health semantics in the European Union**

Elaborate the framework, guidelines and recommendations to drive the basis for semantic standardisation at European level. These guidelines should be prescriptive at EU level but adopted and supported by policies for national-level sources of information.

**G2 – Provide guidance for EU level decisions on health semantics**

Establish mechanisms for capacity building in countries for consideration and use of the Common Semantic Strategy, e.g. by fostering participation in the discussion and approval of EU semantic assets and projects.

**G3 – Ensuring establishment and continuity on health semantics in the EU**

Create sustainability for the eHN Subgroup on Semantics and make the case for stable dynamics of the subgroup.

**Table 1 –** CSS Goals, Objectives and Activities

| Goal | Description | Objective | Activity |
|---|---|---|---|
| **G1** | Structuring a common approach on health semantics in the EU | **O1.1** Realise a Common Semantic Strategy for Health in the EU | **A1.1.1** Communicate with and obtain support from the eHN for five-year CSS |
| | | | **A1.1.2** Analyse current and future data availability, standards and information exchange flows in Member States/countries |
| | | | **A1.1.3** Structure a learning programme to assist capacity building in Member States/countries |
| | | | **A1.1.4** Mid-term evaluation and iterative review |
| | | | **A.1.1.5** Ensure active Member State/country participation |
| | | | **A.1.1.6** Set up an operational plan to ensure the development and completion of the other domains |
| | | **O1.2** Develop common semantic assets for PS, eP/eD, laboratory results, medical imaging and reports, hospital discharge reports | **A1.2.1** Drive the development of common semantic assets for Patient Summary |
| | | | **A1.2.2** Drive the development of common semantic assets for ePrescription/eDispensation |
| | | | **A1.2.3** Drive the development of common semantic assets for Laboratory Results |
| | | | **A1.2.4** Drive the development of common semantic assets for Medical Imaging and Reports |
| | | | **A1.2.5** Drive the development of common semantic assets for Hospital Discharge Reports |
| | | | A1.2.6 Set up common semantic assets: 'Common European Health Semantic Services' |
| | | **O1.3** Provide guidelines for standards adoption | **A1.3.1** Study the current and future data availability and standards in use in the different Member States/countries |
| | | | **A1.3.2** Access and refine common standards for the cross-border exchange of health information |
| | | **O1.4** Establish a solid relationship with key bodies of the EU and key technological partners | **A1.4.1** Liaise with key partners such as SDOs, technology developers etc. relevant to the CSS |
| | | | **A1.4.2** Establish a collaboration routine and mechanisms with key bodies of the EU relevant to the CSS |
| **G2** | Providing guidance for EU level decisions on health semantics | **O2.1** Establish methodology to address alignment to CSS issues at an EU level | **A2.1.1** Propose a mechanism to build capacity in Member States/countries to foster the use of EU semantic standards for healthcare |
| | | | **A2.1.2** Influence EU deployment projects that use semantic standards |
| | | **O2.2** Ensure the alignment with the CSS launch of new initiatives related with semantic assets and projects | **A2.2.1** Propose to the eHN a mechanism to participate in the approval of EU semantic assets and projects |
| **G3** | Ensuring stability and continuity on health semantics in the EU | **O3.1** Sustainable semantics activity in EU | **A3.1.1** Make the case for stable dynamics |
| | | | **A3.1.2** Create a sustainability plan |
| | | | **A3.1.3** Draft a new CSS for 2025-2030 |

# II-5 Value Proposition

Following the Commission Recommendation on Electronic Health Record exchange format (EHRxF) published on 6th February 2019, this chapter aims at presenting five value propositions to better describe and contextualise the need for the establishment of a Common Semantic Strategy for Health in the EU. These propositions relate to the information domain a set out in the EHRxF Commission Recommendation.

The definition of a Common Semantic Strategy is needed to support the adoption of national and cross-border technologies. Furthermore, not all EU countries have the technical possibility to receive electronic prescriptions from other EU countries, since countries are in different states of maturity of electronic systems development. The actual coding standards used by the Member States/countries can be seen in Annex II.2.

## II-5.1 Patient Summary Domain

Patient Summary Guidelines were first prepared by the epSOS project as a starting point for the development and pilot testing of the cross-border transfer of Patient Summaries for citizens who are travelling abroad and need unplanned medical help[49]. Since then, the need to exchange essential clinical data across borders has become increasingly recognised. Citizens of the EU travel for work, study and leisure; and the number of persons seeking medical help abroad continues to grow. In the forthcoming years, even more people are expected to receive medical treatment in facilities located outside of their country of domicile.

The Patient Summary (PS) domain has been deployed in many Member States. Being a concise clinical document, it is universally applicable, and its usability is not limited to emergency care. It is supportive in continuous care of chronic patients and can be used in conjunction with other sources of data.

Access to a PS increases patient safety and helps to optimise the outcome of medical treatment. Patients, health professionals and healthcare providers are increasingly aware of its value and national borders must not be barriers stopping its flow. While past solutions, before the adoption of CEF eHDSI, for getting medical information from another country were often unsafe, incomplete and non-standard, there is a reasonable expectation that the PS is accessible wherever emergency or planned treatment is taking place.

The PS dataset comprises patient administrative data and patient medical history. The patient clinical dataset is divided into several sections: Alerts, Allergies, Medical problems, Medication summary, Surgical procedures, Vaccinations, Implanted devices, Social history, Pregnancy history, Physical findings and Diagnostic tests.

The purpose is sharing information about the medical background and history of a patient from one Member State, 'Country A' (the patient's country of affiliation) with a health professional in another Member State, 'Country B' (the country of treatment). The use case is relevant for people requesting clinical assistance when travelling, working or living abroad.

The setting up of cross-border exchange of PS through the eHealth Digital Service Infrastructure (eHDSI), supported by the Connecting Europe Facility (CEF), is in progress. The following is the latest description of the PS that potentially will be in use in almost all Member States in the not-too-distant future:

*A Patient Summary is an identifiable 'data set of essential and understandable health information' that is made available 'at the point of care to deliver safe patient care during unscheduled care [and planned care] with its maximal impact in the unscheduled care'. It can also be defined at a high level as: 'the minimum set of information needed to assure Health Care Coordination and the continuity of care'.*

[49] https://ec.europa.eu/digital-single-market/en/news/cross-border-health-project-epsos-what-has-it-achieved

### II-5.1.1 Known used standards

The code systems that were used for Patient Summary in epSOS are listed in the Master Value Set Catalogue (MVC)[50], which has been subsequently updated in eHDSI by the eHMSEG Semantic Task Force. The Value Set Catalogue is a collection of the mostly used terms from different international code systems based on definite criteria presented in the methodology section. The MVC is the basis for the creation of the Master Translation/Transcoding Catalogue (MTC) by each deploying country. As use of code systems varies across Member States/countries, it is expected that translation between systems will be necessary. Continuous monitoring of systems used in Member States/countries will thus be important.

### II-5.1.2 Semantic constraints and challenges

The sharing of data through mapping and translation of terminology codes (national and international) could generate loss of information. In many cases, full mapping is not possible between different coding systems, for example NOMESCO Classification of Surgical Procedures (NCSP) and SNOMED CT for surgical procedures.

In addition, for a Patient Summary to be considered valid, there is a minimum set of information to be provided in a structured and coded format. The minimum set of information was decided based on its relevance from a clinical point of view and declared readiness during the epSOS project[51]. The issue raised by some countries is that they cannot provide the minimum set of information within the Patient Summary in a structured and coded format.

In the eHN's Release 2 of the PS Guidelines[52] it is also said: '*It is expected that the eHN will oversee the process by which code systems are kept under review and ensure that appropriate licensing arrangements are in place*'. Based on a change proposal approved by the Commission (DG SANTE) and eHMSEG, the computable CDA Template specifications (based on ART-DECOR[53]) have allowed improvement in the consistency and reliability of the exchange of PS data.

A gradual adoption of the CEN International Patient Summary (IPS)[54], based on the EU PS Guidelines and on HL7 IPS Implementation Guides, will enforce the adoption of international standards and take advantage of the PS derived from epSOS, potentially extending its applicability to planned care.

Content and structure of the PS should be regularly evaluated and adapted as new use cases might create additional semantic requirements, e.g. inclusion of information about rare diseases, and new versions of terminology and coding systems that might better reflect clinical needs of interoperable records. In all cases, thorough feasibility and impact analysis should be done as implementation of new semantic features might have implications for the Member State/country national infrastructure.

## II-5.2 ePrescription/eDispensation Domain

An ePrescription is defined as the electronic document resulting from prescribing medicine using software, performed by a health professional legally authorised to do so, for dispensing, once it has been electronically transmitted to the pharmacy. ePrescribing consists of an electronic prescription of medicine by a health professional and its electronic transmission to a pharmacy where the medicine can then be dispensed.

eDispensation within eHDSI is defined as the electronic document resulting from dispensing medicine using software, performed by a pharmacist legally authorised to do so, of an ePrescription transmitted to the

[50] https://ec.europa.eu/cefdigital/wiki/pages/viewpage.action?pageId=35208905
[51] https://ec.europa.eu/cefdigital/wiki/display/EHOPERATIONS/Patient+Summary+Required+Sections+-+Clarifications+on+the+information+to+be+exchanged
[52] https://ec.europa.eu/health/sites/health/files/ehealth/docs/ev_20161121_co10_en.pdf
[53] https://art-decor.org
[54] http://www.ehealth-standards.eu/results-of-the-international-patient-summary-project-2/

pharmacy. eDispensing is defined as the electronic retrieval of a prescription and the dispensing of the medicine to the patient as indicated in the corresponding ePrescription.

### II-5.2.1 Known used standards

The epSOS Semantic Work Group identified the code systems that were used for ePrescription and eDispensation in the first versions of the Master Value Set Catalogue (MVC), which was subsequently updated in EXPAND and also in eHDSI by the eHMSEG Semantic Task Force. (The MVC has been described in section 4.1).

The MVC includes various classifications relevant to ePrescriptions/eDispensations, for example ATC (Anatomic Therapeutic Chemical classification), EDQM (European Directorate for the Quality of Medicines) for Dose Form, Packages, Route of Administration, Display Labels, Health Professional Roles and Country. The use of international classifications based on ISO IDMP[55] (Identification of Medicinal Products), and other relevant code systems to support semantic interoperability within the EU could be considered in the future. Most countries have national drug code systems, adjusted to their domestic situation, so the possibility of performing mappings between international standards and national code systems can be relevant.

### II-5.2.2 Semantic constraints and challenges

Some technical and legal challenges have occurred in ePrescription and eDispensation.

One of the major constraints is the lack of a uniform classification system or an international standard regarding drugs that is universally accepted. ePrescription/eDispensation systems, when existent, are highly dependent on national code systems, turning semantic interoperability into a true challenge. The variability of the correspondence of drugs between countries (e.g. commercial names of the drugs, dosages, pharmaceutical form, etc.) makes this harmonisation even more difficult. The need for a European-wide univocal identification number or code for a medicinal product and its underlying pharmaceutical product(s) has been acknowledged for many years. The eHealth Network Guidelines on ePrescription[56] and Patient Summary[57] indicate the adoption of the ISO IDMP codes as a way to solve pharmaceutical/medicinal products identification issues.

Ongoing and newly starting projects (such as the UNICOM[58] project), aim at solving the discrepancies and have to be considered further in the work of the CSS Working Group.

## II-5.3 Laboratory Results Domain

Clinical laboratory requests and results play an important role in diagnosis, treatment and follow-up of patients.

Thus, requests and sharing of laboratory results in cross-border health information exchange is an expected and wanted further extension within the CEF eHDSI. Furthermore, exchange of laboratory test orders and result reports will support free movement of the services as one of the key principles of the EU (Commission Recommendation on EHRxF).

It is important that laboratories produce high quality test results as they often are the basis for clinical decision-making. Proper quality management is therefore essential. It is also important that requests sent to the laboratories are of sufficient quality to enable the laboratory to respond in an adequate way to the request, for example including sufficient medical background.

[55] https://www.ema.europa.eu/en/human-regulatory/overview/data-medicines-iso-idmp-standards-overview
[56] https://ec.europa.eu/health/sites/health/files/ehealth/docs/ev_20161121_co091_en.pdf
[57] https://ec.europa.eu/health/sites/health/files/ehealth/docs/ev_20161121_co10_en.pdf
[58] https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/opportunities/topic-details/sc1-dth-09-2019

The Laboratory area is one of the most standardised areas of the medical industry, thanks to the extended use of automation (produced by global companies) while the situation is not without challenges, as well as to a long tradition in the organisation of external quality control programmes.

### II-5.3.1 Known used standards

A recent study on comparison of terminologies for laboratory results shows that 'there are still limitations in electronic transition of lab reports in complex treatment pathways that involve multiple laboratories. Medical laboratories do not only measure analysis, but also strive to make their results actionable for patient treatment. They ensure that laboratory reports are correctly transmitted to the requesting physician with a short turnaround time. Laboratories also assist in the interpretation of their results by providing comments, statements regarding measurement uncertainty, reference intervals, medical decision limits, or other means'[59].

According to a quick survey between Member States/countries represented in the CSS working group, two main international laboratory terminology systems for test coding are being used: Logical Observation Identifiers Names and Codes (LOINC)[60] and Nomenclature for Properties and Units (NPU)[61]. Four countries reported use of LOINC based systems (Austria, Estonia, Portugal and the Netherlands) and four countries use NPU based systems (Sweden, Denmark, Norway and the Czech Republic); several countries are using other national terminologies, a mix of different terminologies, or a defined laboratory terminology has not been decided upon (e.g. Germany, Slovakia, Poland, Slovenia).

It should also be noted that additional code systems are needed for coding of specimen types, anatomic specification, specimen collection, processing and test methods, containers, measurement units, and ordinal or nominal-scale test results.

Terminology-wise, requests are not as well-standardised as reports, where requests more often reflect local ordering practices, where national standardisation is lacking. Some laboratories use standard terminologies like LOINC and NPU also for ordering while others do not.

### II-5.3.2 Semantic constraints and challenges

Exchange of laboratory orders and results is currently not an eHDSI-supported use case. EU countries with well-established electronic laboratory communication will not be likely to change their existing laboratory coding systems, thus transcoding to the selected pivot terminology represents one of the main challenges on the way to the semantic interoperability of the order/result cross-border communication.

Still, while laboratory medicine is relatively well standardised, comparison of results between different laboratories is a major challenge due to differences in methods, instruments, and lack of international calibrators which is certainly true for some areas of laboratory medicine, such as microbiology, immunology and histopathology.

## II-5.4 Medical Imaging and Reports Domain

Medical imaging is an important diagnostic tool and is central in many diagnostic or treatment processes, like orthopaedic diagnostics and follow-up of cancer treatment. In the last decades many imaging areas such as radiology have undergone a shift from analogue to digital technology, allowing new ways of working with

59 https://www.researchgate.net/profile/Stefan_Schulz3/publication/328558872_NPU_LOINC_and_SNOMED_CT_a_comparison_of_terminologies_for_laboratory_results_reveals_individual_advantages_and_a_lack_of_possibilities_to_encode_interpretive_comments/links/5c10c8be299bf139c7524c1b/NPU-LOINC-and-SNOMED-CT-a-comparison-of-terminologies-for-laboratory-results-reveals-individual-advantages-and-a-lack-of-possibilities-to-encode-interpretive-comments.pdf?origin=publication_detail.

60 https://loinc.org/

61 http://www.npu-terminology.org

medical images. As an example, in teleradiology, the communication of images and reports enabled by digitalisation is now common practice. Cross-border communication of imaging data is also routine but typically through point-to-point communication using Digital Imaging and Communications in Medicine (DICOM) standards. In addition to reports, information provided in the request is important for interpretation of results and should also be elaborated on future EU projects.

### II-5.4.1 Known used standards

DICOM is used worldwide as standard in the storage, exchange, and transmission of medical images. DICOM has been central to the development of modern radiological imaging: DICOM standards are used for imaging modalities such as radiography, ultrasonography, computed tomography (CT), magnetic resonance imaging (MRI), and radiation therapy. DICOM includes protocols for image exchange (e.g. via portable media such as DVDs), image compression, 3-D visualisation, image presentation, and results reporting.

The same basic format is used for all applications, including network and file usage, but when written to a file, usually a true 'header' (containing copies of a few key attributes and details of the application which wrote it) is added.

### II-5.4.2 Semantic constraints and challenges

One of the constraints regarding medical imaging and reports is that the results are mostly described with free text. In addition, national value sets are used to identify the medical imaging procedures for reimbursement reasons and therefore mapping the national value sets to international ones can be complicated.

## II-5.5 Hospital Discharge Reports Domain

The discharge report after a hospital stay is a well-established instrument of communication between the hospital and a physician responsible for the post-hospital care of a patient, independently of the setting in which this care is provided. In addition, it is a source of information for the patient and caregivers.

Use of discharge reports is not limited to inpatient episodes. Some health services may also provide discharge reports for emergency care and for ambulatory clinic processes of care.

Discharge reports originated as personal letters written from one doctor to another doctor to provide information on a defined situation during a period of time spent in a health environment; therefore, a discharge report is an important element of information about the patient, which has to respect pre-defined conditions to present a complete set of important information about the patient. This means it should be structured, if possible, containing also coded information, using defined catalogues and tools. The ambition is to have a communicable composition which is an integral part of a national electronic health record, which fits into international formats, and could to a certain extent be translated automatically using the epSOS/ eHDSI infrastructure and covers the requirement of having text which can be understood by physicians and patients.

In addition to information for the post-hospital phase, a hospital discharge report should contain: detailed medical findings during the stay, medication used, laboratory findings and radiology reports.

### II-5.5.1 Known used standards

The intended EU strategy for interoperability of this information object could be informed by several specifications already developed by Member States/countries[62], and by European and international SDOs.

### II-5.5.2 Semantic constraints and challenges

The differences in the requirements for the content of the discharge report from different types of episodes (from different medical specialties), together with historical tradition of structure and content of discharge reports by healthcare facilities, represent a major challenge for semantic standardisation. It should be taken into account that some national medical environments are less inclined to standardise in this area.

However, it is clear that discharge reports (as well as other types of comprehensive medical documents) should not only be understandable to a person, but also be machine-readable. This means that the document should include both a narrative part, intended only for human beings, and a part encoded for further machine processing with clear standardised sections and coded entries. The discharge letters could include, in the future, information provided by other health professionals.

Standards for structure and coded entries need to be specified and agreed between Member States/countries based on common identified patterns.

Decisions on terminologies and other code systems used by national infrastructures should be made. Pre-defined structures of coded entries such as those of the PS (problems, medications, procedures, etc.) should be reused.

## II-6 Common Semantic layers

This chapter aims at providing some insights on key aspects that need to be addressed in order to realise a common approach to health semantics in the EU, aiming at providing the reader with further context about the subject whilst also setting a path for future work by Member States/countries.

It is also important to clarify that some of the aspects presented in this chapter can be discussion items of other EU bodies and their conclusions must be made as part of the final common semantic strategy proposal.

The following figure describes the relationship between the five domains of EHRxF, and potential future domains with the five information domains and the layers of the Common Semantic Strategy (Figure 3). While standardising health information in the five domains listed here and in EHRxF is a goal, in order to guarantee the consistent and efficient development of semantic resources across the five domains, the strategy includes four layers which span the domains horizontally: processes, information, services (applications), technology and their impact on this strategy.

[62] Some MS/C have established Hospital Discharge letters:
https://theprsb.org/wp-content/uploads/standards/5b98da94aa3ef80313a9e97c.xlsx
https://theprsb.org/standards/edischargesummary/
https://digital.nhs.uk/services/transfer-of-care-initiative/edischarge-summaries
https://confluence.ihtsdotools.org/pages/viewpage.action?pageId=29950390

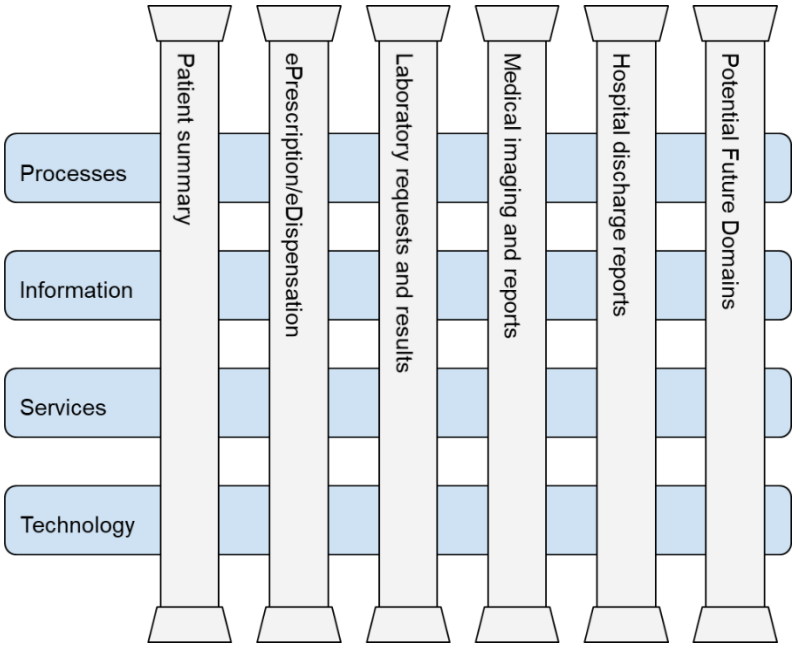


**Figure 3 –** Transversal health information domains among the semantic layers**.**

## II-6.1 Processes

Core processes underpinning the semantic strategy need to be laid out, such as establishing a way to consult Member States/countries for their needs and inputs regarding semantic issues. In this regard, establishing a methodology to prioritise the roadmap leading to semantic interoperability is also required, as well as defining a maturity model to assess or keep track of the maturity of Member States/countries regarding health semantics.

Likewise, it is as important to establish a set of processes that allow the maintenance and update of EU level semantic assets and capacity building within the Member States/countries and NCPs.

## II-6.2 Information

Central to the strategy is the capacity to share health information within Member States/countries and within Europe, with the ability to use and re-use information in the receiving systems for both primary and secondary purposes. This requires the establishment of standardised semantic assets such as information models and code systems.

The eHDSI laid the ground for semantic assets in the field of exchange of PS and eP/eD. These assets will be re-used and, when necessary, expanded in the context of laboratory medicine, medical imaging and hospital discharge reports, as well as future domains brought by EU projects and activities.

Member States/countries are constantly reviewing emerging trends in eHealth, in structured and unstructured formats, including for example adoption of new standards, information models and code systems; this requires monitoring on a strategic level.

## II-6.3 Services

For successful realisation the strategy further depends on services being available for use by Member State/countries and EU projects. As the number of distinct services can be expected to be large, an ecosystem of services, both existing and newly developed, needs to be established. The strategy will be building upon

services already established by, for example, eHDSI, the EU Rare Diseases Platform, EARS-Net, the European Medicines Agency's Referentials Management Services (RMS)[63] and other helpful services.

Examples of such services can be:

- Provision of a 'Common European Network of Health Semantic Services' as a repository for standardised semantic assets
- Provision of testing tools and test plans, together with reference test data.

## II-6.4 Technology

Technology is a key enabler of the semantic strategy, i.e. technology needs to be put in place which allows the results of the activities within the strategy to be implemented. Thus, lack of technology standards is also a barrier. Also, the constant development of new and improved technologies is a challenge for any long-term strategy. The strategy will be agile to adapt to emerging and developing technologies in eHealth.

Here, the strategy will build upon what has been established by the eHDSI and eHMSEG.

Particularly, the success of innovative technologies like Natural Language Processing, AI, and Big Data Analytics will have a dependency on the availability of standardised structured data, i.e. the realisation of this strategy.

Here, the strategy will build upon what has been established by the eHDSI and eHMSEG.

[63] https://www.ema.europa.eu/en/human-regulatory/research-development/data-medicines-iso-idmp-standards/spor-master-data/referentials-management-service-rms

# II-7 Policy and Governance Structure description

The governance aspects proposed are the result of CSS Working Group reflections in workshops and teleconference sessions, as well as considerations from existing eHN and eHDSI governance bodies. This is still to be finally aligned and streamlined with a global approach under the concept of the Joint Coordination Process played out in the EHRxF Recommendation and formally approved by the eHN. A concrete proposal making use of the new eHN Subgroup on Semantics (approved during the 15th eHN meeting, 11th-12th June 2019), as well as other functional and already existing formal/informal bodies, like eHMSEG and its Semantic Task Force, is advanced.

## II-7.1 Guiding Principles

A Common Semantic Strategy (CSS) should consider all semantic requirements that are relevant for healthcare in the EU, focussing initially on the eHealth domains addressed in this paper but progressively expanding on all health-related subjects, including research.

The realisation of a CSS must be guided by the needs of Member States/countries, as well as by 'FAIR' principles: i.e. recommendations of semantic standards will acknowledge that they have to be Findable, Accessible, Interoperable, and Reusable. Implications such as licensing, maintenance or accessibility issues of the recommended standards will have to be considered before their adoption, and solutions to avoid any limitations of use for Member States/countries will have to be addressed.

A CSS will have to be future-oriented towards new developments in the field of standards to be included without the need for redevelopment of the resources and the technical infrastructure. Revisions of included standards (like ICD-10 to ICD-11) need to be addressed once available and a joint approach on the change to the newer version can be beneficial for all involved countries as the burden of evaluation and implementation needs can be shared (like education, technical support etc.).

The strategies elaborated by the eHN Subgroup on Semantics will be presented as guidelines or recommendations at eHN meetings for endorsement. If endorsed, the recommendations should be structured as EU-level guidelines.

### II-7.1.1 Transparency

As the CSS Working Group is discussing topics relevant for international as well as national semantic strategy, all discussions and results should be made public. Even though meetings themselves will be limited in participation to nominated members – to achieve the most efficient outcome of the meetings – the minutes as well as the upcoming topics will have to be available publicly.

## II-7.2 Need for a Common Semantic Governance Framework

To fully achieve the realisation of a CSS within the EU, there is a need to expand beyond the scope of the Patient Summary and e-Prescription/e-Dispensation domains, broadening it to encompass Laboratory Results, Medical Imaging and Reports, and Hospital Discharge Summary domains. This calls for a new approach that simultaneously builds upon the existing work so far realised and also aims to expand beyond it. On the other hand, it uses the new eHN Subgroup on Semantics, for a robust and stable structure, responsible for overseeing all matters concerning its ongoing follow-up and ensuring as much as possible its adoption by Member States/countries.

The eHN Subgroup on Semantics should have as its core attributes the ability to set up rules regarding common semantic artefacts at the EU level, whilst trying to better align them with the needs of each Member

State/country, operating as a steering body for overarching strategic and policy decisions aligned with eHN mandate.

It should likewise be the responsibility of the eHN Subgroup on Semantics to keep track of related work regarding semantics being conducted by other working groups within the EU, thus assuring that efforts are not duplicated, and to create a unified channel for proposals to the eHN and downwards communication from the eHN towards more strategic, tactical and/or operational implementers.

This chapter aims at providing further insights on the responsibilities that should fall upon the eHN Subgroup on Semantics, as well as to how this Subgroup should operate within the context of the EU and the eHealth Network. It also explores and explains the links with eHMSEG Semantic Task Force, as well as other eventual related semantic efforts in temporary Coordination and Support Actions or projects and pilots.

# II-7.3 Proposed Governance Framework

## II-7.3.1 Existing semantic structures

**eHMSEG Semantic Task Force (STF)**

The STF is a group composed of experts on semantics inside the eHMSEG domain. This group's scope is so far limited to Patient Summary and ePrescription/eDispensation, although it could see its 'mandate' expanded to the three new EHRxF domains, as they will, eventually, be part of the eHDSI.

**eHN Subgroup on Semantics**

During the 15th eHN meeting (11th-12th June 2019), the eHN approved the creation of a Subgroup on Semantics within its scope. This group will be composed of the representatives indicated by the eHN member of each Member State/country, allowing the possibility that more semantic experts are incorporated in it in future. In an ideal scenario, each Member State/country should have a representative on this group.

**National Terminology/Semantic Centre**

A national terminology/semantic centre is a body (organisation, group of organisations, or other national body) with the competence, capacity, authority and mandate to create, support and monitor the adoption of semantic solutions in a Member State/country for health, or health and social care.

The representative to the eHN Subgroup on Semantics, mandated by the Member State/country, would be expected to be connected to this national body.

## II-7.3.2 Ongoing and future projects calls and projects (under 2020 and beyond)

**UNICOM Up-scaling the Global Univocal Identification of Medicines – Horizon 2020[64]**

The UNICOM project[65], which started officially in December 2019, aims to implement ISO IDMP standards, establishing definitions and concepts to describe data elements and their structural relationships of products that are required for the unique identification of:

- Regulated medicinal product information - ISO 11615
- Regulated pharmaceutical product information - ISO 11616
- Substances - ISO 11238
- Pharmaceutical dose forms, units of presentation, routes of administration and packaging - ISO 11239
- Units of measurement - ISO 11240

[64] https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/opportunities/topic-details/sc1-dth-09-2019
[65] https://unicom-project.eu/

ISO IDMP standards apply to both authorised and developmental medicinal products for human use.

**Coordination and Support Action (CSA) – Horizon 2020 proposal to adopt EHRxF (X-eHealth Project)**

A project to adopt the EHRxF EC recommendation, proposed under the call 'SC1-HCC-07-2020: Support for European eHealth Interoperability roadmap for deployment' was approved by the Commision and lounched on September 2020. The information domains that have not yet been discussed on the EHRxF recommendation are the focus of this call (Laboratory Results; Medical Imaging and Reports; Hospital Discharge Reports). It is natural that there is a need to assemble new semantic assets for the three new domains, and that some of that work is in line with eHMSEG work, as well as under guidance of the eHN Subgroup on Semantics.

### II-7.3.3 Four-Level Approach

To ensure the fulfilment of the CSS, the eHN Subgroup on Semantics must be part of a robust and stable governance model. The correct layout of this governance model is key to assure overall coherence in the strategy and in semantic interoperability across the EU. Therefore, a governance structure which has strong steering elements addressing both policy and technical issues is needed. Also, given that the semantic strategy is intended to be laid out and carried out initially over the course of five years, that period should correspond to the duration of the eHN Subgroup, after which need for a new, permanent governance structure should be addressed. Outlining that permanent governance model, after 2025, is outside the scope of this document but can be designed according to the ideas set out in this paper, if proven to be effective.

The proposed governance structure includes bodies aligned with:

- eHN Subgroup on Semantics (with representatives from Member States/countries);
- Administrative functions (supported by the EU and Member State /countries);
- Work groups: 'expanded eHMSEG Semantic Task Force'; work groups creating and maintaining semantic assets within EU Projects related to health, such as UNICOM, CSA for EHRxF, other EU funded projects.

It should be noted that this governance structure seeks not to set up new structures, but associate eHN Subgroup on Semantics activities with existing bodies, to the greatest extent possible, as presented schematically in Figure 4.

In order to allow for the widest reach possible within EU projects and planning, the eHN Subgroup should, in addition to reporting to the eHN, also be associated with other EU areas of health, e.g. as in the realm of DG SANTE, DG CONNECT and CHAFEA.

The eHN Subgroup should be composed of national representatives nominated by Member States/countries. Ideally these representatives should be experts in the field of semantics and belong to organisations that have a relevant national mandate or are working as expert or competence centres in this field.

The rules of procedure, as well as chairing and rapporteur functions, of the eHN Subgroup had been developed and approved inspired by the Rules of Procedure of the eHealth Network[66] as this has proven to be an effective setup. Even it is established, additional Terms of Reference can be set, if necessary.

In order to achieve best coverage on health topics, the group shall be open to inputs from all fields of health and must not be limited to eHealth applications. Therefore, mechanisms should be put in place to allow for input of discussion items (requirements) into the work stream of the group. Criteria need to be developed for what requirements the group will address, before deciding on a recommendation.

National requirements can be brought forward additionally to EU requirements if they have the potential to:

- Be of mutual interest
- Be beneficial for EU-wide digitalisation of health sector

[66] https://ec.europa.eu/health/sites/health/files/ehealth/docs/rules_procedures_ehealth_network_en.pdf

- Fill gaps in cross-border communication that have been identified within that country

The eHN Subgroup on Semantics is managed at the EU level and the official DG SANTE secretariat supports their organisation management practicalities. The group is co-chaired by the Commission and one appointed Member State. One additional Member State/country will serve as rapporteur to the group. This will ensure continuity as well as some more capacity to the Subgroup. The above-mentioned management arrangements shall be reviewed after two years, to evaluate their fitness for purpose. As the initial phase of the eHN Semantic Subgroup is set out to be five years, Member States/countries should nominate one expert for the group for this period of time and be prepared to set in place mechanisms to nationally consolidate input to the eHN Semantic Subgroup by the nominated representative.

Meetings should take place twice a year and meeting support (organisation, facilities, travel expenses, etc.) should be provided through the eHealth Network. It is expected that the national consolidation of feedback and the additional work of the experts outside the meeting will be covered by the national bodies seconding experts to this task. In between meetings regular exchange is encouraged but the schedule needs to be defined according to the work requirements.

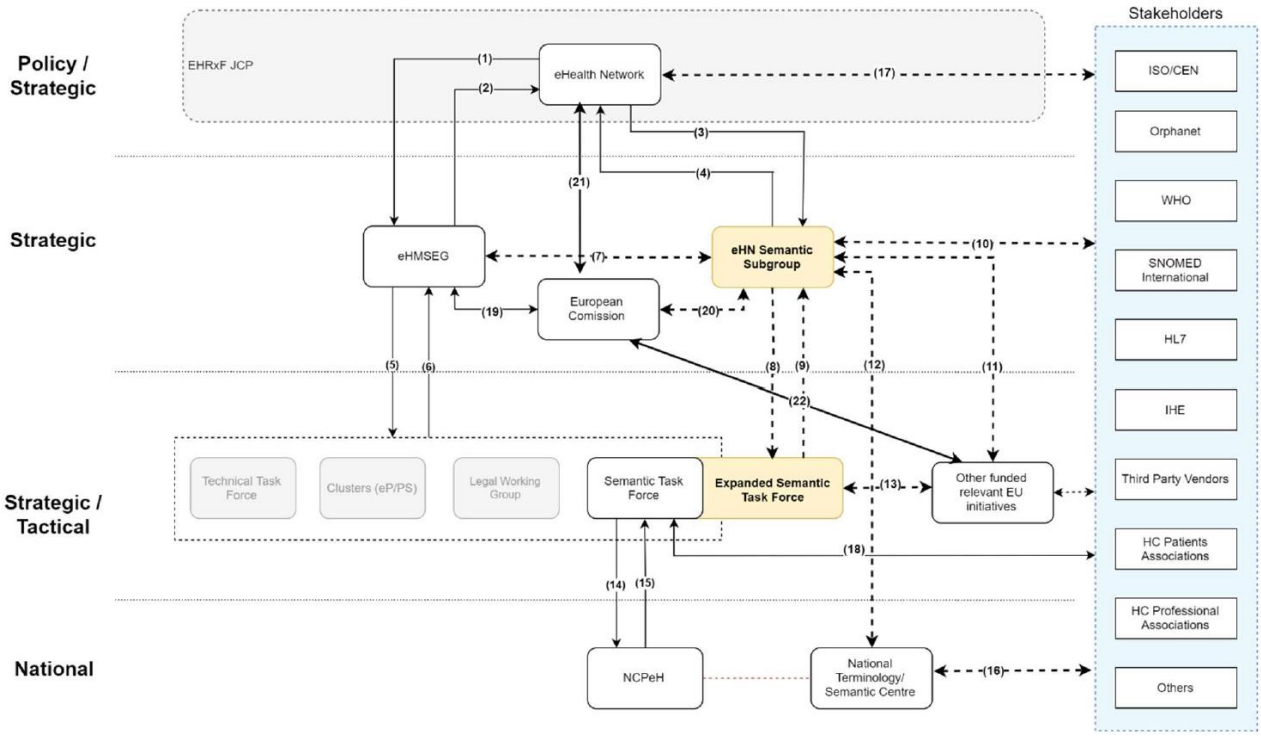


**Figure 4 –** Proposed revised governance framework for semantics in the eHN structure

*This figure details the governance structure regarding semantics in the eHDSI cross-border services spectrum, which can be detailed as follows from the different interactions:*

***Relations (1), (2), (5), (6), (11) and (12):*** *as described in the eHDSI Governance Model document[67];*

***Relations (3) and (4):*** *the eHN Subgroup on Semantics should exert its functions under the eHN scope. The eHN Subgroup shall propose semantic guidance to the eHN for endorsement, in this way acting as a consulting body to the eHN, which in return shall take the eHN Subgroup's proposals and structure them as EU-level guidelines;*

***Relation (7):*** *The eHN Subgroup and the eHMSEG should maintain a strategic collaboration, assuring that there is a convergent view regarding health semantics;*

***Relation (8) (9):*** *The eHN Subgroup should rely upon and expanded version of the Semantic Task Force to carry out strategic/tactical activities, that shall assure the execution of the proposed expanded semantic services/domains*

[67] https://ec.europa.eu/cefdigital/wiki/display/EHOPERATIONS/eHDSI+Governance?preview=/35210447/41287688/ev_20161121_co06_en.pdf

***Relation (10):*** *The eHN Subgroup should act as a liaison agent with key partners, within the EU and the private sector, such as SDOs, technology developers and others relevant to the CSS. From a strategic viewpoint, it is noted to be of particular importance to establish a relationship with the UNICOM project (recently approved large EU project dealing with medication coding (see chapter 6.3.1) and Orphanet, or other relevant large initiatives worthy of inclusion to be decided by the eHN Subgroup;*

***Relation (11):*** *The eHN Subgroup should have the capacity to ensure alignment of new EU funded initiatives' work on semantics with supporting assets that have been created and finalised in the realm of the CSS;*

***Relation (12):*** *The eHN Subgroup should act as a liaison agent to the existing National Terminology/Semantic Centres, assuring that there is a convergent view regarding semantic artefacts at a national level with the ones defined at an EU level;*

***Relation (13):*** *The Expanded Semantic Taskforce should collaborate closely with other relevant EU-funded initiatives relating to health semantics;*

***Relation (16):*** *The National Terminology/Semantic Centres can collaborate with relevant stakeholders as necessary;*

***Relation (17):*** *as described in the eHN Rules of Procedure document[68];*

***Relation (18):*** *The Semantic Task Force has collaborated with stakeholders and will maintain this relationship after its extension.*

***Relation (19):*** *The Commission elaborates proposals to be considered by the eHMSEG.*

***Relation (20):*** *The Commission elaborates proposals to be considered by the eHN SG on Semantics.*

***Relation (21):*** *The Commission elaborates proposals to be considered by the eHN.*

***Relation (22):*** *The Commission may support EU-level initiatives on semantic-related matters.*

## II-7.4 How to implement the Governance Structure

eHMSEG is the body responsible for the initial deployment and operation of services for cross-border health data exchange, currently funded by the Connecting Europe Facility (CEF) and specialising in ePrescription/eDispensation and Patient Summary services. Given the necessity to procure IT services regarding the maintenance and dissemination of semantic assets, resourcing to the eHDSI is a possibility to address this need, whilst also preventing the duplication of efforts and work within bodies of the EU.

While the eHMSEG Semantic Task Force has done terrific work in the fields of eP/eD and PS, there is a strongly-felt need to build upon that work and expand it to other relevant fields, such as laboratory results, medical imaging and reports, and hospital discharge reports. As such, this Task Force should continue its work in the eP/eD and PS domains, to ensure the continuity of the work already in place.

Additionally, other domains such as Laboratory Results, Medical Imaging and Reports, and Hospital Discharge Reports should be picked up through new EU-funded projects and be streamlined with the existing work of the Semantic Task Force. This requires the existence of a strategic relationship and understanding between the eHMSEG and the eHN Subgroup on Semantics, given that until the requirements to continue the work in an Expanded Semantic Task Force and equivalent bodies are met, the current task force should account for proposed use cases from the eHN Subgroup regarding PS and eP/eD.

It was thus proposed to build upon the work carried out by the eHMSEG Semantic Task Force in developments and continue its work even after the end of CEF-funded projects. This continuation was approved in the eHN meeting in November 2019, as part of the approval of this strategy and governance document aligned with the Digital Europe Programme (DEP) funds. All work done at tactical/operational level should follow the strategy laid out by the Subgroup.

Other semantic work streams within the EU may have developed other mechanisms (like the EMA for the implementation of ISO IDMP or the JRC for the development of EU-wide registers for patients with rare diseases). Stepwise these work streams should be addressed, lessons learnt should be considered, and a future joint work programme set, as a way to bring the different developments together. One such way for that is, for example, linking up work with UNICOM project in the case of ISO IDMP for real use in the eP/eD use case.

[68] https://ec.europa.eu/health/sites/health/files/ehealth/docs/rules_procedures_ehealth_network_en.pdf

### II-7.4.1 eHN Subgroup on Semantics

The eHN Subgroup on Semantics, in alignment with the EHRxF Joint Coordination Process (JCP), has the following responsibilities among others:

- Provide input to policies regarding health semantics in the EU;
- Formulate recommendations on the use of certain standards, based on set criteria and guidelines for the acceptance of semantic assets as EU common semantic standards;
- Manage and maintain the 'Common European Network of Health Semantic Services' as a repository for standardised semantic assets.
- Act as liaison with key partners, within the EU and the private sector, such as SDOs, technology developers, patient associations, professionals' associations and others relevant to the CSS;
- Convey strategic decisions regarding the subject of semantics to the eHealth Network.

#### *II-7.4.1.1 Final approval of eHN Subgroup on Semantics recommendations by the eHN*

The strategies elaborated by the eHN Subgroup will be presented as guidelines or recommendations at eHN meetings for endorsement. If endorsed, the recommendations should be structured as EU level guidelines.

### II-7.4.2 eHMSEG Semantic Task Force

In order to allow for a quick start of the work, the existing group within the eHDSI, i.e. the eHMSEG Semantic Task Force (STF), should continue its work to achieve results on PS and eP/eD in a reasonably short period of time. This means the current STF should account for proposed use cases from the eHN Subgroup regarding PS and eP/eD.

#### *II-7.4.2.1 Additional work stream within EU-funded projects*

Inclusion of new domains (Laboratory Results, Medical Imaging and Reports, and Hospital Discharge Reports) should follow shortly afterwards, ideally driven by EU-funded projects in the form of an expanded STF or equivalent bodies. The initial period could include all information domains related to the Commission Recommendation about the EHRxF:

**Present role of STF**

- Patient Summary
- ePrescription/eDispensation

**New roles proposed to be addressed by new EU-funded projects**

- Laboratory Results
- Medical Imaging and Reports
- Hospital Discharge Reports

## II-7.5 Adoption and Compliance Strategy

In order to achieve semantic interoperability across the EU, decisions taken by the eHN Subgroup on Semantics should be taken as prescriptive for common semantic standards as a tool for cross-border healthcare and EU databases, infrastructure and projects; whilst noting that some national semantic strategies of individual Member States/countries can refer to different standards than those set in the EU cross-border space, therefore noting that an EU-level semantic strategy does not imply national adoption of

the recommendation. Still, the recommendations of the eHN Subgroup should be addressed nationally and considered whenever a national semantic strategy is to be set or revised.

## II-7.6 Involvement with SDOs and Stakeholders

The creation of the eHN Subgroup on Semantics presents an opportunity for bridging the gap between the work carried out by the eHN and the Member States/countries regarding semantics, and key partners both within the EU and the private sector. Thus, they are deemed as strategic partnerships, for example:

1. ISO/CEN 'International Patient Summary'
2. Orphanet
3. World Health Organization
4. SNOMED International
5. Health Level 7
6. Integrating the Healthcare Enterprise
7. Multiple technology developers
8. Healthcare patient associations
9. Healthcare professionals' associations
10. Others

It is important that high-level strategic and policy planning are done at the Subgroup level, with the involvement of relevant Directorates-General of the Commission. When strategies are sketched, the Semantic Task Force engages with these organisations to operationalise them through concrete work.

# II-8 Roadmap

## II-8.1 Roadmap to achieve the three main goals of a CSS

The three goals, as specified in chapter 4, will guide the roadmap of the work of the eHN Subgroup on Semantics.

**Goal 1: Structuring a common approach to health semantics in the EU**, by realising a Common Semantic Strategy for Health in the EU, developing common semantic artefacts for the EU and by providing guidelines for standards adoption (capacity building), is a goal that can be addressed in the initial five years and can be expanded upon in the timespan afterwards as the horizon of the work stream of the eHN Subgroup widens. In particular, capacity building in Member States/countries will have to be supported after the initial five years as the adoption of standards will require a substantial period of preparation.

**Goals 2 and 3: Providing guidance to European level decisions on health semantics and ensuring stability and continuity on health semantics in the EU:** these goals are oriented towards the working method of the eHN Subgroup on Semantics, its embodiment in the overall work of the EU and Member States/countries and what can be achieved in the first five years. Still, in Year 5 a decision on continuity will have to be taken; this will present the final step in establishment of the eHN Subgroup, its roles and responsibilities and the way of communication within EU, towards and from Member States/countries and to third parties involved in standards generation and implementation.

In the next section, the work within the first five years is outlined. After this period, further topics will have to be addressed, and a regular cycle to update the decisions on sematic assets has to be established. To allow for maximum reliability for Member States/countries on the availability of CSS results, a favourable model would be to set up a continuous roadmap after the initial five years that will be permanent work within the EU. If such a decision cannot be taken based on the results of the first five years, a second period of five years with another evaluation can be proposed. After the second period it is recommended, though, that a final

decision is taken, and a permanent group is established or the idea is discontinued and work on this topic stopped.

## II-8.2 Roadmap for the first five years

For the first period of five years, a circumscribed program of work is feasible, with the options of additional items being brought forward for discussion if the need arises (Figure 5).

Work of the first year will encompass:

- Establishment of the eHN Subgroup on Semantics with a clear governance scope (endorsed during the 15th eHN meeting – 11th-12th June 2019, Bucharest);
- Capacity building of the eHN Subgroup according to the common goals defined by this paper by consolidating Member State needs and status.

In **Year 1**, Patient Summary will be considered as the first example for a recommendation; work on this recommendation will serve as an exemplar for future work. Based on the first exemplar an operational plan must be drafted to ensure the development and completion of the other domains.

In **Years 1 to 5**, ePrescription/eDispensation, Laboratory Results, Hospital Discharge Reports and Medical Imaging and Reports will be addressed consecutively and finalised in a stepwise approach, with each step recognising and reviewing previously defined semantic assets.

In **Year 5**, recommendations on all five domains will be available. An evaluation of the rationale, working method and effectiveness of the group will be prepared. The evaluation documentation will be provided early in Year 5, in order to enable decisions on the continuity of the Subgroup after the initial five years by the eHN. Together with the evaluation documentation, a plan for next steps in the Common Semantic Strategy will be provided.

The work will have to note that, between the different tasks, overlap is possible (e.g. a hospital discharge report might contain laboratory results). In such cases, the eHN Subgroup on Semantics will have to address these issues once the problem arises and might need to deviate from the timeline indicated above.

Topics for discussion can be brought to the eHN Subgroup from EU-funded projects and national requirements at any time during the first five years and, if necessary, will be prioritised according to the overall strategy of the eHN.

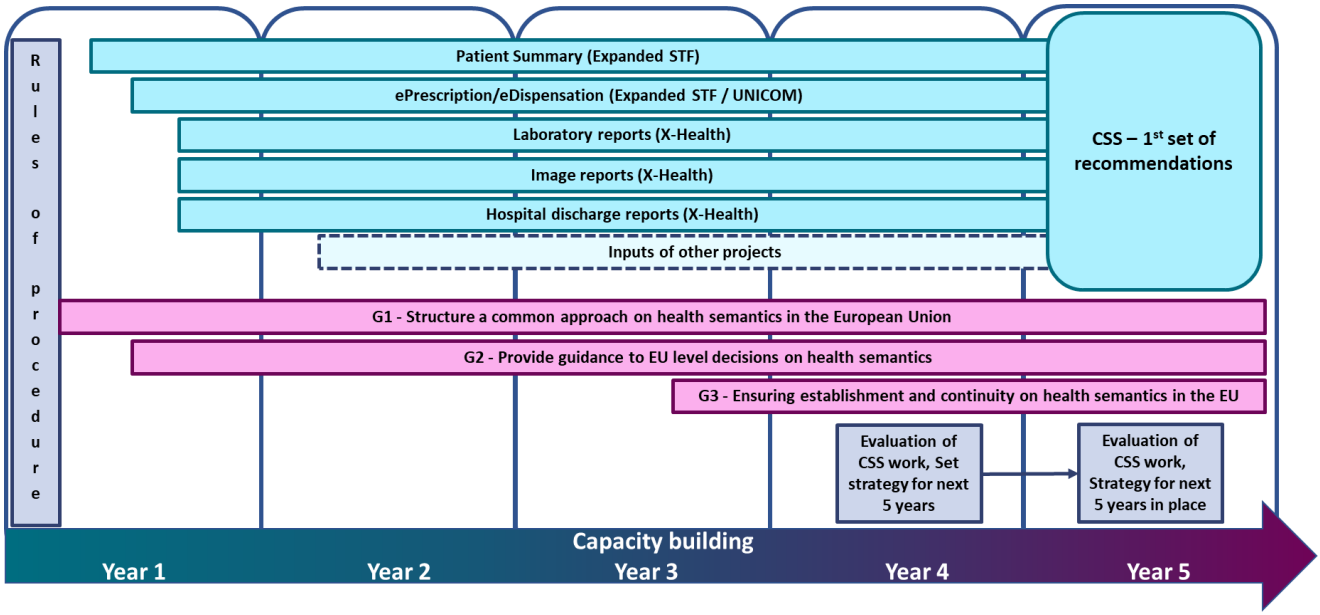


**Figure 5 –** Summarised roadmap

*For details regarding ongoing activities for the five-year plan, please consult Chapter 3.*

## II-8.3 Capacity Building

Capacity building will be an activity that is ongoing over the five years and will have to be continued beyond this initial time frame. Whereas the focus in Year 1 will be on the capacity of the eHN Subgroup on Semantics, capacity building beyond that year will have to address other international and especially national experts in order to be able to transfer the work and knowledge from the CSS to national groups and users. This will enable countries to fully consider benefits and inputs of recommendations and will hopefully foster the adoption of EU suggestions in Member States/countries.

It is encouraged that the European Commission engages activities in capacity building with the Member States/countries regarding semantics.

## II-8.4 Resources to achieve a CSS

Member States/countries will have to recognise that a solid Common Semantic Strategy will require the continuous provision of resources for the different aspects of the work, namely:

1. Resources for participation in the eHN Subgroup on Semantics;
2. Ongoing resources for capacity building on semantic assets in each Member State/country;
3. Continuous resources for the national coordination of the development of the EU semantic assets in order to allow for fitness of purpose of the semantic assets for each country.

### II-8.4.1 Participation in the eHN Subgroup on Semantics

The work of the eHN Subgroup should be supported by the EU but will require countries to allocate a national expert to the work for a continuous period of time.

### II-8.4.2 Capacity building

Whilst capacity building in the eHN Subgroup will be an initial effort, ongoing capacity building within the countries is necessary to enable successful use of the semantic assets in each Member State/country. This can be supported by the EU but will require continuous measures taken by each Member State/country as well.

### II-8.4.3 National Coordination

In order to arrive at solid semantic assets, a process for each Member State/country needs to be in place to check the asset under development in the eHN Subgroup for its fitness for purpose and against national requirements. This might require setting up some national board for discussion of open questions and for discussion on how to integrate semantic assets into national strategies.

# PART III

# D8.2.3 – European eHealth Reference Architecture proposal

# III-1 Executive Summary

The diffusion of eHealth in Europe is speeding up. The Directive 2011/24/EU on patients' rights in cross-border healthcare promotes policy co-ordination and Member State cooperation in eHealth through the eHealth Network (eHN), established by Article 14. In 2014 the eHN (Minutes – Topic 3: Connecting Europe Facility (CEF) ) adopted four priorities for eHealth:

- Cross-border ePrescription and eDispensation service,
- Cross-border patient summary service,
- eHealth services for European Reference Networks,
- Infrastructure services for interoperable Patient Registries,

Through the adoption of cross-border eHealth information services (CBeHIS) and overcoming implementation challenges. According to the common 'European strategy for data' , Member States have to upgrade and streamline national digital health systems in order to participate in and benefit from the future European Health Data Space (EHDS) for primary and secondary use too .

The eHN, through eHAction and several subgroups operating under the eHN, is actively working on establishing a European eHealth vision, developing innovative and cross-border eHealth applications, which have been successfully implemented via ICT. Such ICT developments, carried out via eHealth programmes benefitting from large EU investments, aim to constitute a source of standardisation and interoperability of services and a valuable knowledge exchange platform.

However, strategic alignment and integration of the vast services that have been developed may not continue, anticipate problems or be future-ready if a holistic architecture for eHealth is not adopted.

Most of the solutions developed in the eHealth environment depend on each other to function properly, or only make total sense when they are interconnected. As such, through this document we aim to promote the importance of outlining a Reference Architecture for eHealth based on the Health eGovERA framework, resulting in eHealth interoperability.

This comprises of setting the reference architecture to assist eHealth programmes in reducing duplication, increasing the use of shared services, advancing common planning of eHealth synergies, closing performance gaps, and promoting the empowerment of the European eHealth strategy and goals.

# III-2 Introduction

An architecture is a formal description of a complex whole, and of the principles that are applicable to the development of that whole and all its components. The term architecture is often used as a metaphor for structuring abstraction, to illustrate the importance of an enterprise architecture (EA) approach: It would not be considered appropriate to construct a building without a design or an architectural layout of the whole building. According to the EA approach, the same applies to building and changing organisations.

This analogy is extended to highlight the inappropriateness of developing digital health public services without a quality assurance tool, the eGovERA Health RA. Without an EA-based development of business resources or systems in an environment, the result could be resource duplication, lack of integration, inefficient information exchange or ineffective technology support, lack of valuable information to decision makers and a dispersion of information developed towards eHealth. These issues raise the need for a framework that provides a high-level knowledge about the previous and current projects supported by the European Commission.

A reference architecture is a technology independent content metamodel with a focus providing a baseline for the most salient architectural building blocks to analyse and design a digital solution. In our case, the focus is health digital public service. The adoption of a reference architecture accelerates the delivery through the re-use of building blocks and by the provision of a governance model to ensure consistency and applicability of the used technology. The benefits of this include:

- Improvement of interoperability by establishing standards and common mechanisms for information exchange;
- Reduction of development costs through the reuse of common assets;
- Improvement of national and cross-border communication, since stakeholders share the same architectural mindset.

This document was previously presented to the Commission and, as a result, one representative of the working group and of the Commission were selected to participate in the development of the Health eGovERA[69] framework. The eGovERA framework is a set of solutions for eGovernment portfolio management and digital transformation support decision-making for European public administrations based in the eGovERA Health RA and in the eGovERA Business Agnostic RA. After an eHN request, the topic of health was included in this framework in alignment with the eGovERA Health RA work to date and Commission needs. The use of this tool will be described in this document. Through the cooperation with the eGovERA team a document revision was performed to bring a high-level principle for the implementation of an eHRA in the Member States, aligned with the eGovERA framework.

The presented work contributes to the eGovERA Health RA with the provision of a governance model and recommendations to sustain the eGovERA framework. This framework can contribute to the normalisation of European digital health services and can provide the identification of different digital public services and architectural building blocks that are needed to realise any given digital business capability. The eGovERA also enables Member States to identify the funding mechanisms available to invest in each digital business capability. The first steps of the Health eGovERA project are to provide a tool to identify EU funds available for each digital public service and to support the management of the digital transformation, by taking into consideration existing EU and national building blocks.

[69] https://joinup.ec.europa.eu/collection/european-interoperability-reference-architecture-eira/solution/egovera

## III-2.1 Background

Digitalisation is driving consumers, companies and governments in search of greater efficiency and quality. Although Member States are at different development stages of maturity, they are engaged to develop strategies that promote digitalisation and innovation in the health sector. In order to accelerate Europe's digital transition within the health sector, all Member States should be aware of the benefits of sharing experiences and knowledge on eHealth. Therefore, it is fundamental to outline, propose and conceptualise a reference architecture for a coordinated European eHealth landscape and collect feedback about potential enhancements.

It is essential that the current EU governmental architectural frameworks are identified and compared with the current eGovERA Health RA proposal. One of these frameworks is EIRA[70] (European Interoperability Reference Architecture), which defines a reference model defining the most salient architectural building blocks needed to build an interoperable eGovernment system. The eGovERA Health RA intends to deliver a comprehensive set of viewpoints for decision makers in the eHealth landscape. eGovERA Health RA has a strong policy/strategy scope and is specific to eHealth scenarios.

The eGovERA framework is related with all digital public services across different areas (e.g. health, tax, education, etc.). The eGovERA vision consists of supporting the next generation (for 2030) of European digital public services enabling business continuity, transformation, and co-existence with the current state of affairs. It intends to help identifying the set of building blocks required by health digital business capabilities and the digital transformation roadmap in which they should be tackled, thus providing a strategic orientation for EU funds requests.

The eHRA (initial propose) was firstly developed to address the need of a reference model to navigate, manage and coordinate the development of the eHealth services within the EU. The main goal of this approach was to define the layout of the organisational components and the associated relationships among them, in order to understand the integration of objects for further improvement, based on an understanding of the totality. The rationale behind the initial development of the document was that 'European eHealth governance can benefit from a set of formalised enterprise architectural views'. The reference architecture supports complex changes in the meta-level governance environment, provides transparency and decision-making support, and allows onboarding of actors new to the system.

In July 2020, the eHN analysed the draft D8.2.3 eHRA document in order to ensure that the scope of the document enables the eHN vision relating to eHRA. On 23rd July 2020, the eHN requested eHAction to change the scope of the proposal and align the eHRA with eGovERA in order to include the health domain in the eGovERA framework. A health working group was created under the eGovERA domain, led by DG DIGIT, aiming to develop the elements of the eGovERA Health Reference Architecture, using some relevant principles from this draft document. The group was composed of DG DIGIT members and one Member State representative (Portugal), who worked together from September 2020 to January 2021 to elaborate the Health eGovERA in alignment with Member State needs and the eHN vision.

The result of this integrated work is the development of the eGovERA Health RA tool, that will help the Member States clearly identify problems and solutions, through the identification of all the needed health public services and the building blocks supporting the public health services. This will simplify the implementation of the needed building blocks and assist Member States in the applicable identification of costs.

The Health eGovERA Health RA tool is currently undergoing the early stages of piloting. In this phase, two Member States will be selected that have not previously worked on the development of the tool with an aim

[70] https://joinup.ec.europa.eu/collection/european-interoperability-reference-architecture-eira/about

to using and reviewing it, elaborating a structured feedback to support the improvement of the Health eGovERA Health RA tool.

This development group of the eGovERA Health RA has identified five use cases which the tool could support. Below are the identified use cases on eGovERA Health RA that will be described further on in this document:

1. Applying for EU Funds Support in eGovernment and Digital Transformation
2. Digital Public Services Portfolio Management Decision Support
3. National Digital Agenda Support
4. eGovernment High-Level Architecture Design Support
5. ICT EU Legislation Impact Assessment Support

The original eHRA model can be found in Annex III.1, in order to illustrate the elaboration process that was conducted by the working group. This model shared some principles with the eGovERA framework, and it supported the eGovERA Health RA development.

From this moment on, any reference to the 'eGovERA Health RA' will relate to the 'Reference Architecture Framework'. The reference to eHRA means the set of digital public capabilities, digital public services, architectural building blocks specific to healthcare sector, which are instantiated on eGovERA framework.

## III-2.2 Scope

The reference architecture for a coordinated European eHealth landscape offers a framework that creates a set of views, combining the vision and strategy, business architecture, information systems, and technology domains. The eGovERA Health RA should provide the eHealth Network and the associated Member States with a reference model and a governance framework to be used as a high-level planning tool that provides an overview of eHealth services within the Member States and support them in the identification of all the health services needed to realise the needed digital capability and, therefore, it supports them in the specifying the expected benefits and use of the requested resources.

This document contributes to the development process of the eGovERA framework and eHN for eHealth at EU and national levels. From the perspective of Member States, it proposes an umbrella architecture that aims for a common view of national and European initiatives and the value provided by those initiatives. This reference architecture should not interfere with EU Member State policies but can be used as a tool to support the Member States in the identification of the health public services components needed for their functioning and improvement.

## III-2.3 Motivation and Goals

The proposal on a European eGovERA Health RA aims to propose to the eHN and the Member States the adoption of a reference architecture and a governance framework for this architecture to be used as a high-level planning tool that provides an overview of eHealth services within the EU. The reference architecture is reflected in the eGovERA framework, which provides a structure that aims to constitute a model to navigate, manage and coordinate the development of the health services in the Member State in a sustained manner. At the same time, it should aim to deliver a set of comprehensive viewpoints for decision makers on the current eHealth landscape within the Member States.

The overall purpose of the document 'Proposal on adopting a European eHealth Reference Architecture' is categorised in two main parts:

**STREAM I** – Reference architecture framework: this involves the definition of conceptual reference architectural artefacts that are needed in order to build a reference architecture for eHealth services in EU.

Reference architecture cartography: this involves mapping existing solutions towards the conceptual reference architectural artefacts. To pursue this cartography, a macro working plan proposal is needed for the development and implementation of a reference architecture for eHealth services within the EU.

A reference architecture framework captures the fundamental patterns and concepts that should be applicable for all domains and more specific architectures. It identifies at high level the different components or architectural artefacts needed for more specific implementations. It can also serve as a guide towards designing more specific reference architectures. In order to accomplish the creation of this conceptual reference architecture, there is a need to:

- Identify all the architectural artefacts that are required to deliver a coordinated national eHealth landscape;
- Identify how these architectural artefacts relate to each other;
- Propose a governance framework that represents the structure and the architectural artefacts that support the initiatives promoted by the EU.

**STREAM II** – A governance framework to provide appropriate mechanisms to support the oversight of the eGovERA Health RA. This governance framework may assist the board and management in fulfilling their governance roles and responsibilities.

Governance identifies the planning, decision-making, and oversight processes and groups that will determine how the EA is developed, verified, versioned, used, and sustained over time with respect to measures of completeness, consistency, coherence, and accuracy from the perspectives of all stakeholders. This pillar addresses several accountabilities on executives and stakeholders, namely in leadership aspects, organisational structure, and procedures that ensure that European eHealth supports and achieves its goals and follows the defined strategies.

To fulfil such responsibilities, as well as attain its strategies and goals, the network must understand the status of the eHealth programmes and decide what governance initiatives and controls must be provided to obtain the necessary conditions for the network to move towards achieving these strategies and goals.

# III-3 The Importance of Adopting an eHealth Reference Architecture

## III-3.1 Understanding the Main Concept of Health eGovERA Framework

This chapter intends to present a generic view about the enterprise architecture and the eGovERA framework use cases related with the health domain.

Enterprise architecture (EA) is a strategic activity and planning tool, which facilitates decision-making by enabling a conceptual and holistic view on the subject, which can be an organisation, consortium or, as in the eHealth case, an ecosystem.

In the EA Community[71], enterprise architecture is a framework or 'blueprint' for how the enterprise (one organisation or a group) achieves current and future objectives. It examines the key business, information,

[71] http://www.eacommunity.com/resources/download/bolton_what.pdf

application, and technology strategies and their impact on business functions. Each of these strategies is a separate architectural discipline and EA is the glue that integrates each of these disciplines into a cohesive framework. Aligned with eGovERA framework, Figure 6 identifies the main architectural layers needed to set guidelines for developing public services.

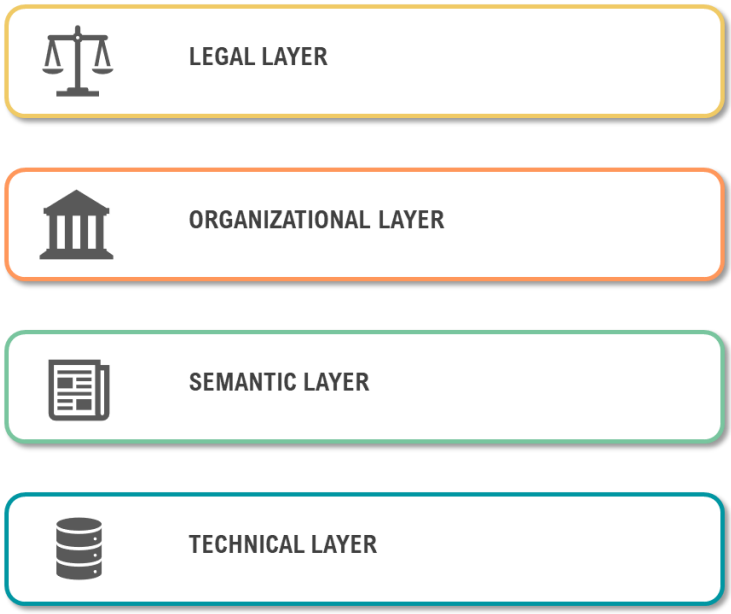


**Figure 6 –** Architecture Layers aligned with the eGovERA framework.

The legal layer aims to ensure that Member States operating under different policies and legal frameworks can work together and legislation does not hinder the development of European public services[72]. This layer includes the architectural building blocks (ABBs) related to the different legal acts, frameworks, policies and strategies influencing or governing the digital public services.

The organisational layer aims to document and align business processes and relevant information exchanged[10]. This layer includes the ABBs related to public administration business processes, responsibilities and expectations to achieve commonly agreed and mutually beneficial goals.

The semantic layer ensures that the precise format and meaning of exchanged data and information is preserved and understood between parties[10]. It describes the data's physical and logical aspects, as well as the management of the data resources. In the context of eHealth, data governance must be considered, enabling primary and secondary use, in compliance with privacy and security principles. This layer includes the ABBs related to format and meaning of exchanged data and information.

The technical layer covers the applications and infrastructures linking systems and services. It provides the foundation that supports the applications, data and business processes identified in the other three architectural layers. This layer covers the ABBs related to the applications and infrastructure systems and services.

[72] https://joinup.ec.europa.eu/collection/nifo-national-interoperability-framework-observatory/european-interoperability-framework-detail

Co-funded by the European Union's Health Programme (2014-2020)

Figure 7 identifies the relationships among the main elements of the eGovERA Health Reference Architecture:

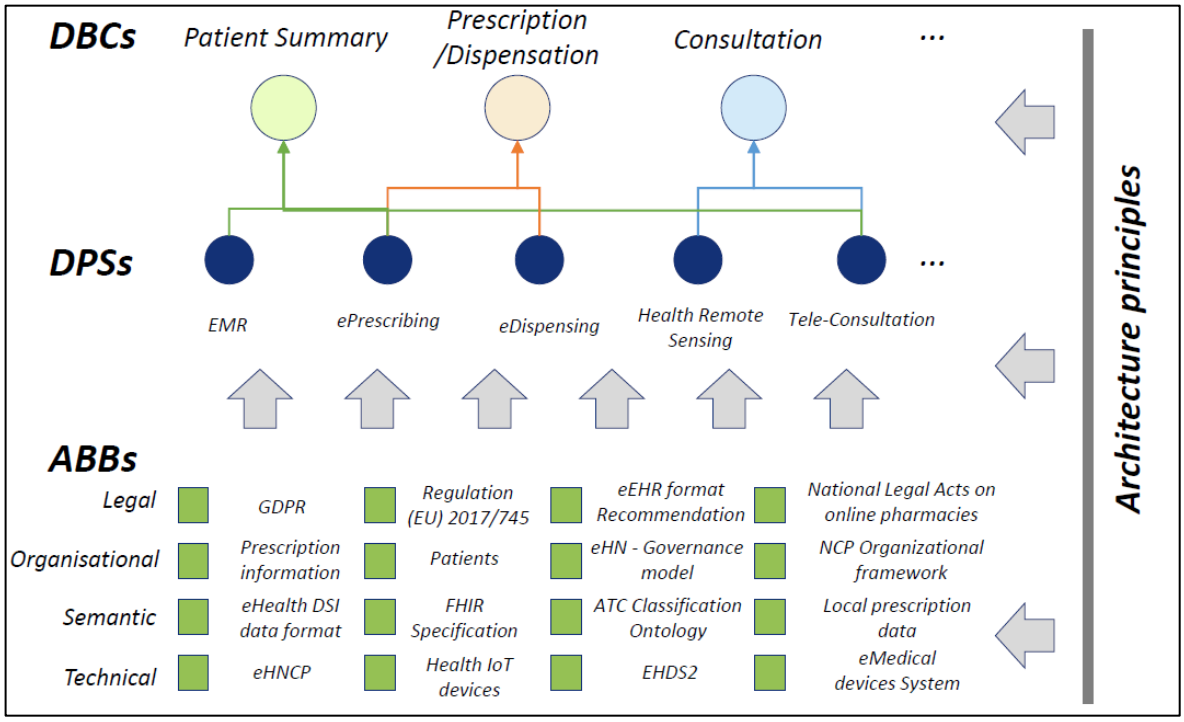


**Figure 7 –** eGovERA© Reference Architecture Components

Below is described the principles presented on the Figure 7:

- ***Domain*** - Policy domain to which the digital public services belong. In particular: 'Health' or 'Business Agnostic' (BA).
- ***Digital Business Capability (DBC)*** – DBCs are the key skills and capabilities a company or a government requires to transform itself into a sustainable and successful business by considering digital technology as the enabling component.
- ***Digital Public Service (DPS)*** – An interoperable DPS is a service provisioned by or on behalf of a public administration in fulfilment of a public policy goals servicing to users either citizens, businesses or other public administrations. A European public service comprises any public service exposed to a cross-border dimension and supplied by public administrations, either to one another or to businesses and citizens in the Union. One or more DPS can realise one DBC.
- ***Architectural Building Blocks (ABB)*** – An abstract component that captures architectural requirements and directs and guides the development of DPSs. An ABB represents a re-usable component of the four presented layers: legal, organisational, semantic and technical.

## III-3.2 The eGovERA Use Cases

The eGovERA framework is currently being developed around five use cases defined by the Commission, with an aim to support the Member Sates in the health landscape. Below is a brief description of these use cases and their relationship with the initial eHRA (Annex III.1).

### III-3.2.1 Applying for EU Funds Support in eGovernment and Digital Transformation

This use case is intended to help identifying the set of building blocks required by health-related digital business capabilities and the digital transformation roadmap in which they should be tackled, thus providing a strategic orientation for EU funds requests.

Through populating the eGovERA platform with data on national building blocks related to health, and based on the resulting assessment, it is possible to identify a quadrant illustrating the prioritised digital business capabilities and the Member State's ability to deliver them; it will result in the identification of the applicable public services that can be improved or developed. The eGovERA Portal will illustrate all the building blocks required to be implemented or improved for the functioning of the service. Based on this information, the Member State can decide whether to request the support of the European Commission to develop one or more digital business capability in order to start its digital transformation process. In the last phase of this process, the Member State leverages the results of the eGovERA Portal to justify the request for funds to the European Commission.

In a similar way that was initially proposed by the eHRA, it is possible to identify all the Member State health building blocks related to public services and analyse which ones should be prioritised to be developed or improved in order to meet national needs.

### III-3.2.2 Digital Public Services Portfolio Management Decision Support

This use case intends to identify a series of elements in order to support the management of decisions related to the health-related digital public services. Some key elements can be seen below:

- Describe the state of the art on the digital business capabilities;
- Establish benchmarks;
- State priorities;
- Define a roadmap to deliver those digital business capabilities.

The Health eGovERA tool, related to business capabilities assessment and the eGovERA transformation roadmap, can be used to identify and prioritise the digital business capabilities that need to be developed or improved, considering the specifics of the state of affairs in the Member State.

### III-3.2.3 National Digital Agenda Support

In some cases, it has been difficult for Member States to identify the objectives and priorities for their national digital agenda, considering that the Health eGovERA tool can support the Member States in addressing this task.

The Health eGovERA portfolio management decision support and the eGovERA digital transformation roadmap will provide guidance to identify the objectives and the priorities on the digital transformation journey. Based on it, the Member State can define a logical roadmap considering the areas that needs development, avoiding duplication of work and reusing the already existents ABBs.

### III-3.2.4 eGovernment High Level Architecture Design Support

The design of the health digital public services can be a hard activity due to the need to identify all fundamental elements that should be implement in my digital public services.

The Health eGovERA reference architectures can be used as a model to guide the development of digital public services (one or multiple in a specific policy area), starting from the needed organisational elements to be put in place, to base registries and systems to be developed or modernised.

### III-3.2.5 ICT EU Legislation Impact Assessment Support

The legal requirements relating to implementation of digital public services must always be considered prior to the design and implementation of any public service. The identification of the related legislation must be taken into account, in order to avoid legal issues on the development of the project.

The Health eGovERA will provide a set of reference architectures, per different policy area, where relevant legislation at EU level is taken into account. Health eGovERA can help public administration officials understand the impact of such legislation when developing digital public services.

## III-3.3 How the Adoption of the European eHealth Reference Architecture can Support Policy Decision Making

The adoption of an eGovERA Health RA intends to help in identifying the set of building blocks that are required by the healthcare sector, such as health-related digital business capabilities and the digital transformation roadmap in which they should be tackled, considering the identified areas that still need more investment in the national health landscape thus providing a strategic orientation for specific EU funds requests.

This approach can bring some benefits to the Member States such as:

- **A clear definition of elements to be financed**
    - Identifying all the needed digital health public services at the national level and evaluating the need of investment considering the current maturity level through a score classification;
    - Identifying the building blocks supporting the digital health public services to be implemented based on the previous evaluation, which will optimise the health investments by prioritising the less developed or non-existent building blocks;
    - Defining a clear step-by-step guide to the implementation of the required building blocks. By identifying the co-dependencies with other building blocks and reusing the already existent structure, duplication of work will be avoided, and in doing so defining a solid efficient implementation plan will be assisted.
- **Enables group decision-making**
    - Supporting Member States in the identification of the associated costs, enabling a faster definition of the cost break-down structure.
    - Supporting Member States in the identification of clear benefits and designation of the use of the needed resources.
    - Providing valuable information for the policy makers, based on the eGovERA tool, with robust scores and a clear benefit list to support the policy decisions based on concrete data. Enhancing the maturity development of the health sector.
- **Holistic approach aligned with LOST (legal, operational, semantic, technical) layers**
    - Achieving a holistic approach, including an architectural view that is in alignment with all the LOST layers.
- **Clear sequence of activity steps to be included in the national digital agenda**

- Indication of the Member State journey to develop the proposed use cases.
- Quick assessment of strategic focus to prioritise the Member State's key objectives.

- **Alignment with a European reference model**
  - A European reference model, detailed per policy area and including the infrastructural elements.

The eGovERA model includes the relevant EU legislation and national legislation.

# III-4 POLICY AND GOVERNANCE FRAMEWORK DESCRIPTION

## III-4.1 Need for an eHealth Reference Architecture Governance Framework

Governance identifies the planning, decision-making and oversight processes and groups that will determine how the EA is developed, verified, versioned, used, maintained and sustained over time with respect to measures of usability, completeness, consistency, coherence, and accuracy from the perspectives of all stakeholders. Governance places several accountabilities upon executives and stakeholders, namely in leadership aspects, organisational structure, and procedures that ensure that the European eHealth supports and achieves its goals and follows the adopted strategies.

To fulfil such responsibilities, the governance framework must account for the status of the eHealth programmes and decide which governance initiatives and controls must be provided to obtain the necessary conditions for the network to move towards these strategies and goals.

A proposed set of actions to accomplish this goal should involve the following stages:

1. Define the stakeholders, roles and responsibilities involved in the identification and definition of digital public services, digital business capabilities and architectural building blocks, responsible for the overseeing of the eGovERA Health RA;
2. Identify recommendations for future work regarding the needs for digital transformation.

## III-4.2 Guiding principles

Considering that EA is most effectively practised when applied in a common way at all levels of scope (national to regional), it is crucial to adopt common principles or general rules that can constrain how the network should fulfil its mission, guiding its stakeholders on the actual design and analysis work that goes into the common programmes and projects.

EA can be the key business to define the best practices that may enable eHealth envisioned efforts to evolve their effective initiatives of today in a roadmap towards the future. It can help to define a clear picture of a broadly accepted vision to guide the mission.

When perceiving the necessity to propose a European eGovERA Health RA, some principles were identified, namely:

***Security and Privacy***

It must be assured that patients and healthcare providers interact with eHealth systems in an environment of trust and in full compliance with the legislation at national and European levels, e.g. Network and

Information Security Directive and General Data Protection Regulation; furthermore, eIDAS conformity for personal identification; this means that eHealth services must guarantee that the privacy of patients and the security and confidentiality of information provided by businesses are respected.

Appropriate security monitoring and planning, including an analysis of risks and contingencies and the implementation of appropriate contingency plans, must be completed to prevent unauthorised access to relevant information. It must ensure that whoever has authorised access will make proper use of data. With a security event log, all activity could be controllable. This principle is enforced more specifically to identity management and security specifications with regards to the usage of technological standards and protocols, notably with specifications of the audit trail. Additionally, EA helps the community apply the principles of the GDPR and incorporate them into the architecture design.

***Transparency***

Within the necessary security constraints, patients and healthcare stakeholders must have the right to verify the information that national and/or European systems have collected from them at both levels and have a meaningful pronouncement on whether this information may be used for purposes other than those for which it was originally agreed. Patients and National Contact Points for eHealth should be able to understand administrative and business processes. They should have the right means to track their procedures and have insight into the principles behind decisions that could involve them.

***Preservation of Information***

Preservation of all electronic information exchanged at the European level must be stored at the national level in accordance with GDPR and national legislation. The goal is to ensure that relevant data is kept along with its legibility, reliability and integrity over time and can be accessed by the relevant parties, considering a common compliance regulation, via security and privacy principles.

***Openness & Reusability***

Interoperability involves sharing and exchanging information and knowledge between relevant stakeholders and organisations; hence, such an environment implies a certain degree of openness and standardisation. Reusability can be the key to an efficient development of European eHealth services. Reusability means that organisations confronted with a specific problem seek to benefit from the work of others by looking at similar problems solved by others, assessing its usefulness or relevancy to their own and decide to benefit from the solutions that have proven their value elsewhere.

***Interoperability Standards***

To reach interoperability, it is imperative to adopt common functional needs and meet them with ‘open’ technology, avoiding ‘tight’ technologies or products not interrelated to each other.

In the roadmap towards European eHealth, Member States should be able to easily adapt and mature their technological environment without compromising their activities. Member States should continue to give access to their eHealth services sovereignly from any explicit technology, product or provider, but universal standards and protocols must be defined so interoperability is easily achieved.

By coupling in standards, Member States will allow maximum interoperability between each other without compromising evolution, being ready to cope with change.

### III-4.2.1 Involvement with Stakeholders

The communication and reporting of an EA function is an important driver in maintaining an understanding of current capabilities and future options for the eHealth mission; a repository of architecture artefacts, plans, solutions, and other information may not be enough. What the EA recommends is a regular reporting

procedure on capabilities and options through the lens of the architecture, delivered in a standardised way and from common dashboards for overall analysis on progress of the eHealth developments.

In order to ensure the fulfilment of the presented Reference Architecture for Health, the definition of a robust and stable governance model is required. This subchapter aims to provide further insights into the responsibilities that should fall upon the eHN Subgroup on Semantics and the eHN Technical Subgroup.

Considering that the eGovERA framework is structured in four layers, previously presented, the eHN Subgroup on Semantics and the eHN Technical Subgroup should be responsible for overseeing the management of the ABBs, regarding their respective layer of expertise. These Subgroups should exert the functions under the influence of the eHN and have strict communication between them in order to achieve mutual support.

In particular, the eHN Subgroup on Semantics should have the ability to set up rules to identify new semantic building blocks, formulate recommendations on the use of common semantic standards at EU level, manage the common EU health semantic services, act as a repository for semantic assets and convey strategic decisions regarding semantics to the eHN.

The eHN Technical Subgroup should contribute to a robust and stable structure regarding technical interoperability issues, as well as providing recommendations for new ABBs, aligned with the needs of the organisational and semantic layers. This subgroup should support the eGovERA tool in reaching substantiated decisions, strategies and measures on technical interoperability issues, to facilitate growth and innovation of the EU eHealth landscape.

For the legal and organisational layers, no specific eHN subgroup exists at this moment. The eHN should define how to address the needs of those layers in the future.

## III-4.2.2 Recommendations

The clear identification of all health structures, capabilities and building blocks, aligned with their respective level of maturity, could be a hard task for the policy makers in different Member States. The need is focused on understanding the relationships and dependencies between business strategy, organisational structure, business processes and supporting information systems in the overall context of enterprise architecture at national level, in order to identify EU funds that meet national needs. It encompasses multi-disciplinary topics, ranging from modelling business processes, through developing enterprise ontology and architectures, and representing information system services, to identifying best practices and patterns.

### Recommendation 1: Secure and take advantage of achievements of other EU projects

The relationship between digital public services/architectural building blocks and outcomes of past/ongoing/future workgroups would allow the Member States to get to know and get access to what has already been accomplished in previous EU projects. To make full use of available outcomes from past and ongoing EU workgroups, the outcomes should be presented in a concise and simple manner to Member States. The eGovERA tool addresses the opportunity for Member States to align their national policies and strategies with EU initiatives. At the same time, it would enable the Member States to follow recommendations included in project deliverables, identify interoperability standards and common regulations for cross-border information exchange and provide some direction for implementation. As a result, reusable components bringing more stability, rationalisation and increased quality of services. More specifically, this would avoid duplication of effort, extra costs and further interoperability problems.

### Recommendation 2: Identify the Architectural Building Blocks regarding the National Landscape

The Commission should identify the key ABBs that are needed, at a national level, to implement the different health services. This activity will also support the Member States to adapt the implementation of the eGovERA health tool according to their specific needs. The eGovERA tool, as a reference architecture, should be able to recommend the best practices to the Member States.

### Recommendation 3: Ensure the existence of feedback mechanisms to the Member States and the Commission, regarding the eGovERA framework

eGovERA aims to be a sustainable framework. It should integrate a survey to collect the user experience in Member States. A process should be leveraged by the framework owner to review, periodically, whether the tool meets Member State expectations and needs. Considering the comments provided by Member States, a report should be prepared and made available for consultation with Member States and the Commission. The evaluation of the framework functionalities would enable a continuous improvement, by adjusting them to needs of the Member States.

### Recommendation 4: Ensure a process of continuous update of ABBs in the eGovERA framework

Digital public services are composed of architectural building blocks, which are divided in to four layers: legal, organisational, semantic and technical. Considering the natural and constant evolution characteristic of the healthcare sector, new building blocks could arise. The eGovERA framework should be able to incorporate these new building blocks as soon as they are identified.

**Recommendation 5: Addition or Revision of ABBs should be leveraged by the existing eHN subgroups**

The relevant eHN subgroups (Subgroup on Semantics, Technical Subgroup) should be responsible to propose a continuous mechanism of identification, evaluation and inclusion of ABBs that are related to the healthcare sector and that fall within their expertise.

## III-4.3 Expected Outcomes of Implementing European eHealth Reference Architecture

The implementation of an EA should be considered to potentially address the ever-increasing costs that the EU and Member States have on healthcare, and any ability to constrain growing healthcare costs will directly and positively impact the future sustainability of Member State healthcare systems via eHealth.

A coordinated European approach to eHealth through an EA strategy would contribute to this situation by improving the capacity of the EU and its involved Member States to do more with the existing resources, and by enabling these resources to be deployed to meet real needs. This would result from improving system quality and safety (and therefore reducing avoidable supply and demand for eHealth services), improving system accessibility and interoperability, and improving system processing and cost efficiency.

From a macro perspective, the implementation of a European eHealth Reference Architecture would provide stakeholders and health organisations with necessary key business tools, such as:

- Mapping the big picture: A Reference Architecture gives a 'systems thinking' view that combines vision and strategy, legal architecture, business architecture, information systems, and technology domains;
- The possibility to align IT investments with business goals: creating a platform for business/ICT stakeholder collaboration is essential. Effective EA supports strategy, analysis, and planning by providing stakeholders with a blueprint of the current state of the business and IT landscapes, and of the desired future state (vision).
- Provide IT developers with common requirements for software applications towards a common maturity: a reference architecture can provide IT developers and/or IT policy makers with the necessary knowledge on the relevant protocols, standards or software requirements of an application towards universal interoperability in the European eHealth community.

Thus, it is worth attempting to understand complex eHealth services, in order to provide eHealth stakeholders with improved and suitable tools for devising healthcare systems, which could enhance eHealth success within Member States.

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# PART IV

# D8.2.4 – Common eID Approach for Health in the European Union

# IV-1 Executive summary

Citizenship of the European Union (EU) entitles every citizen to the right of free movement. Freedom of movement entails the right to cross borders with a valid proof of identity[73]. This freedom also extends to healthcare, given that every citizen of the EU may eventually need healthcare. The right of free movement of people shall be exercised in the context of digital technologies, and electronic identity (eID) needs to be verified and authenticated, to prove the identity of patients and professionals in the course of healthcare provision. The eID is a collection of electronically captured and stored identity attributes that uniquely describe a person within a given context and are used for electronic transactions[74].

The introduction of minimum security and format standards of electronic identification should allow Member States to rely on its authenticity when EU citizens exercise their right of free movement. The adoption of security standards should provide sufficient guarantees to public authorities and private entities to rely on the authenticity of digital identity means used by EU citizens. Should the Member States be able to exchange identifying information contained on a secure storage medium, the formats used should be interoperable, including in respect of automated border crossing points. Extensive discussions have occurred in the eHealth Network about the relevance and critical aspects of electronic identification (eID) for the secure and reliable identification of patients and professionals that would engage or be the subject of professional engagement with digital services and data in the health sector. Since 2012, this topic has been brought to the eHealth Network on different occasions and was scoped in several European Commission funded projects and initiatives (e.g. STORK, eSENS, eHGI and JAseHN). With the advent of cross-border digital services, the enforcement of eIDAS Regulation[75] and the emergence of multiple novel technologies supporting eID, there is now a time, opportunity and a necessity to align eID implementation throughout the EU. Hence, this paper aims to present the basis, the rationale, and a timely proposal for a common approach in eID for health, not just at cross-border level, but rooted in timely adoption at national level.

The **Common eID Approach for eHealth** shall leverage recent EU regulations and create a holistic approach to eID in eHealth and related ICT services. The approach must be supported by sustainable EU policies of both the eID and eHealth worlds. It should promote convergence of efforts between Member States/countries, considering the sensitivity and vulnerability of health data and available standards and technologies. eID shall be considered as a means to achieve innovative use of health data, supported by a future EU roadmap for eHealth. Increased strength and security of identification of persons is to be implemented, enabling interoperability within and across borders. The governance process for electronic identification shall be interlinked with the governance of projects and services for eHealth in Europe, within the framework of the Joint Coordination Process or other governance entities of eHealth and alignment between different Directorates-General of the European Commission and Member States. The scope of this document was agreed by the eHealth Network (eHN) and the Commission in November 2019, and the draft document was approved in June 2020. Following the approval by the eHN, the final approach should be in place from 2021 until 2026.

The common high-level roadmap would support the proposed approach, taking into account the necessary capacity building for full scale eID deployment, and maintaining an open mindset regarding the exact

[73] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32004L0038

[74] http://documents1.worldbank.org/curated/en/600821469220400272/pdf/107201-WP-PUBLIC-WB-GSMA-SIADigitalIdentity-WEB.pdf

[75] https://ec.europa.eu/futurium/en/system/files/ged/eidas_regulation.pdf

technologies that support eID while ensuring common principles and governance of the different steps in the different national contexts.

The Common eID Approach for eHealth is inspired by the vision of '*full scale deployment of electronic identification in the healthcare sector, raising trust in electronic health data exchange, and taking another step forward towards the Digital Single Market, in a progressive manner, and open to diversity of technological solutions as long as basic principles and security are ensured.'*

# IV-2 Introduction

Identification plays a fundamental role in facilitating the interactions among individuals, such as interactions between patients and health professionals. The digital identity for health[76] is a collection of electronically captured and stored identity attributes that uniquely describe a person within the healthcare context and are used for electronic transactions. A digital identity system needs to be supported by processes that aim to manage the lifecycle of individual digital identities.

Healthcare providers and researchers need to identify patients accurately and uniquely in order to record data within healthcare provision as well as to produce health statistics and other data applications for planning, evaluation, emergency response, and improved treatments and disease management. Last but not least, the patient must be enabled to access their own data by digital means[3].

At a cross-border level, managing the identification lifecycle is not an easy quest due to the need to ensure a minimum-level interoperability of eID schemes, high-technological performance and secure schemes. This leads to the need to establish and develop a common approach for the EU to ensure the use of health eID at a cross-border level and support the Member States in achieving a minimum level of trust on eID schemes.

## IV-2.1 Current context

Citizenship of the EU entitles every citizen of the EU to the right of free movement, subject to certain limitations and conditions. Directive 2004/38/EC of the European Parliament and of the Council gives effect to that right. Article 45 of the Charter of Fundamental Rights of the EU also provides for freedom of movement and residence. Freedom of movement entails the right to exit and enter Member States with a valid identity card or passport.

Pursuant to Directive 2004/38/EC, Member States are to issue and renew identity cards or passports to their nationals in accordance with national laws.

Considerable differences exist between the security levels of national identity cards issued by Member States and residence permits for EU nationals residing in another Member State and their family members. Those differences increase the risk of falsification and document fraud and also give rise to practical difficulties for citizens when they wish to exercise their right of free movement.

In its Communication of 14th September 2016 entitled '*Enhancing security in a world of mobility: improved information exchange in the fight against terrorism and stronger external borders*', the Commission stressed that secure travel and identity documents are crucial whenever it is necessary to establish without doubt a person's identity and announced that it would be presenting an action plan to tackle travel document fraud. According to that Communication, an improved approach relies on robust systems to prevent abuse and threats to internal security arising from failings in document security.

The Commission, in the 2016 Action Plan, and in its 2017 EU Citizenship Report, committed itself to analysing policy options to improve the security of identity cards and residence documents.

Regulation 2019/1157 of the European Parliament[77] and of the Council states that the establishment of minimum security standards and the integration of biometric data in identity cards and in residence cards of

[76] http://documents1.worldbank.org/curated/en/600821469220400272/pdf/107201-WP-PUBLIC-WB-GSMA-SIADigitalIdentity-WEB.pdf

[77] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32019R1157

family members who are not nationals of a Member State are important steps in rendering EU citizens to fully benefit from their rights of free movement.

This regulation also states that Member States should take all necessary steps to ensure that biometric data correctly identify the person to whom an identity card is issued. To this end, Member States could consider collecting biometric identifiers, particularly the facial image, as a method of implementation by the national authorities issuing identity cards.

Member States should exchange with each other such identifying information as is necessary to access, authenticate and verify the information contained on the secure storage medium. The formats used for the secure storage medium should be interoperable, including in respect of automated border crossing points.

Electronic Identification (eID) is the digital identification of citizens through national identification numbers, e.g. citizens card, social security and other identification methods. eID allows the recognition of national eID schemes (including smartcards, mobile and log-in), allowing citizens of one EU country to use their national eIDs to securely access services provided in other EU countries. This electronic identification could be used at both the national level and for cross-border health services.

The eIDAS Regulation provides for legal certainty beyond national borders, a predictable regulatory environment for a seamless cross-border recognition of eID, and trust services (e.g. electronic signatures). This regulation foresees that if a Member State offers an online public service to citizens/businesses for which access is granted based on an eID scheme, then that particular Member State's online public service must also recognise the notified eIDs of other Member States by 29 September 2018. This applies to online services that correspond to an assurance level of 'substantial' or 'high' in relation to accessing that service online. Member States remain free, in accordance with EU law, to recognise eID means that have lower identity assurance levels. The eIDAS Regulation thus ensures that people and businesses can use their own national eIDs to access online public services in other EU countries, where eID services are available.

Current ongoing cooperation projects tackling interoperability challenges at a global scale, such as the Global Digital Health Partnership (GDHP), have also highlighted a confident patient identification process as a key prerequisite for safe and efficient interoperability[78].

## IV-2.2 Problem Statement

eHealth Digital Services Infrastructure (eHDSI) services (Patient Summary and ePrescription/eDispensation) and their use cases are in-person (not online) in the country of treatment (country B). Therefore, eIDAS is outside the current scope of eHDSI, although it could be beneficial for future services or use cases (such as patient access to clinical information in a different Member State).

A consensus among Member States regarding operational matters not covered by GDPR, eIDAS Regulation and NIS Directive seem to be still pending at the moment due to many simultaneous legislative reforms. Creating a consensus on this topic seems to be the subsequent step.

The political alignment concerning a common Authentication Assurance Level (AAL) ('substantial' or 'high') for eHealth is not reached as of today. A possible implementation of AAL 'high' is seen as very demanding for

[78] Connected health: Empowering health through interoperability: https://s3-ap-southeast-2.amazonaws.com/ehq-production-australia/57f9a51462d5e3f07569d55232fcc11290b99cd6/documents/attachments/000/102/278/original/GDHP_Interop_2.05.pdf

Member States; AAL activities may be resumed after the legal review of the eIDAS Regulation and GDPR is complete.

Consequently, additional means, services and mitigation strategies need to be identified to assure minimum-level interoperability of eID schemes that guarantee standardised, high-technological performance and secure schemes; or to encourage Member States to enable purely digital identification and authentication such as mobile eID to compensate for specific interoperability issues with eID based on physical tokens. Both options would introduce some operational challenges to the Member States/countries:

- Deployment/rollout of specific hardware (e.g. contact or contactless smartcard readers) and software (smartcard reader drivers and libraries) at the point-of-care of the country of treatment to handle the heterogeneity of physical-token-based eID means;
- Deployment of country-of-treatment service providers (healthcare portals) enabled for physical-token-based eID or newer eID scenarios, e.g. mobile eID.

Additionally, Member States/countries face some operational challenges necessary to comply with the common approach proposed in this document and achieve the goal of eID-enabled use cases:

- Deployment of the National Contact Point for eHealth (NCPeH) by the competent national authorities participating in the CBeHIS (for cross-border scenarios);
- Deployment of eIDAS connectors by the eID-competent national authorities (if not already deployed);
- Deployment of eID means by the country of affiliation for accessing health services, and notification of its scheme (for cross-border scenarios);
- Deployment of electronic patient registries by the country of affiliation;
- Deployment of electronic health professional registries by the country of treatment and engagement with health professionals' associations.

## IV-2.3 Goals

The goals of a Common Approach for using eID in health should be (Table 2):

Structure a common approach on health eID within the EU.

Converge development roadmaps for service providers with adoption of eID also to ensure phased adoption of novel requirements regarding electronic identification that are progressively more demanding.

The work conducted in this document is in alignment with other eID initiatives and recommendations from European Commission and the eHealth Network, such as Electronic Health Record Exchange Format[79] (EHRxF) and others.

79 https://ec.europa.eu/digital-single-market/en/news/recommendation-european-electronic-health-record-exchange-format

**Table 2 –** Common eID Approach for eHealth Goals, objectives and activities.

| Goal | Description | Objective | Activity |
|---|---|---|---|
| G1 | Structure a common approach on health eID within the EU | **O1.1** Define a Common eID Approach for Heath in the EU | **A1.1.1** Define a set of domains related to eID |
| | | | **A1.1.2** Identify available tools and the shortcomings for each tool |
| | | | **A1.1.3 Overview about the current and previous EU eID initiatives;** |
| | | | **A1.1.4** Align current and future research projects/policy initiatives between different DGs within the European Commission, as well as Member State/country efforts, in future definitions of solutions, architecture, assurance levels amongst other common and transversal characteristics |
| | | **O1.2** Develop common eID assets for Patient Identification | **A1.2.1** Drive the development of common eID assets for Patient Admission |
| | | | **A1.2.2** Drive the development of common eID assets for Patient Summary |
| | | | **A1.2.3** Drive the development of common eID assets for ePrescription & eDispensation |
| | | | **A1.2.4** Drive the development of common eID assets for Telehealth |
| | | | **A1.2.5** Drive the development of common eID assets for Consent Provision |
| | | | **A1.2.6** Drive the development of common eID assets for Emergency Call Centre |
| | | | **A1.2.7** Drive the development of common eID assets for Patient eIDs |
| | | | **A1.2.8** Drive the development of common eID assets for Laboratory & Medical Imaging Reports access |
| | | | **A1.2.9** Drive the development of common eID assets for Hospital Discharge Reports access |
| | | **O1.3** Develop common eID assets for Health Professional Identification | **A1.3.1** Drive the development of common eID assets for Consent Provision |
| | | | **A1.3.2** Drive the development of common eID assets for Patient Summary |
| | | | **A1.3.3** Drive the development of common eID assets for ePrescription & eDispensation / Mobile ePrescription |
| | | | **A1.3.4** Drive the development of common eID assets for Death Certificates |
| | | | **A1.3.5** Drive the development of common eID assets for Telehealth |
| | | | **A1.3.6** Drive the development of common eID assets for Laboratory & Medical Imaging Reports |
| | | | **A1.3.7** Drive the development of common eID assets for Hospital Discharge Reports |
| | | | **A1.3.8** Drive the development of common eID assets for Referral Management |
| G2 | Converge development roadmaps for service providers with adoption of eID and ensure phased adoption of novel requirements regarding electronic identification that are progressively more demanding | **O2.1** Establish a methodology to address alignment to Common eID issues at an EU level. | **A2.1.1 Set up a sustainable plan to ensure alignment between Common eID issues at an EU level.** |
| | | | **A2.1.2 Draft new Common eID for 2020-2025** |
| | | **O2.2** Establish a relationship between key bodies of the EU and key technological partners in the digital identity process | **A2.2.1 Identify the key identity stakeholders, their roles and responsibilities** |

# IV-3 State of the Art

## IV-3.1 Understanding the Identity Lifecycle

This chapter aims at providing some insights on key aspects that need to be addressed in order to realise a common approach to eID in eHealth within the EU.

It is very important to consider the four 'domains' on eID to elaborate the common eID Approach:

**Registration / Proof of Identity**

The Registration phase begins with the process of uniquely distinguishing an individual, called Resolution. The first step is the **Enrolment**, in which biographical data are presented to the issuing authority for proof of identity to be carried out. The ***Validation*** begins when the authority determines the authenticity and validity of the data provided and relates it to a living citizen.

Subsequently, the ***Verification*** is carried out, in which relationship is established between the claimed identity and the individual who provides the proof of identity. This 'domain' is directly linked with the mechanism of identification used by the patient or the HP at the moment of the health service attendance.

**Credential Management**[80]

Credential Management consists of the process of creating and distributing virtual credentials as **decentralised digital proof of identity**, such as e-passport, eID card and a unique identifier. The steps are Maintenance (retrieving, updating and deleting credentials) and Revocation (removing the privileges assigned to credentials).

**Authentication and authorisation**

**Authentication** ensures the univocal unambiguous identification of the patient/Health Professional through the established identification process. It will generate an electronic authentication of eID and allows the patient/Health Professional to proceed the next steps of the clinical encounter.

After the authentication process the authorisation takes place. The **authorisation** is responsible for guaranteeing the access by the users only to the data or application domains that were previously granted. For that, levels of authorisations must be defined according to the actor's role. For example, a patient, a nurse and a physician must each have a different level of authorisation according to their role.

**Identity Management**[81]

Identity management is the continuous process of retrieving, updating and excluding attributes of each identity.

Figure 8 summarises the life cycle phases considered for the creation of the digital identity described above.

[80] Technology Landscape for Digital Identification: http://documents1.worldbank.org/curated/en/994115196913704 95/Technology-Landscape-for-Digital-Identification.pdf

[81] Technology Landscape for Digital Identification: http://documents1.worldbank.org/curated/en/994115196913704 95/Technology-Landscape-for-Digital-Identification.pdf

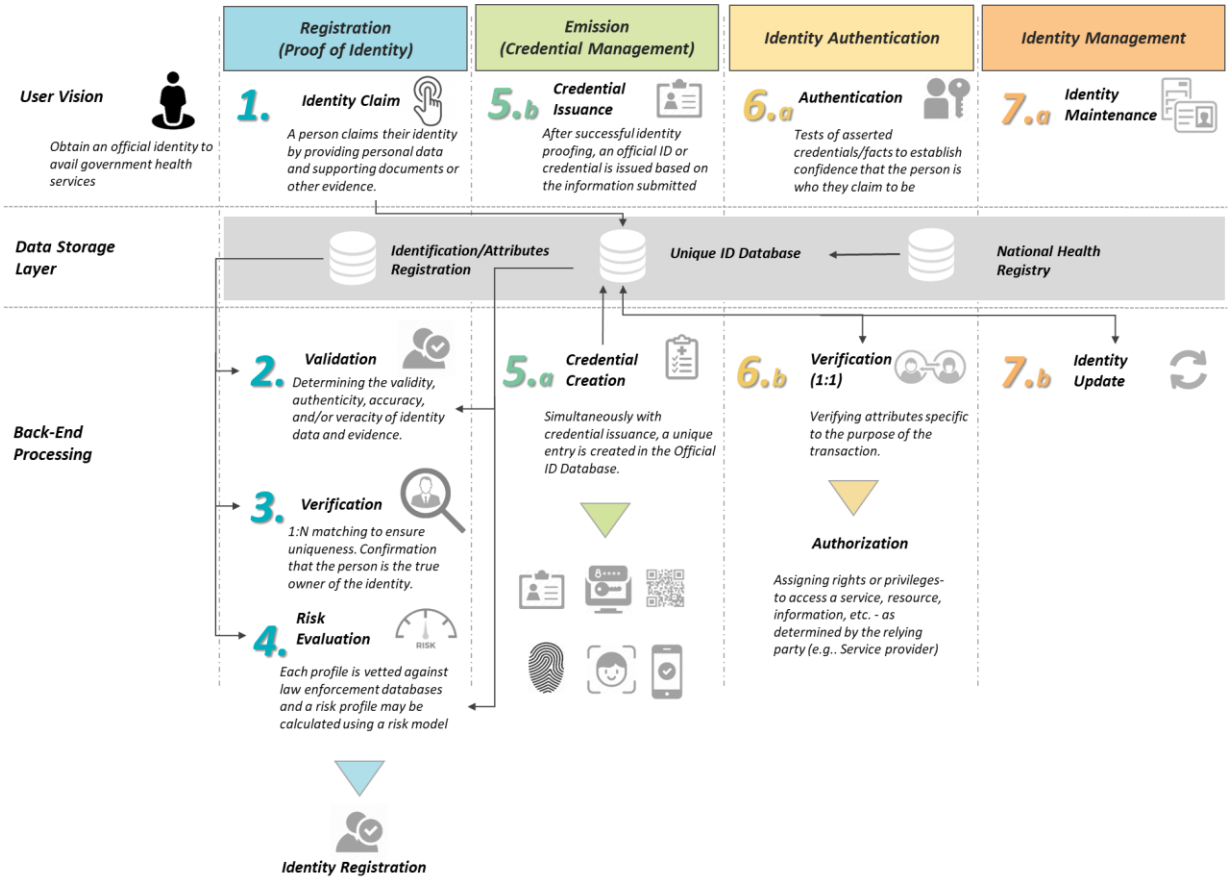


**Figure 8** – The life cycle of digital identity (adapted from Technology Landscape for Digital Identification)

The expansion of the digital market, associated with a unique national recognition of health professionals by information systems requires the definition of a minimum set of attributes that allows the representation of each health professional, as a unique element. These attributes must guarantee the correct identification of each health professional, in order to avoid the risk of exposure of information to unauthorised health professionals.

### IV-3.1.1 Levels of Assurance

Authentication is a stage in the digital identity lifecycle. The type of authentication (weak, secure, strong or very strong) depends on the robustness of the technology and the authenticators used. Considering different types of information exchange, it appears that not all transactions require the highest level of assurance (LoA). Single factor authentication, such as an identification number or knowledge of a password, is insufficient to prove the identity of a citizen or professional and does not constitute an accurate authentication.

In the health context, considering the sensitivity of the information accessed by health professionals, the existence of multiple authentication factors is considered relevant in order to provide stronger security (Figure 9).

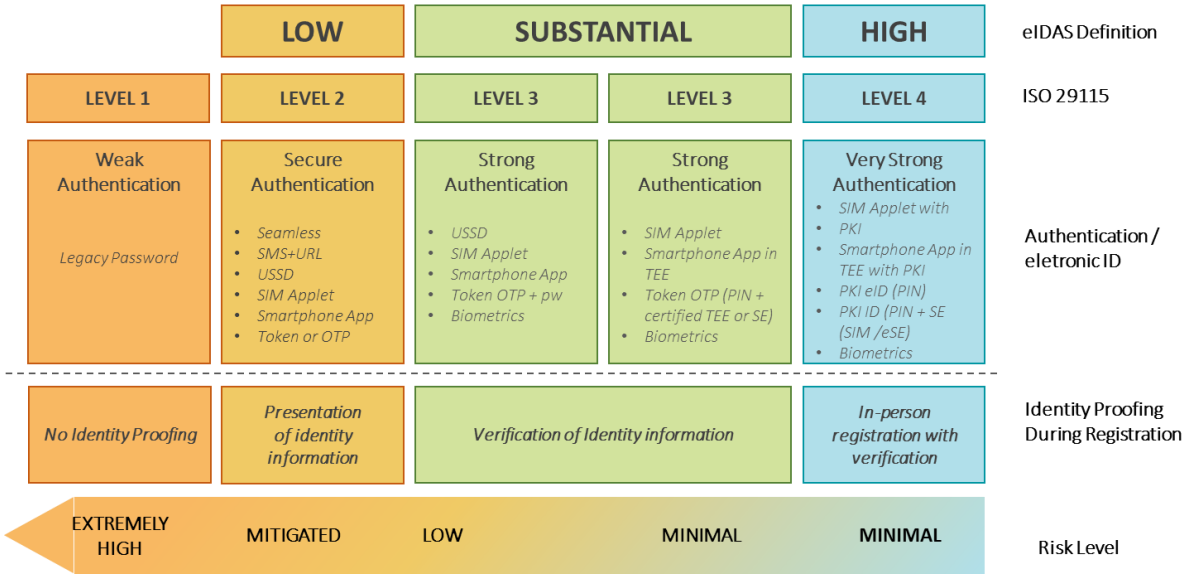


**Figure 9 –** Digital identity levels (adapted from Digital Identity: Towards Shared Principles for Public and Private Sector Cooperation)

## IV-3.2 Previous and Current Projects

The electronic identification of individuals has been tackled over the years in different pan-European projects. One such project was the **S**ecure iden**T**ity acr**O**ss bo**R**ders lin**K**ed (STORK)[82], an eGovernment eID 'Large Scale Pilot' (LSP) that ran from 2008 to 2011. STORK aimed at creating a pan-European eID framework and infrastructure to allow EU citizens who are resident in a Member State other than their own or work in one country and live in another one to access online public services wherever they are located. In that sense, it was the precursor to the current cross-border eID services of the CEF eID Digital Services Infrastructure. At the same time, the European Patient Smart Open Services (epSOS)[83] LSP was also running (epSOS-I, 2008-2011), focusing on piloting the cross-border exchange of Patient Summaries and ePrescriptions, being the precursor to the current CBeHIS of the CEF eHealth DSI[84].

The electronic identification and authentication in eHealth was first addressed in epSOS, by its Identity Management work package, with a view to providing a practical solution to run the LSP. In the scope of the coordination task between STORK and other LSPs, a liaison between STORK and epSOS was materialised in the 'STORK meets epSOS' (STepS) initiative (2009-2011)[85]. The goal was to explore synergies between both LSPs with regards to identity management, ensuring their coordination and enhancing the epSOS identity management processes with the STORK capabilities with regards to identification and authentication of natural persons (patients and health professionals). On the patient side, the selected use case would consist

[82] STORK | Take your e-identity with you, everywhere in the EU: https://ec.europa.eu/digital-single-market/en/content/stork-take-your-e-identity-you-everywhere-eu
[83] Cross-border health project epSOS: What has it achieved?: https://ec.europa.eu/digital-single-market/en/news/cross-border-health-project-epsos-what-has-it-achieved
[84] eHDSI Starting Toolkit: https://ec.europa.eu/cefdigital/wiki/x/WKgSB
[85] STORK D7.11 - Implementation Report on eHealth LSP: https://ec.europa.eu/cefdigital/wiki/download/attachments/78558188/D7.11%20Implementation%20Report%20on%20eHealth%20LSP%20FINAL.pdf?version=1&modificationDate=1552376489209&api=v2

on the substitution of the traditional paper-based identification process in epSOS with the fully-fledged online process developed by STORK. On the health professional side, the focus was on increasing the strength of local authentication mechanisms and enriching the process with authorisation data.

The STepS exercise laid down the foundations for the specific eHealth pilot of the follow-up LSP STORK 2.0 (2012-2015)[86], which focused on:

The epSOS-II (2011-2014) Patient Access (PAC) use case: a patient identifying and authenticating, through STORK, against a foreign service provider to access his/her EHR;

Representative access to EHR: access on behalf of a patient (delegation / mandate);

HP identification: enabling local identification and authentication of health professionals through STORK, with retrieval of additional authorisation information.

All in all, STepS didn't bring a realistic approach to fruition, mainly because the scenarios explored by STORK did not resonate with the on-site presence of the patient and the cross-border transmission of patient identifiers submitted by the health professional, on behalf of the patient. As a result, epSOS did not address the issue of electronic patient identification. This topic was explored in the e-SENS LSP (2013-2017)[87], as part of its eHealth pilot, and the relevant contributions were invaluable in understanding the implications of eIDAS for cross-border eHealth. Apart from a legal analysis, e-SENS piloted different levels of eID in eHealth, from the baseline epSOS process to a distributed cross-border authentication using STORK 2.0 / eIDAS infrastructures, with a vision towards a fully virtual mobile eID scenario. The work from e-SENS helped the Joint Action to support the eHealth Network (JAseHN)[88] to elaborate policy and recommendation papers on eID, which were adopted by the eHealth Network[89].

The latest of this series of projects is HEALTHeID (2018-2019)[90]. Benefiting from the lessons learned from e-SENS, this project introduced the paradigm shift in the current CEF eHDSI use cases needed to properly address the eIDAS Regulation, by offering a set of patient-directed online services as suitable candidates for a strong authentication of patients via the eIDAS infrastructure, empowering them through their personal smartphone.

CEF eHDSI builds on specifications initially designed in epSOS, thus inheriting much of its identity management processes. The importance of this topic is further reinforced in the Agreement between National Authorities or National Organisations responsible for National Contact Points for eHealth based on the criteria required for the participation in Cross-Border eHealth Information Services (Agreement), adopted by the eHealth Network in May 2017 and signed by the competent national authorities participating in the CBeHIS, with references, in its Clause II.1.1.2 and II.1.1.3, to the identification of patients, health professionals and healthcare providers as well as to the authorisation of a health professional. Although the work on eID in eHealth is far from recent, it hasn't yet made its debut in the currently operational CEF eHDSI services. A new project, X-eHealth (2020-2022), has a task that aims to leverage the experience of HEALTHeID and

[86] STORK 2.0 - Secure idenTity acrOss boRders linKed 2.0 (STORK 2.0): https://joinup.ec.europa.eu/collection/secure-identity-across-borders-linked-stork/document/stork-20-secure-identity-across-borders-linked-20-stork-20

[87] e-SENS Pilots - 5.2.1 ePrescription / Patient Summary: http://wiki.ds.unipi.gr/display/ESENSPILOTS/D5.6-2+-+5.2.1+-+ePrescription_Patient+Summary

[88] JAseHN: https://webgate.ec.europa.eu/chafea_pdb/health/projects/677102/summary

[89] Policy paper on eID specific framework for eHealth - Release 1: https://ec.europa.eu/health/sites/health/files/ehealth/docs/ev_20170509_co04_en.pdf

Policies Regarding eIDAS eID and Health Professional Registries: https://ec.europa.eu/health/sites/health/files/ehealth/docs/ev_20180515_co11b_en.pdf

[90] HEALTHeID: https://www.spms.min-saude.pt/healtheid/

national projects of eID in eHealth to define a way towards a seamless cross-border eIDAS solution that can be finally integrated in CEF eHDSI, in line with the Commission Recommendation on a European Electronic Health Record exchange format. The eID is not the main focus of this project, however the inclusion of this kind of initiative in projects reflects the need for establishment of a strong eID Approach for health in EU.

Last but not least, a reference should be made to the CEF European Blockchain Services Infrastructure (EBSI), where the bleeding-edge use case of a European Self-Sovereign Identity Framework (ESSIF) is being explored, envisioning an individual in full control of their identity (e.g. via a digital identity wallet)[91]. The eHealth sector should keep an eye on this project, not only due to its innovative use of digital identity data, but also to its draft amendments of the eIDAS Regulation[92], the consequences of which for the eHealth sector are still unknown. The current revision of the eIDAS Regulation should also be scrutinised.

## IV-3.3 Policy and Legislation

In the context of regulation and standardisation at the EU level, the following stand out:

- Regulation (EU) No 910/2014 of the European Parliament and of the Council of 23 July 2014 on electronic identification and trust services for electronic transactions in the internal market and repealing Directive 1999/93/EC: this so-called 'eIDAS Regulation' aims to guarantee the use of national eID systems to access public services in other EU countries where eID systems are available.
- Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (Text with EEA relevance)
- Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare: EU directive on the right to exercise access to cross-border healthcare.
- Directive (EU) 2016/1148 of the European Parliament and of the Council of 6 July 2016 concerning measures for a high common level of security of network and information systems across the Union: the so-called 'NIS Directive' on security of network and information systems provides legal measures to boost the overall level of cybersecurity in the EU.
- The Commission will come in 2Q 2021 with a proposal for an EU-wide framework for secure public electronic identification. Offering a framework for the use of digital identity attributes (eHealth attributes among others) linked to identity to all European citizens is being considered in this context.

In the international context, highlighting the contribution from the International Organisation for Standardization (ISO) relating to management of authentication: the ISO/IEC29115:3013 standard identifies four levels of assurance of authentication and proposes measures to reach each of the four levels and guidelines for mitigating threats.

[91] About SSI eIDAS Bridge: https://joinup.ec.europa.eu/collection/ssi-eidas-bridge/about

[92] Introducing the SSI eIDAS Legal Report: https://ssimeetup.org/introducing-ssi-eidas-legal-report-ignacio-alamillo-webinar-55/

# IV-4 Brief Definition of Use Cases

This chapter aims at contextualising the need for the establishment of a common eID Approach for health within the EU by presenting the two most common identification use cases (value propositions) of the healthcare sector: identification of patients and health professionals.

## IV-4.1 Electronic identification of Patients – use case

Patient identification is the process by which the set of attributes describing the identity of the natural person interacting with health services (either the patient seeking healthcare or managing his/her own health data) are unambiguously recognised. The result of patient identification and authentication is a proof that the patient is who they claim to be. Electronic identification of patients is the process by which the patient identification and authentication is established using any electronic means or, using eIDAS terms, is the process of using person identification data in electronic form uniquely representing a natural person (the patient). While recent health data access models were born with electronic patient identification in mind (e.g. patient access to their own data through a portal or app), more traditional business processes where the patient is identified by a health professional (e.g. by presenting an identification card to the admission clerk) still rely on purely non-electronic and passive participation of the patient. Patient eID has the power to turn the patient into an active participant in this process, elevating the strength, assurance and trustworthiness of the claimed identity by exploring new generation technologies and digital infrastructures (some emerging from recent regulations, e.g. eIDAS or GDPR).

Specifically, in the case of CBeHIS, in the current eHDSI deployment, the patient identification process is performed by the HP, and the patient is identified and authenticated using demographic data, without any kind of eID, based on the national policies for patient identification in the country of affiliation. After successful identification of the patient by the country of affiliation, the HP still has to verify, by themselves, the demographic data returned against the one present in the identification document provided by the patient. As the eHDSI has already shown, there is a wide variety of identification means available across Europe. Even within a single country, more than one may be available. This creates a huge burden for the HPs of the country of treatment, forcing them to be aware of this diversity and to perform the manual identity confirmation in order to adequately identify a foreign patient (an administrative duty which is alien to the HP's regular organisation of work). Electronic identification removes such barriers and opens the possibility for patient self-identification and authentication. On the other hand, electronic identification by the HP could also create certain challenges such as the need to support a large number of eID schemes (even if these are only software-based) used in other Member States in every single point of care. A possible solution could be a common software-based eID standard which all Member States agree to support. Finally, the usage of eID for patients should take into account scenarios such as break-the-glass, wherein the urgency of healthcare is of the utmost importance and certain safeguards are allowed to be bypassed.

Research on Master Patient Indexes have shown that patient identification based on human handling of demographic data (subject to the risk of misspellings and other mistakes) results in a relevant rate of patient mismatching and duplication of records. 'Reasons that duplicate records continue to plague healthcare systems include varying methods of matching patient records; departmental system silos; lack of data standardisation; lack of policies, procedures, and data ownership; frequently changing demographic data; multiple required data points needed for record matching; and default and null values in key identifying fields.' Study authors conclude that 'To improve patient matching, increasing the use of more sophisticated technologies is critical. For example, using biometrics, smart card readers, and advanced algorithms (...)'.

Electronic identification of patients comes in a way to guarantee uniqueness in patient identity, helping to solve these issues and, in the end, increasing data quality.[93]

Based on the two previously mentioned patient-centred approaches to health services – seeking healthcare and managing their own data – the following non-exhaustive list of use cases demonstrate the potential for benefitting from electronic identification of patients:

- Patient admission at the admission desk/counter: patient could be identified through, e.g. mobile means, in the best case avoiding even the waiting line/time and the contact with the admission clerk;
- Person acting on behalf of: this would allow proper and secure identification in cases where the data subject (the targeted patient) is not the person directly requesting the healthcare service. This use case is currently being developed in CEF eHDSI. Examples of its application include:
    - ePrescription/eDispensation in a pharmacy: electronic identification of the person acting on behalf and, additionally, triggering the electronic identification of the patient he/she is acting on behalf of (e.g. sick patient at home being requested to identify through mobile means upon a relative's request for dispensation of his/her medication at a pharmacy), allowing a fully informed dispensation by the pharmacist;
    - Patient Summary: the patient is a minor and one of the parents must be electronically identified to give the HP access to the minor's Patient Summary document. Another case is when the patient is an incapacitated or disabled adult and another person is authorised/entitled to act on their behalf;
- Consent (or other legal document) provision: patient eID would increase the authenticity, correctness and non-repudiation of electronic consents and other legal documents stemming from GDPR, strengthening the certainty of this legal act. The cross-border version of this use case was, to some extent, explored by the HEALTHeID project, where patient eID enables the proper acknowledgement of the Patient Information Notice of the country of treatment (as deemed necessary according to the GDPR);
- Patient access to their own laboratory results, e.g. exploring patient eID as a secure means of accessing this kind of information in its cross-border fashion (following one of the new information domains identified in the Commission Recommendation about Electronic Health Record Exchange Format[94]);
- An emergency call centre health professional being able to automatically and securely identify a patient, leveraging the latter's mobile phone as an eID means;
- A patient sharing his/her own health data collected from personal devices (e.g. wearable devices): patient eID would allow immediate sharing of such data with health professionals and its aggregation in the patient's EHR;
- Patient eID as a means for closely-linked cross-sectoral cooperation, e.g. identifying the patient as an insured person under the Electronic Exchange of Social Security Information (EESSI) domain (Annex IV.4).

[93] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4832129/

[94] https://ec.europa.eu/digital-single-market/en/news/recommendation-european-electronic-health-record-exchange-format

Other emerging use cases should also be considered to be included on the eID use cases with focus on the patient-centred approaches to health services, at national and cross-border levels. During the COVID-19 pandemic there is a pressing need to support new use cases (e.g. vaccination/test proofs or vaccination appointments). The common eID Approach should be aware of the emerging use cases and be able to identify and define a specific implementation plan and adopt it in a short-term Approach, ensuring the further high-quality provision of healthcare assistance regarding these new use cases.

Cross-border use cases can find in the reuse of the CEF eID Building Block a good ally for proper eID implementation. The benefits of patient eID reflect on the patient identification process, the first step of the current eHDSI use cases, as already described. On the other hand, a cost-benefit analysis of the usage of the eID Building Block on a case-by-case basis would be warranted.

This means that overall, accurate and secure patient identification introduces several benefits in healthcare in the areas of patient management and treatment (e.g. improved quality of care; transition and continuity of care; reduction in duplicate diagnostic testing; longitudinal healthcare record), health insurance and benefits programs (e.g. streamlined billing and claims processing; reduction of fraud) and data collection for planning and research (e.g. public health; big health data).[95]

### IV-4.1.1 Known used standards and means

Since electronic-based identification of citizens began to be a matter of concern for society, both public and private sectors of the political-economic spectrum started to address the technological challenge mainly from the same perspectives:

- **Technology:** Realising how the most recent electronic devices and systems, over the years, could provide ways to identify a person;
- **Social engineering:** Taking advantage of the technological possibilities and finding how to use them for identification purposes, causing the least possible impact in the society habits and routines.

In this sense, the citizen identification systems moved from credential-based authentication applications to mobile-based authentication systems, going through several stages of evolution, such as the usage of smartcards for the purpose.

Although the eID trends followed by countries all over the world share the principles described above, the same cannot be realised when analysing the system implementations, that were designed and built to serve eID purposes of each country/geopolitical area; in other words, each implementation standard of eID relies on the administrative environment variables (e.g. politics, demography, administrative division, economy, etc.) of the region where it was implemented.

Taking into consideration only the technological aspects, nowadays there are several identification standards, or proof of concept projects, with capabilities to provide support for the wanted purpose for citizen identification. In the following paragraphs, the results are presented of an analysis made about available techniques that are, or could be, used to identify a patient against a healthcare related system.

- **Credential based authentication** – An authentication based on a secret shared between the user and the system (e.g. a password). Regarding the password lifecycle, a password can be persistent over time, or can be used only once (an **OTP**, one-time-password), usually requested/acquired through mobile devices (e.g. using an IVR system, SMS or other dedicated systems like **QR code generators**).

[95] http://documents.worldbank.org/curated/en/595741519657604541/The-Role-of-Digital-Identification-for-Healthcare-The-Emerging-Use-Cases.pdf

- **Smartcard Authentication** – A standard that uses the information contained in the smartcard to identify the user, although to grant the access to that information it is always necessary for the user to introduce a PIN to assure the authenticity. These systems are widely used by governments to provide identification documents in this format (e.g. citizen cards, Foreign Cards, Diplomatic Identity, etc.).
- **Mobile Authentication** – A system that identifies the user by the identification of their smartphone, making use of some technological frameworks, such as special SIM cards or the identification of the device itself containing private keys of the user in systems based in asymmetric-encryption for authentication.
- **Biometric Authentication** – A standard that makes use of biometric characteristics (e.g. iris, fingerprints, etc.) of a user to identify them against the system. Nowadays, with the growth of the use of smartphone computing capabilities and their proliferation among the general population, these identification systems now have a renewed importance since it is possible to perform biometric recognition through a mobile device anywhere.

As it was stated previously, although these technologies are used widely all over the world, there is no mainstream standard used, not even agreed, inside the EU context, causing every identification authority to define its own implementation/usage protocol. In Annex IV.1, the overall state of play about this matter across the EU is depicted, presenting the technologies/protocols adopted or under development for eID purposes within each country. Moreover, specific constraints may apply in the context of healthcare provision, as some means of identification cannot be applied in specific situations, e.g. due to patient's acute health condition, deteriorated health, or lack adequate of e-skills.

### IV-4.1.2 Electronic identification constraints and challenges

An **electronic patient register** is required for both national and cross-border data exchanges, as a means to identify the natural person engaging with the healthcare service and properly connect him/her to his/her clinical data through one (or a combination of) identifier(s). Thus, setting up of such digital infrastructure is seen as a mandatory step to achieve proper electronic identification of patients. This encompasses not just the technical activities of creating the registry and enabling connection with specific eID means of the end-user but also the organisational activities, related to the updating of patient data collected during his/her encounters with the healthcare services and the definition of business processes needed to qualify the patient register with an authoritative and trustworthy status. Furthermore, in the legal field, challenges arise with regards to GDPR-compliant processing of personal data, but also national legislation for setting up and operating existing or future national patient registries may vary significantly between Member States, for example in their content, scope, use case and level of detail.

Constraints exist in current business processes where a health professional performs patient identification on the patient's behalf. Moving to a patient-centric electronic identification demands a significant shift in the current paradigm of these business processes, impacting the people, as well as the organisations. New business processes, potentially changing in a significant way the actors and their interactions, need to be defined and integrated into daily organisations' routines in the smoothest way possible. The eID aproach and policies shall support an intensive programme on digital literacy for eID at different levels (patients, HPs, organisations and decision-makers).

Other constraints exist with regards to the eID means. The usage of physical-token eID means (e.g. smartcards) demand additional hardware and software solutions at the point-of-care, which increase the operational burden of such eID solutions, from technical, organisational and financial points of view (e.g. rollout of smartcard readers in the healthcare institutions of a country that should be compliant with ISO

7816[96], leading, if needed, to be installed properly in order to read up to 20 different smartcards and in some cases, change hardware e.g. contact vs contactless). Such constraints also apply in the case of a patient-triggered eID (e.g. the burden of a patient having to have a smartcard reader to authenticate against his/her patient portal). Therefore, virtual authentication schemes can be the preferred approach to overcome this challenge.

On an organisational level, governance and operation of healthcare services and national eID schemes may fall under the responsibilities of different organisations and ministries. Policies for these two different worlds may be provided by different cooperation groups. Most notably, in the cross-border world, we have the eHealth Network and the eIDAS Cooperation Network as the policy bodies ruling the procedures to be followed by organisations and ministries of each realm. Connecting eID to eHealth will demand a close alignment between these kinds of entities, both at national and EU levels. Healthcare may already have a legacy means of electronic identification, and implementation of new eIDAS compliant means may thus require substantial investments in ICT infrastructure and applications, such as investment in new eID reading devices and implementing software services for provision of healthcare - specific identifiers.

## IV-4.2 Electronic identification of Health Professionals – use case

HP identification is the process by which the set of attributes describing the identity of the natural person interacting with health services (the HP providing healthcare) are unambiguously recognised. The result of HP identification and authentication is a proof that the HP is who he/she claims to be and that he/she is entitled to access health data. Electronic identification of HPs is the process by which the HP identification and authentication is established using any electronic means (eID) or, using eIDAS terms for online services, is the process of using person identification data in electronic form uniquely representing a natural person (the HP). Authorisation to access particular types/sets of data is defined based on the role and profile of the HP.

With the emergence of EHRs, electronic identification of HPs became a reality and is now common practice. But there is a huge diversity in eID means: they vary within an organisation and between software vendors, groups of health professionals, country regions and between countries. Additionally, some of these means may not provide the necessary level of assurance needed for the processing of health data by the professionals, in accordance with the recent data protection legislation.

There is a need to introduce, maintain and interconnect heath professional registries for authentication of health professionals. Apart from eIDs, the registries shall provide information about professional qualifications as an essential criterion to evaluate rights for access to health data. As the source of authoritative information, health professional registries should fulfil minimum requirements for accurate and secure identification, authentication and authorisation of health professionals. The heterogeneity of registries may raise some concerns on their regulation, data quality, control and trustworthiness, once they are integrated through eID means. Having a common vision and approach for HP eID in Europe would assure a least common denominator on electronic identification processes and means, guaranteeing appropriate security levels, legal certainty and completeness of information.

The European Commission identified the need for the creation of a common European Health Data Space, which would foster the sharing of different kinds of health data within the EU, thus supporting the delivery

[96] https://www.iso.org/obp/ui/#iso:std:iso-iec:7816:-8:ed-4:v1:en

of healthcare, as well as the development of new treatments, medicines, medical devices and services[97]. Regarding the current situation related to the COVID-19 pandemic, information exchange to support research and statistics has become more urgent.

The following non-exhaustive list of use cases demonstrate the potential for benefitting from electronic identification of health professionals:

- Consent (or other legal document) provision: to trace to whom the patient provided his/her consent or other legal document stemming from GDPR;
- Secondary use of data: promote cross-border health-data exchange to support research and statistics in the field of health;
- Telehealth: accurate identification of the HPs participating, e.g. in a video-call;
- Referral management: to have a full trace of referrals between HPs, their specialties and the healthcare organisations in which they are working;
- Mobile ePrescription or Death Certificates: ensuring access of HPs to mobile versions of these use cases and secure linkage for the HP authoring of these clinical documents;
- Digital Signatures by health professionals: eID can be applied for digital signatures of discharge reports, medical certificates and other types of medical documents that need to be duly signed by a health professional;
- All the use cases included in the Commission Recommendation about EHRxF: Patient Summary, ePrescription/eDispensation, Laboratory results, Medical imaging and reports, Hospital discharge reports
    - Enriching the cross-border exchanged documents with trustworthy information on the identity of the HP (or HPs) who authored the clinical document;
    - Allowing fine-grained traceability of the requester of clinical data on both countries;
    - Elevating the trust, by the country of affiliation, in an identification and authentication process carried out by the country of treatment.

Similarly, relating to the patient ID use case, cross-border use cases may explore the reuse of the CEF eID Building Block for proper eID implementation. The benefits of HP eID reflect on the HP identification process, a prerequisite of the current eHDSI use cases.

Consequently, all use cases starting with the identification of the HP have increased benefits, although implementation costs should also be taken into account.

### IV-4.2.1 Known used standards and means

Regarding the identification of a professional against an IT system, in broad terms, is in fact based on the premise that a professional is, first and foremost, a citizen. In this sense, and in general, currently the methods used to enable professional authentication does not depend on an interface used to perform identification, it is mostly based on the capability of the corporate dedicated systems to establish the connections between citizen metadata and its certified professional.

97 https://ec.europa.eu/digital-single-market/en/news/member-states-meet-european-commission-discuss-protection-personal-data-health-sector

Following this principle, both private and public corporate entities implemented their own identification systems based on the technological trends enunciated in section 4.1.1, taking advantage of the intrinsic features that a dedicated system has to offer in this context:

- **Data Ownership** – Once a system is designed and implemented to serve the requirements of a determined organisation only, it can be adapted to use every kind of person identification, because the correlation between an identified citizen and its professional data is made by the system itself, and does not depend on the identification interface (e.g. citizen smartcard, credentials, etc). At this level, as the professional metadata of the users is managed by the same system that uses it to grant professional identification, the information distribution among systems opened a set of advantageous opportunities of interoperability and integration between different platforms.
- **Interoperability and Integration with third-party systems** – Due to the distribution of the data operated by each organisation to perform professional identification, third-party platforms (e.g. Active Directories; Microsoft Office 365) began to be used as a data source to perform identification of users, taking advantage of some organisational processes already consolidated, such as the mandatory usage of Office 365 accounts to enable user authentication inside a corporate IT applications domain.

Regardless of the consolidated identification paradigms, nowadays, as consequence of some initiatives about personal and professional data aggregation in the context of eID purposes, it is already possible to commute the mainstream paradigm of professional information distribution, gathering that data in the same format as the adopted standards for personal identification. In this sense, there are already some projects, at different levels of reliability and execution, to unify both personal and professional identification in the same process and using the same technological interfaces (e.g. Professional Attributes Certification System in Portugal); more details are presented in Annex IV.1.

### IV-4.2.2 Electronic identification constraints and challenges

An electronic register of health professionals (one or more, according to national needs) is required for both national and cross-border data exchanges, as a means to identify if a person or an entity is entitled to access particular sets of data. Thus, setting up such digital infrastructure is seen as a mandatory step to achieve proper electronic identification of health professionals. This encompasses not just technical activities of creating the registry and enabling connection with specific eID means of the end-user but also organisational activities related to the engagement of national health professionals' associations and the definition of business processes needed to qualify the health professional register with an authoritative and trustworthy status. Furthermore, in the legal field, challenges arise with regards to GDPR-compliant processing of personal data, but also national legislation for setting up and operating existing or future national professional registries may vary significantly between Member States, for example in their content, scope, use case and level of detail.

The guideline of the Joint Action to support the eHealth Network on 'Interoperability of Electronic Professional Registries'[98] explores the idea of defining a minimum common denominator for data elements representing relevant health professional information, considered sufficient for interoperability purposes. In addition, such a document could not extract in detail the semantic requirements of such an interoperability scenario, e.g. the need for an associated controlled vocabulary to enable transformation, translation and encoding of the national health provider information into a pan-European format. Thus, a close link to the eHN's Semantic Subgroup is anticipated, to properly address the semantic aspects of the controlled

[98] https://ec.europa.eu/health/sites/health/files/ehealth/docs/ev_20170509_co05_en.pdf

vocabulary and any other related semantic requirements; not as a replication, but to ensure similar logics are used, and also since many semantic knowledge bases have been used to characterise professionals (e.g. what is meant by midwife, or nurse, may seem obvious but, without a clear commonly-agreed meaning, what some countries call one or the other may differ). A link to 'common professionals' recognition' across the EU and the Commission units working on that is likely to be needed at some stage.

Other constraints exist with regards to the eID means. The usage of physical-token eID means (e.g. smartcards) demand additional hardware and software solutions at the point-of-care, which increase the operational burden of such eID solutions from the technical, organisational and financial points of view (e.g. rollout of smartcard readers over the healthcare institutions of a country). Therefore, virtual authentication schemes can be the preferred approach to overcome these challenges.

Just like the patient eID use case, other constraints can be found in the adaptation of business processes to eID, potentially changing some actors and/or interaction patterns, impacting on people and organisations. To assure smooth adoption of eID, approach and policies shall support an intensive programme on digital literacy for eID at different levels (HPs, professional associations, organisations and decision-makers).

As in the patient eID use case, on an organisational level, governance and operation of healthcare services and national eID schemes may fall under the responsibilities of different organisations and ministries. Policies for these two different worlds may be provided by different cooperation groups. Most notably, in the cross-border world, we have the eHealth Network and the eIDAS Cooperation Network as the policy bodies ruling the procedures to be followed by both the organisations and ministries of each realm. Connecting eID to eHealth will demand a close alignment between these kinds of entities, both at national and EU levels.

# IV-5 Policy and Governance Structure description

## IV-5.1 Guiding Principles

The principles defined in this chapter enable a structured cooperation between the different stakeholders belonging both to the public and private sector.

*Universal Coverage – Inclusion – Simplicity*

- Ensure access by health professionals who work in the public and private sectors;
- An individual's use of their digital identity should be simple and intuitive.

*Integrity – Security – Confidentiality*

- Ensure data consistency;
- An individual has the right to keep their digital identity information private;
- The use of digital identity to access the patient's clinical information must guarantee data security and privacy. The professional who accesses the data must have permission to access it.

*Open Data – Openness – Reusability*[99]

- Adoption of standards and norms to facilitate interoperability;

[99] https://ec.europa.eu/isa2/sites/isa/files/eif_brochure_final.pdf

- The level of openness of a specification/standard is decisive for the reuse of software components implementing that specification;
- All stakeholders have the opportunity to contribute to the development of the specification and a public review is part of the decision-making process;
- The specification is available for everyone to study;
- Reuse and share solutions and cooperate in the development of joint solutions when implementing EU public services.

*Once-Only Principle*[100,101]

- Ensure that citizens and businesses are requested to supply the same information only once to a public administration;
- Citizens and businesses should not have to supply the same information to public authorities more than once for the cross-border exchange of evidence.

*Building and Sustaining Trust – Transparency – Data Privacy – Fair Use*

- Ensure privacy and data protection;
- Right to know who had access to the data – transparency regarding who accessed it.

*User Centricity – Ownership – Consent*

- An individual's digital identity should not be used or shared without their explicit consent, or as permitted by law;
- Individuals own their identity and personal data.

*Zero trust principle*

- Treat everything connecting to eHealth infrastructure as untrusted until an access request (by patient/HP) is unambiguously identified.

## IV-5.2 Proposed Governance Framework and Involvement with Stakeholders

In order to ensure the fulfilment of a Common eID Approach for Health, the eHN is asked to indicate (e.g. eHN Technical Sub-group) or create a group as an intervening of a robust and stable governance model. This group will be responsible to manage the eID approach, and to coordinate and support its development. Within the digital identity ecosystem there is a set of primary stakeholders that play complementary/supporting roles in the eID processes in the context of each country. The governance model is the key to achieve overall coherence in the eID approach (Figure 10).

[100] Proposal for a Regulation of the European Parliament and of the Council on establishing a single digital gateway to provide information, procedures, assistance and problem solving services and amending Regulation (EU) No 1024/2012, COM(2017) 256 final, 2017/0086 (COD) https://eur-lex.europa.eu/legal-content/PT/TXT/?uri=CELEX%3A52017AE2781
[101] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52017XX1011(01)&from=PT

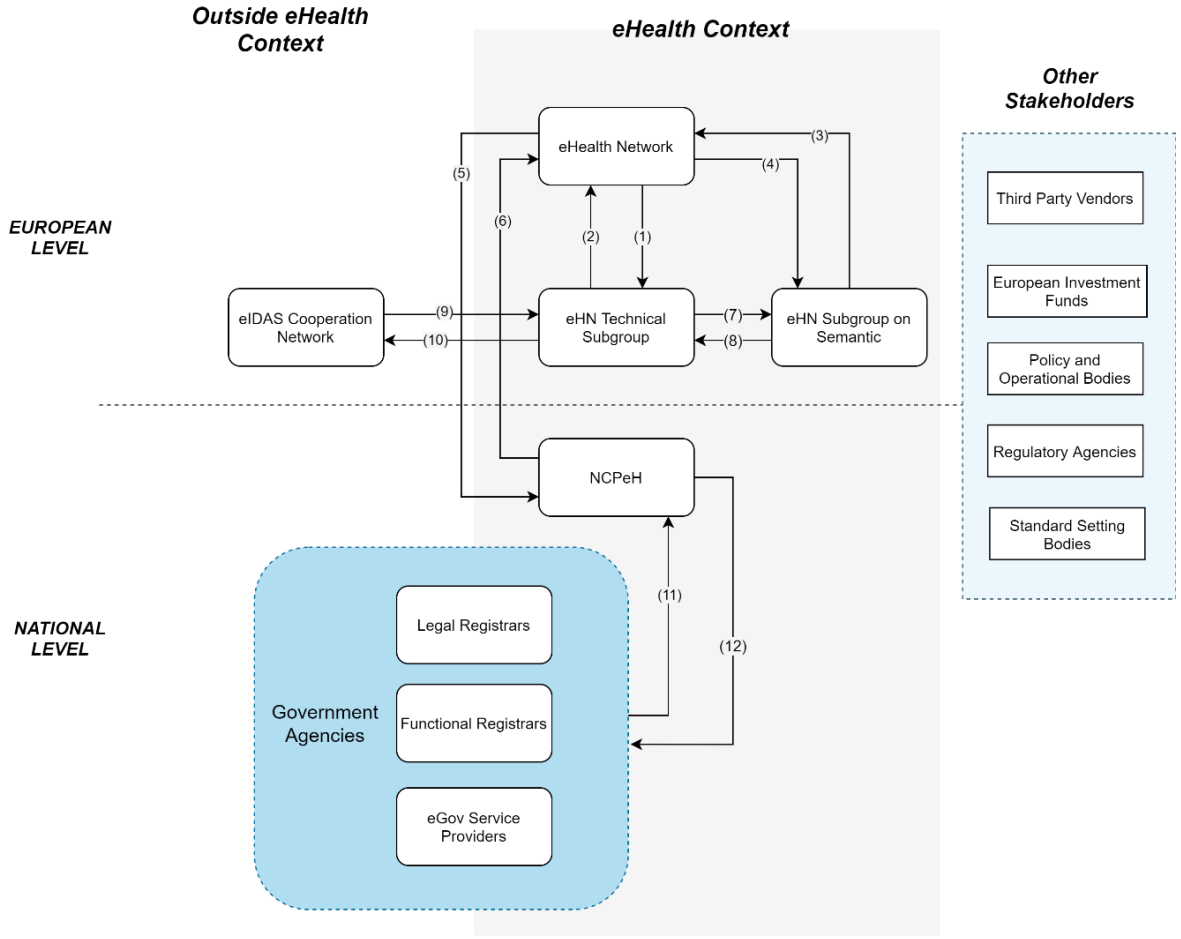


**Figure 10 –** Proposed governance framework for Health eID in the EU

*Relations between the bodies:*

***Relationship 1 and 2:*** *the eHN technical Subgroup supports the eHN on technical issues. This group is focused on the use cases.*

***Relationship 3 and 4****: the eHN Semantic Subgroup exerts its functions under the eHN scope. The eHN Semantic Subgroup shall propose semantic guidance to the eHN for endorsement, in this way acting as a consulting body to the eHN, which in return shall take the eHN Semantic Subgroup's proposals and structure them as EU level guidelines.*

***Relationship 5 and 6****: the NCPeH uses the guidelines and recommendations produced by the eHN in order to take forward the deployment/operation of the cross-border services. The NCPeH is the national body responsible to exchange the national data in the cross-border context.*

***Relationship 7 and 8****: these Subgroups are under the influence of eHN and have strict communication between them in order to achieve mutual support.*

***Relationship 9 and 10****: the eIDAS Cooperation Network will exchange information regarding good practices on electronic identification schemes with the eHN Technical Subgroup to ensure an alignment about the use of eID on national and cross-border contexts.*

***Relationship 11 and 12****: the relationship between NCPeH and the Government Agencies can be managed directly with Legal Registrars, Functional Registrars and eGov service providers or could be performed by an intermediate agency.*

***Other Stakeholders*** *represent additional different parties that have an interest in the development of eID and can either affect or be affected by the course of the eID initiative. The eID approach must have a close relationship with the other stakeholders to ensure the development of this approach. These stakeholders can be important in some phases of the approach.*

A brief description of the main stakeholders and their roles in the digital identity ecosystem is provided in Table 3. Each stakeholder is intended to define a relevant organisation that may be set up at a national, EU or global level in order to support or carry out follow-up actions related to digital identification. The stakeholders were organised within the following two fundamental categories[102]:

- ***Government Agencies*** – comprising national bodies that play one or more principal role(s) in the digital identification lifecycle.
    - ***Legal registrars*** are the agencies in charge of providing legal identification to citizens. These may include national identification authorities in charge of creating and maintaining national ID cards and other documents.
    - ***Functional registrars*** are agencies that create and maintain identity registries for a specific purpose or service, e.g. Medical Council, Pharmaceutical Society and other Health and Social Care Councils and identity provider agencies responsible for registries of health professionals.
    - ***eGov service providers*** are government agencies or platforms that provide online services to citizens or residents which require some proof of identity and entitlement.

- ***Enablers*** – agencies which enable and support the identity systems. These enablers can operate at an EU and global Level.
    - ***Regulatory agencies and organisations*** regulate, control and audit digital identity systems. The goal of these actors is to ensure that digital identity and authentication providers follow legal standards and best practices for the collection, storage, and use of personal data.
    - ***Standard setting bodies*** are organisations that provide protocols for digital identification and authentication. The goal of these agencies is to increase interoperability and build open and scalable identity solutions.
    - ***Policy and operational bodies*** are agencies which enable and support identity systems at a strategic, technical and operational level.

It is important to highlight that Table 3 presents a general view about the stakeholders' role in the eID ecosystem, however they can be different among the Member States due to different types of organisation.

[102] Digital Identity: Towards Shared Principles for Public and Private Sector Cooperation

**Table 3** – Key identity stakeholders and their main roles

| | STAKEHOLDERS | PROVIDERS | ROLE |
|---|---|---|---|
| **GOVERNMENT AGENCIES** | ***Legal Registrars*** | **NATIONAL LEVEL**<br>• National ID Agency;<br>• Birth Register;<br>• Passport Agency;<br>• Ministry of Interior | • Digital ID providers<br>• Attribute providers<br>• Authentication providers<br>• Service providers |
| | ***Functional Registrars*** | **NATIONAL LEVEL**<br>• Health and Social Care Councils or Professional Associations, such as Medical Council or Pharmaceutical Society<br>• Agencies for Registers of Health Professionals<br>• Hospitals<br>• Primary Care | • Digital ID providers<br>• Attribute providers<br>• Authentication providers<br>• Service providers |
| | ***eGov Service Providers*** | **NATIONAL LEVEL**<br>**(examples of eGov Service Providers)**<br>• e-Identita, I.CA (Czech Republic)<br>• SI-TRUST (Slovenia)<br>• EESTI (Estonia)<br>• Autenticação.Gov (Portugal)<br>• State Treasury (Hungary) | • Authentication providers<br>• Service providers<br>• Service entitlement authorisation providers |
| **ENABLERS** | ***Regulatory Agencies*** | **NATIONAL LEVEL**<br>• National Data Protection Authority<br>**EUROPEAN UNION LEVEL**<br>• European Data Protection Board | • Regulation & oversight |
| | ***Standard Setting Bodies*** | **GLOBAL LEVEL**<br>• Global Digital Health Partnership<br>• International Organization for Standardization<br>• International Electrotechnical Commission | • Standard setting<br>• Provide technical and data standards<br>• Build trust<br>• Support information security and cybersecurity |
| | ***Policy and Operational Bodies*** | **EUROPEAN UNION LEVEL**<br>• DG DIGIT<br>• DG CONNECT<br>• eHealth Network<br>• eIDAS Network<br>• CIO Network<br>• eGov Steering Board<br><br>**NATIONAL LEVEL**<br>• Ministry of Defence – Committee of Digital Security<br>• National Health Insurance<br>• State Audit Office<br>• Ministry of Health<br>• Ministry of Finance | • Entitled to EU healthcare services with European Health Insurance Card (EHIC) |

# IV-6 Recommendations

Following the need for common electronic identification, recommendations on how to address this issue are provided.

**Recommendation 1: Preferable use of eIDAS infrastructure, for the cross-border eHealth context**

The use of cross-border authentication through the eIDAS Infrastructure (Opinion No. 5/2019 of the Cooperation Network on version 1.2 of the eIDAS Technical specifications[103]) provides a clear legal framework, both for interoperability and level of security/assurance. The eIDAS Regulation provides a reliable, and convenient manner for online services to identify their users. Is important to note that these services are applicable only for online services.

**Recommendation 2: Development of software based eID Strategy for eHealth services**

Considering the trend towards mobile services, eID schemes should be provided in mobile compatible forms. Each Member State should ensure that authentication schemes are suitable for mobile and ensure the development of a mobile-friendly service when choosing the appropriate eID scheme. This consideration is aligned with the recent Commission Recommendation '*Embracing mobile identity for eGovernment*'[104] in relation to mobile eID. The strategy must ensure a fallback mechanism to the traditional identification means for the particular cases where the patient is unable, for some reason, to use these innovative solutions. Some notified eID schemes under eIDAS which are mobile oriented have LoA 'high', i.e. comparable with the LoA of smartcards.

**Recommendation 3: Ensure that the use of the traditional identification means for offline services (e.g. citizen card, passport) is still a possibility**

Even with the development of electronic means of identification, the Member States should ensure that traditional means of identification for the use cases in offline services be possible. For offline (in person) services provided at the point of care, the use of an eID scheme should be possible but optional.

**Recommendation 4: Use of a sector-specific eID scheme, with a sector-specific patient identification number for eHealth use cases**

The use of a sector-specific eID scheme, with a sector-specific patient identification number, should be preferred. In those cases where the use of a specific health eID scheme is not possible, the use of a national eID scheme is recommended, whether notified under eIDAS or not, with a unique identifier that is used as the patient identification number for eHealth use cases. This could be possible through reconciliation between eIDs from the multiple national sectors. Nevertheless, appropriate personal data protection measures must be considered. For both offline and online digital health services, further work is needed for citizen eID schemes. The work should focus on the interoperability of already-existing healthcare-specific citizen eID schemes in the Member States.

[103] https://ec.europa.eu/cefdigital/wiki/pages/viewpage.action?pageId=148898549

[104] https://ec.europa.eu/cefdigital/wiki/display/CEFDIGITAL/2020/05/06/Embracing+mobile+identity+for+eGovernment?pk_campaign=XSELL-Bulletin49-202005&pk_source=email&pk_medium=CEFbulletin&pk_content=success_story

**Recommendation 5: Use of a sector-specific eID scheme, with a sector-specific health professional identification number for eHealth use cases**

The use of a sector-specific eID scheme, with a sector-specific health professional identification number, should be preferred. In those cases where the use of a specific health eID scheme is not possible, the use of a national eID scheme is recommended, with a unique identifier that is used as the health professional identification number for eHealth use cases. Nevertheless, appropriate personal data protection measures must be considered.

**Recommendation 6: Implementation of a 'High' Level of Assurance for health professionals**

The security and integrity of health data is key for patients, doctors and other health professionals in research and innovation uses and for society, as a whole, to preserve potential information assets. Access to health data must be independent of where the data is located and must comply with GDPR and other data protection legislation. What must be guaranteed is that unauthorised access will never occur; the system must be set up to prevent this. It is advisable to set this aim along the lines of 'zero trust'[105], which is becoming commoner nowadays. This principle excludes the possibility of human faults or malicious activity in the operation of the systems. In order to ensure that these statements be achieved, the Level of Assurance of the eID schemes should be 'High' (at least to the equivalent of two-factor authentication), preferably targeting the eIDAS concept of 'High', to allow trust in the related services, as portrayed in Figure 9, Chapter 2. However, the use of the eIDAS-compliant schemes should be optional.

**Recommendation 7: Use of sector-specific non-notified eID schemes for cross-border eHealth use cases (eID schemes outside the eIDAS Regulation)**

In cases where it is not possible to use eIDAS-notified eID schemes, the use of national health sector-specific eID schemes (e.g. with unique patient or health professional identifiers and further demographic data) is recommended. These eID schemes are provided by the national identity issuers where the identity data are managed (e.g. health insurance companies or medical associations).

In a cross-border context, patient or health professional identification can always be ensured without eIDAS eID schemes in accordance with data protection laws. The fact that proof by means of notified eID means can be suitable in terms of data protection law does not oblige exclusive use of these notified eID schemes.

The eHN highlighted, in its 16th meeting[106], that '*some Member States remarked that there are new technologies and possible identifiers not notified under eIDAS framework. It is important to ensure that the proposals on the table are open but new possibilities also fit the purpose of healthcare and are not just pushed by other sectors'.*

[105] Zero Trust – Treat everything connecting to eHealth infrastructure as untrusted until the patient or healthcare professional requesting access is unambiguously identified

[106] https://ec.europa.eu/health/sites/health/files/ehealth/docs/ev_20191128_sr_en.pdf

**Recommendation 8: Member States should create the conditions necessary for their national bodies to set up and govern eID schemes**

Member States should use their national government structures to provide eID schemes and/or improve the existent schemes in order to achieve a high level of assurance and their use in the health context.

**Recommendation 9: The need for specific value sets to support eID use cases should be referred to the eHN Subgroup on Semantics.**

For countries who have a national value set for professional categories, performing mapping between international standards and national code systems is recommended. The adoption of standards to ensure interoperability principles is recommended. Consequently, the analysis of ISCO-08[107] (International Standard Classification of Occupations) is required for the eHN Subgroup on Semantics. This classification organises jobs into a defined set of groups according to the tasks and duties undertaken in the job.

**Recommendation 10: The eHealth Network should promote the necessary work to fulfil the eID use cases**

The eHN should support the development of the eID use cases on the national and cross-border levels for the Member States, taking into account the different eID schemes among the Member States.

**Recommendation 11: Extend the health eID to reach also the private sector, for cross-border sharing of information[108]**

The eHN could promote the use of the national eID schemes for Health in the private health sector. It is important to support an effort to converge towards the approach to achieve a common eID for Health in the EU.

**Recommendation 12: The possibility of developing and adopting a common eID for all Member States should be considered[30]**

The eHN should promote the adoption of eID schemes for digital identification among the EU Member States. The EU is developing and improving the interoperability framework of the eHealth sector and it is fundamental that the all Member States consider adopting the common strategies to strengthen the sector and ensure the correct identification of citizens (patients and health professionals) wherever they are in the EU.

**Recommendation 13: Coordinating the development of the eHealth eID with the future European Digital Identity**

The new Commission proposal for a trusted and secure European Digital Identity covering all EU citizens expected in Q2 2021 may bring important benefits to identification in the health sector. The development of eHealth eID cross-border should be closely coordinated with this project to avoid overlap.

[107] https://www.ilo.org/public/english/bureau/stat/isco/isco08/
[108] https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12528-European-Digital-Identity-EUid-

# IV-7 Roadmap

The following section shows a roadmap for the different aspects of the common approach at high level (6.1) as well as at the goal/objectives level (6.2).

## IV-7.1 Roadmap for approach approval and implementation

### IV-7.1.1 Preparatory phase (September 2019 – March 2021)

The approach building process required alignment between different Directorates-General of the European Commission and the Member State co-chair of the eHN between September 2019 and March 2021, and the acceptance by the eHAction Steering Council of its inclusion as a possible extra activity between April 2021 and the official start of its implementation.

It is key to interlink between DG DIGIT (and CIO Network) and DG CONNECT (and eGov Network and eIDAS Trust Services Workgroup) activities on this matter, and as such this document shall be presented and further discussed with all parties, given their roles in the subject being discussed. The Commission is currently evaluating the eIDAS regulatory framework[109] and ran an open consultation from 24 July to 2 October 2020. It is important to consider the revision of the eIDAS and the emergence of new technologies, in the elaboration of this document, in order to support the continuous development/improvement of eID schemes among EU Member States.

There was full agreement on the scope of this document by participants in the eHAction Steering Council in March 2020, as well as support by eHealth Network representatives and the Commission for the draft in November 2019, and then approval of the draft document in June 2020; the final approach should be approved in June 2021 by the eHN and should be in place when EU bodies are aligned to drive this common approach at cross-border level.

### IV-7.1.2 Implementation phase

The necessary collaboration mechanisms would be set up in the first six months. Upon the start of the implementation period, the following high-level roadmap would support the approach proposed in this document, maintaining an open mindset regarding the exact technologies that support eID at any given moment, but ensuring common principles and common governance of the different steps in the different national contexts.

Before to start the implementation of the eID approach, is needed an agreement between the Member States, and European working groups (such as eHN subgroups and others) about the minimal authentication level. This level of authentication can be different for patients (at least 1-factor of authentication) and healthcare professionals (at least 2-factor of authentication).

[109] https://digital-strategy.ec.europa.eu/en/policies/trust-services-and-eid

# IV-7.2 Roadmap for the first three years

Below, in Figure 11, a roadmap is presented for the first three years. It has options to cover additional items that can be raised for discussion if the need arises.

In **Year 1** the approach is focused on Goal 1: 'Structure a common approach on health eID in the EU'. The work on this goal during the first year of the approach will ensure the achievement, by Member States, of a minimum structure needed to establish a common approach: approval of the action plan of the eID Health approach, technical analysis of previous and ongoing projects related with eID, and identification eID initiatives that could be related with eID.

In **Years 1 to 3** the work initiated on Goal 1 will continue and Goal 2, 'Converge development roadmaps for Service providers with Adoption of eID', will be initiated. At this stage, the Member States will converge efforts to adopt the eID approach for Health and start the implementation of the eID assets and ensure a phased adoption of novel requirements progressively.

In **Year 3** the recommendations for the following three years will have been prepared. An evaluation of the work done on this approach will have been carried out and the elaboration of a new approach for the following years could be initiated. The work done in this year will support decisions about the continuation of the approach and how it can be achieved.

The common eID approach for health is already in alignment with some projects, however this common approach must be open to alignment with new initiatives regarding eID.

- **Common Semantic Strategy (CSS)** – the CSS is being developed by the eHN Subgroup on Semantics. This group is working towards adoption of standards facilitating large-scale exchange of health information in the EU, by facilitating convergence on interoperability standards for all Member States.
- **X-eHealth** – this is a project to implement the EHRxF Commission Recommendation. The information domains referred on the EHRXF Recommendation that have not yet been discussed in other projects are the focus of this project (i.e. laboratory results; medical imaging and reports and hospital discharge reports). This project has a task (T4.1: Electronic Identification implementation) that is directly related with digital identification for eHealth services.

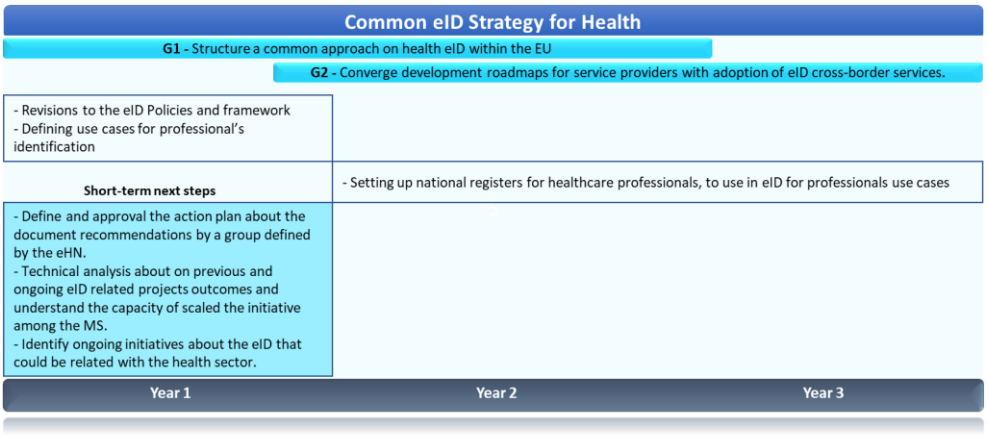


**Figure 11** – Roadmap for the development of eID for eHealth and objectives during the first three years of the Common eID Approach for eHealth.

# Annexes

## Annexes to Part I (D8.2.1)

## Annex I.1 – EHRxF Workshops

### Annex I.1.1 – 1st EHRxF Workshop

**9th and 10th July 2018, SPMS – Lisbon, Portugal**

The following paragraph contains some conclusions and findings; they are listed here without the pretence of completeness.

A list of priorities was informally created. This does not mean efforts will necessarily follow such ad-hoc listing, but it helped reflecting Member State priorities and needs:

- Oral/Dental Information;
- Immunisation Information systems – Improvement of the vaccination records etc;
- Image sharing;
- Discharge summaries etc.

**#1 Outcome - Deliverable and Endorsement process**

A European Commission Recommendation to Member States does not require the co-writing of Member States, nor does it formally need any sort of support from Member States. Nevertheless, there was consensus that, following the eHealth Network decision in May 2018 for a joint effort approach, it makes perfect sense that a European EHRxF recommended by the Commission should be based on an extensive exchange of views and needs between Member States and a concrete contribution of the Member States to the Commission recommendation.

Three DGs were present in the 1st Workshop: DG SANTE, DG CONNECT, DG DIGIT. Useful involvement and interaction of the eHealth Action and the eHealth Network as formal bodies was consolidated in the meeting. This is to say that for eHN to endorse whatever version of a Commission Recommendation, this text needs to be formally submitted to eHN Secretariat for a priori circulation to its members, and it is critical by that time, that eHN Member State representatives have enough information about the process as well as the context and its possible implications for EU and eventually their respective countries. For this to happen, ongoing collaboration via teleconferences and face-to-face meetings is key.

Cluster exercises are perhaps possible and useful. A list of priority areas seemed relevant to many people.

### Annex I.1.2 – 2nd EHRxF Workshop

**25th September 2018, Albert Borschette Congress Centre – Brussels, Belgium**

The following paragraphs contain some conclusions and findings; they are listed here without the pretence of completeness.

To provide further definition for the Commission policies, it is essential to make national efforts and share the best practices on semantics. The main focus of EHR Exchange format should include terminologies and semantics, as well as the technical format for realisation of the exchanged information. According to ReEIF, IT infrastructure aspects such as data compression, ICT infrastructures and transport layers must be realised and solved as well, but these aspects are not the main focus of EHR Exchange format.

The study of JAseHN D7.5 could be the mechanism to facilitate the access to the patient information, consent and involvement.

The technical and semantic standards according to EU Regulations were discussed. The main difficulties are the translation terms and the interactions between the information.

It is important to structure the data for re-use and map the coding. However, it is needed to have capabilities to use free text field to get flexibility to the ICT system and be capable to perform the defined workflow when the coding sets are limited.

The eHN should approve guidelines on regarding the use of imaging exchange and others EHR components. Professional groups and SDOs should develop a list of technical information to be included in the document. The eStandards Nordic country benchmark[110,111] are an example for this subject.

## Annex I.1.3 – 3rd EHRxF Workshop

**5th December 2018, Berlaymont building – Brussels, Belgium**

The following paragraphs contain some conclusions and findings; they are listed here without the pretence of completeness. This workshop was highlighted by discussion of the Non-Paper document.

**Introduction by DG CONNECT**

Wrap-up from previous meetings and iterations

Prior to the meeting, 15 countries sent comments about the Non-Paper on EHRxF.

**Summary:**

- The purpose of the Non-Paper document is to describe a possible approach to taking forward work to develop an exchange of European Health Records in the EU.
- Overall, this was a good and constructive working meeting. The meeting went through the different comments received from Member States to the Non-Paper circulated, but also included more fundamental discussion on the strategic and in particular technical path forward.
- It was an opportunity to discuss a shared view of concepts such as guiding principles, importance of the link to the semantic discussion, use cases, funding (via CEF, the European Regional Development Fund and others).

[110] https://eur03.safelinks.protection.outlook.com/?url=https%3A%2F%2Fnorden.diva-portal.org%2Fsmash%2Fget%2Fdiva2%3A1093162%2FFULLTEXT01.pdf&data=02%7C01%7CAnderson.Carmo.ext%40spms.min-saude.pt%7C72ec41d7932d44bc812508d6abad8600%7C22c84608f01d46c5802463cc962e5f51%7C1%7C0%7C636885159098115239&sdata=3K4JvhaS%2BPZDdAx%2BC1A3rp%2BoRMUhB1Qsw%2F2PkuovtJc%3D&reserved=0

[111] https://eur03.safelinks.protection.outlook.com/?url=http%3A%2F%2Fnorden.diva-portal.org%2Fsmash%2Fget%2Fdiva2%3A821230%2Ffulltext01.pdf&data=02%7C01%7CAnderson.Carmo.ext%40spms.min-saude.pt%7C72ec41d7932d44bc812508d6abad8600%7C22c84608f01d46c5802463cc962e5f51%7C1%7C0%7C636885159098115239&sdata=JlbJNC63WMe%2FJQb1DSOWxBwiibAwPJoni7Fr8V%2F%2BhhQ%3D&reserved=0

- There was advice to keep specifications relatively wide and indicate how they are currently being used (e.g. by the eHDSI) that would give an indication of current value cross-border but not close the door to wider standards.
- We need to make an agreement on what the content of the format should be.
- The pathway of implementation would depend on national infrastructure.
- We need a technical committee to manage this topic, with the role to consider ICT and clinical aspects.
- The table of technical recommendations could be in appendix. The recommendation is just a possible way to move further, changes on the document can be adopted.
- Proposal on the role of eHN to take decision or for the technical committee to have the mandate to take the decision.
- Formalise the governance structure, or the functional committee and technical committee should meet, discussion on what this should entail (who it should involve, etc.) and its expected outcome.
- Shape should be given to the Open Governance Framework, such as clarification of the individual functions/bodies that should be part of it (clinical, technical, political) and include dates/timeframes. There was support for a gradual process, and flexibility. How to involve a wider group of stakeholders (civil society such as patient/consumer groups) was mentioned.
- Start with the stepwise approach to implementation in Member States.
- What is the (technical) role of the Commission in this work to align this type of activities.
- It's important to have reference content building blocks.
- The relationship between the different aspects of information sharing (clinical, technical, infrastructural) was also discussed.
- Make clear that the purpose of the exchange relates to citizen/patient/clinician sharing of health records to improve cross border clinical care, and that as regards its contribution to the development of large data sets for scientific purposes, further steps between Member States and at the EU level are needed.

**Main comments/inputs:**

- Definitions of the terms need to be rephrased. It can be improved based on Antilope and eHDSI glossaries.
- More clear evidence regarding the advantages in this approach.
- Categorise IHE profiles (the ones for sharing of health data and security profiles); it can be based on the Antilope project[1].
- Include the ReEIF model in the text, as a reference model for the different exchange formats.

# Annex I.2 – EHRxF Surveys

## Annex I.2.1 – Survey 1

**Legal**

Although a considerable percentage of Member States/countries do not have a clear legal basis (a national law or other regulatory policy governing the privacy, security and safety for EHR), part of them can provide a

strategy for interoperability of EHR and access to citizens' health data. The patient consent can have influence on this strategy, since it is needed the GPDR or national laws to protect patient data, which is not properly applied in the sector.

It is expected that half of Member States/countries do have formal collaboration agreements to exchange of EHR, even the third-party entities, to adapt some of the practices to their legal scope and guarantee efficient exchange.

**Organisational**

Most of the Member States/countries have national infrastructures to access EHR and citizen health data. This framework has organised patient data records, which is a fundamental support to the EHR implementation and data exchange.

Although the guidelines for interoperability are not aligned in a common system it should be flexible and versatile to possibly integrate different Member States/countries. There are no standard guidelines for this purpose, however most of the countries uses semantic and technical standards in specification of public procurement, which are fundamental tools for user's research and communication.

Even the use of an interoperable EHR exchange format to access health data – resulting in integrated care pathways and shared workflows / information – is non-existent, or stills needs a to be developed and improved.

However, the Member State/country strategies reflect the results of ongoing dialogue, debate, and consensus among industry stakeholders.

So, it is a priority to stablish standards for EHR exchange access and interoperability in order to create proper EHR guideline system.

**Semantic**

Most of the Member States/countries have a national / regional semantic authority or health terminology centre, which is crucial for the communication. For this purpose, is relevant to implement the standards and specifications that can best be used to address specific clinical health information interoperability needs.

The guidelines for EHR standardisation system need a governance model or infrastructure for data model, coding and terminology, so the format on exchange of the health information be developed.

*Terminologies used by Member States/countries:*

- Most frequently: International Classification of Diseases (ICD), and its Clinical Modification (ICD-CM) (these ones are the most used); Systematized Nomenclature of Medicine - Clinical Terms (SNOMED CT), national drug dictionaries, ATC Codes.
- Frequently: International Classification of Primary Care (ICPC), Medical Dictionary for Regulatory Activities (MedDRA), Logical Observations, Identifiers, Names and Codes (LOINC), EUCLIDES and International Classification of Functioning, Disability and Health (ICF).
- Not used: GALEN, Unified Medical Language System (UMLS) and External Causes of Injury (ICECI).

(There is still one Member State/country that uses a different terminology from the ones presented in the survey).

*Patients datasets used by Member States/countries:*

- Most frequently: ePrescriptions and epSOS Patient Summary.

- Frequently: EPIRARE common dataset (rare diseases), ENCR standard dataset (cancers) and BIRO common dataset summary (diabetes).
- Not used: EFFORT-EAR minimal datasets (arthroplasty), CARDS data standards (cardiology), FSHD care dataset (neuromuscular disorder) and EUReMS care dataset (multiple sclerosis).

*Identifiers used by Member States/countries:*

- Most frequently: Citizen's number.
- Frequently: Social security code, Health insurance number, Health number - National Patient ID.
- Not used: Tax Number.

(Several countries reported that also use different data subjects in their registries).

**Technical**

The data roadmap is received through digital systems, mostly electronic record systems. These registries used by Member States/countries are:

- Most frequently: Electronic Health Record, electronic laboratory reports and Databases.
- Frequently: Online questionnaires and web based applications.
- Less Frequently: Mobile applications.

(Some Member States/countries use different electronic sources of data for registries from the ones presented in the survey).

Most countries think that the specifications are mostly self-defined (e.g. IHE Profiles, Continua Guidelines…) as standards-related, so it is important to have a compliance test strategy for EHR. The compliance Assessment Scheme is not totally positively assessed by all.

## Annex I.2.2 – Survey 2

The aim of this survey is focused on the following questions:

- **WHAT** should be the content of the EHRxF.
- **HOW** could the EHRxF be built.
- **WHEN** should the EHRxF components be prioritised and in what sequence.

The standard norm for EHR communication is a reference path to introduce to the European Commission and Directorates-General. For that, the working group (WG) related to the EHR exchange needs to focus on: terminologies (e.g. SNOMED, LOINC), semantics, compression, ICT infrastructure, transport layers (technology standardisation), work on building blocks and use cases.

To initiate a standardisation process among the EHR exchange, it is crucial to stablish a multilaterally agreed convention (e.g. Patient Summary or ePrescription specification) and, less relevant, published standards (e.g. CEN/ISO13606). The EHR communications (Healthcare Interoperability Resources) frequently used between EU Member States are HL7 FHIR (64.7%) and HL7 CDA (52.9%) (Survey 2 analysis). To prioritise this communication to standardise the EHRxF, it is very important to guarantee:

1. Patient identification
2. Summary documents
3. Problem list
4. Therapy & medical products

5. Health care record (laboratory results, imaging)

Most Member States have a specific policy regarding standard terminologies for health data:

- 80% of the Member States have a policy regarding patients to have access to their personal health data;
- 60% of the Member States have a policy regarding structural standards for EHR communication;

Thus, the EU EHR exchange format is on right path and with the help of the digital evolution EHRxF is the future of eHealth.

# Annexes to Part II (D8.2.2)

## Annex II.1 – Relevant factors and processes for Common Semantic Strategy development

To define and organise elements of the composition and roadmap for a stable semantic group in the EU, a mind map scheme has been developed. This scheme has been built in a collaborative way, including the contributions that each Member State/country has made and reaching partial consensus. The diagram describes the vision on input, output, resources and standards.


**Figure 12 -** A mind map describing relevant factors and processes for CSS development

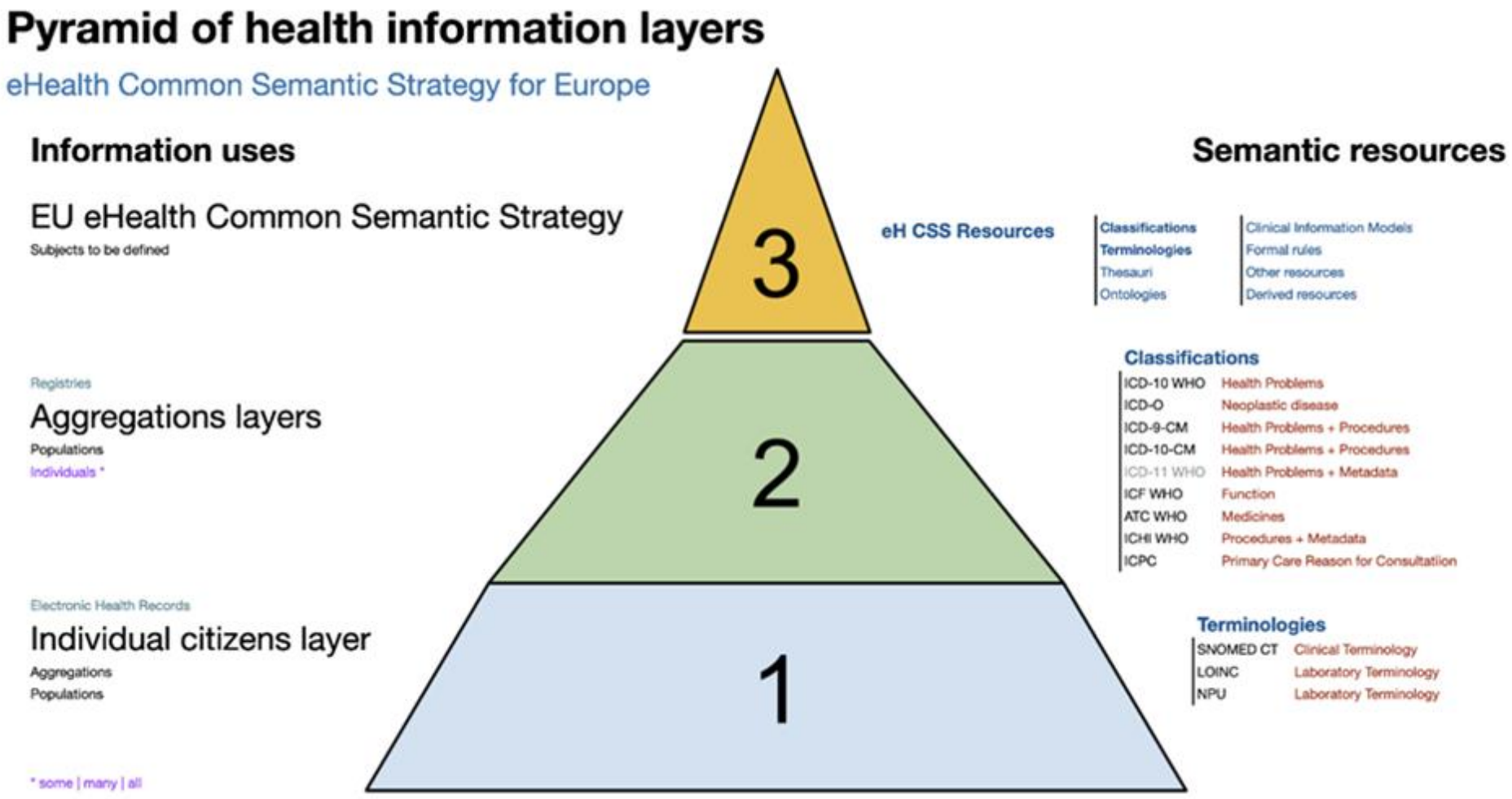


**Figure 13 -** Three-layer pyramid of health information uses, associated with semantic resources of choice

# Annex II.2 – Survey about coding standards used in EU Member State/country

**Table 4 –** Main health terminology codes used in the EU

| | Diagnosis | Cancer diagnosis | Procedures | Drugs | | Laboratory | Disability | | | Primary care | Rare diseases |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | ICD-10 | ICD-O | ICD | ATC | SNOMED CT | LOINC | ICF | NPU | Pathology | ICPC-2 | Orpha |
| **Austria** | X | X | | X | X | X | Rare | | | Rare | |
| **Belgium** | X (BE: 1) | X | ICD-10-CM / ICD-10-PCS | X | Rare | X | X | | | X | X |
| **Croatia** | X | | | X | | | | | | | |
| **Cyprus** | X | X | ICD-9-CM | X | X | | X | | | | |
| **Czech Rep.** | X | X | ICD-TNM | X | X | | X | X | | | |
| **Denmark** | X | X | | X | X | | X | X | X | X | |
| **Estonia** | X | | | X | X | X | | | | | |
| **Finland** | X | X | National Classification | X | X | FinLOINC | X | | X | ICPC | X |
| **Germany** | X(DE:1) | X | OPS | X | | **UD** | X | | | | UD |
| **Hungary** | X | X | | X | | **UD** | X | | | | |
| **Ireland** | X | | ICD-10-AM 9th ed | X | X | X | | | | X | |
| **Italy** | X | | ICD-9-CM | X | **UD** | X | **UD** | | | X | |
| **Latvia** | X | | | X | | | **X** | | | | X |
| **Lithuania** | X | | ICD-10-AM | X | X | | | | | X | |
| **Malta** | X | X | ICD-9-CM | X | X | | | | | X | X |
| **Netherlands** | X | X | ICD-10-NL | X | X | X | X | | Linked to SNOMED CT | ICPC-1 | |
| **Norway** | X | | | X | X | | X | X | X | X | |
| **Poland** | X | X | ICD-9-PL | X | X | X | | | | | |
| **Portugal** | X (PT:1) | X | ICD-9-CM | X | X | X | | | | X | |
| **Romania** | X | | ICD-10-AM | X | | | X | | | | |
| **Slovakia** | X | | ICD-10-SK | X | X | X | | | | | |
| **Slovenia** | X | | | X | X | | | | | | |
| **Spain** | X (ES:1) | X (ES:2) | ICD-9-CM / ICD-10-CM (ES:3) | X (ES:4) | X | X | X | | | X | |
| **Sweden** | X | X | | X | X | | X | X | | | |

This survey was answered by some of the CSS representatives and shows the terminology coding used most in these Member States/countries. It represents an image of the heterogeneity, as well a starting point for the work of the CSS. (The X means that this coding system is used in the Member State/country; UD - Under consideration; BE:1, ES:1 and PT:1 Used for classifying causes of death; DE:1 ICD-10-GM used for morbidity coding; ES:2 ICD-O-3.1 Morphology used for hospital discharge classification; ES:3 Since 2016; ES:4 Used for adverse event classification.

# Annex II.3 – Methodology of document elaboration

Since the creation of the Common Semantic Strategy Working Group, that was endorsed by the 13th eHN meeting (May 2018), all the Member States of the eHN and eHAction were formally invited to name one representative from their country to take part in the CSS Working Group. Along the almost one year of intensive work to elaborate the D8.2.2 document, the Member States/country that did not name a representative and the Member State/country that, for any reason, the representative left the group, were re-invited to re-join the CSS group. Through these initiatives the group could be enlarged and obtain value contributors from the representatives to contribute to the global thinking about how achieve semantic interoperability among the EU Member States.

The development of the work was aligned through regular teleconferences (14 in total); all representatives were invited to contribute, including representatives who were absent for a long time from the meetings. Similar invitations were made for the three workshops (held in Lisbon in Oct. 2018 and Mar. 2019 and in Brussels in Sep. 2019); the attendance of the meetings can be observed in Table 5. The costs for the workshops was supported by the eHAction budget, including the travel costs for the face-to-face meetings. In each meeting, the representatives discussed previous work, gave inputs and aligned thoughts to improve document content.

The CSS representatives were able to give all necessary inputs to improve the D8.2.2 document according to the general agreement, discussions at the meetings and exchange of communications via email, for the presented strategy.

Through this collective effort by the representatives, it was possible to construct the *Common Semantic Strategy for Health in the European Union* document, that summarises the general view on what should be done and how to achieve real semantic interoperability across the EU.

This initiative is a huge step to align European countries to establish semantic interoperability.

**Table 5 –** Number of participations in the CSS meetings

| Country | 1st CSS Workshop 1 & 2 Oct. 2018 | 1st Tcon (14 Jan) | 2nd Tcon (28 Jan) | 3rd Tcon (11 Feb) | 4th Tcon (25 Feb) | 5th Tcon (11 Mar) | 2nd CSS Workshop 18 & 19 Mar. 2019 | 6th Tcon (25 Mar) | 7th Tcon (01 Apr) | 8th Tcon (8 Apr) | 9th Tcon (27 May) | 10th Tcon (18 Jun) | 11th Tcon (15 Jul) | 12th Tcon (29 Jul) | 13th Tcon (19 Aug) | 3rd CSS Workshop 2 & 3 Sep. 2019 | 14th Tcon (06 Sep) | Total of participations |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Austria | N | N | N | N | Y | Y | N | N | N | N | N | N | N | N | N | Y | N | 3 |
| Belgium | N | N | N | N | N | N | N | N | N | N | N | N | N | N | Y | Y | Y | 3 |
| Croatia | Slides | Y | N | Y | Y | Y | N | Y | Y | Y | Y | N | Y | N | N | N | N | 9 |
| Cyprus | N | N | N | N | Y | Y | N | Y | N | N | N | N | N | N | N | Y | Y | 5 |
| Czech Rep. | N | Y | Y | Y | Y | N | Y | N | Y | N | N | Y | Y | Y | N | N | N | 9 |
| Denmark | N | Y | Y | N | Y | Y | N | N | Y | N | N | Y | N | N | Y | N | Y | 8 |
| Estonia | N | N | Y | Y | Y | Y | Y | Y | Y | N | Y | Y | Y | N | Y | Y | N | 12 |
| Finland | N | N | Y | Y | Y | N | Y | Y | Y | Y | Y | Y | Y | N | Y | Y | Y | 12 |
| France | Y | N | N | N | N | N | N | N | Y | N | Y | Y | N | N | N | N | N | 4 |
| Germany | Slides | Y | Y | N | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | N | Y | N | 13 |
| Hungary | N | Y | Y | N | N | N | Y | N | N | N | N | N | N | N | N | N | N | 3 |
| Ireland | Slides | Y | Y | Y | N | Y | N | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | 14 |
| Latvia | Y | N | N | N | N | N | N | N | N | N | N | N | N | N | Y | Y | N | 3 |
| Lithuania | N | N | N | N | Y | N | N | Y | Y | Y | N | Y | N | N | N | N | N | 5 |
| Malta | Y | Y | Y | N | N | N | N | N | N | N | N | N | N | N | N | N | N | 3 |
| Netherlands | Y | Y | N | N | N | N | Y | Y | N | N | N | Y | N | Y | Y | N | N | 7 |
| Norway | Y | Y | N | Y | N | Y | N | N | N | N | Y | Y | Y | N | Y | N | Y | 9 |
| Poland | N | N | Y | Y | N | N | Y | Y | Y | Y | N | Y | Y | Y | Y | N | Y | 11 |
| Portugal | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | 17 |
| Romania | N | Y | N | N | N | N | N | N | N | N | N | N | N | N | N | Y | N | 2 |
| Serbia | Y | N | Y | y | Y | N | N | Y | N | Y | Y | Y | N | N | N | N | N | 8 |
| Slovakia | N | N | N | N | N | N | N | N | N | N | N | N | N | N | N | Y | Y | 2 |
| Slovenia | Y | Y | N | Y | Y | Y | Y | Y | N | N | Y | Y | Y | N | N | Y | Y | 12 |
| Spain | Y | Y | Y | Y | Y | Y | Y | Y | Y | Y | N | Y | Y | N | N | N | N | 12 |
| Sweden | Slides | Y | Y | Y | Y | N | Y | Y | Y | Y | Y | N | Y | Y | Y | Y | Y | 14 |
| European Commission | Y | N | N | N | N | N | N | N | N | N | N | N | N | N | N | Y | N | 2 |
| Semantic Task force | N | N | N | N | N | N | N | N | N | N | N | N | Y | Y | N | Y | Y | 4 |
| Total | 10 | 14 | 12 | 12 | 14 | 11 | 11 | 14 | 13 | 10 | 11 | 15 | 13 | 8 | 11 | 15 | 12 | |

# Annexes to Part III (D8.2.3)

## Annex III.1 – European eHealth Reference Architecture (eHRA)

### Annex III.1.1 – Reference Model

The correct structure of a reference model is key to assure the coherence between the strategy, tactic and operation levels across the EU. A reference model is an abstract framework or a conceptual model that aims to interlink a set of clearly defined concepts. Therefore, a framework which has strong steering elements addressing both strategy and technical issues is needed. Figure 14 represents the designed framework to get a visual description of the structure inherent to EU health services and how each artefact relates to each other.

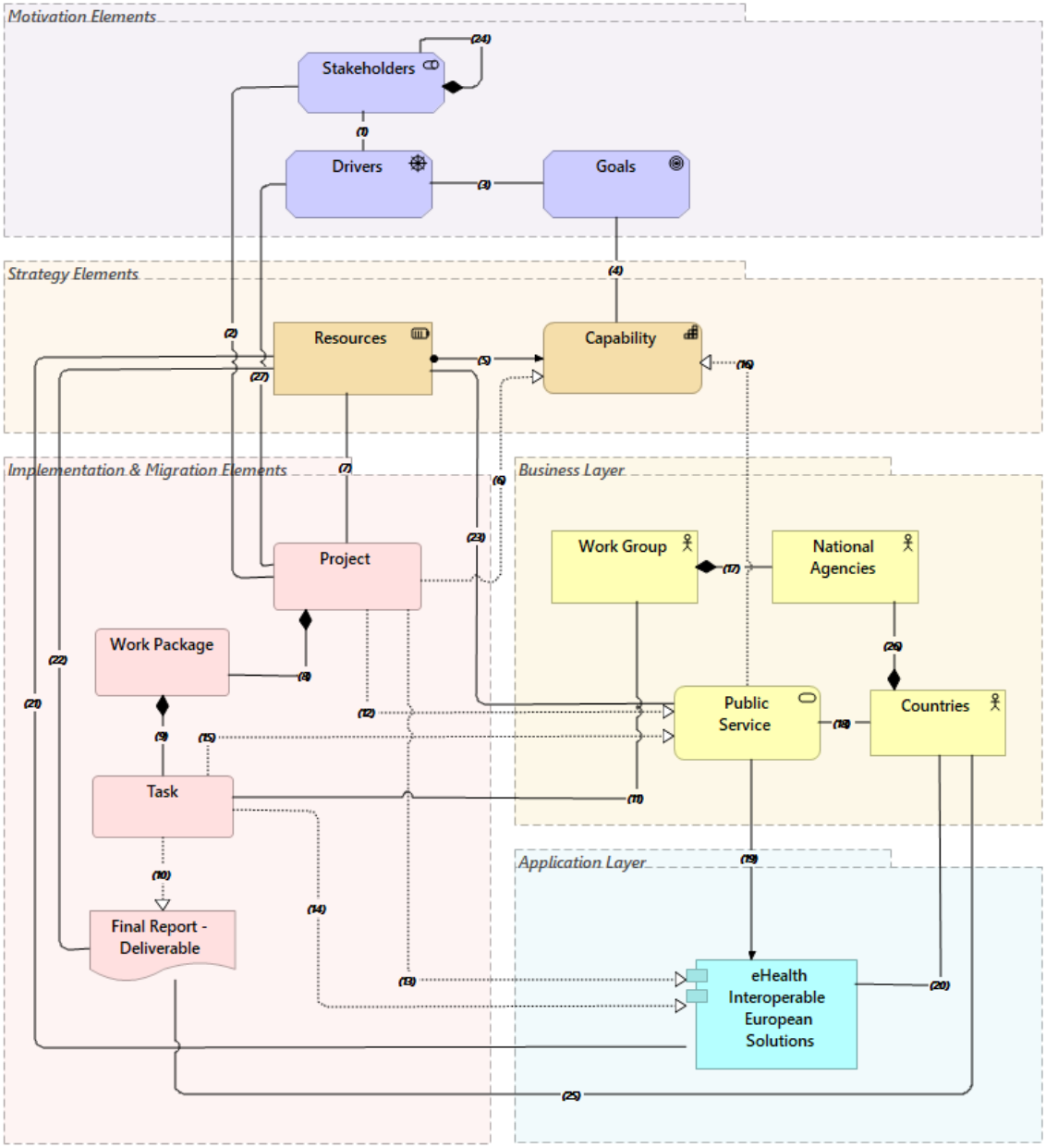


**Figure 14 -** Proposed EU eHealth Digital Services framework for enterprise architecture

The proposed framework is a planning tool which aims to facilitate strategic activity to support decision making by enabling a conceptual view of the whole. The framework is composed of five domains of enterprise architecture:

1. Motivation Elements;
2. Strategy Elements;
3. Business Layer;
4. Application Layer;
5. Implementation and Migration Elements.

The creation of a common understanding is necessary to achieve coordination between all Member States. Therefore, for each architectural artefact a common terminology was defined, based on the ArchiMate[112] language.

## Motivation Elements*113*

The motivation level of enterprise architecture is utilised for modelling the motivations or reasons which significantly guide the design of an architecture. Components on this level primarily comprise of stakeholders, associated drivers and pursued values, goals as well as outcomes that impact these motivations.

Motivation elements are used to model the motivations, or reasons, that guide the design or change of an enterprise architecture.

- ***Stakeholder*** - Represents the role of an individual, team or organisation. A stakeholder has one or more interests in, or concerns about, the organisation. In order to direct efforts to these interests and concerns, stakeholders change, set and emphasise goals. Examples of stakeholders are DG CONNECT, DG DIGIT, DG SANTE, eHealth Network and eHMSEG. ***Relationship (1)*** indicates the needs or concerns identified by each *stakeholder,* since not all the stakeholders pursue all drivers. ***Relationship (2)*** exhibits how each *stakeholder* or groups of stakeholders are related with each *project*.
- ***Driver –*** Also called 'concerns', they represent an external or internal condition that motivates an organisation to define its goals and implement the necessary changes, in order to achieve them. The drivers are forces that shape an organisation's strategy. ***Relationship (3)*** indicates the definition of *goals*, based on the defined *drivers*. For each *driver* one or more goals can be addressed. Examples of *drivers* can be security, interoperability, data protection, etc.
- ***Goal*** **-** Represents a high-level statement of intent, a direction, or desired end state for an organisation and its stakeholders. ***Relationship (4)*** indicates the *capability*/competency that may be achieved with the accomplishment of the proposed *goals.*

[112] https://www.archimatetool.com/

[113] https://pubs.opengroup.org/architecture/archimate3-doc/chap06.html#_Toc10045334

## Strategy Elements*114*

The strategy elements are typically used to model the strategic direction and choices. They can be used to express how the organisation wants to create value for its stakeholders, the capabilities it needs for that, the resources needed to support these capabilities, and how it plans to configure and use these capabilities and resources to achieve its aims.

- ***Capability*** **-** Represents the ability that an organisation, person, or system possesses. The ability to achieve a desired effect under specified standards and conditions through combinations of means and ways to perform a set of tasks[115]. ***Relationship (4)*** indicates the set of skills and competencies (*capabilities),* provided by a set of *resources* or abilities, that, being developed and applied, allow the organisation to achieve a result in a certain field.
- ***Resource*** **-** Represents an asset owned or controlled by an individual or organisation. Financial assets are examples of resources. In our reference model the resources can be associated with the available funds for an existing project or new calls for projects, but they can be also deliverables produced by other work groups, such as standards (e.g. SNOMED CT, LOINC, DICOM, HL7), legislation, (cyber)security policies, data models, technical or semantic specifications, business processes, application components, application services, etc. These types of *resources*, used or available to each *project* and *task*, are made explicit by ***Relationships (5), (7) and (8). Relationships (21) to (23)*** aim to identify the deliverables produced by other work groups that can be used or continued in the subsequent *projects* and *tasks.*

## Business Layer*116*

Business layer elements are used to model an organisation in a technology-independent manner, whereas strategy elements are used to model the strategic direction and choices of the enterprise.

- ***Business Actor*** **-** Represents a business entity that can perform a behaviour. A business actor can represent such business entities at different levels of detail and may correspond to both a person and an organisation. In our reference model, we identified three types of business actors:

  ***Work Groups*** *– such as Electronic Health Record exchange format (EHRxF), Common Semantic Strategy (CSS), Digital_ID4Health. Work groups are set up to pursue one or more tasks (****Relationship (12)****).*

  ***National Agencies*** *– each work group is composed of national agencies, through which each country is represented by both* ***Relationship (18)*** *and* ***Relationship (26).***

  ***Countries*** *–* ***Relationships (20) and (22)*** *indicate which countries are using each public services, applications and technologies produced in the context of the projects funded by the European Commission.*

- ***Business Service / Public Service*** **-** Associated with a value, a public service is an activity that public authorities identify as being of importance to citizens, businesses and public administrations and that would not be supplied (or would be supplied under different conditions) if there were no public intervention[117]. The EU countries consume public Services *(****Relationship (20)****).*

[114] https://pubs.opengroup.org/architecture/archimate3-doc/chap07.html

[115] https://essay.utwente.nl/65421/1/Papazoglou_MA_MB.pdf

[116] https://pubs.opengroup.org/architecture/archimate3-doc/chap08.html

[117] https://joinup.ec.europa.eu/sites/default/files/distribution/access_url/2017-10/eira_v2_0_0_overview.pdf

## Application Layer*118*

The Application Architecture provides a framework focused on developing and/or implementing applications to fulfil the business requirements and to achieve the quality necessary to meet the needs of the business.

The application and technology layer are related with an operational level, guided by the documents produced by the working groups from the business layer.

- ***eHealth Interoperable European Solutions/Application component*** – represents an encapsulation of application functionality aligned with implementation structure, which is modular and replaceable. These application components facilitate the delivery of electronic public services and cross-border exchange of information between public administrations (or citizens) according to the implementation and advancement of EU, national or local public policies[119]. Examples of *Application Components* are the NCPeH and the eIDAS Node. These implemented *Application Components* can be used by *EU Countries (**Relationship (22)**).*

## Implementation and Migration Elements*120*

The implementation and migration level specify how to deliver the architecture that best meets the stakeholder requirements by modelling work packages, deliverables, gaps and implementation events which are required in order to achieve a change in state related to the architecture implementation or migration. With respect to the motivation and strategy level of enterprise architectures, deliverables represent concrete realisations of the strategically defined goals.

The implementation and migration include modelling implementation programs and projects to support program, portfolio, and project management.

- ***Project*** – a temporary effort that has a defined beginning and end in time, and therefore defined scope and limited resources in order to create the unique and measurable outcome[121]. Projects can create public services *(**Relationship (13)**)*. Projects can also be related to the implementation of an application component *(**Relationship (14)**)*. A project may be divided in to work packages and tasks. Examples:

  ***Projects*** – *e.g. eHAction, JAseHN. **Relationship (8)** indicates the parts that each project comprises;*

  ***Work Packages*** – *e.g. WP8. Each work package is responsible for delivery of part of the project or management and aggregates different tasks (**Relationship (9)**);*

  ***Tasks*** *– e.g. Task 8.2. Each task will develop a defined activity to be integrated in the WP. **Relationship (11)** defines the groups of specialists created in order to pursue the proposed tasks. These groups are created according to project needs; it could be present or not in a project.*

- ***Deliverable –*** is a plan addressing the proposed strategic goals and represents the result of a task, also named as the final report (indicated by ***Relationship (10)***). Deliverables can include: data models, data policies, dataset catalogues, data standard catalogues, data-level mapping, representations, specifications (legal, organisational, semantic or technical), etc. Since a semantic catalogue is a type of deliverable, ***Relationship (25)*** allows the identification of what each country is using as a semantic catalogue/value set.

[118] https://pubs.opengroup.org/architecture/archimate3-doc/chap09.html#_Toc10045389

[119] https://joinup.ec.europa.eu/sites/default/files/distribution/access_url/2017-10/eira_v2_0_0_overview.pdf

[120] https://pubs.opengroup.org/architecture/archimate3-doc/chap13.html

[121] https://www.pmi.org/about/learn-about-pmi/what-is-project-management

# Annex III.1.2 – Cartography Process – a Practical Example

## eHRA High-Level Viewpoints

Throughout this section, architectures within a subject area where each represents a different viewpoint will be summarised. A viewpoint specifies the elements expected to be represented in the view that may be formally or informally defined.

These viewpoints are starting points for modelling efforts. They can accelerate architectural efforts, support organisational standards, facilitate peer review and aid new modellers. However, these basic viewpoints should not constrain modelling activities. Organisations and individual modellers should address stakeholder concerns by selecting from the basic viewpoints, modifying them, or defining new ones.

For each viewpoint, the grey colour highlights the view we want to catch. If we need to see the detail of a specific stakeholder, the *Stakeholders Viewpoint* focuses on the reference model artefacts subset related to that stakeholder. Each viewpoint represents a part of the architecture and comprises elements from different layers.

The Organisational view is one of the most important viewpoints that shall be considered to support organisations, in an effort to present a view and to allow the widest reach possible within EU projects and planning.

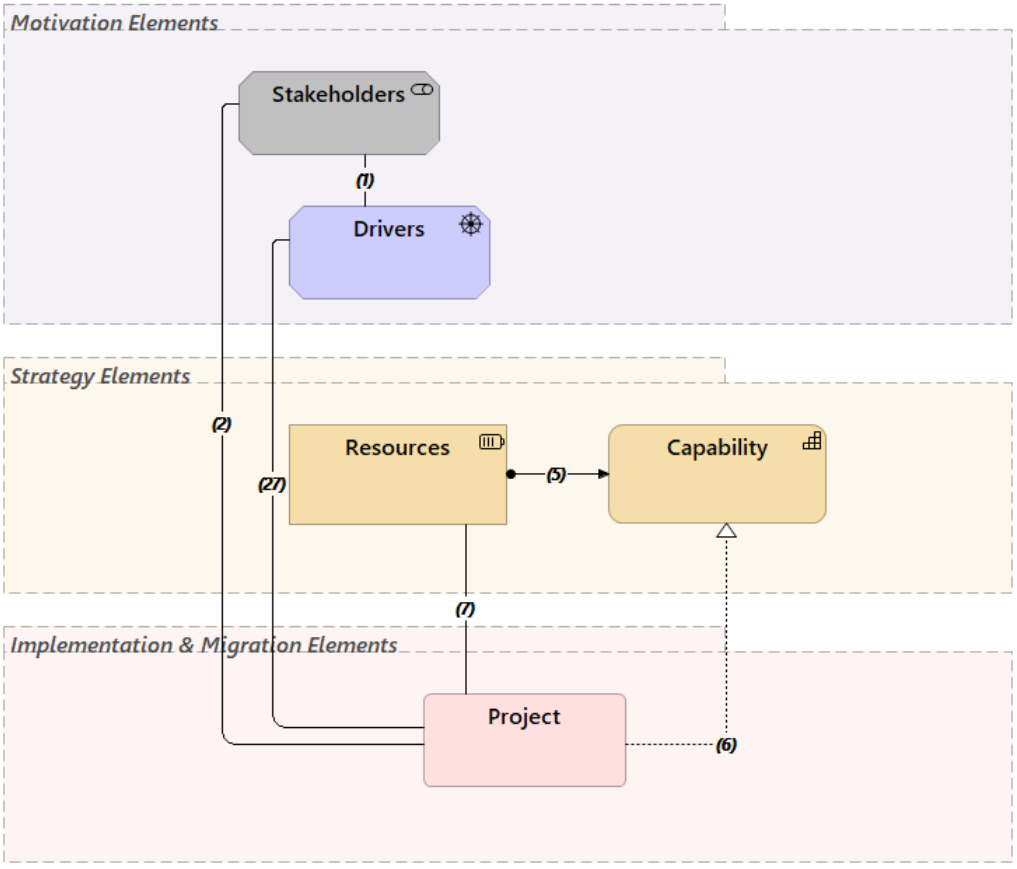


**Figure 15** – Stakeholders Viewpoint

***Narrative [Figure 15]:*** The *Stakeholders Viewpoint* enables the vision about all projects related to each stakeholder. Considering each project, this viewpoint identifies the drivers that conduct the configuration of

each project and which capabilities are added or created by each project outputs. Furthermore, for each project, the financial resources can be identified.

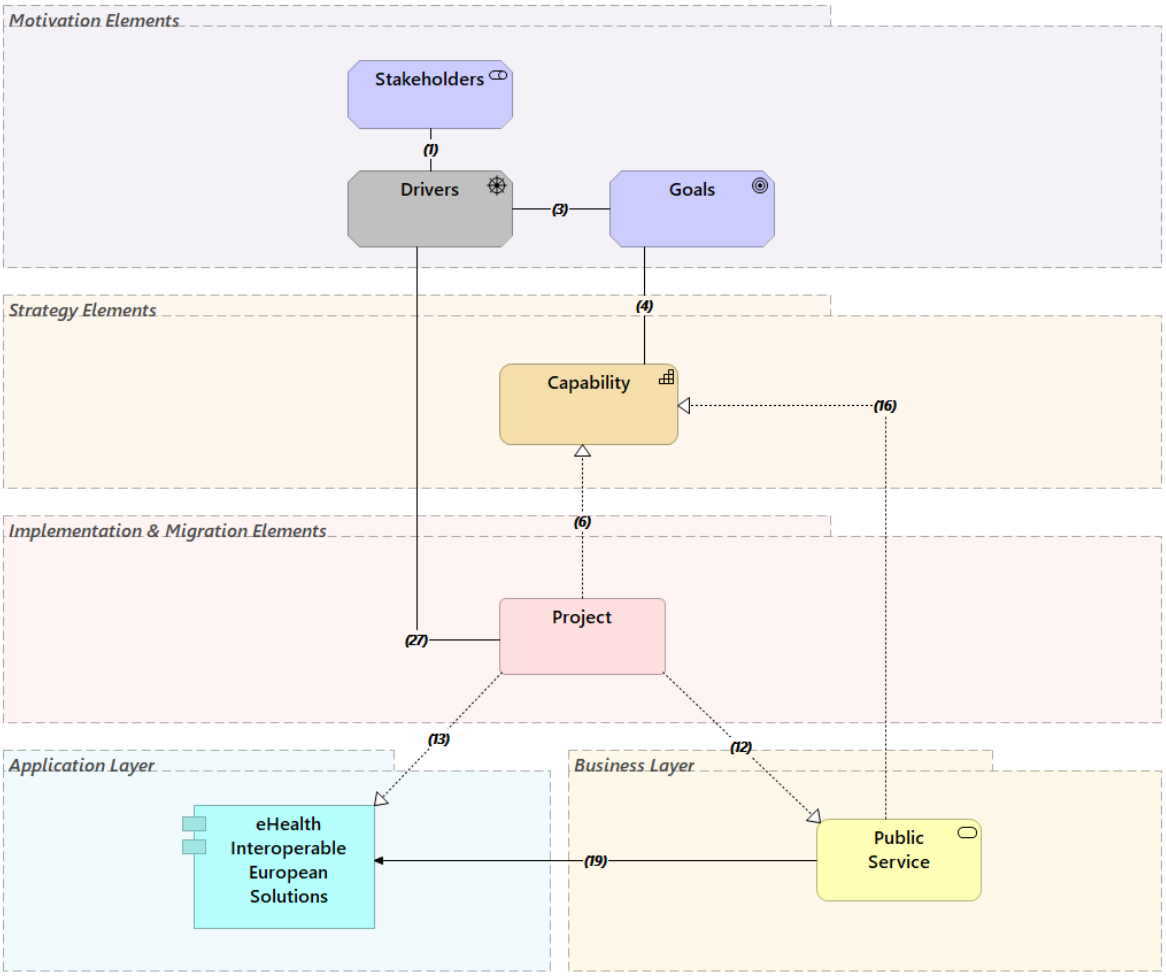


**Figure 16** – Drivers Viewpoint

***Narrative [*Figure 16*]:*** The *Drivers Viewpoint* identifies the project goals and stakeholders related to the chosen driver. The outputs of each project, such as technical components or public services, are also identified in this viewpoint. Additionally, the capabilities that are added or created by each project output are also presented in this viewpoint.

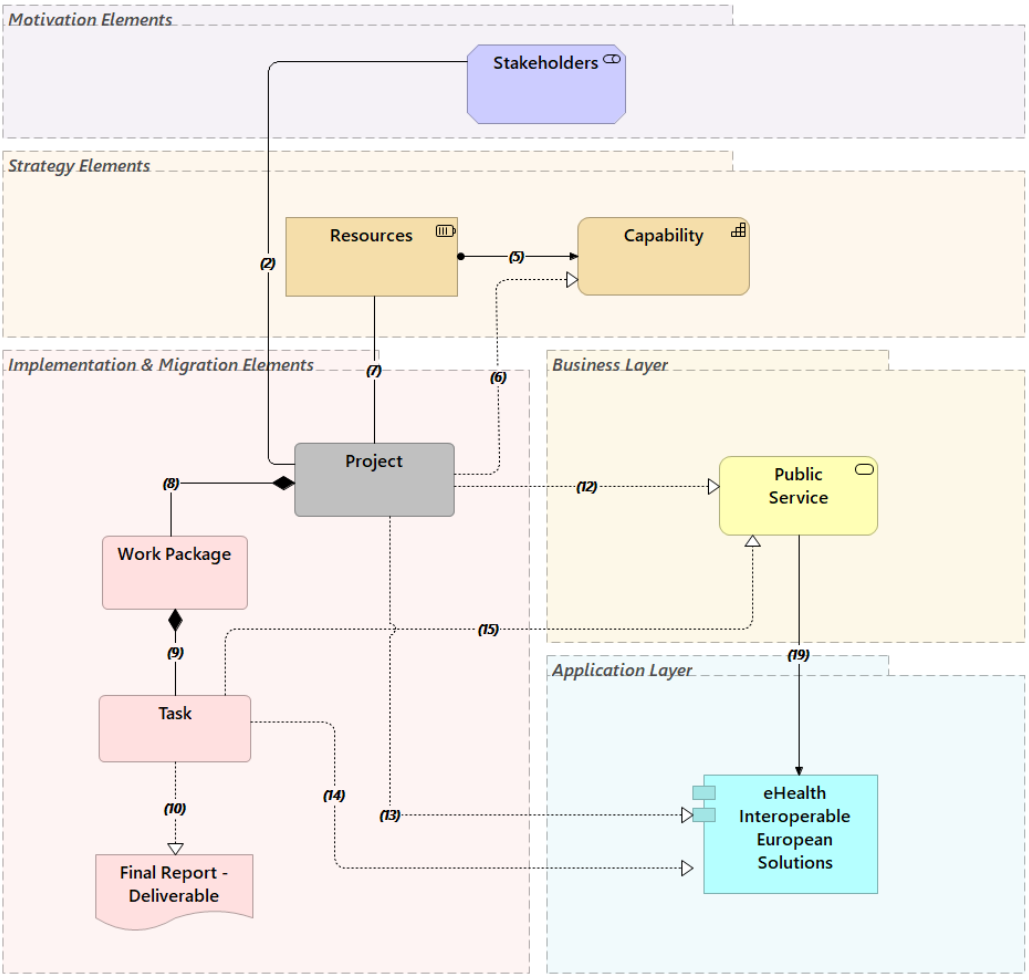


**Figure 17** – Project Viewpoint

***Narrative [Figure 17]:*** The *Project Viewpoint* illustrates each project structure. A work package is a group of related tasks within a project. Since work packages look like projects themselves, they can be perceived as sub-projects within a larger project. The output of each task, final report, public service, or technical component, is also depicted in this viewpoint. The capabilities added or created by each project output are also presented in this viewpoint. In addition, the stakeholder related to the project is also presented, as well as the financial resources available for the project or other resources required to carry out project tasks (deliverables produced by other work groups, standards, legislation, cybersecurity policies, data models, technical or semantic specifications, etc.).

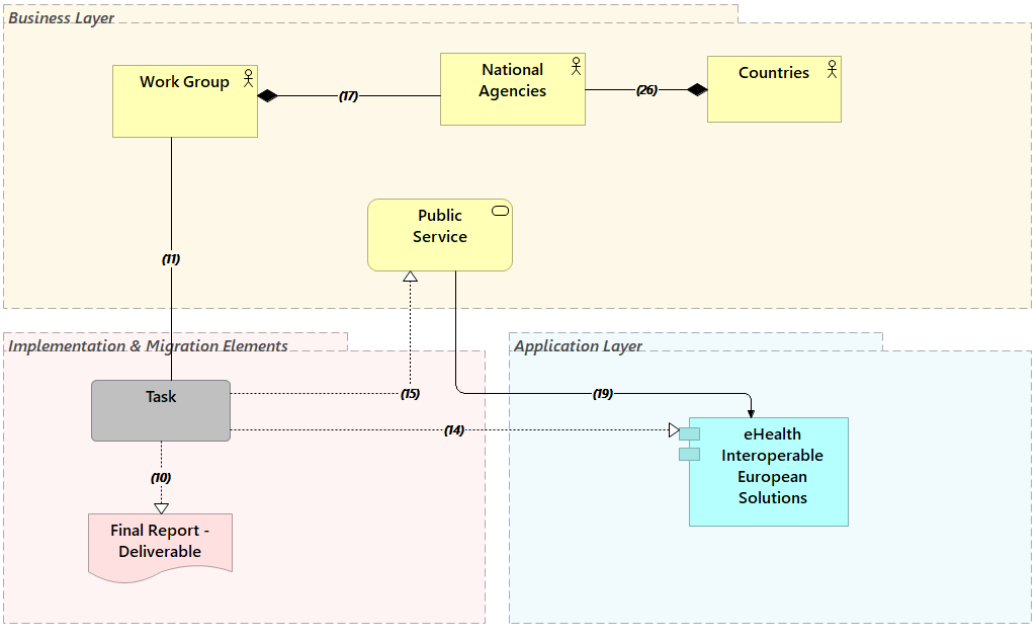


**Figure 18** – Task Viewpoint

***Narrative [Figure 18]:*** The *Task Viewpoint* identifies the outputs of a given task, deliverables, public services, and technical components, along with the participants who are responsible for performing the task or part of it. If needed, a work group could be created and it could be composed of participants from different countries (international project consortia), which are represented by their national agencies or affiliates.

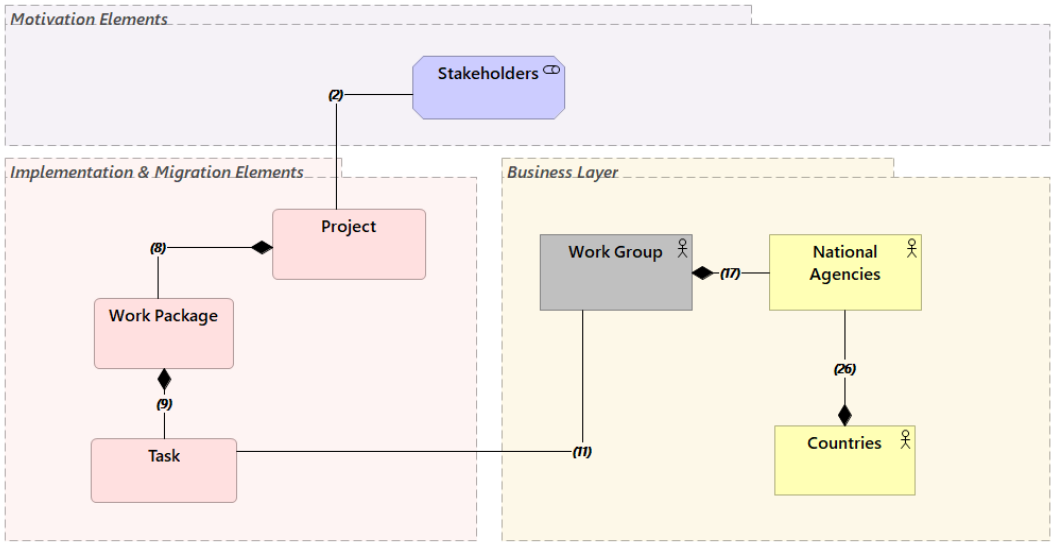


**Figure 19** – Work Group Viewpoint

***Narrative [Figure 19]:*** The *Work Group Viewpoint* identifies the work group composition, all of the national agencies involved, by country. For each work group, the tasks which were within their responsibility are present, as well as the related projects. The stakeholders, who are interested in the project's outcome, are also represented.

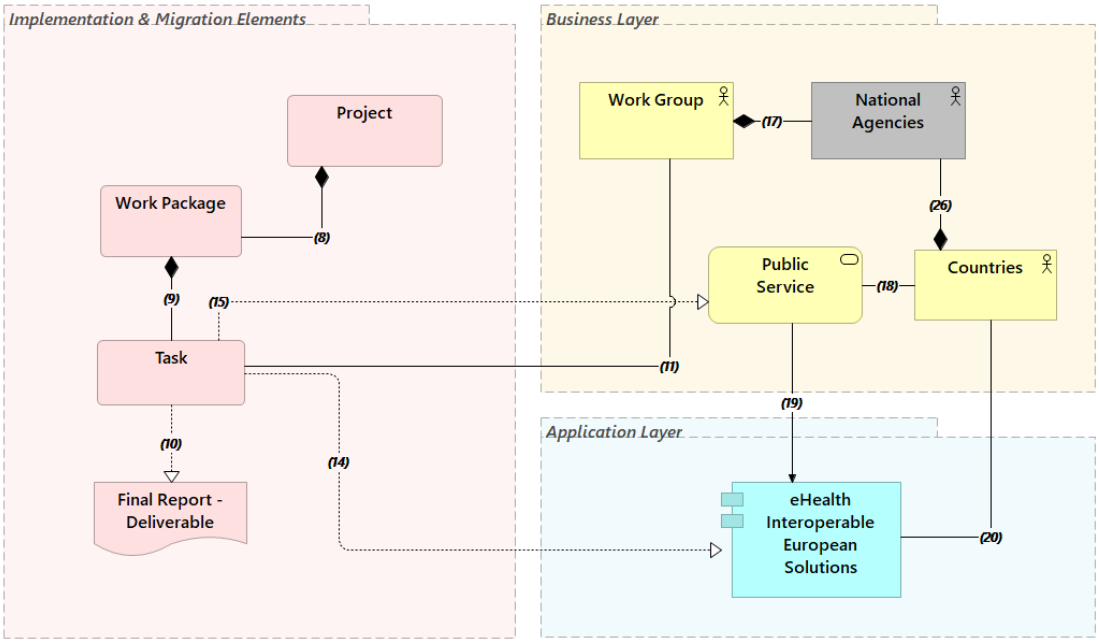


**Figure 20** – National Agencies Viewpoint

***Narrative [Figure 20]:*** The *National Agencies Viewpoint* allows an understanding of which projects the national agencies of each country are involved in, as well as which task and project they are contributing to. Furthermore, this viewpoint identifies the results of the work the national agency is involved in, the deliverables produced, the public services created or improved, and even the technical components implemented.

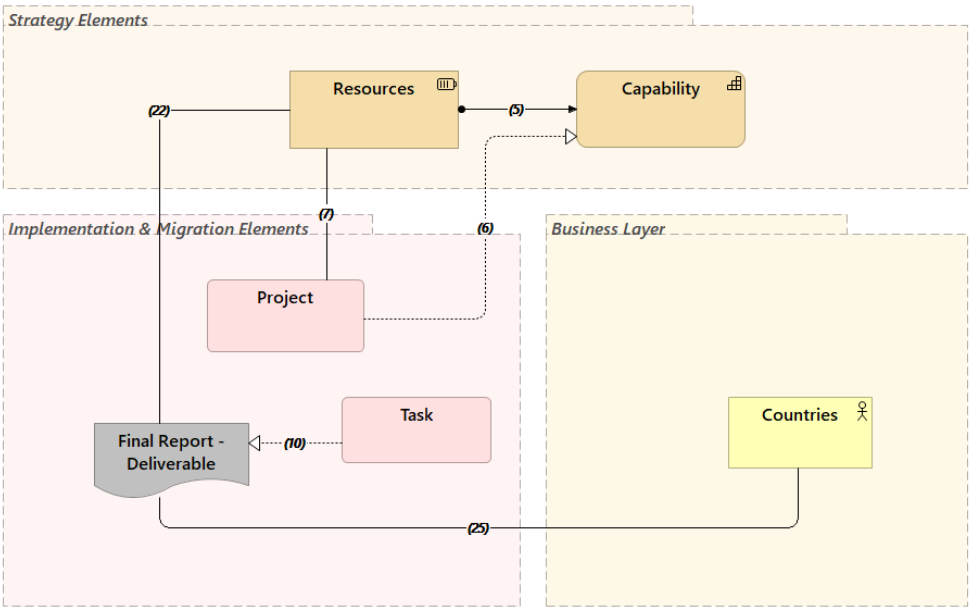


**Figure 21** – Final Report Viewpoint

***Narrative [Figure 21]:*** The Final Report *(or Deliverable) Viewpoint* identifies whether a given deliverable was a resource for another project and which capability the project achieved. This viewpoint also enables one to understand which countries are using or adopting the deliverable.

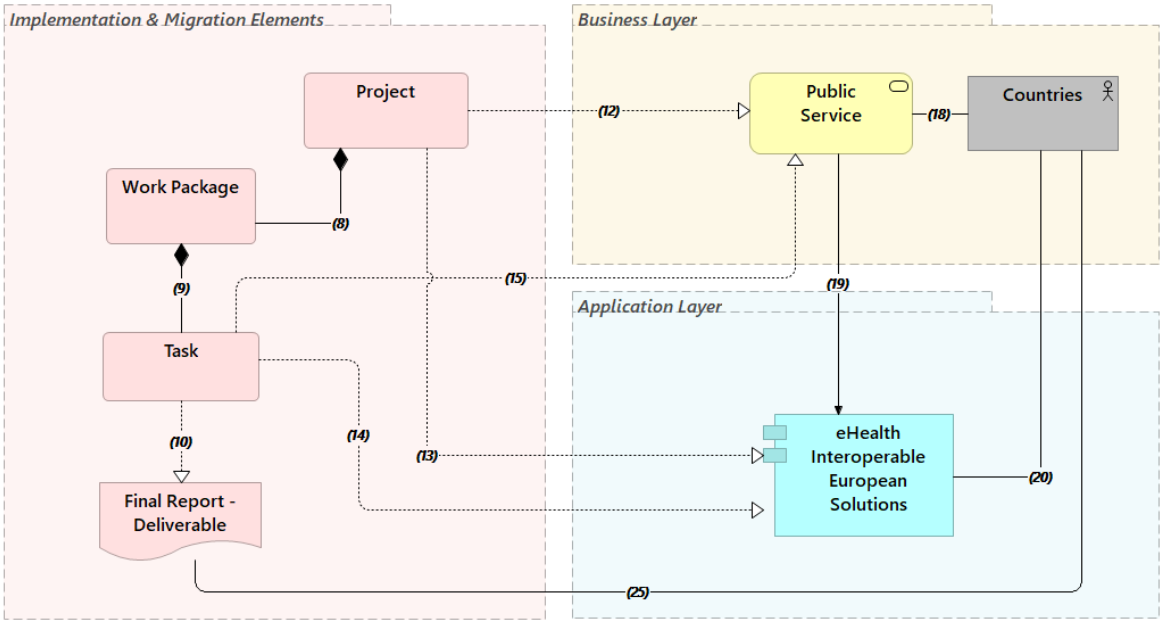


**Figure 22** – Countries Viewpoint

***Narrative [Figure 22]:*** The *Countries Viewpoint* gives the perspective of what public services, technical components and deliverables (such as sematic catalogues, technical specifications, etc.) are being produced in order to be adopted by a given country.

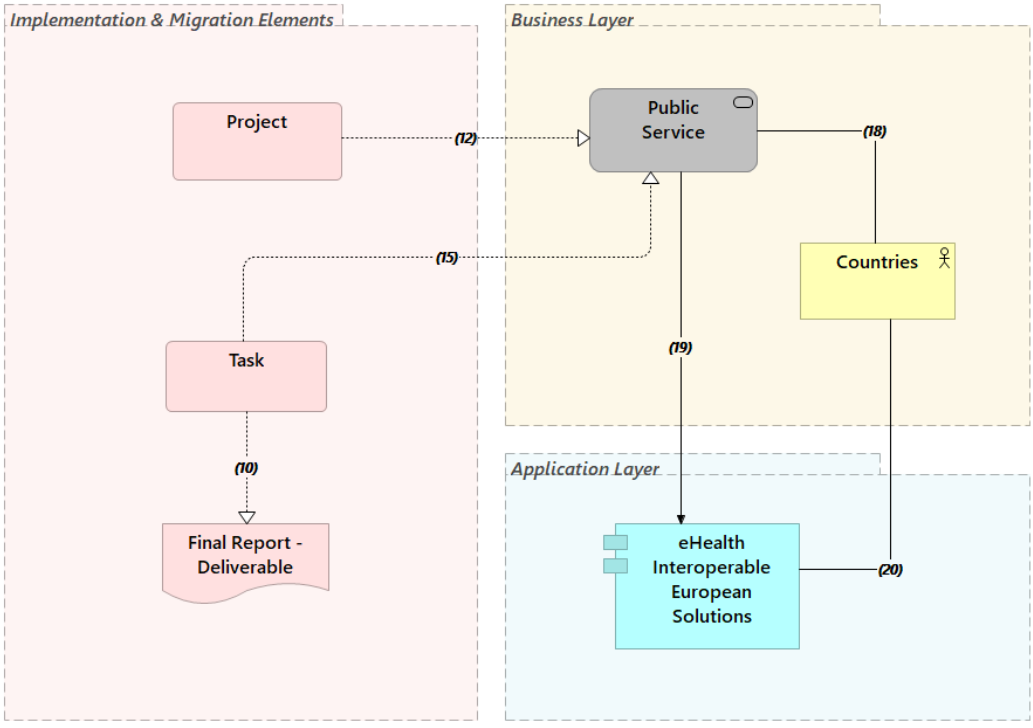


**Figure 23** – Public Service Viewpoint

***Narrative [Figure 23]:*** The *Public Service Viewpoint* exhibits the projects, work packages tasks and deliverables related to a given public service, and what countries are adopting and/or improving that public service. Furthermore, this view presents the eHealth solution that supports each public service.

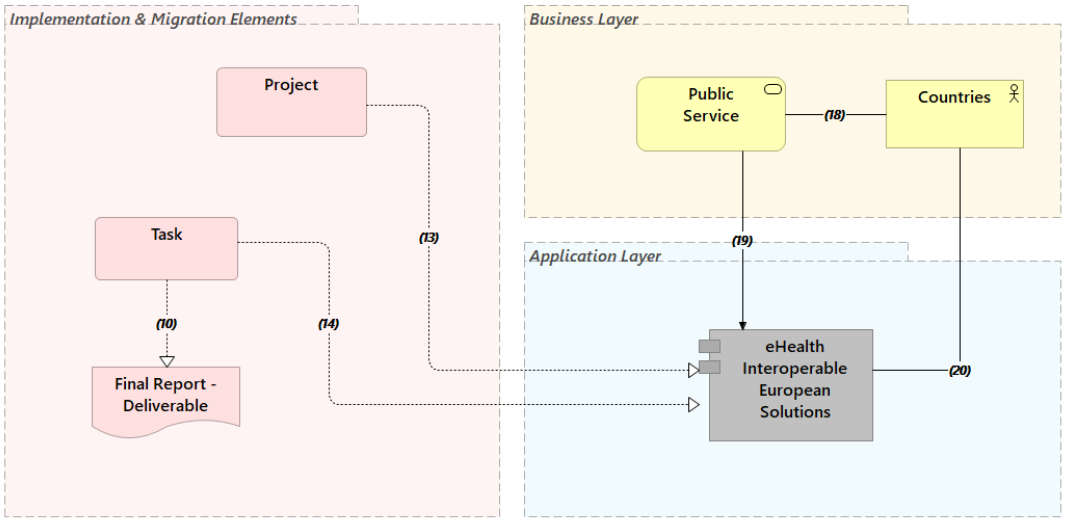


**Figure 24** – eHealth Interoperable European Solution Viewpoint

***Narrative [Figure 24]:*** The *eHealth Interoperable European Solution Viewpoint* is similar to the *Public Service Viewpoint.* This viewpoint displays the projects tasks, the deliverables related to a given technical component, and what countries are adopting that component. Furthermore, this view presents the all the public services supported by a given eHealth solution.

# Annexes to PartIV (D8.2.4)

## Annex IV.1 – List of notified eID schemes under eIDAS

**Table 6** – Information about the pre-notified and notified eID schemes under eIDAS:

| Member State | Title of the scheme | eID means under the scheme | Level of assurance | Status |
|---|---|---|---|---|
| **Portugal** | Chave Móvel Digital | Digital Mobile Key | High | NOTIFIED |
| **Belgium** | Belgian eID Scheme FAS / Itsme® | itsme® mobile App | High | NOTIFIED |
| **Portugal** | Cartão de Cidadão | Portuguese national identity card (eID card) | High | NOTIFIED |
| **Czech Republic** | National identification scheme of the Czech Republic | CZ eID card | High | NOTIFIED |
| **German** | German eID based on Extended Access Control | National Identity Card Electronic Residence Permit | High | NOTIFIED |
| **Estonia** | Estonian eID scheme: ID card<br>Estonian eID scheme: RP card<br>Estonian eID scheme: Digi-ID<br>Estonian eID scheme: e-Residency Digi-ID<br>Estonian eID scheme: Mobiil-ID<br>Estonian eID scheme: diplomatic identity card | — ID card<br>— RP card<br>— Digi-ID<br>— e-Residency Digi-ID<br>— Mobiil-ID<br>— Diplomatic identity card | High | NOTIFIED |
| **Netherlands** | Trust Framework for Electronic Identification (Afsprakenstelsel Elektronische Toegangsdiensten) | Means issued under eHerkenning (for businesses) | Substantial, High | NOTIFIED |

| Member State | Title of the scheme | eID means under the scheme | Level of assurance | Status |
|---|---|---|---|---|
| **Italy** | Italian eID based on National ID car d (CIE) | Italian eID card (Carta di Identità elettronica) | High | NOTIFIED |
| **Latvia** | Latvian eID scheme (eID) | eID karte<br>eParaksts karte<br>eParaksts karte+<br>eParaksts | Substantial, High | NOTIFIED |
| **Denmark** | NemID | Key card (OTP)<br>Mobile app<br>Key token (OTP)<br>NemID hardware<br>Interactive<br>Voice/Response (OTP)<br>Magna key card (OTP) | Substantial | NOTIFIED |
| **Netherlands** | DigiD | DigiD Substantieel<br>DigiD Hoog | | PEER REVIEWED |
| **Portugal** | Sistema de Certificação de Atributos Profissionais | Professional Attributes Certification System | | PRE-NOTIFIED |
| **Lithuania** | Lithuanian National Identity card (eID / ATK) | Lithuanian National Identity card (eID / ATK) | | PEER REVIEWED |
| **Spain** | Documento Nacional de Identidad electrónico (DNIe) | Spanish ID card (DNIe) | High | NOTIFIED |
| **Slovakia** | National identity scheme of the Slovak Republic | Slovak Citizen eCard<br>Foreigner eCard | High | NOTIFIED |
| **Croatia** | National Identification and Authentication System (NIAS) | Personal Identity Card (eOI) | High | NOTIFIED |
| **Belgium** | Belgian eID Scheme FAS / eCards | Belgian Citizen eCard<br>Foreigner eCard | High | NOTIFIED |
| **Luxembourg** | Luxembourg national identity card (eID card) | Luxembourg eID card | High | NOTIFIED |

| Member State | Title of the scheme | eID means under the scheme | Level of assurance | Status |
|---|---|---|---|---|
| **Italy** | SPID – Public System of Digital Identity | SPID eID means provided by:<br>Aruba PEC SpA<br>Namirial SpA<br>InfoCert SpA<br>In.Te.S.A. SpA<br>Poste Italiane SpA<br>Register.it SpA<br>Sielte SpA<br>Telecom Italia Trust Technologies S.r.l.<br>Lepida SpA | Low, Substantial, High | NOTIFIED |
| **Hungary** | Hungarian personal identification cards (eID) | • Permanent personal identification card<br>• Temporary personal identification card | High | NOTIFIED |

***Legend:***

NOT NOTIFIED: The Member State has not officially communicated its intention to notify its eID scheme to the European Commission.

PRE-NOTIFIED: The Member State has officially communicated its intention to notify its eID scheme to the European Commission.

PEER REVIEWED: The eID scheme has been peer reviewed by representatives of other Member States.

NOTIFIED: The country has notified its eID scheme to the European Commission and the information has been published to the Official Journal of the European Union.

NB: Recognition of the notified eID schemes shall take place no later than 12 months after the publication to the OJEU.

# Annex IV.2– Survey Results: List of notified eID schemes

**Table 7** – Information about the pre-notified and notified eID schemes under eIDAS and eID schemes outside of eIDAS (based on survey 1)

| *Member State* | *Title of the scheme* | *eID means* | *Level of assurance* | *Hardware or Software based* | *Status* |
|---|---|---|---|---|---|
| *Czech Republic* | National identification scheme of the Czech Republic | CZ eID card | High and Medium | Hardware and Software | NOTIFIED |
| | Datové chránky | Datové chránky | | | |
| | National Health Insurance number | National Health Insurance number | | | |
| | National Healthcare Client ID | National Healthcare Client ID | | | |
| | National Healthcare professional ID | National Healthcare professional ID | | | |
| *Germany* | German eID schemes | German eID based on Extended Access Control (not for patient identification) | High | Hardware and Software | NOTIFIED |
| | | Certificate based Identity Provider of National Telematics Health Infrastructure (Smart Card) | Medium | Software | NOT NOTIFIED |
| | | Federated eID scheme by the state health insurances | Medium (for mobile use cases); Low (for web scenarios) | Software | NOT NOTIFIED |
| *Greece* | Taxis | | Low | Software | NOT NOTIFIED |
| | HERMIS | | Low | Software | NOT NOTIFIED |

| | | | | | |
|---|---|---|---|---|---|
| | THEX | | | | NOT NOTIFIED |
| ***Latvia*** | Latvian eID scheme (eID) | eID karte | High | Hardware | NOTIFIED |
| | | eParaksts karte | High | Hardware | NOTIFIED |
| | | eParaksts karte+ | High | Hardware | NOTIFIED |
| | | eParaksts | High | Software | NOTIFIED |
| ***Spain*** | Documento Nacional de Identidad electrónico (DNIe) | Spanish ID card (DNIe) | High | Hardware | NOTIFIED |
| | Cl@ve | Spanish citizens & legal immigrants | High, Medium, Low | Hardware and Software | |
| ***Ireland*** | MyGovID (DEASP) | | | Software | |
| | MyAccount (Revenue) | | | Software | |
| | Revenue Online Service (Revenue) | | | Software | |
| | IHI (Individual Health Identifier) | | | Software | |
| ***Estonia*** | Estonian eID scheme | ID card | High | Hardware | NOTIFIED |
| | | RP card | High | Hardware | NOTIFIED |
| | | Digi-ID | High | Hardware | NOTIFIED |
| | | e-Residency Digi-ID | High | Hardware | NOTIFIED |
| | | Mobiil-ID | High | Hardware | NOTIFIED |
| | | diplomatic identity card | High | Hardware | NOTIFIED |
| ***Slovenia*** | | Qualified digital certificates on doctor's cards | | Hardware and Software | |
| | | Digital personal ID card | | Hardware | |
| | | Mobile/cloud eID | | Software/Cloud | |
| ***Hungary*** | National Identity Card | e-ID cards contain: Fingerprint The data required for creating an electronic signature and signature certificate | High | Hardware and Software | NOTIFIED |

| | | | | | |
|---|---|---|---|---|---|
| | | Social security identification number<br>Tax identification number<br>Unique electronic identifier<br>Up to two telephone numbers to be called in the case of emergency | | | |
| | Electronic Residence Permit (non-resident eID card) | Residence permit | High | Hardware | NOTIFIED |
| | Health Insurance Cards | Social security identification number | High | Hardware | NOT NOTIFIED |
| ***Romania*** | National Health Card | | | | |
| | European Health Card | | | | |
| | Electronic Health Record | | | | |
| | Electronic Prescription | | | | |

***Legend:***

NOT NOTIFIED: The Member State has not officially communicated its intention to notify its eID scheme to the European Commission.
PRE-NOTIFIED: The Member State has officially communicated its intention to notify its eID scheme to the European Commission.
PEER REVIEWED: The eID scheme has been peer reviewed by representatives of other Member States.
NOTIFIED: The country has notified its eID scheme to the European Commission and the information has been published to the Official Journal of the European Union.

NB: Recognition of the notified eID schemes shall take place no later than 12 months after the publication to the OJEU.

# Annex IV.3– Survey Questions

**1. Considering the health context, please fill in the table considering your national digital identification schemes.**

**1.1. Considering all actors, fill in the following table:**

| eID schemes that your country uses. (please refer any eID schemes) | Are they eIDAS compliant ? | Are they notified under eIDAS? If yes, when were they notified? | When are they planned to be notified? | Are they deployed at a national level? | Which actors can be identified by which schemes? | Which schemes are hardware base, and which are software base? | Which level of assurance does the scheme provide? (high, medium, low) |
|---|---|---|---|---|---|---|---|
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Please, use one line per eID Scheme.

**1.2. Considering the patient and the schemes identified in the previous table, fill in the following table:**

What eID schemes does your country use? (please refer any eID schemes specific to patient identification)

| What eID schemes does your country use? (please refer any eID schemes specific to patient identification) | Are they used exclusively for patient identification? | Are they used or planned to be used for patients to access their data? | Do they relate to patient consent? (please specify) |
|---|---|---|---|
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**2. The categories of health professional, currently in use under ISCO-08 in the HDSI services are as follows:**

1. Medical Doctor
2. Nursing professionals
3. Midwifery professionals
4. Pharmacists
5. Pharmaceutical technicians and assistants
6. Dentists
7. Physiotherapist
8. Dieticians and nutritionists
9. Audiologists and speech therapists' nutritionists
10. Optometrists and ophthalmic opticians
11. Medical imaging and therapeutic equipment technicians
12. Health professionals not elsewhere classified (e.g. Others)

a. Considering these categories and 'others', please fill in the following table:

| **Does your country use this reference set at a national level, or does it use another value set?** | **Does your country use other international reference sets? Please specify.** | **Is there a professional association for managing and maintaining professional categories? Please specify.** | **Does your country possess national identity providers? Please specify which.** | **Is there a national agency for managing and maintaining these identity providers? Please specify.** |
|---|---|---|---|---|
| | | | | |
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Considering the European Health Dataspace concept, please provide answers to the following questions:

b) Does your country consider the European Health Dataspace for other categories of users of eHealth data? E.g. social care and research. (please specify)

c) Does your country include and categorise other actors referring to secondary use of data? (please specify)

**3. Regarding the adoption of eIDAS in the health context, please provide answers to the following questions:**

a) Do you find that there is added benefits for your country and, specifically for the eHealth context, in the usage of the available eIDAS infrastructure?

b) What do you find to be the drawbacks of the adoption of eIDAS to support eHealth services? (please specify in regard to challenges and potential losses, including costs of opportunity)

c) Does your country have in place a Mobile Strategy for eHealth services? If so, does it regard the use of mobile to address patient identification?

# Annex IV.4 – eID and EESSI

More than looking at eID solutions for EESSI, there is an ongoing initiative called 'European Social Security Number', which is basically about digitising what we call 'portable documents', such as the European Health Insurance Card (EHIC), and the verification of social security coverage.

There are two steps in the process, just like in eHealth:

1. the identification and authentication of the citizen;
2. the actual use case, which could be, for example, the verification of health insurance coverage, for unplanned care, in a hospital, as a substitute to EHIC.

The EHIC could indeed be out of date while still having an expiry date which is still valid, so the verification it provides is not fraud-proof: people could present a EHIC which is still valid on paper while at the same time the citizen is not covered anymore, because he moved to another country, or dropped from social security coverage for any other reason.

One of the ideas regarding identification of citizens was to create a new European Social Security Number as a unique means of identification, or at least a unique identifier to which all Social Security identifiers could be mapped, but we now think that we could also potentially simply use the eIDAS framework, the eID building block, and the eIDAS nodes which have been put in operations recently, and for which a group of countries have sent notification to the Commission.