eHAction

Joint Action supporting the eHealth Network

D8.3 - Sustainability plan and recommendations

Post-2021 scenarios for eHealth policy cooperation

WP8 – Integration in National Policies and Sustainability

20-04-2021

Version 2.4

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Abstract

The purpose of this document is to present the eHealth Network with the **eHAction's vision for the enhanced collaboration and cooperation between Member States on the sustainability of eHealth in Europe post-2021**. Included in this document is information about background, **context and vision on eHealth domains across Europe.**

The deliverable is organised into two main parts:

- The **first part** is focused on **sustainability** (reasons, benefits and barriers), **integration** with **national policies** and details on **nine enabling core elements.**
- The **second part** is focused on **framing sustainable post-2021 policy cooperation** and aggregating **a set of recommendations** to achieve this.

Key Words: eHealth; Recommendation; Policy Cooperation; Sustainability

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Disclaimer

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Acronyms

Acronym	Description
B2B	Business to Business
CBeHIS	Cross-border exchange of health data
CEF	Connecting Europe Facility
CoP	Community of practice
CPD	Continuing professional development
CSS	Common Semantic Strategy
EDPB	European Data Protection Board
EEHRxF	Electronic Health Record exchange format
eHAction	eHealth Action – Joint Action supporting the eHealth Network
eHDSI	eHealth Digital Service Infrastructure
eHMSEG	eHealth Member States Expert Group
eHN	eHealth Network
eHOMB	eHDSI Operational Management Board
EHR	Electronic Health Record
eHRA	eHealth Reference Architecture
eID	Electronic Identification
eIDAS	Electronic Identification Authentication and trust Services
ENISA	European Union Agency for Cybersecurity
eP	ePrescription
epSOS	Smart Open Services for European Patients project
ESCO	European Skills, Competences, Qualifications and Occupations
GDPR	General Data Protection Regulation
HCP	Healthcare Provider
HiAP	Health-in-All-Policies
HP	Health Professional
ICT	Information and Communication Technology
INEA	Innovation and Networking Executive Agency
JCP	Joint Coordination Process

MFF	Multiannual Financial Framework
MWP	Multiannual Work Programme
NCPeH	National Contact Point for eHealth
NDHN	National Digital Health Networks
OECD	Organisation for Economic Co-operation and Development
PCSD	Policy Coherence for Sustainable Development
PS	Patient Summary
ReRIF	Refined eHealth European Interoperability Framework
WP	Work Package

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Introduction

Cognisant that eHAction is the last Joint Action supporting the eHealth Network (eHN), this deliverable intends to present a set of recommendations to promote the continuation of eHealth policy cooperation and sustainable development in the EU.

Building upon a reflective analysis of both the eHN's Multiannual Work Programme 2018-2021 priority areas and the current eHealth state of play, this document represents the culmination of three years of work between multiple national authorities, eHealth competence centres and key stakeholders. Notwithstanding, it is intended to go further than just a reflection.

The initiatives developed by eHAction have helped to better understand the EU's eHealth ecosystem; namely, to understand what the needs and priorities among the different Member States are. Moreover, it has been shown that the eHealth community needs an aligned set of priorities at EU level that all Member States can aspire to, regardless of their stage of eHealth transformation.

In this sense, and by representing the considered views of all contributors, this deliverable is being produced as a set of recommendations in which a number of measures and guidelines on the best course of action are proposed, to direct EU policy cooperation towards sustainable transformation in the health sector.

Given Member State plans to drive the digitalisation of healthcare, sustainability becomes even more central in the current COVID-19 pandemic and challenging situation that national health systems and services are experiencing (see Figure 1). For this reason, the recommendations proposed by this document are ultimately aimed at promoting

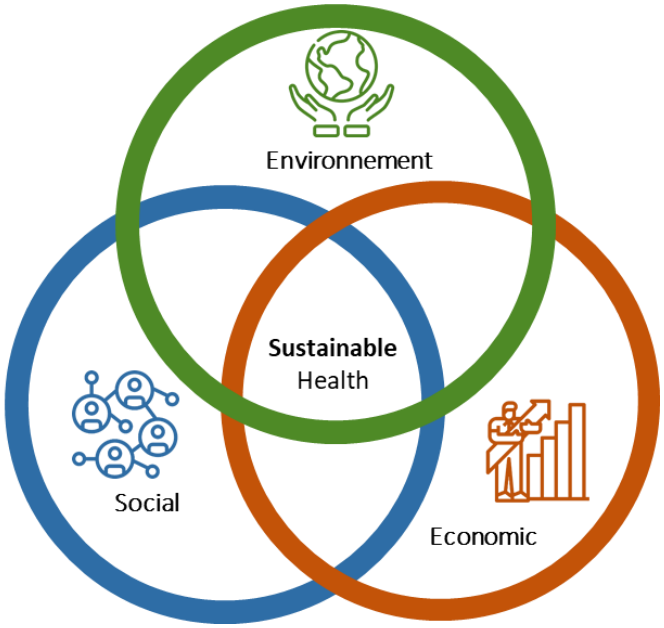

Figure 1 – Integration in national policies and sustainability

harmonisation between national solutions in order to build confidence for Member States to deepen cross-border cooperation.

It is also important to highlight the relationship between the eHN decision-making process and the implementation of recommendations at the national level after the conclusion of eHAction. A Member State may be able to implement a recommendation in part or in full, or a recommendation could simply serve as an inspiration to a Member State to develop its own strategy for policy cooperation on sustainability.

That being said, the recommendations for *Post-2021 scenarios for eHealth policy cooperation* were designed with a practical focus on processes, in an attempt to enhance the period of implementation, so as to facilitate its adoption by eHN after the conclusion of the current Joint Action.

Scope of the Document

This document is directed to the eHealth Network's Member State representatives, national health policymakers and adopters, and health-related bodies with relevance for healthcare provision. Nonetheless, D8.3 should be made available to a broader stakeholder audience.

D8.3 intends to present readers with a set of measures and guidelines on the best course of action to direct EU policy cooperation towards sustainable transformation, given the post-2021 eHealth policy structure, considering that eHAction is the last Joint Action to support the eHealth Network.

The end goal of D8.3 is to provide the eHealth Network and the European Commission with a way forward to establish the proper mechanisms, so as to encourage the development of a stronger community that foster the implementation of national digital eHealth services.

The information presented in this document was developed taking into account the information collected from the two D8.3 workshops (December 2020, February 2021), desk research, and eHAction's outcomes and deliverables.

1. Sustainability – Reasons, Benefits and Barriers

This chapter focuses on the concept of sustainability as it applies to Member State cross-border relations in the field of digital health. The reason for sustainability, its relevance and barriers to further progress, are the topics to be addressed in the following sections.

Sustainability

is the ability to exist constantly. The name sustainability is derived from the Latin sustinere (tenere, to hold; sub, under). Sustain can mean "maintain," "support," "uphold," or "endure".

1.1. The need for post-2021 sustainability for eHealth cooperation

While there are several ways to describe different sectors in the digital age, when it comes to cross-border cooperation in digital health in the EU, solutions and mechanisms to streamline the organisational and procedural model are needed.

The project-driven framework in which the eHN, Member States, and different organisations and entities have been cooperating in the EU, have been shown to be insufficient to ensure national and European policy agendas are in line with the technical groundwork. Therefore, there is a risk that the innovations in eHealth solutions, processes, etc. of recent years will not reap the rewards in terms of efficiency, effectiveness and patient outcomes and public health.

This is because EU cooperation in public policies has a direct effect on national ecosystems, motivating and inspiring the actors, and supporting their efforts to improve national systems. Any reduction in this cooperation would result in a looser, uncoordinated Member State approach, that would damage sustainability in the long term.

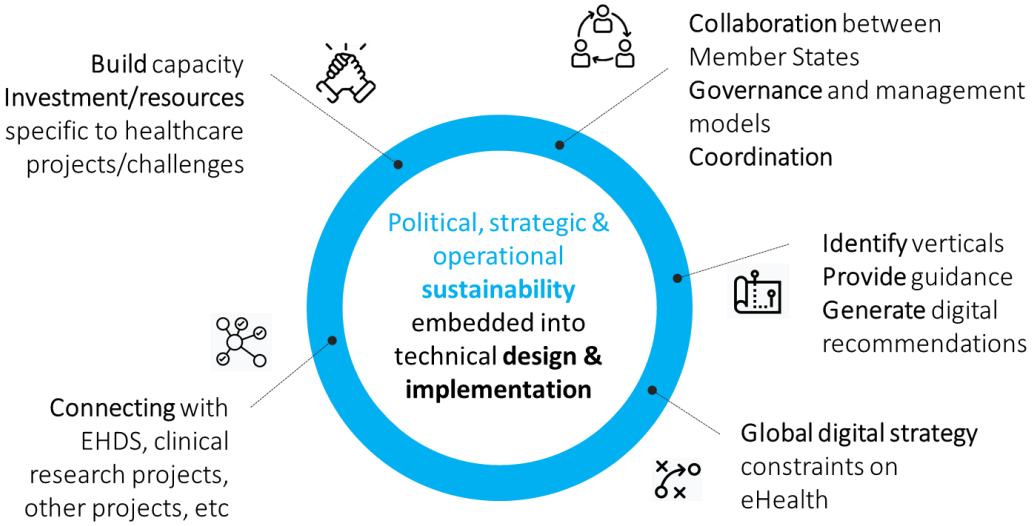

Figure 2 – Political, strategic & operational sustainability (technical design and implementation)

In this sense, sustainable development of eHealth can be supported by linking Member State political agenda topics with technical capabilities and implementation. This would ensure structural eHealth cooperation in Europe, creating significant value in shaping strategic decision making within a culture of appropriate technical decision-making (see Figure 2).

In this regard, political sustainability would be embedded into the technical design settings of new eHealth systems, projects and services under development.

1.2. Defining sustainability in eHealth policy cooperation

Having emphasised the relevance of addressing the sustainability of eHealth cooperation, this section introduces the definition of sustainability applied in this document.

In this regard, the outcome of stakeholder involvement, in the two workshops held by the authors of this deliverable (D8.3), is presented below as a reference source for developing post-2021 scenarios for eHealth policy cooperation.

Workshop's participants feedback on outcomes:

What does sustainability in eHealth policy cooperation mean?

Sustainability in eHealth policy cooperation can be realised through the co-creation of a joint agenda for EU digital services among decision making and technical bodies, sharing best practices with well-established processes. This links in with the EU4Health initiative[1] promoting 'sustainability in cooperation'.

Member States have different views on what is required for sustainable policy development, so efforts to coordinate priorities at EU level give Member States ambitious targets to aspire to, without the sole driver of financial incentives. Key aspects of the relationship between policy and process help the movement forward in strategic, cohesive and transparent way, ensuring interoperability and ultimately patient safety.

This coordination is critical as a risk mitigation as, by default, Member States will be motivated by national interest primarily, and the promotion of the common good is facilitated by a policy co-creation process.

Another critical factor is the stage on the digital transformation journey that each Member State is at, with a culture of inclusion to have all Member States on board. This can be implemented by having a focus on citizen and patient awareness and their personal digital health literacy.

Information collected during eHAction D8.3 workshops. It represents a specific point of view from participants.

[1] For more information on EU4Health programme, go to: https://ec.europa.eu/health/funding/eu4health_en

Workshop's participants feedback on outcomes:

What should the core message of D8.3 be? What is the key audience?

- The key audience is the eHN and the Member States.
- The eHN is the key audience but the message must be that:
  - without a joint action or similar instrument, there is a risk that we won't make progress.
- To the eHN mainly, but not exclusively.
- Health policy makers, health policy adopters.
- The key audience is eHN members and national policy makers:
  - A strong community that will foster the implementation of national digital eHealth Services.
- Are we targeting as an audience the EU, governments or European citizens with their new expectations about European eHealth development?
- Start with the eHN, but make it accessible for everyone interested in sustainable cooperation.
- A set of measures and guidelines on the best course of action are proposed to direct EU policy cooperation towards sustainable transformation.
- Sustainability of eHN work, cross-border collaboration.
- Member States and national policy makers.
- Joint Action to continue this work:
  - Recommend that this Joint Action be supported by the European Commission through the EU4Health.
- Emphasis on EU citizens – people need to be aware:
  - More communication to the citizen. People don't need technicalities; they demand a system that works.

Information collected during eHAction D8.3 workshops. It represents a specific point of view from participants.

Workshop's participants feedback on outcomes:

What does a post-2021 scenario in eHealth mean? How do you envision it?

- A model to be used/implemented after 2021:
  - Building such a scenario is going to be linked to a global assessment of the maturity level of eHealth in each country.

- How we can build an agenda for 2030, and agree on a 'moonshot' for digital health.
- A set of recommendations that each Member State can use to help direct them.
- A scenario represents a description on how actors interact with each other in a common framework. These two features create a system, which generates its own dynamics. All this, seen from above, is a scenario perspective.
- Model – flexible model would be used after 2021 to help Member States progress towards digital transformation:
    - Flexible and dynamic so that Member States can amend the model (guideline) to suit its own interests better.
    - As Member States, we can look to a guidance model, which aims to act as a checklist, whose end-goal is to improve cross-border interoperability so that citizens may gain access to healthcare elsewhere in the Union.

Information collected during eHAction D8.3 workshops. It represents a specific point of view from participants.

Workshop's participants feedback on outcomes:

From which perspective should we frame a set of recommendations?

- By performing a systemic overview of involved stakeholders, processes and framework in which they operate.
- Approaching as Member States and local authorities to understand how to aspire/work towards regardless of rate/velocity of transformation.
- From the patient's perspective, focusing on patient-centric design, considering a holistic approach to the patient.
- Considering the timeframe of this recommendation aggregation, the end of the Joint Action post-2021 and trying to propose a concrete governance framework to lead with eHealth.
- By elaborating long-term scenarios for collaboration until 2030 and a possible way forward to work as a network.
- Addressing healthcare professionals, patients, governments and private companies with dedicated recommendations.
- Describing the methods by which the ecosystem can work together, governance and coordination points of view.
- As an interoperable set of specific domain-related recommendations, sometimes enabling transfer between main categories.

Information collected during eHAction D8.3 workshops. It represents a specific point of view from participants.

1.3 Barriers/challenges to sustainability

Without doubt, eHealth sustainability is of critical importance to maintain and improve the current work of Member States on cross-border collaboration.

There are many challenges ahead, including lack of interoperability of existing digital services at national level in each Member State, limited access to health data, no benchmarking between Member States/countries for Digital Health, ad hoc implementation of standards, no investment in 'new' infrastructures by governments or national competence centres in a common way, eSkills for IT and healthcare professionals, and data quality and inputs.

These challenges were again highlighted at a D8.3 workshop held in December 2020.

Workshop's participants feedback:

Thinking of COVID-19 as an example, can you name a gap?

Interoperability	• Interoperability of COVID-19-registries • Difficulties to share data • Tracing apps interoperability • Technical opportunities • Infrastructure, integrated information systems
Data	• Disparate data standards (eHealth, communicable disease surveillance) • Good quality data (for use in operations, decision making and planning), including data consistency • Data interoperability (data formats, semantic interoperability, data portability, integrated data management) • Regional-level epidemiologic data
Inclusive	• Being inclusive of all the population • Digital literacy • Data access trust (awareness) • Widespread implementation • Telehealth adoption and understanding • Resistance of healthcare sector
Governance	• Shared vision about data privacy (tracing apps) • Anticipatory actions

	• Member States not using each other's experiences to progress their agendas • Lack of coordination, collaboration • Member State preparedness • Lack of knowledge transfer from technicians to politicians

Information collected during eHAction D8.3 workshops. It represents a specific point of view from participants.

However, more recent events (such as EU/eHN response to COVID-19) have highlighted the many benefits of a collaborative and dynamic approach to tackling EU /worldwide issues in a timely and flexible way.

2. Integration of national policies and sustainability

The main objective of Work Package 8 (WP8) is to frame the implementing efforts of all eHAction work packages into a bigger picture of integration and sustainability in the EU.

In this regard, this chapter presents:

- WP8's conclusions on national eHealth strategies (section 2.1),
- An analysis on the main eHealth activities occurring beyond the EU (section 2.2), and
- A reflection on the expected outcomes of Multiannual Work Programme (MWP) 2018-2021 and the value created by eHAction (section 2.3).

Overview of joint actions supporting the eHealth Network

In terms of eHealth policy as influenced by the current and past eHealth Actions, sustainability has become an increasingly important characteristic in EU's technical-political cooperation.[2]

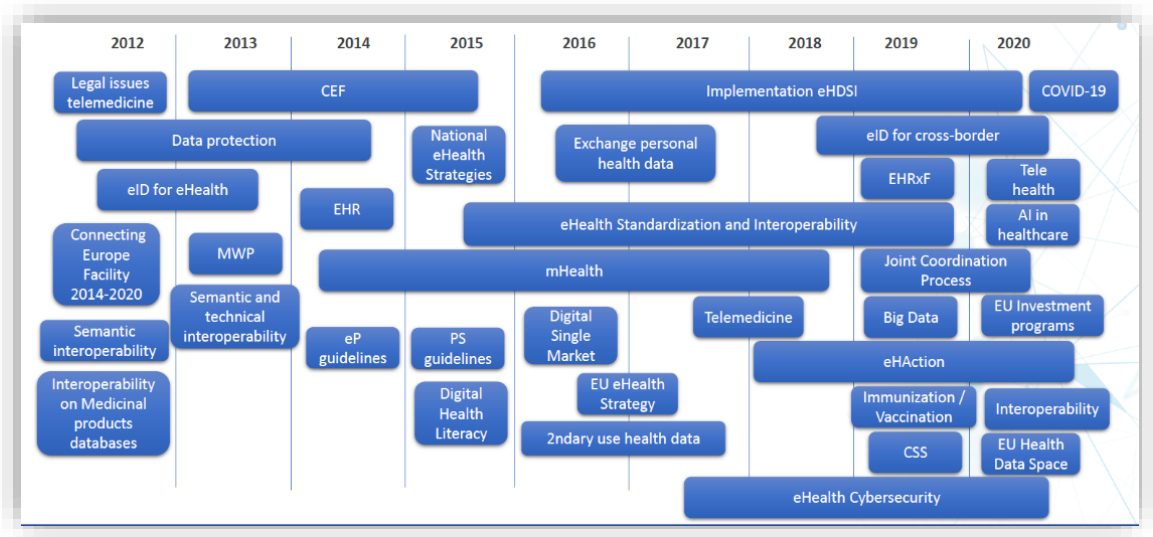

Figure 3 – Main eHN subjects discussed through the years.

The series of joint actions and initiatives undertaken by the health ministries of European countries have made a major contribution to constructing a framework for continuous improvement of healthcare systems, with roadmaps, legislation, standards and pragmatic recommendations (see Figure 3).

[2] As presented by the European Commission at the Infoday on Joint Actions on 3 June 2020, upcoming EU-funded projects require a new mandatory work package focus on sustainability. It aims to support the integration in policies and support national plan development.

The most recent of these are[3]:

- ***European Commission Recommendation on a European Electronic Health Record exchange format (EEHRxF)***[4]
    - In which the ideas of National Digital Health Networks (NDHN) and a Joint Coordination process (JCP) were put forward (ideas further developed in Chapters 4 and 5).
- ***Common Sematic Strategy (CSS)***
    - The definition of the EU eHealth semantic strategy gave origin to the eHN Subgroup on Semantics that is responsible for driving the current strategy and proposing a new one to ensure semantic alignment in the EU.
- ***Common electronic Identification (eID)***
    - A set of recommendations to leverage the latest EU regulations and create a holistic approach to eID in health and ICT services.
- ***eHealth Reference Architecture***
    - An enterprise architecture framework and a set of recommendations to enhance interoperability in eHealth systems and programmes.

However, it is important to emphasise that the specific instrument (joint actions supporting the eHN) from which these achievements arose, is the same instrument hitherto applied to operationalise the vision put forward by the MWPs (2012-2014; 2015-2018; 2018-2021).

Having said this, and acknowledging that the supportive joint actions to the eHN will be concluded by 2021, it is crucial to rearrange the structural organisation in which eHealth cooperation currently takes place in the EU, in a way that gains achieved in health quality and availability could be maintained, with budgets, infrastructure, governance and critically professional skills all playing a role in this sustainability.

This done, organisational sustainability upholding eHealth policy cooperation would promote unblinkered work practices that allow agile responses[5]. These are crucial features to face unexpected events like the COVID-19 pandemic or other natural disasters. Flexibility must be

[3] These contributions are further addressed throughout the document, namely in chapters 3,4 and 5.
For more information on the contributions outlined (EEHRxF, CSS, eID, eHRA), go to: http://ehaction.eu/wp8-ehealth-national-policies-and-sustainability/

[4] For the full recommendation, go to: https://ec.europa.eu/digital-single-market/en/news/recommendation-european-electronic-health-record-exchange-format

[5] As an example, in a short time span, eHealth Network technical cooperation was able to achieve a common framework for contact tracing apps, in compliance with national requirements, and relying on a wide range of stakeholder engagement. Notwithstanding, such technical cooperation activities occurred on an ad hoc basis. To achieve a stronger and sustainable European eHealth Union, such cooperation activities need to be sustained.

considered as a core component, and all actors, clinical, administrative, policy, ICT, facilities, etc. must orient with ease into new circumstances.

2.1. eHAction overview on National eHealth Strategies in the EU

This section presents an overview of the findings of D8.1 – *Report on National eHealth strategies*[6], and is used to help best understand the European eHealth environment.

The main objective of this deliverable was to describe the main initiatives and common obstacles from each Member State, so as to develop a solid knowledge base for policy cooperation in the EU. This was done by collecting information on present and future eHealth strategies and analysing the information received from the 19 EU Member States surveyed.

Results of this comparative analysis do not reveal unsuspected findings but rationalise some well-known facts about governance aspects, such as the programmes landscape, including initiatives and the relationship with stakeholders.

➢ D8.1 Conclusion on Governance Strategies

D8.1 comparative analysis concluded that there is a great diversity of governance schemes among countries.

As Figure 4 illustrates, there is no common approach to advancing eHealth in the EU. On the contrary, it is clear that the domestic environment and systemic organisation of each Member State stand as the main drivers in defining the level of strategic action. This diversity indicates

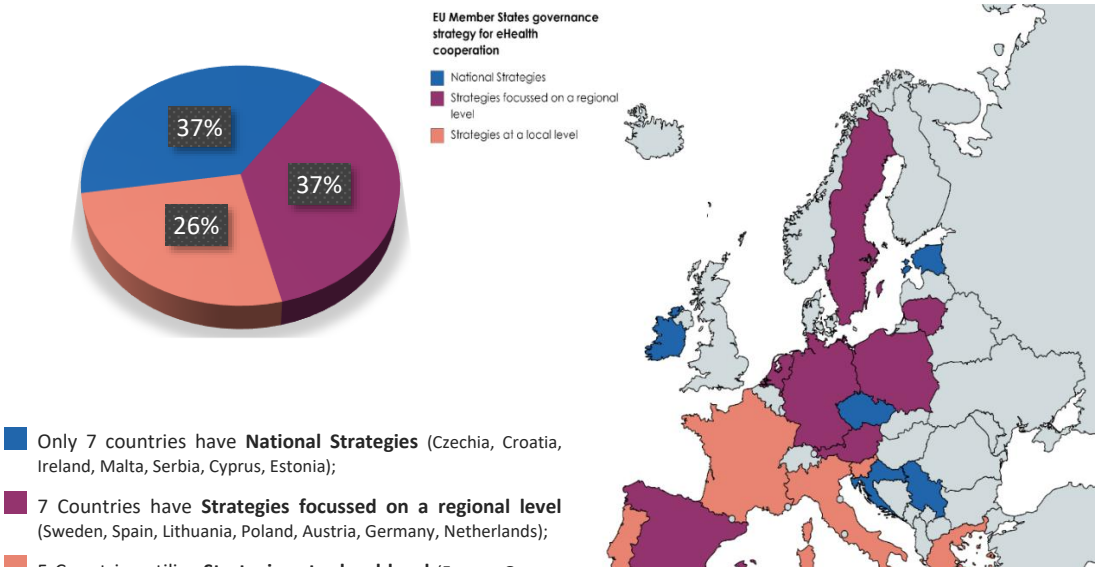

Figure 4 – EU Member States governance strategy for eHealth cooperation

[6] To read the full paper, go to: ehaction.eu// D8.1-Integration-in-national-policies-and-sustainability_eHAction_16th-eHN_ANNEX.pdf

that the sharing of best practices is essential to promote the alignment of the different levels of digital transformation between the Member States in the eHealth sector.

The analysis showed that there are several national institutions[7] that play a relevant role in eHealth cooperation activities. Nonetheless, national institutions with governmental competence stand as the biggest players for eHealth cooperation, most likely due to cross-border information sharing services (Patient Summary and ePrescription) being under the scope of governmental bodies. Only a minority (3 out of 19) presented eHealth initiatives at a regional level, and no initiative at the local level was identified.

[7] This analysis found that national bodies such as ministries of health, national bodies for insurance funds, regional health agencies, and medical councils all play an important role in almost all the Member States' eHealth affairs.

➢ Insights on Member State (e)Health Programmes Landscape

Concerning the action level of eHealth programmes landscape, Figure 5 illustrates well the rationale underlying the definition of Member State strategy. National level actions are clearly hegemonic vis-à-vis regional and cross-border initiatives.

This analysis highlights that at the top of Member State agendas stand the strengthening of national healthcare systems and services. As such, the cross-border realm is not a driver in the strategy design. Notwithstanding, one can conclude that the high number of programmes and initiatives performed to date confirms the dynamism of the transformation of the sector. Hence, there is a lot of room for nourishing national concerns by sharing experiences from other countries. Improving access to healthcare services, generating efficiency gains in health services delivery, guaranteeing quality and safety of care, and enhancing health system organisation are the top four priorities addressed by countries. These are common axes of objectives that can be observed between the respondents of the D8.1 survey (see Figure 6).

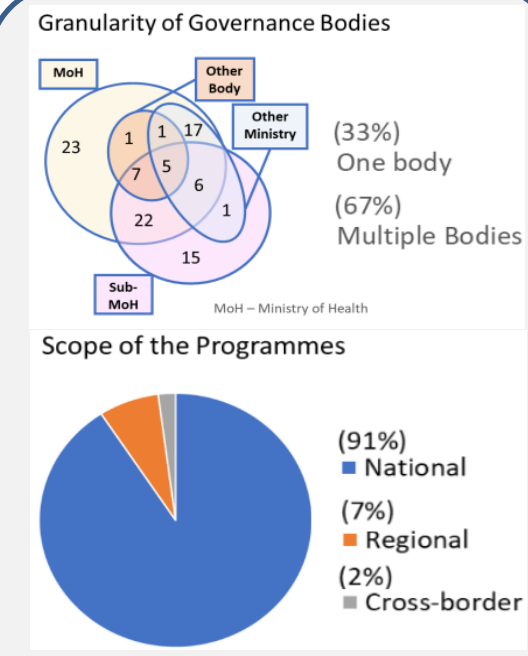

Figure 5 - Member States scope of action for eHealth affairs, and granularity of governance bodies

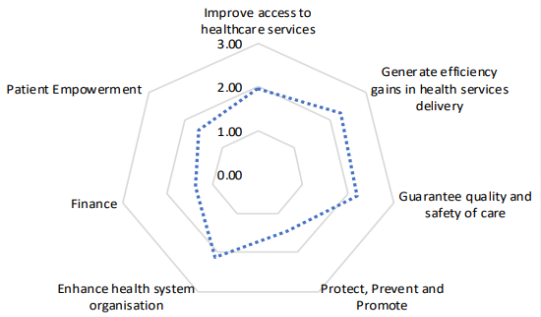

Figure 6 – Programme Landscape overview by eHealth priority areas (all countries interviewed in D8.1)

National governments share the same priorities. This can be explained by the fact that health sectors are going through the same issues in different EU countries and there has been a realisation that eHealth has the potential to be an important lever to help in overcoming those challenges.

This said, digital transformation in healthcare stands as a preference for national development. Table 1 briefly outlines some cross-sectional priority areas that support national eHealth environments and bring innovation in.

Table 1 - Scope of action, initiatives and digital enablers

National Priorities & Scope of Action		
Access & exchange of health information and data transparency	Digitalisation, modernisation and transformation of healthcare	Independence & involvement of the patient / Patient-centric systems
Initiatives – digital enablers		
❖ **Standards & interoperability** ❖ **Infrastructure & building blocks** o Electronic Health Records exchange Format o Physical infrastructure – networks o Building blocks – national registers o Security of data and services – ePrescription ❖ **Innovation** o Electronic medical record accessible online by doctors o Smart ID card to access medical files and reports o Administrative and reimbursement data o Social security via the blockchain		
Enablers are used in various ways to support the different strategies. Some more common foundations on the enablers are needed to help reaching the goal of European interoperability.		

➢ The role of Stakeholders

A close relationship with stakeholders is essential to achieve a vibrant and functional ecosystem. The analysis carried out by D8.1 demonstrated that nine stakeholder groups play a significant role in advancing the eHealth ecosystem, both at the national and European level (see Figure 7).

This is particularly the case in the areas of providing expertise, reducing and uncovering risk, and increasing the successful development of eHealth services and systems.

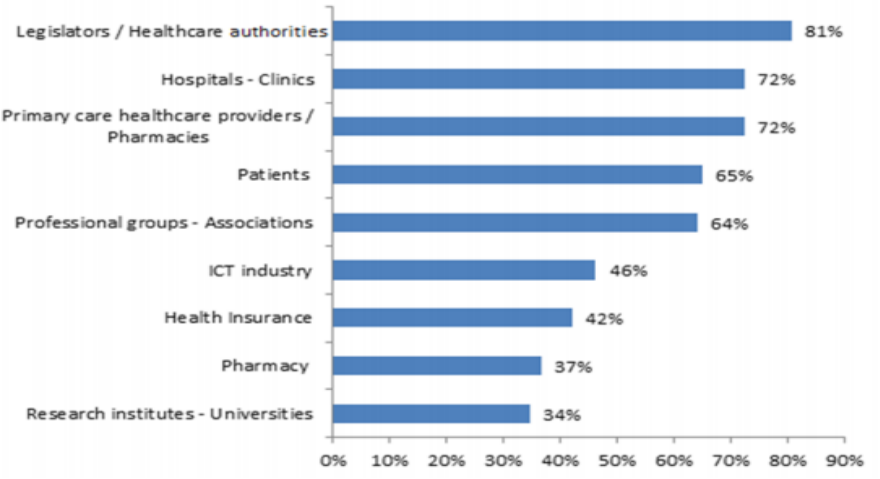

Figure 7 - Percentage of stakeholder groups representation in relation across all reported eHealth initiatives

2.2. eHealth Developments: Beyond the EU

This section presents an overview of the main eHealth ecosystems developing outside of the EU[8].

To this end, the findings of the JAseHN deliverable D8.1.4 – *Main eHealth Activities Outside of the EU*[9] are herein outlined in order to provide D8.3 relevant knowledge on important analysis and evaluation tools arising in the other four continents.

➢ eHealth as a component of eGovernment

What countries define as eHealth must be considered in relation to the characteristics of the country or region, and with the state of health conditions and of healthcare systems.

This is to say, national elements such as socio-economic, cultural and legal, and societal characteristics such as education, infrastructures, internet access and mobile phone coverage, are all dependent variables when carrying out comparative analysis between ecosystems.

National backgrounds resulting from the above-mentioned factors have tremendous impact on public health strategies, healthcare systems and services, therefore, also in the definition of eHealth.

Even though eHealth is often associated with common objectives and techniques in various countries, eHealth development is always closely linked to national culture, the level of economic development, information and education of the population and of the professionals concerned.

eHealth is a Moving Target

Example:

Since health diseases are different and have different evolutions,

national eHealth strategy, programmes and indicators are, therefore, defined accordingly.

eHealth strategies and developments are a multifactorial phenomenon. This is not to say that there are not fundamental objectives and constraints common to all countries, but the paths do differ widely.

Nonetheless, the following trends cut across all the analysed countries:

- **Universal access:** eHealth is an answer to social and technical divides that affect healthcare access for populations isolated from the main healthcare system, hospitals and specialists;

[8] Section 2.2. presents an overview analysis on 11 countries (Australia, Argentina, Brazil, India, Morocco, Nigeria, Senegal, Singapore, South Africa, Tunisia and the USA) and the role played by the PAHO (Pan American Health Organization) and World Bank for the development of eHealth ecosystems.
[9] For the full paper, go to:
https://ec.europa.eu/health/sites/health/files/ehealth/docs/ev_20180515_co15_en.pdf

- **mHealth and People Empowerment:** mHealth might become the main factor influencing patients and professionals for higher empowerment, as a means to reach health systems;
- **Interoperability:** reduction of healthcare systems fragmentation;
- **Trust:** the greatest obstacle comes from fear about security, safety and privacy.

These trends are also observed in EU Member States. However, it is important to say that the way to explore the full potential of eHealth is not an easy one. Ambitious programmes and statements are everywhere, but they often struggle to overcome existing obstacles.

This study revealed that many projects are initiated and supported by pioneers. The actors learn from mistakes made during the first attempts. They acknowledge the crucial need for better communication and cooperation with the healthcare sector players i.e., the general public, healthcare professionals, researchers, ICT specialists, etc.

The role of non-governmental Pioneers:

In bringing together ecosystem actors and promoting the establishing of observation mechanisms to support decision making.

Use cases:

→ the Tunisian Society of Telemedicine

→ Office of the National Coordinator for Health Information Technology in the USA

I. Initially, initiatives are scientifically and technically driven;

II. In a second phase, programmes began to integrate key aspects that underpin sustainability: monitoring through evaluation indicators, capacity building, workforce motivation and consultation with healthcare professionals and patients.

➢ Think Global – Act Local

This analysis also showed that, in most cases, decentralisation brings more stable results than centralisation. Bottom-up approaches allow for better respect for local conditions, stakeholder engagement, close-to-the-field innovations and better usage.

At the legal level, features such as privacy and responsibility of healthcare professionals and healthcare provision are a condition for the involvement of actors (including patients) as well as an essential condition for successful large-scale developments. Security and safety must be addressed at the general data circulation level instead of being ensured within the fortified

walls of every healthcare institution[10]. This means that, even though regulation may sometimes act as barriers to further development, it is the multiple-stakeholder perspectives that push unfit regulations to update.

eHealth is more and more a key component of globalisation

In the information society, there is no such thing as a completely closed domain. A bottom-up approach portrayed by the all-inclusive participation of all actors, from all levels, is instrumental for the sustainable transformation of healthcare systems. Therefore, instrumental for the emergence of a new type of health, are:

- **Patient empowerment:** the patient controls his own health data and shares it voluntarily;
- **mHealth:** Systems interoperability and data portability;
- **Mitigation of States boundaries:** mHealth and its users should not be hampered by administrative and bureaucratic issues;
- **Innovative applications and processes:** develop the potential of artificial intelligence and big data.

This said, Table 2 lists the most frequent approaches applied in the different countries.

Table 2 - Most frequented approaches followed by the analysed countries.

Inescapable needs and constraints	
Personal Identity ***Directories of resources***	Personal identity is a fundamental building block of eHealth projects, and a condition for data exchange in any digitalised system. e-Registry – eHealth development implies the identification of healthcare facilities and healthcare professionals, and construction and maintenance of interoperable registries providing necessary details (such as localisation, status, specialties).
Main difficulties – *Population and healthcare professionals mistrust*	
Safety, security, privacy	A prerequisite to any development. In order to protect open health information systems and communication tools against errors and attacks, to ensure integrity of managed and exchanged data, and to protect privacy. National/federal governance considers it critical and a prerequisite for all eHealth programmes.
Technical difficulties – *which appear progressively*	
Interoperability, standards and health data	Slow progression, in the sense that, most of the involved actors (administrative, HPs, ICT specialists) perceive interoperability as a technical challenge.

[10] As to what concerns the EU, this means that discussion and cooperation on overarching topics such as the GDPR and the development of a code of conduct for the European Health Data Space should be held at the European level. The opposite would be each healthcare organisation developing its own code of conduct, resulting in more fragmented and non-interoperable systems.

	It takes time to progress through the layers to the truly most critical and more difficult one, the **semantic layer**. This layer is closely related to culture, language and organisational features.
Electronic Health Record – *an essential objective for all countries*	
Public Health needs more comparable data and more data collection capacity	Publication of data dictionaries and compatible codes for different types of records and specialties. Understanding the importance of knowledge diffusion and circulation. Establishment of national bodies/agencies, e.g. national knowledge network. Virtual Health Libraries that promote inter-institutional partnerships to produce health information. E.g. electronic journals portal. Bilateral agreements focused on scientific information exchange.

As for the main difficulties identified in the studied countries, several barriers detected in one country were detected as well as in others. Education and training stand as the main barrier hindering a digitally empowered workforce.

The legal field also plays a central role, since the development of eHealth is hampered by laws established in the past. Moreover, the communication and promotion of new services and systems is insufficient, resulting in low engagement. In addition, local conditions and particularities are often neglected, as existing infrastructures and equipment do not reach remote areas where they are needed the most.

2.3. Multiannual Work Programme & eHealth Joint Action

This section aims to correlate eHAction Work Package areas under the umbrella of a sustainable eHealth policy.

To do so, the expected outcomes put forward by the MWP 2018-2021[11] will serve as the basis for a reflective analysis on what has been stated on paper vis-à-vis real progress made by eHAction.

Figure 8 – MWP main priority areas / eHAction work packages

➢ From paper to reality

Adopted by the eHN at its 12th meeting in November 2017, the MWP 2018-2021's overarching strategy heightened the purpose for which the eHN was conceived:

> *To work towards delivering sustainable economic and social benefits of European eHealth systems and services and interoperable applications, with a view to achieving a high level of trust and security, enhancing continuity of care and ensuring access to safe and high-quality healthcare.* [12]

Building upon this, the MWP gives particular emphasis to developing a common electronic identification (eID) therewith authentication measures, as well as to progress towards the secondary use of data in order to enable the use of medical information for public health and research. To achieve this, a close cooperation with the eHealth Stakeholder Group was put forward as essential to co-produce enduring eHealth standards.

By acknowledging that digital health sector is continuously evolving at a rapid pace, the different degrees of digital transformation in the Member States (therewith their own

[11] For the full paper, go to:
https://ec.europa.eu/health/sites/health/files/ehealth/docs/ev_20171128_co01_en.pdf
[12] Article 14, eHealth Network, of the Directive 2011/24/EU on the application of patients' rights in cross-border healthcare. For more information go to:
https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:088:0045:0065:en:PDF

ambitions and strategies) impact considerably on international cooperation activities. This situation stands as a main challenge ahead for eHealth policy harmonisation at EU level.

Cognisant that policy on digital health is taking shape at EU and national level, the voluntary network that gathers Member State competent authorities responsible for eHealth plays a major role, acting as a platform for discussion and development of cross-border cooperation in healthcare. Despite that, the legal framework in which the eHN current operates (dating from 2011), now proves to be suboptimal to address eHealth's complex and challenging reality.

A revision of the eHN's role regarding digital health policy was deemed instrumental to best face future developments in the sector concerning the eHealth Digital Service Infrastructure (eHDSI), cross-border exchange of information and the new requirements on data protection under GDPR. Acknowledging this, the Commission Implementing Decision 2019/1765 established the optimal terms for *the management and the functioning of the network of national authorities responsible for eHealth*.[13]

Table 3 – eHealth Network's scope and fields of action.

eHealth Network Legal Framework Evolution[14]	
Directive 2011/24/EU (eHN) ***2011 – 2019***	**Commission Implementing Decision 2019/1765** ***2019 – current***

• **Deliver** sustainable economic and social **benefits** of European eHealth **systems and services.**
• **Interoperable applications.**
• Achieving a high level of **trust and security.**
• **Enhancing continuity of care.**
• **Ensuring access to safe and high-quality healthcare.**
• Developing **common identification and authentication** measures to **facilitate transferability of data in cross-border** healthcare.
• **Draw up guidelines on:**
  • patients' summaries.
	• Facilitate greater **interoperability of the national information.**
	• **Transferability of electronic health data** in cross-border healthcare.
	• **Empowering citizens to access and share their own health data.**
	• Improving **digital skills of patients and healthcare professionals.**
	• Exchange of good practices:
	  • **telemedicine.**
	  • **m-health.**
	  • **big data and artificial intelligence.**
	• Supporting **health promotion & disease prevention.**

[13] Commission Implementing Decision 2019/1765 of 22 October 2019: https://eur-lex.europa.eu/eli/dec_impl/2019/1765/oj

[14] The information present in this table derives from an analysis of Directive 2011/24/EU and the Commission Implementing Decision 2019/1765

• effective methods for enabling the use of medical information for public health and research.	• Provide guidance on the necessary **use cases for clinical interoperability** and the tools for achieving it. • **(Cyber)Security of the eHDSI** for Cross-Border eHealth Information Services.

As illustrated in Table 3, for the upcoming years, great focus is placed on citizens' wellbeing, supported by the application of technology for better patient experiences and healthcare outcomes. eHAction delivered great progress for interoperability and semantic alignment in the EU, nonetheless, further work to underlie the European Health Data Space (EHDS) is needed. i.e. frameworks and mechanisms for higher data exchange and reuse, to upscale the eHDSI infrastructure, as well as to ensure trust and transparency.

As such, it is fundamental that Europe's multi-level governance (supranational, national, regional, local) shares the same digital vision to achieve sustainability in eHealth policy cooperation. Such commitment would boost European public and private enterprises into the frontline of innovation on one hand and strengthen the EU's ability to better face public health challenges that lie ahead on the other.

> *The healthcare sector is a data-intensive industry generating large volumes of data.*
>
> MWP 2018-2021, eHN

Having briefly presented some of the eHealth developments up to the present moment, the information that follows provides an overview of eHAction's real progress for eHealth.

➢ Empowering People

One of the key elements of a sustainable healthcare system is that patients take an active part in their healthcare process. For this, they need to be informed and provided with the right (digital) means. Moreover, they need to possess adequate digital (health) skills.

With the above in mind, eHAction WP4 – Empowering People, developed a *Policy Framework on People Empowerment*[15] framed upon a three-pillar approach (see Figure 9) and whose purpose was to help citizens gain control of their health and achieve empowered behaviour. To improve field empowerment among

[15] & [14] For these documents, go to: http://ehaction.eu/wp4-empoweringpeople/

Member States, a policy proposal[16] containing 22 recommendations divided among 9 priority areas was put forward.

Figure 9 – AMO Framework (*Ability, Motivation and Opportunity)*

Lessons Learnt

Acknowledging that Member State focus areas/starting point differ widely, the scenarios/recommendations should be developed on a flexible basis, therefore containing different areas or layers to be applicable for every Member State. Furthermore, it is important to include not only as many stakeholders as possible to gather as much information as possible, but also the newest developments to make sure the results are applicable for many years to come.

How can stakeholders (ecosystems) continue to benefit from People Empowerment created value?

The priority areas of the Refined eHealth European Interoperability Framework (ReEIF) model (see Figure 10) can be used to structure an approach or scenario. The Ability-Motivation-Opportunity (AMO) model is a great and broad framework that can be used in order to change behaviour, even on policy level.

As for the potential impact of this work, Member States can encourage and increase empowered behaviour in their populations by incorporating these recommendations into their policy (see Figure 11). Moreover, the AMO framework can be used as a model for Member States to develop their own strategy or approach.

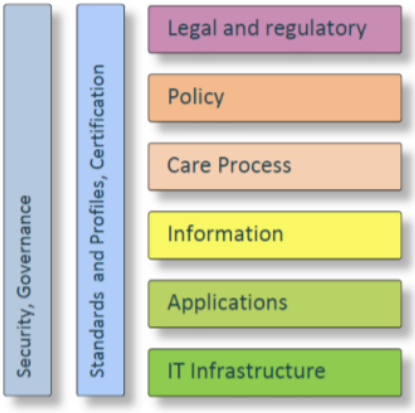

Figure 10 – The Layer Framework / ReEIF model

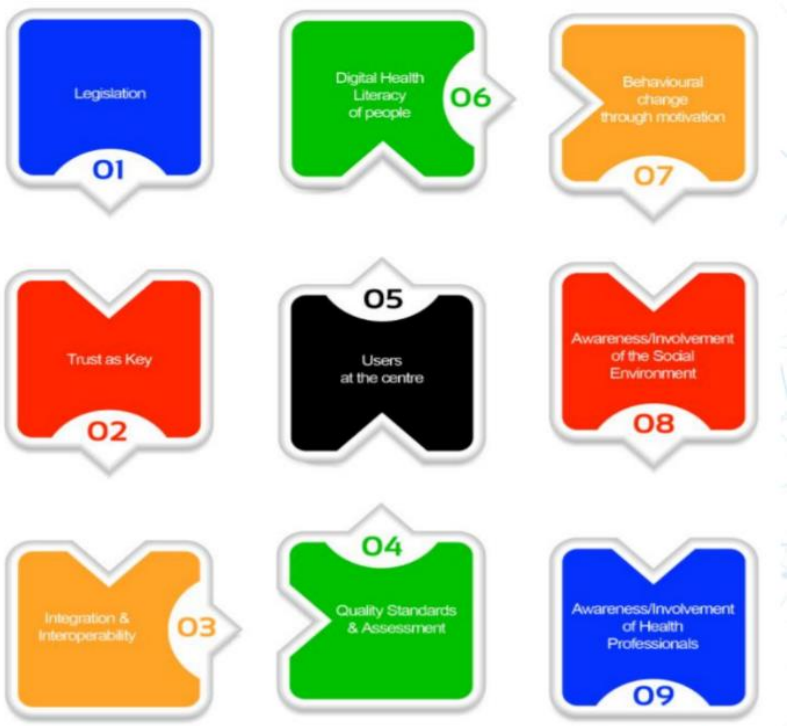

Figure 11 – 9 priority areas of Policy Proposal

➢ Innovative Use of Health Data

exploring the use of health data to develop knowledge for healthcare policy and other purposes

The MWP 2018-2021 emphasised that the use of large volumes of health data could unlock great potential in the healthcare; however, an EU approach for sharing expertise but also raising the awareness of the potential benefits of the secondary use of health data is lacking.

In this regard, eHAction's WP5 delivered a set of recommendations aimed at helping eliminate obstacles on the following matters:

- Raising of awareness on using big data in healthcare,
- Developing a common vision on innovative use of data in healthcare, and
- Governance and methodologies for innovative use of health data, including big data.

The work carried out by WP5 strived to leverage the benefits of using health data (primary and secondary) for better public health, research and quality assurance outcomes in healthcare. To do so, the best practices and ideas gathered on how to overcome the

challenges hindering the innovative use of health data will be shared among policy makers and other key stakeholders' groups by three informative/guiding documents[17]:

- Practical governance of big data / innovative use of health data,
- Principles to help implement the proposed recommendations and use cases,
- Guidance for the implementation of the principles.

Regarding the main obstacles hindering the innovative use of health data at the national and cross-border levels, three general features were narrowed down as the main reasons hampering translation of policy-level recommendations into actions: (i) lack of trust; (ii) legal uncertainties, and (iii) lack of funding and financial resources (see Figure 12).

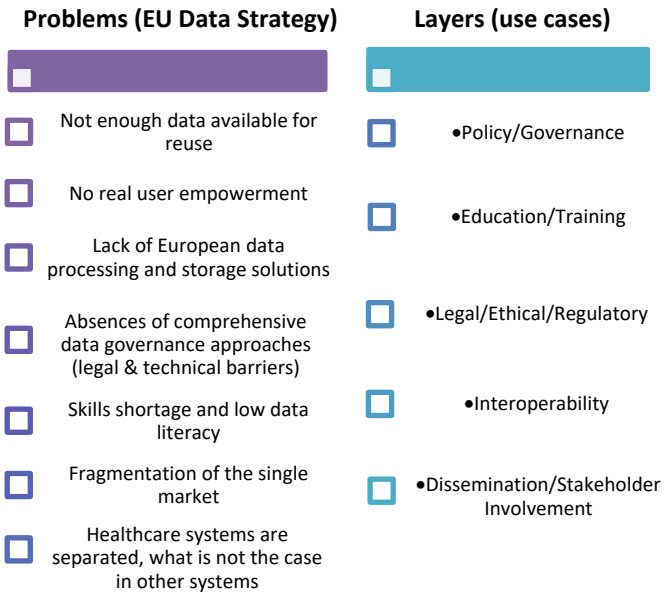

Figure 12 – Root causes hindering further progress in data reuse.

Having outlined the root causes hindering further progress in data reuse, and having identified the use case layers applied to collect such information (see Figure 12), WP5 developed a set of common principles for practical governance of big data (see Table 4).

To promote the continuation of this work, WP5 will deliver to the eHN a guiding document with next steps for national and common implementation. This document aims to enhance national dialogue on how to use Table 4 insights, to make decision-makers aware of the added value of these principles for future field work.

[17] For these documents, go to: http://ehaction.eu/wp5-innovative-use-of-health-data/

Table 4 - Clusters & Principles for Practical Governance of Big Data

Clusters & Principles for Practical Governance of Big Data
Cluster 1: Increase trust in privacy protection and cyber security
Principle 1 – Work with anonymised or pseudonymised data
Principle 2 – Develop digital health literacy
Principle 3 – Disseminate data re-use purpose well
Principle 4 – Make a great effort to secure and protect data
Cluster 2: Increase efficiency of using funds and financial resources
Principle 5 – Use existing technical standards
Principle 6 – Involve stakeholders in co-creation
Principle 7 – Consider current and future needs
Principle 8 – Foster data re-use
Cluster 3: Foster common interpretation of legal and ethical rules
Principle 9 – Adapt model to the settings
Principle 10 – Create code of conduct
Principle 11 – Speak the same language
Principle 12 – Aim for win-win of all stakeholders

➢ Enhancing Continuity of Care

The MWP stressed that it was crucial to ensure that the conditions needed to provide and expand eHealth Cross-border eHealth Information Services (CBeHIS) are met; namely, through the establishment of the necessary legal agreements, communication plans, IT service management procedures and monitoring of CBeHIS implementation, operation and benefits realisation. In this regard, the eHAction WP6 – Enhancing Continuity of Care – delivered the following output[18]:

- **A Roadmap on future eHDSI use cases and features of NCPeH (D6.1)**

This roadmap puts forward a collaborative way to prepare the construction and maintenance of an eHDSI roadmap based on the current use cases. This roadmap gives particular emphasis to (i) communication, community and user engagement, (ii) governance, strategy definition and policy, and (iii) interoperability assets and solutions.

- **eHDSI Legal Report (D6.2)**

A summary of the legal environment of the eHDSI for the members of the eHN and a non-lawyer audience is provided by this report, and this increases legal awareness and certainty for eHDSI between Member States/countries and the European Commission.

- **Report on eSkills for Professionals (D6.3)**

[18] For these documents, go to: http://ehaction.eu/wp6-enhancing-continuity-of-care/

The current practice in eSkills development for healthcare professionals is presented here, and the report proposes an innovative, structured approach for the future to ensure a highly skilled eHealth workforce.

Figure 13 – The Layer Framework / ReEIF model linked to WP6.

As for the potential impact, this work aspires to further connect the actors within and across the different interoperability layers identified in Figure 13, as well as to provide tools and frameworks to build knowledge and, more important, use it.

Moreover, it aims to create confidence in the ability of healthcare professionals to sustain the work of the various eHealth actions by building eSkills competences into professional development criteria at all levels of health science education.

Lessons Learnt

Building on existing proven frameworks and structures for:

- New use cases: *interoperability assets*
- Legal challenges: *leverage existing frameworks (eIDAS)*
- Skills: *competence framework*

How can stakeholders (ecosystems) continue to benefit from Enhancing Continuity of Care created value?

Online tools and a knowledge base represent two instruments that can play a major role in a sustainable eHealth ecosystem.

In addition, the eHN can raise awareness of the need for a professional, structured approach to eSkills development in the EU.

➢ Overcoming Implementation Challenges

As the EU faces challenges in providing interoperable eHealth services, the MWP emphasised the need to develop a strategy on European semantic interoperability, as well as the need to address the organisational, legal and technical challenges raised by GDPR.

In this regard, eHAction's WP7 – Overcoming Implementation Challenges – delivered two guidance documents[19] aimed at acting as a the 'basics' for a Community of Practice of an eHAction network of healthcare professionals and expert organisations:

- **An eHealth Interoperability Guide**

The base for the establishment of a Community of Practice of interoperability practitioners and procurers in large healthcare organisations.

- **A Data and Systems Security Guide**

A cybersecurity meta-guide to help to navigate the EU guidance documents including those delivered by the NIS Cooperation Group and by ENISA, under the NIS Directive with high level descriptions and links to sustainable trusted information online.

These two documents were developed based on a *think globally – act locally* rationale so as to further facilitate national interoperability framework efforts.

Lessons Learnt

In order to overcome implementation challenges, eHAction's WP7 work concluded that feedback and further engagement from the user community is fundamental to validate the Interoperability Guide and to further elaborate the organisational framework for collecting and publishing content.

This is to say, feedback from as many stakeholders and experts is key to gather best practices/experiences to formulate the main content of the guide.

Furthermore, it would be of great value that the European Commission could further facilitate consultations with relevant EU groups, such as the advisory eHealth Stakeholder Group.

How can stakeholders (ecosystems) continue to benefit from Overcoming Implementation Challenges created value?

In order to ensure the sustainability of the Interoperability Guide following the conclusion of eHAction, a possible solution would be to hand it over to an entity that can maintain its content, in collaboration, where necessary, with organisations that contribute to detailed guidance on specific topics (e.g. IHE, I~HD, HL7, etc.).

In addition, an environment that is conducive to the creation of a self-sustained community of practice, which actively contributes with knowledge and exchanges good practices, in the

[19] For these documents, go to: http://ehaction.eu/wp7-overcoming-implementation-challenges/

post-2021 period would be a major asset for eHealth. This can be done with a connection to the X-eHealth project.

With regard to the Cybersecurity Guide, the approach described above could deliver sustainable outcomes as well; in particular, by considering handing it over to the NIS Cooperation Group's Work Stream (WS) 12, after proper analysis with its members.

3. Nine core elements for a sustainable ecosystem

In this chapter, the notion of an eHealth ecosystem is underlined as a vital component to ensure high levels of access, security, quality and sustainable practices regarding health services and systems in the EU.

On this basis, this document defines an ecosystem as a set of interdependent stakeholders (Member State representatives, national eHealth agencies, healthcare professionals' institutions and associations, and experts' academics) connected through various interactions within Europe to foster cooperation and collaboration in the eHealth domain.

It is also important to underline that the ecosystem is not a static image but a living community (through existing programmes, eHealth Network experts and related workgroups) with strategic and structural interactions.

The retrospective presented in the previous chapter on the value created by eHealth cooperation helped to better understand the needs and priorities between different Member States, namely with regard to (i) empowering people, (ii) innovative use of data, (iii) enhancing the continuity of care, (iv) overcoming implementation challenges, and (v) integration of national policies and sustainability (chapter 2 and section 2.3).

Within this frame of reference, and in order to advance the digital transformation in health, the authors of this document acknowledged the need to narrow down the areas of action for post-2021, heightening the importance of cooperation in streamlining specific matters.

This chapter presents nine transversal core elements, whose relevance is considered instrumental to structure, maintain and streamline the ecosystem progress. These are:

- ✓ **People Empowerment and Access:** addressing patients as individuals who should take an active role in their healthcare process (digital health literacy, approach to patient access, sharing and reuse of health data).
- ✓ **eSkills for Professionals:** explaining healthcare professionals' access to knowledge, use and application of digital health.
- ✓ **Interoperability (EHRxF):** ensuring quality and safety of patient care, managing public health communication and cooperation between all stakeholders.
- ✓ **Infrastructure:** defining storage, access, and analysis of health data.
- ✓ **Cybersecurity/Security:** setting a common security framework for eHealth, and provisions to ensure integrity, authenticity, confidentiality, availability, and auditability.

- ✓ **Enterprise Architecture (eHealth reference architecture):** addressing management of structures and behaviours (roles and processes) to improve effectiveness, efficiency, agility, and continuity of operations in eHealth.
- ✓ **Coordination and Governance Model:** involving stakeholders in the process of consensus-forming, managing policy and procedures, adopting of institutions.
- ✓ **Innovation (CSS – common semantic strategy):** evaluating the impact on the use of health data, as well as assisting data-driven innovation leading to patient-centred health systems, evidence-based health policies and decision-making.
- ✓ **Legal Challenges:** undertaking legal challenges and advancing a common EU legal framework.

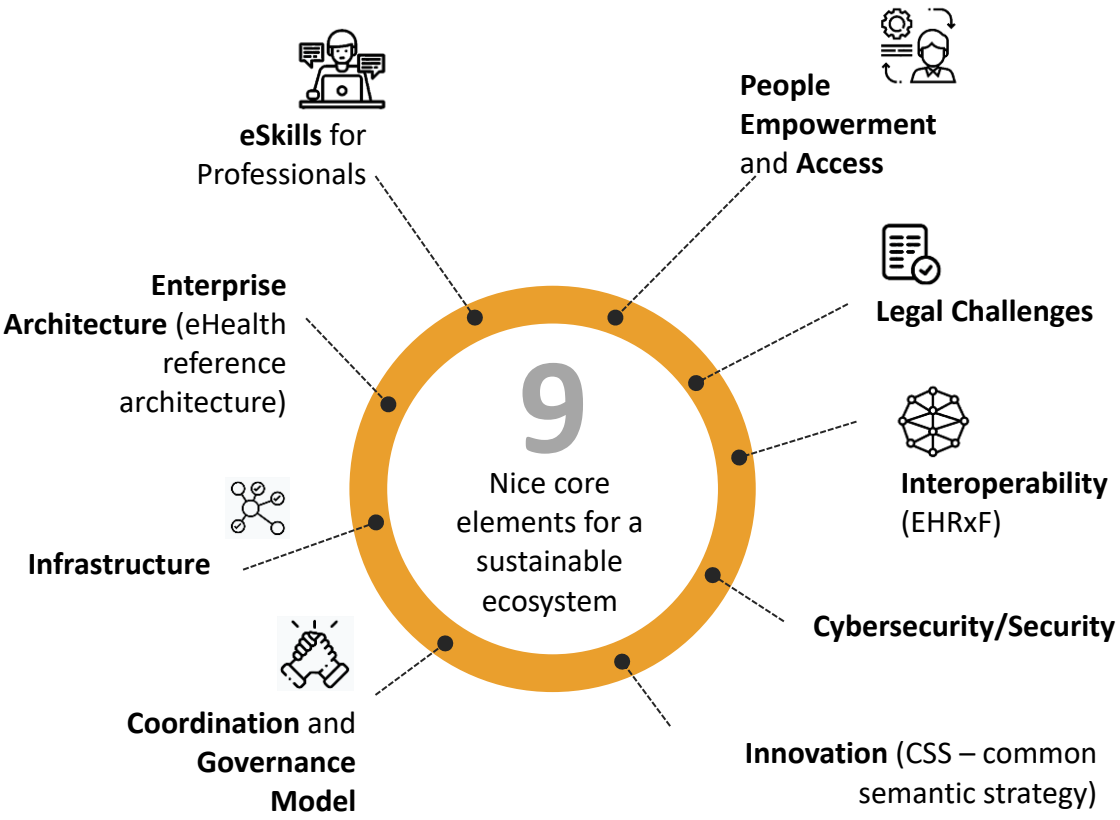

Figure 14 – The 9 core elements for a sustainable ecosystem

3.1 People Empowerment and Access

Worldwide, healthcare reforms focus on more coordinated forms of care provision, with the patient perspective increasingly considered critical in an integrated care delivery solution. Empowerment is an important facet of the patient perspective and is achieved through the involvement of all health stakeholders.

> EMPOWERMENT
>
> Enabling patients' control over their own health, through informed and sustainable uptake of digital tools in healthcare.

At a global level, this is recognised by the WHO which defines empowerment as 'a process through which people gain greater control over decisions and actions affecting their health' and it is listed as one of five interdependent and strategic directions in the WHO's framework for supporting people centred and integrated health services.[20] This empowerment is further elaborated as involving a clear role definition, sufficient knowledge and skills and a facilitating environment.[21]

In Europe, the EMPATHiE[22] project developed a conceptual framework for patient empowerment. The tender EMPATHiE aims to deliver a research project to the European Commission to achieve a common understanding of the concept of patient empowerment (PE) and identify good practices, success factors and barriers. The study recommends a European strategy and action plan with patient empowerment as a starting point.

The final report from the study (2014) recommended a European strategy and action plan on patient empowerment, and formulated a set of recommendations as a starting point to improve patient empowerment:

- Providing better education to patients and the wider audience.
- Improving healthcare professionals' education in holistic thinking and communication.
- Restructuring healthcare delivery and developing a central common electronic record accessible by patients as well as professionals.

A helpful clarification on this is the reference to 'Empowering People', one of four priority areas of the current MWP of the eHealth Network.[1] A focus on 'people' as opposed to 'patients' emphasises the health of the population rather than the treatment of illness. Empowering people means supporting all citizens to use eHealth to make good decisions about maintaining or improving their health and wellbeing. In 2018, the eHAction Joint Action

[20] WHO global strategy on people-centred and integrated health services, March 2015, available at: https://www.who.int/servicedeliverysafety/areas/people-centred-care/global-strategy/en/
[21] Angelmar R, Bermann BP. Patient empowerment and efficient health outcomes. Financing sustainable healthcare in Europe. 2007 :139–162.
[22] For more information, go to: https://www.eu-patient.eu/Members/Weekly-Mailing/empathie-finalreport/

was launched to advance the issue and develop a policy framework and a policy proposal for empowering people.

What needs to happen to empower people to engage themselves in eHealth?

An empowered population will be confident about the availability of trusted digital health information, health authority systems and services, and will understand their relevance for individuals and the benefit for personal health and wellbeing. This confidence comes with digital health literacy and encompasses an appreciation of its benefits (understanding of health maintenance and illness prevention). People empowerment makes healthcare more effective and compassionate for its consumers and all stakeholders in the health ecosystem.

The second characteristic of an empowered patient is trust. People entrust their most confidential data to healthcare professionals and must have confidence in its security and in the accuracy of the information returned to them. They rely on systems developed to the highest international standards and following data protection legislation for their personal data. This trust covers all interactions with digital health; from interrogating health databases to using online GP appointment systems, fitness wearables, diagnostic devices and EHR type applications. In parallel, health service managers and healthcare professionals must have confidence that eHealth systems will streamline processes, enable improved decision making through greater access to data and ultimately improve health service delivery. Patients must trust that sharing data will enable them to become partners in the development of their personalised healthcare plans.

Lastly, empowered people need to have the skills to access and use eHealth systems appropriately and effectively. General national digital literacy schemes are aimed at getting the population 'online' but do not necessarily focus on eHealth technology, systems, or apps. In practice, the healthcare professional or caregiver instructs their patients or clients to use new technologies, systems, or online processes. eHealth systems and online platforms that are based on universal design principles with the user in mind will increase the likelihood of adoption, and increasingly, technology companies and software developers see the commercial benefits of involving patients and healthcare professionals as co-creators of the health systems they will ultimately use. Agreed standards increase interoperability between disparate health systems across Europe, and competence frameworks can be used as a common language to describe a minimum e-skills competence needed by healthcare professionals to exploit such systems. Common, agreed, 'system' and 'skills' standards facilitate cross-border sharing of data and ultimately improve the quality of healthcare that European citizens can expect.

Achieving an 'empowered people' is an ambitious objective, requiring a supporting system that aligns government, industry, academia, and society around a common vision of integrated healthcare provision.

What needs to happen to obtain people's trust in eHealth services?

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 regulations, 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.

The Common eID strategy for eHealth shall leverage recent European regulations and create a holistic approach to eID in eHealth and related ICT services. The strategy 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 innovative use of health data supported by a future European roadmap for eHealth.

The digital identification is a transversal theme that passes through different areas at governmental and private services provider levels. The definition of a common strategy to digital identification related to the health sector could represent an important milestone that intends to converge efforts to achieve the correct identification of EU citizens in the cross-border context in Europe.

Table 5 – People Empowerment and Access on mHealth, use of data and digital literacy

Telehealth and mHealth		
A separate issue for physicians when it comes to mHealth and telehealth is the concern over increasing workload. This illustrates a need to integrate such tools with existing work processes and ensure interoperability. Such activities are still largely lacking, particularly for mHealth.	Telehealth, and particularly mHealth suffer from a lack of assessment and quality standards, which could, in turn, cause a lack of funding and reimbursement. Instituting more rigorous quality standards and assessment frameworks is therefore likely to contribute to overcoming a variety of issues, including user-centred, institutional and economic barriers.	Both mHealth and telehealth suffer from a lack of enabling healthcare policy, as well as a lack of legislation and regulation, stakeholder willingness and clear priorities.
Patient Access and Use of Data		
People are motivated to access and use their online data when it is user-	The main factor regarding ability for people to access and use online health data is	Once people are actually accessing and using their online health data, it is

friendly and understandable (considering the different patient groups) and when trust, security and privacy issues are taken care of.	having digital knowledge/ competence. Even though a Member State is offering digital solutions, people can miss out because of low digital health literacy.	expected that they achieve a deeper understanding of their health condition, which can impact self-management. Raising awareness and understanding are very important factors in this process.
Digital Health literacy		
Healthcare professionals and the social environment are important motivators in the process of increasing digital health literacy and can function as coaches or as a support system.	To increase the opportunity, people need to be provided with online access to useful information anytime, anywhere and from any device. To increase the ability and motivation, information and education are given as important factors.	The most mentioned category for both barriers and enablers for digital health literacy is the user-centred category. The most-reported enablers are training and education which should be accessible for everyone at any place and any time; the support of healthcare professionals; and having a national digital health literacy agency.

3.2 eSkills for Professionals

'Common standards or frameworks can be exploited as part of a structured methodology to develop the eSkills necessary to support eHealth'

An ambitious approach is needed to set out a vision for clinical breakthroughs, will be facilitated and expedited by allied developments in governance, facilities, modes and locations of care, all underpinned by highly skilled professionals in all healthcare roles. e-Skills will be embedded in general education and competence measures, and no longer considered an additional area for focus.

However, a practical set of recommendations is presented alongside the sustainability vision. These will encompass steps to ensure this integration of e-skills into general training of all healthcare professionals, and benchmark basic competences against agreed standards. In line with research and best practice proposals for the development of high-level digital skills for all professionals, several scenarios could be considered:

E-SKILLS

The European Commission and the Member States should take steps to ensure that eHealth is part of the curricula of healthcare professionals.

Supporting digital skills of the health workforce is even more needed in the view of the constant changing nature of healthcare systems and healthcare delivery.

eHealth Stakeholder Group

- A digital skills framework to be identified, modified, or created as the baseline standard to benchmark the e-skills development of all healthcare professionals in Europe.
- A minimum set of learning objectives to be included in all medical curricula, based on standardised competences from the framework.
- A set of occupational qualification standards to be developed for the wide range of roles in healthcare.
- A recognised continuing professional development (CPD) process to be implemented to plan appropriate educational interventions.
- Expansion of the professional experience and clinical expertise with a mobility programme, validated by transparent competence indicators.

These scenarios encompass a broad ecosystem of stakeholders, with the sustainability of the healthcare system assured with a consolidated and uniform approach to e-skills development.

A professional approach is needed to bring this to fruition, and a goal-oriented, aspirational strategy employed. Recommendations from D6.3, eSkills for Professionals[23], provide a sound starting point:

- Online tool to capture e-skills competence within the health workforce.
- A deeper exploration of the use of competence frameworks in developing e-skills in the health workforce (adapted to professionals' domain and role).
- The practical implementation of competence frameworks in assisting the development of such curricula could be taken up by health science educational institutions as soon as possible, in tandem with professional workforce upskilling initiatives.
- Inclusion of universities and healthcare institutions in the process of designing educational strategies and the promotion of continuous professional development.
- Further research and/or exchanging best practice between Member States/countries, which could be of benefit.

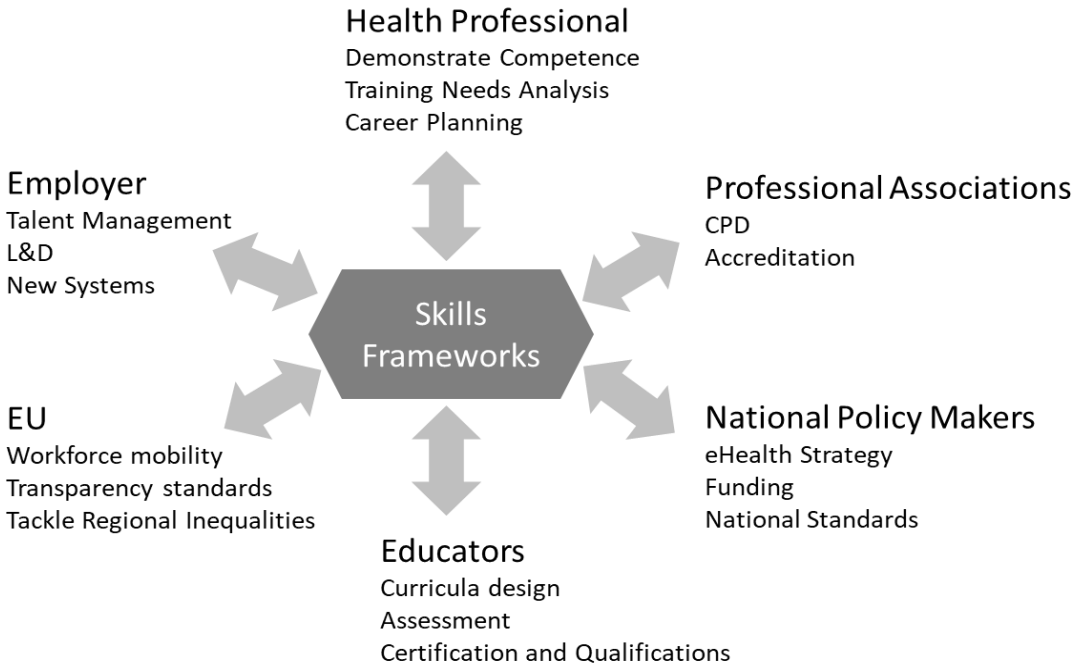

Figure 15 - eSkills framework for specific roles

[23] To see D6.3 – e-Skills for Professionals recommendation, go to: https://ec.europa.eu/health/sites/health/files/ehealth/docs/ev_20190611_co322_en.pdf

Another contributory resource will be existing national strategies and policy documents that have already been influenced by the eHealth Action culture of collaboration and sharing of best practice. The eHealth Network acknowledged its interest in structured, standards-based digital upskilling for eHealth professionals, and that professional competence is a key pillar in the European Data Strategy.

There is a global focus on improving the digital skills of healthcare professionals, but approaches vary from implementing prescribed curricula to taking a more experimental approach. Frameworks and standards in varying formats complement workforce development initiatives from specific and detailed expressions of multi-dimensional competency to higher level capability statement.

3.3 Interoperability (Electronic Health Record exchange format – EHRxF)

The access and sharing of Electronic Health Records (EHR) are very relevant to the patient treatment abroad and has captured the political interest of the Member States and the European Commission, so the Commission needs to prioritise policies to support Member State approaches[24]. This need comes up from the eHN[25] (May 2018), that strongly endorsed the creation of a working group about the EHRxF to manage and align standards on EHR. It drove a common set of standards that is needed for establish an EHRxF to achieve interoperability in health sector.

Some principles were defined in the group to support this demand and present a shared view about the EHRxF:

INTEROPERABILITY

Refers to the ability of technical systems to cooperate on a technical-syntactical, semantic and organisational level.

Technical and syntactical interoperability aims at the exchangeability of data over networks in a specific data format, so that sender and receiver can identify the same information units.

Semantic interoperability is intended to ensure that sender and receiver have a uniform and identical understanding of the meaning of the exchanged information and its context.

Organisational interoperability defines the social and legal framework in which, for example, the roles of the actors and their access and interaction authorisations are recorded.

[24] Commission Communication on enabling the digital transformation of health and care in the Digital Single Market; empowering citizens and building a healthier society (2018). https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:52018DC0233&from=EN

[25] eHN's 13th meeting minutes (2018) https://ec.europa.eu/health/sites/health/files/ehealth/docs/ev_20180515_mi_en.pdf

COMMISSION RECOMMENDATION EHRXF (2019)

The Recommendation sets out a framework for the further development of a European EHR exchange format that will enable citizens to securely access and exchange their health data across borders in the EU.

The Recommendation underlines that moving towards interoperable EHRs in the EU should go hand in hand with ensuring data protection and security, in line with the GDPR, and full compliance with the cybersecurity framework.

A joint coordination process involving the Member States and the Commission is envisaged in order to support the further elaboration of the European EHR exchange format.

This process will also engage all relevant stakeholders, including healthcare professional organisations, national competence centres, industry actors and patients groups, as well as other Union and national authorities.

- No change (or minimal) to national systems is mandated. However, some changes should be necessary to implement the EHRxF among the Member States.
- Based on widely used common frameworks/specifications to interface.

After the end of work in the EHRxF group, the Commission published a Recommendation[26] on EHRxF, that covers the aspects discussed by the group and supports new initiatives with similar scope. The achievement of a common EHRxF in EU represents a huge step towards EU eHealth interoperability.

This recommendation was subsequently used by the CSS to support the correspondence of the five eHealth domains that should be present in the EHRxF. The connection between these initiatives ensures the continuity of work and intends to leverage the development of the eHealth interoperability among EU Member States.

Background

This Recommendation builds on several initiatives and projects put forward by the Commission and the Member States in their efforts to facilitate the cross-border exchange of health data in the EU.

Work on technical specifications for health data exchange has been carried out under the eHDSI, which is implemented by the Commission and the Member States through the Connecting Europe Facility (CEF) Programme[27]. The eHDSI connects eHealth national contact points allowing them to exchange two sets of health data: patient summaries and ePrescriptions.

[26] Commission Recommendation on a European Electronic Health Record exchange format (2019). https://ec.europa.eu/digital-single-market/en/news/recommendation-european-electronic-health-record-exchange-format

[27] For more information, go to https://ec.europa.eu/inea/en/connecting-europe-facility/cef-telecom/apply-funding/2020-ehealth

The first exchanges took place between Estonia and Finland in January 2019. 22 Members States are expected to exchange such health information by 2021. This Recommendation builds on and contributes to the further development of eHDSI, by facilitating the EU-wide interoperability and exchange of comprehensive electronic health records.

Important groundwork on the interoperability of EHRs was carried out in the framework of the project Smart Open Services for European Patients (epSOS), a large-scale pilot funded by the Commission between 2008-2014. epSOS tested the cross-border sharing of patient summaries and ePrescriptions, and with the support of the EXPAND project paved the way for the roll out of the eHDSI. Several other projects supported by the Commission, such as Antilope and HITCH, have also been instrumental to the development of the Refined eHealth European Interoperability Framework (ReEIF)[28].

Health information on specific cases can currently be exchanged across borders through one of the 24 thematic European Reference Networks (ERNs). These networks enable virtual panels of clinicians to diagnose and treat patients suffering from rare, complex, and low prevalence diseases. About 900 highly specialised healthcare units located in around 300 hospitals of 25 Member States (plus Norway) take part in the ERNs. Individuals do not have direct access to these networks. Healthcare providers refer patients to the relevant Network, with their consent and in accordance with the national health systems rules.

The WHO report[29] declares: 'A Roadmap for Cross Border Data Flows: Future-Proofing Readiness and Cooperation in the New Data Economy' 2020, Section: Prioritise connectivity, technical interoperability, data portability and data provenance:

WHO Policy Recommendations
✓ Governments should prioritise the development of connectivity infrastructure as a prerequisite to building a local data economy.
✓ Governments should collaborate to develop cross-border data sharing agreements that support similar minimum levels of national and international bandwidth and/or coordinate spectrum usage in order to minimise costs, increase reliability and enhance redundancy (optical fibres, satellite earth stations, IXPs, etc.)
✓ More ambitious like-minded countries should consider common policies regarding the deployment of 5G networks, as well as coordinating access to high-performance computing in their data sharing agreements.
✓ The use of open or standard application programming interfaces (APIs) for data sharing should be encouraged by governments to improve technical interoperability. However,

[28] eHealth Network (2015) Refined eHealth European Interoperability Framework. For more information, go to: https://ec.europa.eu/health//sites/health/files/ehealth/docs/ev_20151123_co03_en.pdf
[29] For the full report, go to : http://www3.weforum.org/docs/WEF_A_Roadmap_for_Cross_Border_Data_Flows_2020.pdf

governments should stop short of mandating specific standards that could hinder novel approaches.

- ✓ Data portability at the B2B level should be facilitated both domestically and internationally, particularly with a view to supporting start-ups and SMEs.
- ✓ Cross-border agreements should contain reference to data provenance and place the onus on data publishers to ensure the integrity of data before it crosses borders to avoid bad outcomes for machine learning or contaminated data lakes.

3.4 Infrastructure

The Connecting Europe Facility (CEF) supports trans-European networks and infrastructures in the sectors of transport, telecommunications and energy. The European Commission has proposed a series of guidelines for telecommunications covering the objectives and priorities for Digital Service Infrastructures (DSIs) and broadband networks. In the current programming period CEF Telecom has a budget of approximately 1 billion euro, out of which 870 million euro are dedicated to DSIs delivering networked cross-border services for citizens, businesses and public administrations. The rest is for connectivity networks. For the 2021-2027 period the Commission proposed a budget of 3 billion euro, mostly focused on connectivity aspects, still subject to an agreement on the overall long-term EU budget.

CEF supports multiple DSI projects which contribute to improvements in the daily lives of Europeans through digital inclusion, the connectivity and interoperability of European digital services, and the development of a Digital Single Market.

Sector-specific DSIs deploy complex trans-European digital services based upon mature technical and organisational solutions in diverse areas. The DSIs known as building blocks provide basic and re-usable digital services. Building blocks can be integrated into other DSI and IT projects and can be combined with each other.

Sector-specific DSIs supported so far cover, for example, the areas of cybersecurity, eHealth, and online dispute resolution. The current building block DSIs include: eIdentification, eSignature, eInvoicing, eDelivery, and Automated Translation.

Within CEF DSI projects, the eHDSI is an open interoperability architecture that supports the cross-border exchange of Patient Summaries and ePrescriptions for the purpose of supporting unplanned and emergency care abroad.

INFRASTRUCTURE

Health data infrastructures are information technology (IT) infrastructures used for storage, access, and analysis of health data.

They typically support research activities (e.g. at research performing organisations such as pharmaceutical companies) or healthcare activities (e.g. at medical practices and hospitals). Whereas cost-optimisation has driven a major shift towards public or private cloud-based infrastructures, for security reasons many health data remain in traditional, in-house datacentres.

This is especially true of data generated during healthcare delivery, in which handling of personally identifiable information (PII) is the norm.

White Paper on: "Better Utilisation of Data Infrastructures to Support Secondary Uses of Health Data"

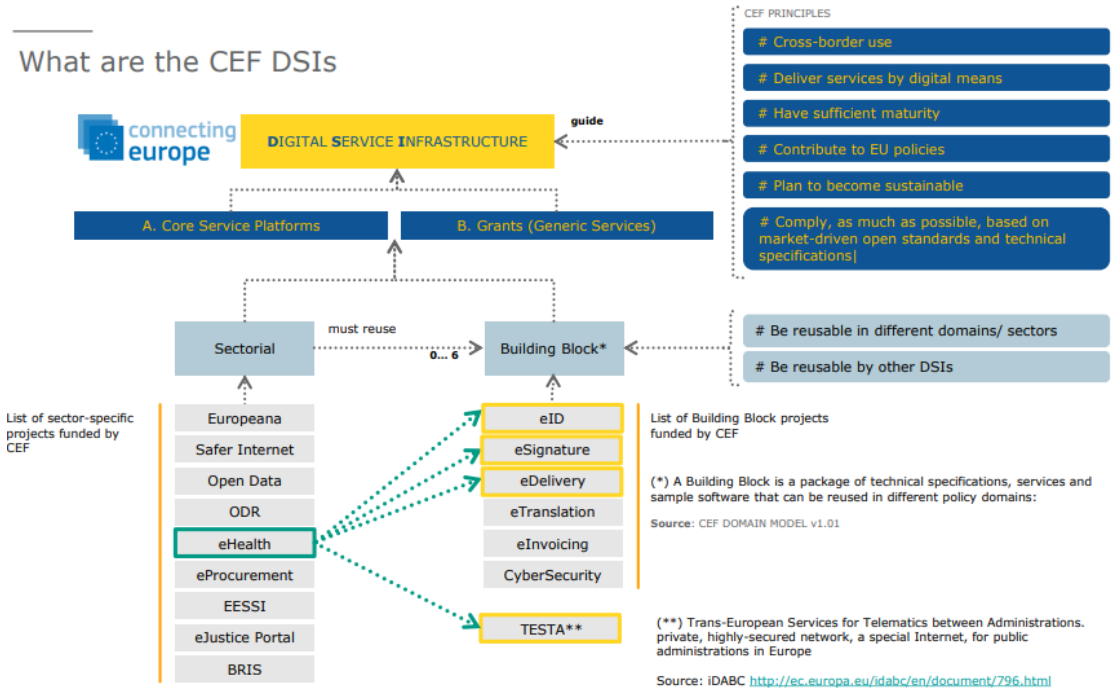

Figure 16 – CEF DSI relationships and building blocks

Many EU citizens travel to or work in another Member State. However, their clinical information is not always accessible in the Member States where citizens may need healthcare. The increased mobility of citizens coupled with the advancements of digital technologies requires both health policies and health systems across the EU to be more and more interconnected, more interoperable. The eHealth DSI lays a set of services and the ICT infrastructure enables cross-border healthcare services. Two of the first uses cases that have been identified to be deployed by Member States partners are:

- Patient Summary: provides access to a healthcare professional to verified key health data of a patient during an unplanned care encounter while abroad;
- ePrescription: enables patients to be dispensed medication treatment while abroad equivalent to what they would receive in their home country;

Furthermore, in line with the EEHRxF Recommendation, and operationalised by the X-eHealth[30] project, the following health information domains are expected to complement the existing eHDSI use cases in the near future:

Medical Images | Laboratory Results | Discharge Letters |Rare Diseases

[30] For more information, go to the official website of the X-eHealth project: https://www.x-ehealth.eu/

3.5 Cybersecurity/Security

When discussing about cybersecurity/security, priority objectives are:

- **Integrity:** The original content of documents – regardless of where they come from, what they are used for or where they are shown – must always be the same and changes of the content must be consistent and traceable. From the physical perspective these requirements can be achieved by using mechanisms that protect the transmission of documents and guarantee both entities (sender and requestor/receiver) unchanged content. This protection must be included in the basic infrastructure of communication interfaces between different systems.

- **Authenticity**: When health-related data are modified or exchanged, both sides (sender and requestor/receiver) involved in such a transaction must be assured that all entities in the communication process (in terms of data transfer) are authorised to execute the designated process steps. The technical aspects such as non-repudiation, auditing of 'who requested/changed what', etc. are under the conceptual responsibility of Security Service Specification.

- **Confidentiality**: From the security point of view the physical layer of this issue can be satisfied by usage of encryption methodologies which prevent data from being humanly readable. Appropriate infrastructures and mechanisms have to be established by the countries themselves, but the requirements are defined within Security Policies.

- **Availability**: authorised users have access to information and associated assets when required.

eHDSI SECURITY OBJECTIVES

The objective of the security policy is to establish the basic security provisions that must be satisfied in order to ensure the security of data and system continuity and to prevent and minimise the impact of security incidents by implementing a stable, reliable and secure infrastructure.

- To make actors sensitive to the operated means of protection and the risks which they cover
- To create a general security framework adapted to the eHealth DSI information system needs
- To elaborate and put in place those measures, instructions and procedures
- To enhance user and patient trust in the information system
- To ensure that the information system in place respects national and European legislation in force on privacy and data protection

- **Accountability/Non-Repudiation (Liability)**: each communication and each data transaction can be tracked back to a certain originator in a traceable chain of activities.

The eHAction Data and Systems Security Guide (D7.3)[31] is intended to support healthcare providers in designing and implementing information security systems that can protect the healthcare providers' critical information infrastructure and information resources. This is pursued through supporting them to navigate the available guidance documents that are created collaboratively and maintained at international level. Such decisions are typically shared with the higher management executives in the hospitals responsible for procurement of equipment, ICT systems and related services. Furthermore, it is necessary that every stakeholder involved in eHealth programmes is aware of the cybersecurity of the systems they work on. It could be thanks to training or a webinar.

Implementation of Information Security Management Systems

Management Responsibility: In order to introduce a sustainable information security management system in any healthcare organisation, it is advisable to introduce certain roles in the organisation structure or enhance current roles with new responsibilities and authority. Information security is also an enabler, particularly in the digital transformation of healthcare. The possibility of introducing further automation and cost-effective processes (anything from surgical robots to remote patient care, patient workflows and administration of medicine) needs assurances regarding patient safety and consequently, a high level of information and systems security.

- Appoint a Chief Information Security Officer (CISO) and a cybersecurity team with an appropriate skill mix to cover all critical areas of operation who should be able to develop a suitable Cybersecurity Strategy and co-ordinate the development and implementation of an Information Security Management System;
- Introduce, amongst the team, roles for an Information Security Architect and an Information Security Manager;
- Encourage cooperation of clinical, legal and security professionals; it is through their collective skills, co-creation and alignment that the most effective, efficient and broadly acceptable strategies and measures may be developed.

Implementation: Information security is a complex topic and, in structured environments such as healthcare organisations, it may take considerable time to develop and implement. Challenges related to implementing information security are not only technical; they also involve changes in processes and the behaviour of all participating parties, including staff, vendors and even patients. With this in mind, it is recommended to look at information security and its implementation in terms of a continuous effort and adopt a maturity model

[31] To see D7.3 documents, go to: http://ehaction.eu/wp7-overcoming-implementation-challenges/

enabling assessment of the current level of achievement in various areas related to information security and the planning of future advancement, development priorities and goals. Within the EU, the NIS Cooperation Group and ENISA have been tasked with the elaboration of guidance and support of operators of essential services (OES). ISO and its national counterparts have also dedicated a substantial amount of effort in producing information security standards. Most methods share a common basic approach based on a small number of key principles:

- Know your assets: what data, devices, systems and processes related to your information and its processing are in place, what their value or importance is for the organisation and key stakeholders for the provisioning of healthcare, such as patients, staff, management, owners, authorities, etc.;
- Identify and manage risks: what harm can be done (or just happen) to your assets, what are the root causes, how probable it is, what you can do in terms of either preventing it from happening or minimising its impact);
- Implement appropriate and proportionate to the risk posed, technical and organisational measures to manage the risks posed to the security of network and information systems and having regard of the state of the art;
- Document and be consistent: implement a formal system to constantly monitor your assets and risks, increase awareness among all involved, improve your procedures and learn from mistakes.

In their effort to design and implement appropriate network and information security measures, healthcare providers may find valuable guidance in the Cooperation Group reference document [32]on security measures for Operators of Essential Services, published in 2018. The document provides a synthesis of common approaches to the security measures today in Member States and provides guidance on elaborating such measures, organised under four main cybersecurity domains: governance and ecosystem, protection, defence, resilience.

In addition to this proposed framework used for the identification of suitable measures, the ENISA 'Procurement Guidelines for Cybersecurity in Hospitals'[33] provides a comprehensive taxonomy of healthcare threats and lists the most common risks per type of asset subject to procurement in a hospital. The report offers cybersecurity guidelines when procuring services, products and infrastructure. It addresses primarily hospital procurement officers and CISOs/CIOs, providing the context for addressing cybersecurity in procurement.

[32] https://ec.europa.eu/information_society/newsroom/image/document/2018-30/reference_document_security_measures_0040C183-FF20-ECC4-A3D11FA2A80DAAC6_53643.pdf
[33] https://www.enisa.europa.eu/publications/good-practices-for-the-security-of-healthcare-services

In the WHO report[34] 'A Roadmap for Cross Border Data Flows: Future-Proofing Readiness and Cooperation in the New Data Economy' 2020, section 'Prioritise cybersecurity', the policy recommendations are:

WHO Policy Recommendations
✓ Governments should endorse the concept of cybersecurity as a fundamental condition of doing business in an economy.
✓ Governments should enact robust data security legislation to position themselves as trustworthy data transfer destinations, including data security requirements on public- and private-sector organisations and data security breach notification requirements.
✓ Governments should create, support and respect robust data security infrastructures and refrain from demanding data access without due process or technology back-door systems.
✓ Cross-border data sharing agreements between governments should in turn mandate data security measures.
✓ Cross-border data sharing agreements should contain an anti-snooping clause, i.e. a clause that forbids governments and connectivity providers from viewing the data being transmitted across borders, except in certain prescribed instances.
✓ A clear cooperation mechanism between authorities needs to be established to enhance trust.

[34] For the full report, go to:
http://www3.weforum.org/docs/WEF_A_Roadmap_for_Cross_Border_Data_Flows_2020.pdf

3.6 Enterprise Architecture (eHealth reference architecture)

This initiative was proposed to support the implementation of a health reference architecture (eHRA) on the Member States, in alignment with the eGovERA[35] framework.

In this regard, eHAction cooperation works towards delivering a *proposal for adopting a European eHealth Reference Architecture (D8.2.3)*[36]. This proposal presents a set of high-level principles within a framework aimed at providing the eHealth Network and the associated Member States with an insightful planning tool that offers an overview of eHealth services within the Member States and support them in the identification of different digital public services and architectural building blocks that are needed to release a given digital business capability.

The main use case defined by health eGovERA is to enable the Member States to identify the financial resources available to invest in each digital business capability. Therefore, the Member State will be able to clearly specify the solution to the problem that it has to address to increase its maturity in the health domain.

The architecture is distributed within several domains, which can be presented as layers, built upon a robust health information system, standardised interchange platform of patient data, through network infrastructure, hardware equipment, and software solutions. Interactions between those domains need to be based on an interoperable and secured architecture.

The view of architecture domains as layers can be presented thus:

Enterprise Architecture

An Enterprise Architecture (EA) establishes the organisation-wide roadmap to achieve the mission through optimal performance of its core functions within an efficient information technology (IT) environment. Enterprise architectures are blueprints; they define the organisation's current (baseline) and desired (target) settings, and specify the mechanisms to transform the enterprise to achieve target outcomes systematically.

It can be seen as a set of principles, rules, standards, and guidelines, expressing and visualising a vision and implementing concepts. Describing the organisation through a set of independent, non-redundant artefacts, explaining how these deliverables interrelate with each other and developing a set of prioritised, aligned initiatives and roadmaps to understand the organisation, communicate this understanding to stakeholders, and move the team forward to its desired state.

[35] For more information, go to: https://joinup.ec.europa.eu/collection/european-interoperability-reference-architecture-eira/solution/egovera
[36] For more information, consult the eHAction's deliverable 8.2.3. - http://ehaction.eu/

- Environment (the external entities and activities monitored, supported or directed by the business);
- Business Layer (business functions offering services to each other and to external entities);
- Data Layer (business information and other valuable stored data);
- Information System Layer (business applications offering information services to each other and to business functions);Technology Layer (generic hardware, network and platform applications offering platform services to each other and to business applications).

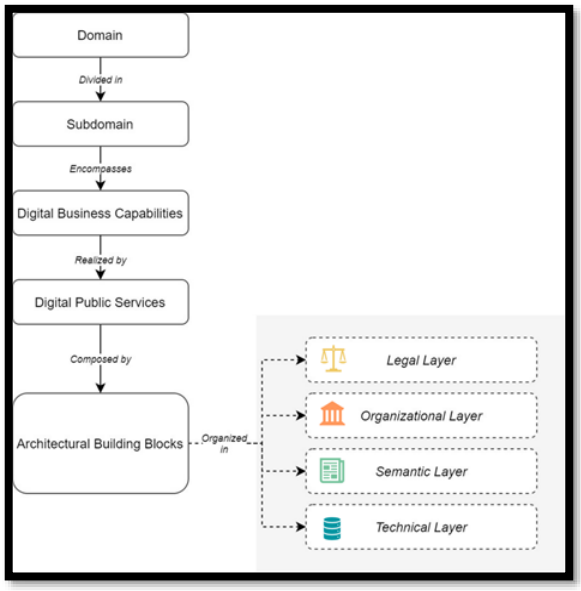

Figure 17 – Architectural principles from the eHRA.

Each layer delegates work to the layer below. In each layer, the components, the processes and the services can be defined at a coarse-grained level and decomposed into finer-grained components, processes and services.

eHAction's perspective on eHRA

Most of the solutions, initiatives and projects developed in the eHealth environment depend on each other to function properly, or only make total sense when they are interconnected; as so, the eHRA document was aimed to promote the importance of outlining a Reference Architecture for eHealth based on the Enterprise Architecture (EA) framework resulting in higher eHealth interoperability so as to strengthen the building blocks related to health services.

This comprises of setting the principles for using EA to help eHealth programmes to reduce duplication, increase the use of shared services, advance a common planning of eHealth synergies, close performance gaps, promote the empowerment of European eHealth strategy and goals, as well as to support the Member States to request EU funds.

A strategic alignment and integration of the vast services that have been developed may not meet continuity, anticipate problems or be future-ready if a holistic architecture for eHealth. It could support the current and new projects in order to ensure a continuity of the important activities that intends to improve and support the eHealth environment among the EU Member States.

3.7 Coordination and Governance Model

Governance models and recommendations

The European Commission's Joint Research Centre (JRC), together with the French Université Paris-Est (ENPC, LATTS) Cite Descartes, conducted the study 'Policy-making in science and technology policies: the "OECD model" unveiled', L. Henriques and P. Larédo[37]; this was a study on the Organisation for Economic Co-operation and Development (OECD)'s approach towards research and development policies in the 1960s. The study explains OECD's analysis of the national reviews conducted, identifying five central functions that organise the policy process and its implementation.

The study, in section 4, Functions and 'implementation structures', states: 'The model is simple and anchored in the overall government policy cycle. Five main functions were identified:

1) horizontal coordination and advising,

2) planning and budgeting,

3) priority-setting,

4) resources allocation, and

5) administration.

Associated to each of these functions, the model defines an implementation structure, with particular characteristics to serve the specificities of the research sector but sufficiently flexible to fit in the overall framework of a policy-making cycle and to correspond to the rationale targeted.'

Governance

Governance refers to the different ways that organisations, institutions, businesses, and governments manage their affairs. Governance is the act of governing, and thus involves the application of laws and regulations, but also of customs, ethical standards and norms. Good governance means that affairs are managed well, not that the laws, regulations or norms are themselves necessarily "good".

Global governance refers to the way in which global affairs are managed. As there is no global government, global governance typically involves a range of actors including states, as well as regional and international organisations. However, a single organisation may nominally be given the lead role on an issue, for example the World Trade Organisation in world trade affairs. Thus global governance is thought to be an international process of consensus-forming which generates guidelines and agreements that affect national governments and international corporations.

World Health Organization

[37] "Policy-making in science and technology policies: the 'OECD model' unveiled", L. Henriques and P. Larédo https://ifris.org/wp-content/blogs.dir/1/files/2014/10/Henriques-Laredo-2013-OECD-policymaking-model.pdf

State of the art for cross-border exchanges

The eHDSI is the initial deployment and operation of services for cross-border health data exchange under the CEF. The core services are set up and deployed by the European Commission using its own resources and through calls for tender financed by CEF. The generic services are funded from the national sources and supported by grants from the CEF through a call for proposals. The grant agreements for generic services are managed by the Innovation and Networking Executive Agency (INEA).

Figure 18 – Governance: A system of checks, balances and established norms

… ranging from formal institutions to informal processes, governing the interactions between major entities through to the expectations and performance of individuals.

The eHDSI needs a robust governance model to succeed as a health policy and initial deployment and operation of service. The governance also needs to assure an overall coherence of the European Interoperability ecosystem which is being built. epSOS was a large-scale research and development project under 7th Framework Programme, with an appropriate project organisation.

The current cross-border exchanges are based on eHDSI governance[38] (see Table 6):

Table 6 – eHDSI governance bodies, roles and eHN supportive instrument

eHDSI Governance Bodies

[38] To know more about the eHDSI Governance Model, go to: https://ec.europa.eu/cefdigital/wiki/download/attachments/35210447/ev_20161121_co06_en.pdf

Bodies	Responsible	Role (tasks or work perimeter)
eHealth Member States Expert Group (eHMSEG)	Managers responsible for National Contact Points for eHealth, nominated by participating Member States	➢ is the body where Member States implementing NCPeHs cooperate and work together closely to make their NCPeHs interoperable
eHDSI Communities or Task Forces	- Operations Community - Semantic Community - Technical Community (OpenNCP)	➢ are the communities in charge of eHDSI operational tasks responsible for its development ➢ each community has its own specialty: technical, operations, semantic, legal, etc.
eHDSI Operational Management Board (eHOMB)	European Commission - DG SANTE (B3, A4), CNECT (H3), DIGIT Chair and co-chairs of eHMSEG	➢ the different Directorates-General of the European Commission (such as DG CONNECT, DG GROWTH, DG SANTE, etc.) come together in this body ➢ the chair and co-chair of eHMSEG participate in the eHOMB ➢ approves the changes of the eHDSI
The DSI Solution provider	European Commission - SANTE (A4), DIGIT (A3, B4)	➢ is responsible for the technical solution provided by the European Commission to all Member States
eHN and supportive instrument		
eHealth Network	eHealth Policy Owner	➢ is the 'supreme body' and therefore the highest-level decision-making body ➢ has the right to adopt non-binding guidelines, frameworks, etc. for use by Member States
eHAction (Joint Action supporting the eHN)	Consortium composed by representatives from 30 European countries in close collaboration with the European Commission, DG SANTE, DG CONNECT, DG DIGIT and other EU stakeholders.	➢ provides operational support to the eHN

Although this model has its pros, such as opportunities to validate work, simplified collaboration with the Commission, and services provided by the Commission, it can be burdensome by its difficulty to adapt to new considerations over the years.

On the same approach, the eHDSI is a move from a project to deployment phase of cross-border exchange of health data (CBeHIS). A new governance model is needed, which has strong steering elements addressing both policy and technical issues. In this regard, particular emphasis should be given to the Governance model for the eHealth Digital Service Infrastructure and eHealth Network during the CEF funding, considering that the last update was in 2016[39].

Governance model for the eHDSI during CEF funding (2016)

The governance model presented […] stems from the general CEF governance model. This […] adds the eHealth policy structures and adapts the CEF model to the specificities of the health sector considering existing actors, structures and bodies.

The eHDSI governance model consists of bodies dealing with:

- Policy governance (eHealth Policy Owner, Member States Policy Support);
- IT governance (DSI Owner and Co-owner, Operational Management Board, Member States Expert Group, DSI Solution Provider and Member States Operational Support);
- Stakeholder liaison (DSI community, standardisation bodies, patients, professionals, industry and other stakeholders);
- Secretariat functions (across above-mentioned bodies).

The governance model seeks not to set up new structures but associate the eHDSI tasks to existing bodies to the extent possible.

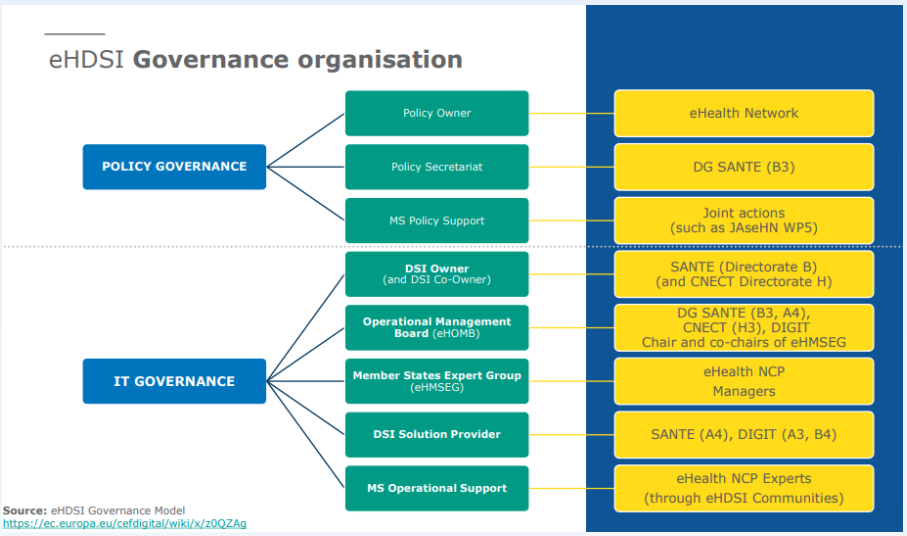

Figure 19 – eHDSI governance model

[39] For the full document, go to: https://ec.europa.eu/health/sites/health/files/ehealth/docs/ev_20161121_co06_en.pdf

Afterwards, other governance models could be investigated to maintain the collaboration without support from a third party such as a Community of Practice (CoP), Global Observatories, Health in All Policies (HiAP) approaches. All those models are investigated in the recommendations section.

The main purpose of a CoP's style model is to develop its participants/members capabilities to build and share knowledge; in the case of the eHAction: aiming to reflect digital health importance as a complementary resource for public health and services, as well as embracing change and contributing to better healthcare in Europe. The practice mentioned in our use case might be referred as: 'increasing the sustainability and effectiveness of health systems, enabling personalised care and empowering people is what we are striving for.'

Table 7 - Extract table from a snapshot comparison, 'Communities of Practice: The Organisational Frontier', Harvard Business Review

	What's the purpose?	What holds it together?	How long does it last?
Community of Practice	To develop members' capabilities; to build and exchange knowledge.	Passion, commitment and identification from the group's expertise.	As long as there is interest in maintaining the group.
Formal work group	To deliver a product or service.	Job requirements and common goals.	Until the next reorganisation.
Project team	To accomplish a specific task.	The project's milestones and goals.	Until the project has been completed.
Informal network	To collect and pass on information.	Mutual needs.	As long as people have a reason to connect.

Communities are often subdivided by geographic region (in the EU's perspective, typically Member States) but Communities of Practice are organised by subject matter (i.e. semantic, operations, strategy, and research). One of the main success factors of a Community of Practice is having a core of organisational participants whose passion for the topic energises the community; where intellectual and social leadership is shared. Also, participants should have a strong sense of identity tied to the community, being encouraged to take part actively at all levels.

Coordination, sustainable and efficient framework

Chapter 5 '*policy coordination and the institutional framework*'[40] from the *Cambridge Economic Policy Review Volume 8 No 2* (1982) states that the many interactions which occur between different spatial policies and between these policies and national sectoral policies mean that there needs to be a high degree of coordination if all the different objectives are to be secured effectively.

> **Coordination / Cooperation**
>
> International policy cooperation is the adoption of institutions and procedures by which policymakers can inform each other of their objectives and share data.
>
> "The European Semester provides a framework for the coordination of economic policies across the European Union. It allows EU countries to discuss their economic and budget plans and monitor progress at specific times throughout the year."
>
> European Commission Official Website

The process of coordination involves consultation, bargaining, compromise and agreement between departments on the discharge of their functional responsibilities and subsequently on the implementation, monitoring and evaluation of the policies pursued. Inefficient coordination is likely to lead to ineffective and conflicting policies, wasteful expenditure and failure to take action at all on occasion. Efficient horizontal coordination across different government departments requires agreement on a common set of aims and on the spatial impact of different sectoral policies as well as a recognition of the trade-offs between the different objectives of each department, including spatial policy objectives. However, the problems associated with the coordination of spatial and sectoral policies between different central government departments are compounded by the need for vertical coordination between central and local government.

To help in fulfilling this sustainable coordination, the OECD has developed guidance on good institutional practices to support Policy Coherence for Sustainable Development (PCSD). Drawing on the OECD's experiences and lessons learnt, the guidance offers recommendations to support governments and stakeholders to enhance PCSD at the national level. Together with this set of recommendations, a list of tools and methodologies to enhance policy coherence and coordination are available for further framework exploitation.

The Policy Coherence for Sustainable Development (PCSD) online toolkit provides practical guidance, self-assessment checklists, good practice examples and tools to analyse, enhance and track progress on policy coherence in the implementation of the Sustainable Development Goals (SDGs).

[40] Extract document from cpes, Chapter 5 Policy coordination and the institutional framework: http://cpes.org.uk/om/files/original/4060880da6e7d14800062110195fff19.pdf

It aims to guide decision-makers and practitioners in:

- Conducting analysis to improve understanding on the interactions among SDGs and targets (synergies and trade-offs) and their implications;
- Strengthening existing institutional mechanisms which can support a more coherent and integrated implementation of the SDGs;
- Identifying options for monitoring, assessing and reporting progress on policy coherence for sustainable development.

The analytical framework is based on the report 'Better Policies for Sustainable Development 2016'[41].

A Europe fit for the digital age

Within six priorities for 2019-24, the European Commission puts in place new digital methods and digital diplomacy tools to enhance policy coordination and cooperation with all Member State stakeholders. Ursula von der Leyen, President of the European Commission, declared, in the Political Guidelines for 2024[42]: 'I believe this will make the institution more agile and flexible, as well as more transparent in the way it works. This will also help instil a new and more inclusive leadership and work culture, with fewer hierarchies and more cooperation. This will help us change our mindset and embrace the future.'

The Commission is determined to make this Europe's 'Digital Decade'. Europe must now strengthen its digital sovereignty and set standards, rather than following those of others – with a clear focus on data, technology, and infrastructure. The EU's digital strategy aims to make this transformation work for people and businesses, while helping to achieve its target of a climate-neutral Europe by 2050.

[41] OECD (2016), Better Policies for Sustainable Development 2016 : A New Framework for Policy Coherence, Éditions OCDE, Paris, https://doi.org/10.1787/9789264256996-en
[42] Political Guidelines For The Next European Commission 2019-2024: https://ec.europa.eu/info/sites/info/files/political-guidelines-next-commission_en_0.pdf

3.8 Innovation (common semantic strategy)

The European Commission has acknowledged the need for eHealth interoperability for more than a decade. In May 2018, the eHN[43] discussed the need for a common semantic approach towards standardised exchange of health information in the European Union.

In November 2018, the eHN endorsed the work of the Working Group on common semantic strategy (CSS) created within the eHAction Joint Action to come up with a solid proposal for a five-year strategy, that was discussed and approved in November 2019. To support the development of such strategy, the eHN created the *eHN Subgroup on Semantics.* In regard, one can say initiatives like the CSS should be encouraged among the EU Member States, so as to achieve cross-border interoperability. The document D8.2.2 – *Common Semantic Strategy for Health in the European Union*[44] – aims to set a foundation for the development of a CSS for Health in the EU, whilst addressing some of the needs to be sorted out, and possible steps to achieve a solid basis within five years, 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 the semantic strategy is a matter for at least 10 years and, once established, needs ongoing maintenance and evaluation.

Due to the lack of regulations 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. Therefore, the decision on which norm to adopt has been taken in Member States/countries according to their exchange and analysis needs, and not according to any alignment with other European authorities. This document elaborated on a set of goals, specific value proposition within each use case

Innovation in (e)Health

The health sector today faces the need to use technology to modernise existing systems and services, or to create totally new ones, that can fully connect and interoperate with others, nationally and in cross-border settings.

A common semantic strategy will ensure that information exchanged at the cross-border level, between countries, will contain accurate information without loss of content and meaning, thus allowing better treatment and higher precision in healthcare outcomes.

Innovation (or better harmonisation) in semantics would create bigger opportunities for the European health ecosystem, promoting interoperability in health systems, resulting in a dynamic Digital Single Market for health.

[43] Summary minutes of the 13th Meeting of the eHealth Network (2018): https://ec.europa.eu/health/sites/health/files/ehealth/docs/ev_20180515_mi_en.pdf
[44] For the full document, go to: https://ec.europa.eu/health/sites/health/files/ehealth/docs/ev_20190611_co242_en.pdf

(Patient Summary, ePrescription/eDispensation, Laboratory Requests and Results, Medical Imaging and Reports, Hospital Discharge Reports) and the global semantic strategy to adopt.

The established Common Semantic Strategy for the standardised exchange of health information in the EU has been working towards facilitating convergence of interoperability standards. Such work builds upon EU policies, exchange flows between countries, conditions of availability of data, and the national standards that countries have adopted in the absence of European regulation. The governance process for semantic efforts is interlinked with the governance of projects and services in eHealth in Europe within the framework of the Joint Coordination Process.

Common Semantic Strategy for Europe:

In order to align to the Common Semantic Strategy by 2025, three strategic goals are set for the upcoming period of five years:

- ↘ 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 supporting at national level.
- ↘ Provide guidance to EU level decisions on health semantics: Establish mechanisms for capacity building in countries for consideration and use of Common Semantic Strategy, e.g. by fostering participation in the approval of EU semantic artefacts and projects.
- ↘ Ensure establishment and continuity on health semantics in the EU: Establish a Common Semantic Strategy Committee under the eHN mandate and gather one representative from each MS/C to participate in all CSS decisions.

To realise the CSS, there are four main architectural domains that need to be addressed:

- ✓ **Processes:** to achieve a common approach to health semantics interoperability in the EU, technical aspects also need to be considered. Processes need to be established to manage semantic queries from members.
- ✓ **Information:** The eHDSI project laid the ground for semantic assets in the field of exchange of PS and eP/eD. These assets will need to be expanded in the context of laboratory, imaging and discharge summary. Common ontology should play a significant role in the mutual understanding of key concepts in EU wide information sharing.

- ✓ **Services (applications):** The Services Architecture provides a framework focused on developing and/or implementing applications to fulfil the systems' requirements to achieve the quality necessary to meet the needs of semantic interoperability.
- ✓ **Technology:** The Technology Architecture provides the foundation that supports the applications, data and processes identified on the needed services. Technology is a key aspect in semantics. To achieve semantic interoperability, there is a need for an EU terminology server solution in which semantic artefacts, such as terminology catalogues, can be maintained.

3.9 Legal Challenges

With cross-border activities in healthcare increasing, patients tend to be treated in other Member States more often than in the past, especially since there are waiting lists in some countries. The considerable affordability of digital health solutions within the digital market provides healthcare professionals, hospitals and laboratories with instruments to best communicate and exchange health data for treatment and other purposes.

The data protection legislation adopted in May 2016 aims at making Europe fit for the digital age. More than 90% of Europeans say they want the same data protection rights across the EU and regardless of where their data is processed.

Exchanging health data cross-border legally is challenging as each country has its own legal framework. For the sake of European eHealth, adapting national legal frameworks to EU regulations is inevitable. And having EU regulations are key to advance on a common EU legal framework.

Achieving Trust in Health

The quality and success of healthcare depends on the relationship and cooperation between the healthcare professional and the patient. Cooperation is based on two principles:

→ information and trust

There is a big challenge ahead: finding a balanced way to ensure that information is shared and transferred while being protected reliably.

This has been proven in the past with legislation such as:

- **The General Data Protection Regulation** (GDPR[45]) applicable from 25 May 2018 in all Member States to harmonise data privacy legislation across Europe.

[45] https://gdpr-info.eu/

The Regulation is an essential step to strengthen individuals' fundamental rights in the digital age and facilitate business by clarifying rules for companies and public bodies in the digital single market. A single law will also do away with the current fragmentation in different national systems and unnecessary administrative burdens.

- **The Directive 2011/24/EU on the application of patients' rights in cross-border healthcare**[46] whose aim is to:

Set out the conditions under which a patient may travel to another EU country to receive safe and high-quality medical care and have the cost reimbursed by their own health insurance scheme, as well as to encourage cooperation between national healthcare systems.

- **The Data Protection Directive**, legal instrument Directive 95/46/EC:

The principles set out in the Data Protection Directive are aimed at the protection of fundamental rights and freedoms in the processing of personal data. The General Data Protection Regulation, adopted in April 2016, has superseded the Data Protection Directive and became enforceable on 25 May 2018.

- **The eIDAS Regulation (EU) N°910/2014**[47], on electronic identification and trust services for electronic transactions in the internal market (Electronic IDentification Authentication and trust Services) adopted on 23 July 2014:

provides a predictable regulatory environment to enable secure and seamless electronic interactions between businesses, citizens and public authorities. In this regard, the eIDAS Regulation:

- ensures that people and businesses can use their own national eID schemes to access public services in other EU countries where eIDs are available;
- creates a European internal market for electronic trust services – namely electronic signatures, electronic seals, time stamp, electronic delivery service and website authentication – by ensuring that they will work across borders and have the same legal status as traditional paper-based processes.

These are few examples of EU legislation that is necessary for Member States to exchange and use health data at a cross-border level. For some EU legislation, Member States need to change their law to be compliant which takes a considerable time; another challenge to face to achieve a common legal framework at EU level.

In term of national data protection authorities, EU countries have set up national bodies responsible for protecting personal data in accordance with Article 8(3) of the Charter of Fundamental Rights of the EU.

[46] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:32011L0024
[47] https://ec.europa.eu/futurium/en/content/eidas-regulation-regulation-eu-ndeg9102014

In order to ensure the consistent application in the European Union of the General Data Protection Regulation and of the European Law Enforcement Directive, the European Data Protection Board (EDPB) contributes to the consistent application of data protection rules throughout the European Union. It is an independent European body, which also promotes cooperation between the EU's data protection authorities.

The EDPB can adopt general guidance to clarify the terms of European data protection laws, giving stakeholders a consistent interpretation of their rights and obligations. Furthermore, Member States are also empowered by the GDPR to make binding decisions towards national supervisory authorities to ensure a consistent application.

The EDPB is composed of representatives of the national data protection authorities, and the European Data Protection Supervisor (EDPS). The supervisory authorities of both the EFTA and EEA States are also members regarding the GDPR related matters and without the right to vote and being elected as chair or deputy chairs. The EDPB is established by the General Data Protection Regulation (GDPR) and is based in Brussels. The European Commission and – with regard to GDPR-related matters – the EFTA Surveillance Authority have the right to participate in the activities and meetings of the Board without voting rights.

Instrument	Date	Programme	Scope
Treaty on the Functioning of the European Union	2009	Public Health Art. 168	• Coordination • Guidelines & Indicators • Exchange of best practices • Periodic Monitoring & Evaluation
Directive 2011/24/EU	2011	Responsibilities & Cooperation in healthcare	• NCPs • European Reference networks • eHealth Network
Regulation (EU) No 283/2014	2014	Guidelines for Trans-European Networks	• Telecommunications infrastructure • DSI
Commission Decision (EU) 2015/1302	2015	Integrating the Healthcare Enterprise	• Standardisation • Referencing in Public Procurement
Commission Implementing Decision 2019/1765	2019	Functioning of the eHealth Network	• eHDSI for Cross-Border eHealth Information Services • Governance Model

4. Framing Sustainable Post-2021 Policy Cooperation

A lot has changed since work on this deliverable began, not least the impact of the COVID-19 pandemic and its effect in accelerating demand for eHealth solutions. Very different organisational arrangements exist in the Member States, and the supporting activities of the eHealth Network demonstrate how this heterogeneity can impact on cooperation activities.

The quick and decisive action of the eHN has shown the capabilities of Member States to come together and deliver workable solutions in a proactive and dynamic manner. These solutions have already become essential in digitalising (public administration) services whose processes have been critically impacted by the COVID-19 pandemic.

Perhaps even more importantly, much of the resistance to eHealth development has been significantly reduced or removed due to the urgency and necessity to develop and deliver eHealth solutions at every level: local, regional, national and international. Fears around data privacy, data quality, technical or clinical proficiency regarding eHealth solutions have been replaced by a demand for eHealth to provide a rapid solution.

Many new and planned eHealth services enabled and accelerated by COVID-19 have, understandably, been built reactively and at great speed, neither of which are ideal factors in ensuring risks are minimised and technical opportunities are maximised.

Health tracking apps, online consultation, large scale testing and vaccination programmes powered by eHealth, along with a workforce and public who want to see real-time reporting on the impact of these interventions, has led to a much more data-literate stakeholder population as a whole. Future eHealth policy needs to build on this literacy and use it to power future public health interventions.

The following sections reflect the main areas of collaboration. You may notice that some of the suggestions in one section may also be true of another section. This would indicate a greater area of collaboration and these areas should work in tandem. To avoid repetition or lengthen the document, we only mention these once.

4.1. Organisational Commitment

The biggest challenge to face is having a sustainable, working, and efficient model with support from the Commission and other contributors.

Although financial support would ensure continuation and sustainability of the work done to date, key elements of the work done so far can be kept and built upon, preserving a solid cooperation for cross border exchanges and other eHealth Action recommendations:

At the EU level, relations between Member States and with the European Commission:

• Ensure sustainable alignment between Member States and the Commission remains active;
  ○ **eHealth Network**
  ○ **National Digital Health Networks**
  ○ **Global Observatories**
  ○ **Investigate alternative policy options at EU and global levels**
  ▪ WHO, OECD, EU/US, EU/China – effects at local, Member State, EU levels
  ○ **Annual Sustainability Forum (eHealth ASF)**
  ○ **Succession Planning**
  ○ **Facilitate consensus among Member States**
  ▪ Exchanging views
  ▪ Recognising the validity of differing opinions
  ▪ Conflict resolution – internal and external
  ▪ External influences – international policy etc

Continued identification and engagement with key actors in each Member State to progress ongoing work through sustainability in eHealth;
• **Framework for the alignment of political priorities with technical implementation** • **Breaking down silos through cooperation between all other eHealth relevant initiatives e.g. eID, CEF, etc**
Contribution to or provision of the infrastructure that will support communities of practice and enable them to apply their expertise effectively (this matter is already addressed through the past and ongoing projects, initiatives, joint actions and CEF European infrastructures);
• **Communities of Practice** • **Common platforms/tools (SharePoint/Confluence)** • **Repository of all relevant previously published documents, results and achievements**

At local level a commitment to progress within the Member State organisations/institutions/authorities through:
• **Identifying key contributors and stakeholders within each Member State's local ecosystem** • **Closer relationship between local representatives on the EU Committee of the Regions** • **Establishing local contact points; internal organisations should identify their own contact points, as main contributors, supporting relevant activities** • **A coherent policy on education and skills for healthcare, from ensuring that all citizens have the basic digital health literacy skills, to advanced education and continuous professional development for healthcare professionals** • **Embedding sustainability into local policymaking so as to best reflect the needs of local communities in line with eHealth developments, therefore mitigating the impact resulting from changes in the political context.** • **Local collaboration between different government departments**

In section 3, other governance models, e.g. WHO or OECD, have been investigated to maintain the collaboration without support from a third party.

- **National Digital Health Networks:** To enhance the interoperability and security of national health systems and support the secure exchange of health data across borders.
- **Global Observatory**: a structure providing strategic information and guidance on effective practices and standards. (Example of the WHO Global Observatory for eHealth: an initiative dedicated to the study of eHealth—its evolution and impact on health in countries.)
    - **Annual Sustainability Forum (eHealth ASF)**: an annual meeting/event that provides an opportunity/platform to the eHealth ecosystem, by gathering leaders and stakeholder groups from Europe to discuss digital health matters. The eHealth ASF could be supported by a Portfolio Management Office/Observatory (idea further developed in chapter 5.)
- **Beyond the EU:** JAseHN deliverable *D8.1.4 - Main eHealth Activities Outside of the EU* (see section 2.2)
- **Framework (political / technical):** this framework shows the work done at political level is reflected in the technical innovations and output (see Figure 20). In this regard, a Portfolio Management Office, carrying out this function, could be an added value to the promote policy sustainability in the EU (idea further developed in chapter 5).

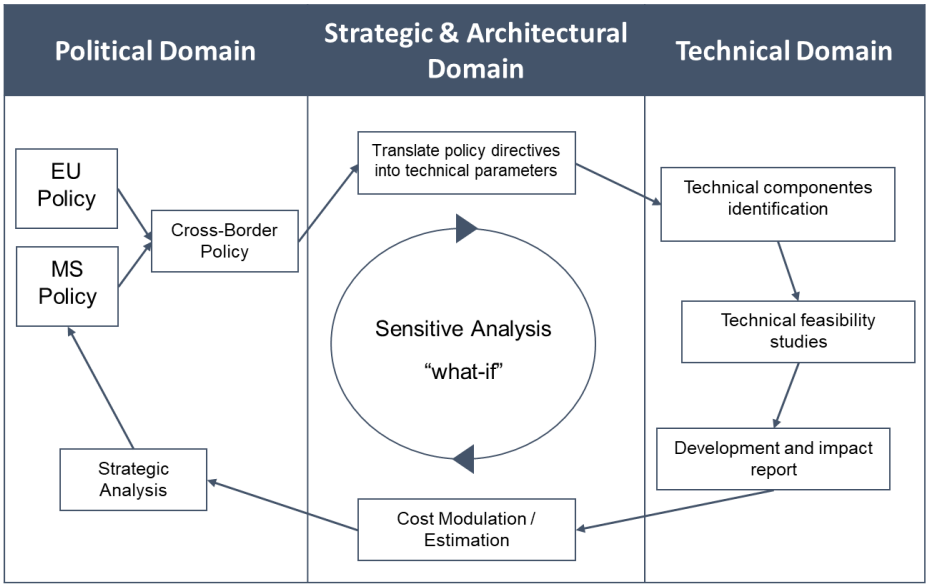

Figure 20 – Political-Technical Framework.

- **Community of Practice (CoP**): Communities of Practice are groups of people who share a concern or a passion for something they do and learn how to do it better as they interact regularly. The main purpose of it is to develop its participants/members capabilities to build and share knowledge[48].
- **Common Platforms:** Having a common platform to collaborate, organise or exchange content between stakeholders is required. This platform should also be supported by the European Commission for neutrality, legitimacy and safety.
- **Common eHealth Repository:** A shared library of resources, links and other relevant material from previous and current eHealth Joint Actions. This will make it easier for Member States to look back on work previously carried out to review the learning and minimise any duplication of effort.
- **Health in All Policies (HiAP):** an approach to public policies across sectors that systematically considers the health implications of decisions, seeks synergies, and avoids harmful health impacts to improve population health and health equity. As a concept, it reflects the principles of: legitimacy, accountability, transparency and access to information, participation, sustainability, and collaboration across sectors and levels of government.

[48] For more information on communities of practice, go to: https://hbr.org/2000/01/communities-of-practice-the-organizational-frontier

4.2. Building Networks

Network building means essentially working together within a group, between groups or between communities so to achieve a specific goal that otherwise would be difficult.

Using the eHealth sector as an example, and to ensure patients' rights in cross-border healthcare, a group of national authorities responsible for eHealth matters was formed to enhance interoperability in cross-border services and systems. This group was named eHealth Network and meets twice a year (Article 14, Directive 2011/24/EU)[49].

Building networks with institutions/organisations that have similar goals or challenges is a way of sharing information, a source of support and a means to detect other similar themed programmes (e.g., European Reference Networks). In this sense, forming a group represents a way of building a network.

It is important that we take advantage of existing networks. There is a vast amount of expertise and commitment in these networks but at this point we need to revitalise and motivate them so they can contribute to the post-2021 scenarios. We can identify the factors that make them successful and leverage that against future work. There is also a need to develop strategies to include the consulting of stakeholder groups like patient groups, industry, academia, medical professions, etc. In this sense, consultation processes and their output must be materialised in proposals to lobby government and EU support.

A helpful tool for managing sustainability and for ensuring that previous research and recommendations are taken account of, would be to develop or take advantage of an existing common online platform to record successes of Member States. A model for this practice can be seen in the existing EU-level programme Interreg[50], which curates best practices at national level.This could serve as a valuable use case for replication / expansion, in orderto deliver a similar initiative to manage cross-border eHealth initiatives. Interreg could also expand their portfolio to include cross-border eHealth initiatives. Another example of sharing best practice among European states is the Digital Skills and Jobs Coalition Core and Generic Services Platforms[51], whose development is currently funded by CEF.

In terms of eHealth policy as influenced by the current and past eHealth Actions, sustainability has become an increasingly important characteristic in EU's technical-political cooperation.

A series of initiatives undertaken by the health ministries of European countries has made major contributions to constructing a framework for continuous improvement of healthcare systems, with roadmaps, legislation, standards and pragmatic recommendations. By identifying and capitalising on connections between existing groups to further develop a non-

[49] For more information, go to: https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:088:0045:0065:en:PDF
[50] For more information, go to: https://www.interregeurope.eu/policylearning/good-practices/
[51] For more information, go to: https://ec.europa.eu/digital-single-market/en/digital-skills-and-jobs-coalition

exhaustive list of contacts will raise awareness of the possibility of mutually beneficial efforts between these stakeholders.

The implementation and benefits of the eHealth strategies, developments, innovations must be high on the agenda of national and EU policy. To ensure political alignment, sustainability needs to be prioritised within each Member State and across the EU. An action is politically sustainable if it allows for the fulfilment of current political goals and resource needs without compromising future goals and needs. Politically sustainable actions simultaneously build support for, and advance, an item on the political agenda. However, it is important that Member States ensure that the eHealth agenda is ultimately embedded in national policy through measures that prioritise eHealth and all its benefits. The networks referenced in this document can be instrumental to keeping eHealth on the agenda. Actions that are not politically sustainable advance a current agenda item at the expense of future support.

Figure 21 – Public eHealth Landscape 2021+

Infographic provided by GOEG, MOSA, NICTIZ and SPMS for D8.3.

There is an abundance of expert people and good networks that could be useful in sustaining the advances of eHealth and building on it for the continued improvement in healthcare effectiveness and patient outcomes. These expert groups are already engaged in significant work of digitising the state and providing all government services fully online or online first. Taking the lead from industry, across all economic sectors, digital transformation focuses on process refinement and business improvement alongside enhanced technology use. This approach makes sense for healthcare, where professional skill sets are enhanced rather than defined by technology.

Healthcare domain professionals and their networks are the key experts to enlist to influence national and European policy for post-2021 cooperation. Collaboration among these experts, the eHealth Network Member State representatives and National Contact Points for cross-border eHealth can work to maintain and sustain the progress made and the potential for healthcare system interoperability and semantics integration.

4.3. Raising Awareness

The purpose of this section is to focus on how citizens, professionals and governments can be made aware of eHealth, to ensure the best returns from innovation in this area in support of citizen well-being and how it can contribute to overall improved patient outcomes. Clearly, sharing strategies and results of different approaches to raising awareness is key to maximising the effectiveness of all actions.

Awareness Among Citizens

For the citizen, the goal is to move towards a preventative approach to healthcare, where individuals take a proactive role in their own well-being. Member States can raise public awareness by supporting a robust programme of digital health literacy through education, formal and informal. Improved competence in this area for citizens will prompt a change in their behaviour so that they make informed decisions regarding their health and well-being, resulting in a positive impact on their daily lifestyle, activities and health. Citizens will become drivers of eHealth.

Public awareness of the benefits of eHealth goes beyond self-care and is also concerned with the use of health data. The quality of data collected by professionals and provided by citizens is important for healthcare management, promoting efficiency and cost savings, as well as contributing to overall better healthcare. Public sector organisations and corporations involved in health and care management, provision and policy development need high quality data. This will only be available to them when citizens are informed about, and consent to, the appropriate use of their data. They must trust that it will be kept secure and confidential. Qualitative data sets, which are the basis of many innovations in eHealth, are more often provided on a voluntary basis by citizens and patients via eHealth portals and personal devices, than as a result of empirical research and investigation; this underlines the importance of trust in eHealth systems, and in those who operate and manage them.

Promoting Awareness Among Citizens and Healthcare Professionals

This enhanced role of citizens in their own healthcare makes it imperative that data and information are available in a clear and easily understood format. Citizens are increasingly becoming partners with doctors and other healthcare professionals, interpreting their medical information and making decisions. Therefore, citizens must be enabled to make this contribution to the doctor-patient partnership by a strong, accessible and well-designed awareness strategy in Member States.

In eHealth, as in banking, educational efforts have often focussed on professionals first, but missed the opportunity of empowering citizens, or patients. Best practice in health literacy development indicates that digital health literacy education must begin with the young,

preferably in schools. For example, in Portugal it forms an element of the core curriculum, as part of citizenship education. This is a recognition that citizens can only exercise control over their own data, and subsequently use that data, if it is presented in simple, understandable language, and in a format that is compatible with user-friendly devices and interfaces.

Government and Policy

There is a positive correlation between awareness in individuals and higher engagement in eHealth, and the willingness to provide and interact with health data. This is good for the citizen, but also for healthcare professionals who therefore have access to better-quality data. The positive impact of this extends beyond citizens and doctors, to healthcare institutions, providers and corporates providing innovative services in eHealth. High levels of awareness have led to an increased willingness to interact with technology and innovative health solutions, leading to better quality of care and improved health outcomes. Overall, better management within health institutions and facilities result efficient, cost-effective and successful healthcare provision.

Post-2021 policy focused on sustaining the advances in eHealth must include a focus on informing and educating citizens and professionals, as well as government, and influencing their attitudes, behaviours and beliefs. Ultimately this will support a broad, agreed policy landscape. It is important to provide trusted, factual, balanced information on eHealth sustainability, to strengthen multi-stakeholder cooperation between all actors such as citizens, healthcare professionals, governments, media and others, with the common objective of providing better quality of care. Policy development must take into consideration that technology is advancing and is enabling citizens to be advocates for as well as users of eHealth. This is a positive change, delivering better care and health for citizens, who take advantage of eHealth services. Well-considered post-2021 policy will ensure the maintenance of citizen participation and engagement in their own health and well-being.

Awareness Raising Strategies

Strategic information campaigns can highlight the ability of eHealth developments for people in different sectors of society. Information appropriate to age and occupation has a beneficial effect on arousing the interest of students, for example, as well as workers in different fields, unemployed and marginalised people, as well as older adults.

Appropriate policy influences approaches to engaging young people, even children in school. It extends digital skills on primary and secondary curricula to cover digital health skills. Technology brings many positives to the lives of young people, and as we teach them to use it responsibly, the opportunity presents itself to include the benefits of eHealth to their health and wellbeing. Discernment in selecting eHealth services, such as apps and monitoring devices is a key skill to include in information and education campaigns. Making this an integral part of policy has a positive impact on eHealth sustainability.

The communication media are an important consideration in awareness raising, as different cohorts have different preferences for news and information consumption. However, equally important for effective information sharing is the message itself, its accuracy, and the tone it is delivered in. A mixture of government-sponsored and commercial messaging might be appropriate, provided that the commercial input is monitored and supportive of overall policy.

Outside of the formal education system, awareness raising must take advantage of the media immediately available to the defined target groups, including social media platforms, press releases, television and radio, and print. In addition, valuable messaging can be provided by professionals in health and social care, as well from education and culture domains. Champions from the sporting music or fashion world, the 'influencers' of modern Europe could usefully help to spread the word. This type of communication can be enhanced by including high interest content and leveraging the value of storytelling in grabbing attention of citizens. Another contemporary innovation is the use of free online courses. These tend to have large audiences and the coverage of eHealth awareness topics in massive open online courses (MOOCs) and other learning platforms could have a real benefit for spreading information.

The responsibility of national governments to participate and disseminate information of use to citizens in the eHealth area must be clearly enshrined in post-2021 policy and must extend beyond health and education ministries. The WHO report 'From Innovation to Implementation'[52] is a useful reference for governments, with many useful recommendations. Its foreword urges 'all Member States and relevant partners within the WHO European Region to recognise and act upon the key messages and recommendations presented in this report. We need to ensure the collective, intersectoral engagement of all stakeholders for the future of eHealth and to leverage the strengths of each in implementing the Health 2020 policy in Europe.'

An example of an initiative that provides valuable information for the healthcare community is the X-eHealth common framework, on the two-way exchange of medical information (eP, PS, eD, labs, etc). This can exploit the long-term deployment of secure data transfer if appropriate professionals are aware of it. This framework also delivers a document on building trust in eHealth data and management processes.

In that context, Health in All Policies (HiAP) is worth mentioning. This is an approach to public policies across sectors that systematically considers the health implications of decisions, seeks synergies, and avoids harmful health impacts to improve population health and health equity. As a concept, it reflects the principles of legitimacy, accountability, transparency and access to information, participation, sustainability, and collaboration across sectors and levels of government.

[52] For more information, go to: https://www.euro.who.int/__data/assets/pdf_file/0012/302331/From-Innovation-to-Implementation-eHealth-Report-EU.pdf

Like all communication and awareness, information that is shared is only of value if it is trusted. Patients and healthcare professionals must have confidence that what they hear about eHealth developments is correct and safe, and also that their sharing of their own data on digital platforms, portals etc is secure, and strictly managed according to the GDPR. In this regard, attention is drawn to the building confidence coverage in eHAction WP4, and other conclusions on generating trust among eHealth users.

In summary, the communication channels discussed can be effective in raising awareness about the advances in eHealth and the sustainability of the outputs of eHealth projects, actions and general scientific and technological innovation. These all contribute in a significant way to the well-being of the citizens of Europe. We must particularly be cognisant of the experience and learning from JAseHN and other work packages of this eHealth Action, and to synergise with the communications recommendation from these initiatives.

4.4. Financial Support

This section aims to highlight the needed financial investment to achieve an interoperable ecosystem[53] to make the most of the potential of data exchange, hence reinforcing the resilience of national health systems.

We are living in an age in which the digitalisation of the healthcare sector plays a major role to tackle public health emergencies and reinforce preventive approaches. It is therefore clear that a well implemented digitalisation of health and care have the potential to significantly improve health and care outcomes.

Digital health is the future and every effort should be made to help Member States continue their eHealth journeys.

The use of digital health services and products for the provision of healthcare has increased substantially during the last years and particularly during the COVID-19 pandemic. However, the free movement and provision of these services and products is limited, as heterogeneous legal bases, different methods of certification and authorisation, liability and reimbursement rules have been put in place at national level, resulting in limited mutual recognition. Moreover, the organisation and financing of the health sector requires a specific approach on digital health technology.

[53] The idea of an eHealth interoperable ecosystem put forward in this document is in line with the concept put forward in the document: eHealth Network (2019) – *eHealth Guidelines on an interoperable eco-system: investment programmes for a new generation of digital infrastructures*. https://ec.europa.eu/health/sites/health/files/ehealth/docs/ev_20190611_co922_en.pdf

The importance of data exchange

Health data exchanged within and beyond national borders is instrumental to support effective decision-making, including decisions that have a financial impact. By building suitable knowledge databases and by interacting with other databases and registries, this enables the potential of big data analytics and technological autonomy to support better research, policy making and health outcomes. Better use of data also results in more resilient national health systems. The transition to digital information and the creation of EU data spaces remain as political priorities to ensure the resilience of national health systems.

Having said this, European financial instruments should be applied to update existing or establishing new digital health infrastructures. The focus of these digital health infrastructures should be data used by healthcare professionals and healthcare providers and should also enable patient access to and management of their health data.

For this reason, the principles laid down in the *Refined eHealth European Interoperability Framework (ReEIF)* (legal and regulatory, policy, care process, information, applications, IT infrastructure) should be considered as a basis for achieving an interoperable ecosystem in Europe.

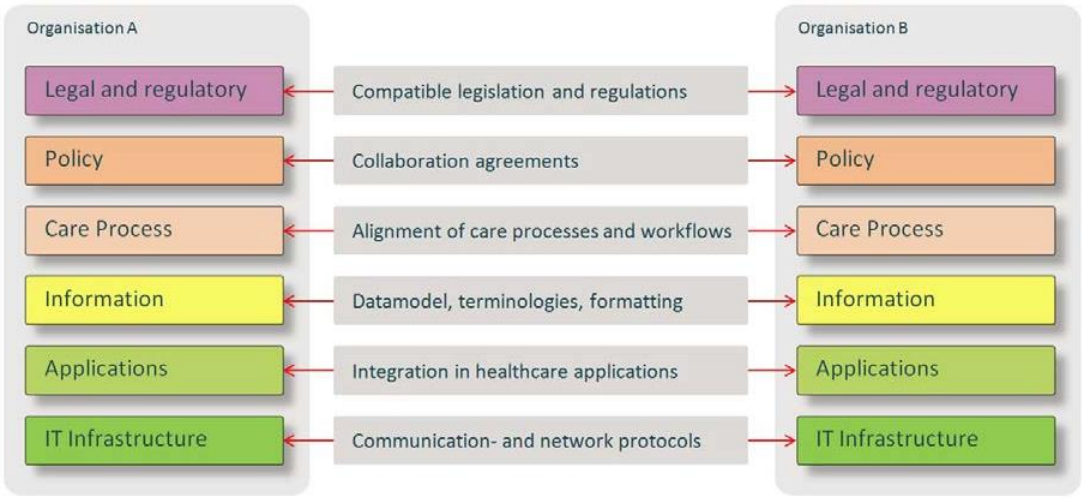

Figure 22 – ReEIF model – alignments that are necessary on the different levels of interoperability

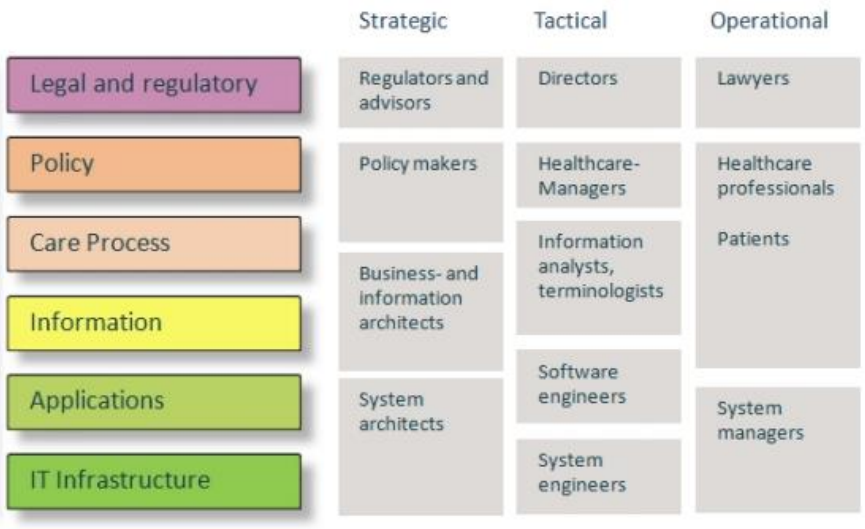

Figure 23 –ReEIF model – stakeholders

In order to ensure progress in relation to layers of the framework (Figures 22 and 23), the following EU funding instruments are available and might be beneficial for Member States.

This in line with the Commission's priorities to ensure a long-term, sustainable and inclusive recovery that promotes the green and digital transitions.

Programme/Framework	Description
Multiannual Financial Framework **2021-2027** ***(MFF, €1.8 trillion)***	The EU has put together a comprehensive financial package of €1.8 trillion in 2018 prices for the coming years to tackle the socio-economic consequences of the COVID-19 pandemic and address the EU's long-term priorities. It combines: ▪ €1,074.3 billion multiannual financial framework (MFF) ▪ €750 billion extraordinary recovery instrument, Next Generation EU (NGEU)
NextGenerationEU ***(NGEU 2021-2023, €750 billion)***	Recovery and Resilience Facility (RRF, €672.5 billion) The Recovery and Resilience Facility is the key instrument at the heart of NextGenerationEU to help the EU emerge stronger and more resilient from the current crisis (grant + loans).
EU4Health ***(€5.1 billion)***	EU4Health is EU's response to COVID-19, which has had a major impact on medical and healthcare staff, patients and health systems in Europe. By investing €5.1 billion, therefore becoming the largest health programme ever in monetary terms, EU4Health will provide funding to EU countries, health organisations and NGOs. Funding will be open for applications in 2021.

Digital Europe Programme (DEP)[54] ***(€9.2 billion)***	DEP will boost investments in supercomputing, artificial intelligence, cybersecurity, advanced digital skills, and ensuring a wide use of digital technologies across the economy and society, including through Digital Innovation Hubs. [55] DEP will take over the role of CEF: selected CEF Building Blocks, selected ISA2 actions and the Open Data Portal will be consolidated in a Digital Transformation Platform Ecosystem supporting in particular the public sector, but open to take-up by the private sector as well. The ecosystem can expand to integrate other digital offerings from the Commission - such as the EU INSPIRE Geoportal - into a cohesive ecosystem.
Connecting Europe Facility (CEF2) [56] ***(€3 billion)***	The Connecting Europe Facility (CEF2) Digital programme aims to support and catalyse investments in digital connectivity infrastructures of common interest during the period 2021-2027.
Horizon Europe ***(€92 billion)***	Horizon Europe is the research and innovation framework programme running from 2021-2027. Notwithstanding the importance of these extraordinary public funds, it might be helpful to improve the governance of (some) funded initiatives to achieve common goals.

Notwithstanding the importance of these extraordinary public funds, it might be helpful to improve the governance of (some) funded initiatives to achieve common goals.

For instance, the establishment of a centralised portfolio management office with alignment and observation functions, could promote knowledge transfer, resource efficiency and succession planning between and across projects. Therefore, increasing consistency for future developments.

Workshop's participants expectations on outcomes:

Outputs on financial issues which may also impact participation in a sustainable eHealth ecosystem in the absence of any further joint actions specific to eHealth:

- Most Member States join actions because of the financial incentive to do so. Needs more political motivation from Member States;
- Member States are limited to move forward due to financial constraints;
- Rather than 'new kinds' of investment, it might be helpful to improve the governance of (some) funded initiatives to achieve common goals;

[54] https://ec.europa.eu/eip/agriculture/en/find-connect/online-resources/digital-europe-programme
[55] https://ec.europa.eu/digital-single-market/en/europe-investing-digital-digital-europe-programme
[56] https://ec.europa.eu/digital-single-market/en/connecting-europe-facility-cef2-digital

- Explore specific funds for these activities, like FEDER[57] and others;
- Engage other stakeholders – beyond the policy level;
- Create a new joint action on a sustainable interoperable ecosystem;
- Consider funding from an established eHealth organisation/entity (e.g. ENISA);
- Commission-led financing on sustainability;
- Finance Member States on concrete progress made on the availability of source structured data to be exchanged cross-border;

Information collected during eHAction D8.3 workshops. It represents a specific point of view from participants.

As we move forward with an agenda to sustain the advances and victories of eHealth without the support of further joint actions, Member State and corporate European policy must make it strategic and attractive to continue the good work and positive trajectory put in place in recent years. Once Member States no longer have financial incentives to participate in innovative projects, political motivation must increase to do this for the good of the individual Member State and of the European Union as a whole.

Financial constraints are a reality, but other, 'new kinds' of investment can be found, and optimised by improving the governance of (some) funded initiatives to achieve common goals. It is the responsibility of Member States to explore specific funds for sustainability activities, like FEDER, for example.

Additional progress can be made by engaging other stakeholders in practical actions to stimulate activity, even beyond the policy level. Consideration should be given to seeking funding for sustainability initiative from an established eHealth Organisation (e.g. ENISA), or from Commission led financing on sustainability.

4.5. Legal Landscape

This section aims to provide context on the current legal framework upon which eHealth policy cooperation takes place in the EU, and identifies the main legal constrains to cross-border exchanges of health data.

The COVID-19 pandemic has heightened the importance of having timely access to health data for research and policy-making purposes. Yet, the current situation of fragmentation, differences in and barriers to access health data in the cross-border context, including by patients, researchers and policy-makers, as well as limited interoperability, shows that action

[57] European Regional Development Fund: https://ec.europa.eu/regional_policy/en/funding/erdf/

by individual Member States is not sufficient and that it requires a common framework at EU level.

The eHealth Network is a voluntary network, set up under Article 14 of Directive 2011/24/EU. It provides a platform of Member States' competent authorities dealing with eHealth. Nonetheless, existing arrangements and tools only partly deliver and respond to the persisting challenges.

The level of digitalisation at national level varies considerably and interoperability between healthcare providers remains limited. The eHealth Network – and its related IT infrastructure – has improved the cross-border exchange of health data for healthcare, such as patient summaries and e-prescriptions (primary use of health data). However, among other challenges are its voluntary nature and the non-binding nature of its guidelines which has affected the uptake and impact of its decisions.

Few Member States apply the voluntary eHealth Network guidelines[58]. Even though recommendations on a European Electronic Health Record Exchange Format exist, in practice they are not sufficiently applied, which reduces interoperability between systems, creates barriers in the Single Market and poses a significant challenge for businesses, enterprises and national healthcare systems when integrating innovations in healthcare.

The same is true for patients to exercise access and control over their own data. The fact is that EHRs are not yet fully implemented across the whole EU; many patients cannot easily access and use the information they contain or transfer them between healthcare providers when moving across borders. This leads to duplication of efforts, inefficiencies and higher costs.

Further to the above, access to, and exchange of, health data for scientific research and innovation, policy-making and regulatory activities remains very limited in Europe (secondary use of health data). The collection, access, storage, use and re-use of data in healthcare poses specific challenges that need to be addressed within a regulatory framework that best serves citizens' interests and rights, in particular as regards the processing of sensitive personal data relating to individuals' health.

Using the General Data Protection Regulation[59] as an example, Member States have further specified some aspects regarding the use and re-use of health data, which in turn result in different applications of the GDPR, therefore increasing fragmentation and raising obstacles for access of researchers, innovators, public bodies or regulators. The wide range of national approaches impact in policy cooperation as well, since not all Member States have set up/hold

[58] Inception impact assessment: https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12663-A-European-Health-Data-Space-
[59] For more information, go to: https://ec.europa.eu/info/law/law-topic/data-protection/data-protection-eu_en

specific bodies to facilitate access to health data, and different methods of certification and authorisation resulted in limited mutual recognition.

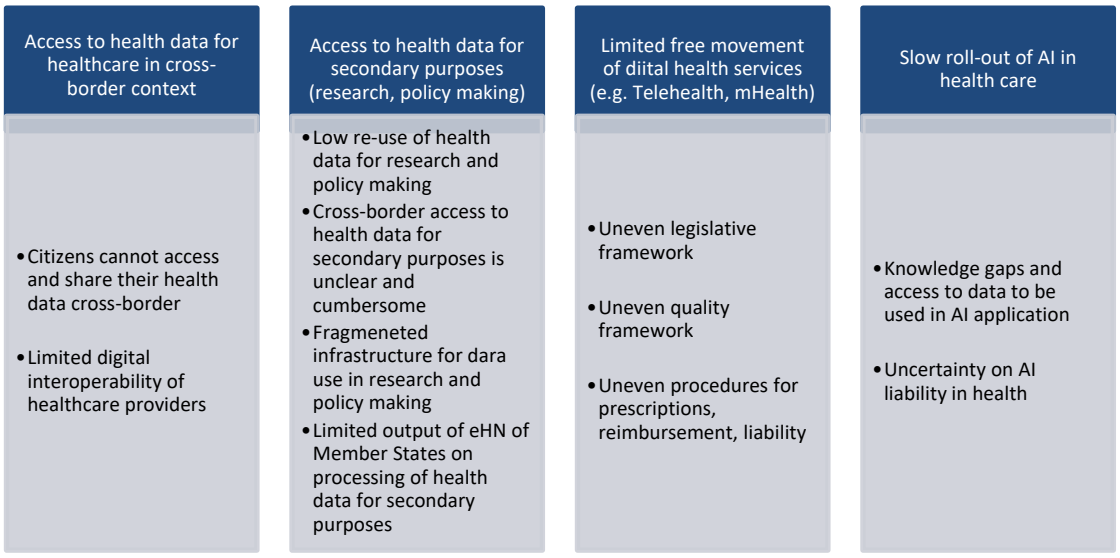

Figure 24 – Main legal challenges to health data exchange in the EU.

Having highlighted some of the core limitations hindering the potential of digital health tools and sustainable cooperation, legislative action is needed to reduce these divergences, so that these actions can be better achieved at EU level.

As things stand, Member States would continue implementing the Cross-border Healthcare Directive, supported by the eHealth Network; that is to say, the exchange of patient data for healthcare (primary use) would continue between healthcare professionals, for specific use cases and on a voluntary basis, thus not fully satisfying the needs of patients.

As for the access to health data for research, policy and regulatory activities (secondary use), Member States would continue to develop their own national policies and legislation, framed to a certain extent by the draft proposal for a horizontal framework[60] for common European data spaces and the GDPR. This would result in fragmented access and re-use of health data, limiting the effectiveness and resilience of public health action such as in the case of infectious diseases (e.g. COVID-19) or rare diseases. Moreover, patients access to their health data may not occur through a European electronic exchange format, limiting their ability to transmit data, and the development and deployment across the EU of innovative healthcare solutions would in turn face further interoperability barriers.

[60] Data Governance Act. For more information, go to: https://ec.europa.eu/digital-single-market/en/news/proposal-regulation-european-data-governance-data-governance-act.

This being said, addressing the legal considerations outlined above are fundamental to achieve an enabling digital health ecosystem, therefore promoting the sustainability of post-2021 policy cooperation in the EU.

Investment in cross border interoperability is contingent on agreements to have the appropriate legal requirements in place. This emphasises the need for a EU level strategy towards a common vision to cover the access to and exchange of health data for healthcare provision, research, policy-making and regulatory activities.

In this regard, the scope and mandate of the voluntary eHealth Network could be broadened. Moreover, in the absence of a Joint Action supporting the eHN (supporting policy cooperation between the Member States), a mechanism/instrument could be established to support observation and evaluation actions. Chapter 5 presents a set of recommendations in this regard.

Workshop's participants feedback on outcomes:

Outputs on legal considerations which may impact participation in a sustainable eHealth ecosystem in the absence of any further joint actions specific to eHealth:

- data security laws
- further clarity on eID legal requirements
- Identifying the Data Controller is an issue for many Member States especially emanating from the work of the eHMSEG Legal Task Force and its questions to EDPB
- Suggested use consensus processes from one or several SDOs, because they proved sustainable and are accessible by all stakeholders.
- Further work on data protection obligations under GDPR
- Patient data security

Information collected during eHAction D8.3 workshops. It represents a specific point of view from participants.

Raising Awareness on EU Legislative Initiatives

The European Electronic Communications Code (EECC) recommendations[59]

An important part of the **European Electronic Communications Code** (EECC) is the security of electronic communications, which contains detailed security requirements for electronic communications providers and empowers the competent authority to implement and enforce those requirements in Articles 40 and 41. Compared to the old regulation, there are seven important changes:

- ↘ more communication services in scope like Gmail, Viber, Skype, etc.,
- ↘ EECC provides definition of security and security incidents,
- ↘ state-of-the-art measures and end-to-end encryption,
- ↘ promote the use of encryption,
- ↘ clarifies the incident notification parameters,
- ↘ collaborate with law enforcement authorities, national CSIRT and authorities,
- ↘ take measures to mitigate significant threats.

5. Recommendations for Post-2021 scenarios for public policy cooperation

Many Member States are in the process of initiating or rolling out large-scale eHealth investment and implementation programmes. Some Member States have been granted financial support from European structural or regional funds to reform their national healthcare systems. Thereby, Member States have a unique opportunity to build national solutions on common European or global standards that enable continuity of care across borders. **If Member States do not seize the opportunity, there is a clear risk that national investments will be less efficient, more expensive and will not provide the potential benefits for citizens that otherwise would be possible.**

Following an extensive review of eHAction Work Packages and numerous partner consultations, D8.3 authors have developed a (non-exhaustive) list of comprehensive recommendations for the successful continuation of the current eHealth ecosystem.

The recommendations are grouped in four overarching clusters, and presented as follows:

A. **Recommendations to the eHN, supported by the European Commission;**
B. **Recommendation on the establishment of a centralised portfolio management office;**
C. **Recommendations for promoting/creating networks;**
D. **Recommendations for national action;**

A – Recommendation to the eHN, supported by the European Commission

To better adapt to the post-2021 environment, it is recommended that eHN progress work in the following key areas:

- Continue to adopt the MWP which could involve the assessment of new mechanisms/solutions, including funding, to ensure sustained Member State collaboration and successful implementation of MWP's focus areas.
- Elaborate long-term scenarios for collaboration until 2030 and a possible way forward to work as a network.
- Describe the methods by which the ecosystem can work together; governance and coordination points of view.
- Continue and extend the collaboration with SDOs and other stakeholders (e.g., X-eHealth).
- Raise awareness for professional, structured approach to eSkills development in the EU.
- Develop strategies to include the consulting of stakeholder groups like patient groups, industry, academia, medical professions, etc.
- Promote an Annual Sustainability Forum on eHealth.
- Continue to develop the work of the Joint Coordination Process, in line with the EEHRxF recommendation, either through the network itself or a centralised portfolio management.

Furthermore, it is also recommended that eHN collaborates with the European Commission to progress work in the following areas:

- Rearrange the structural organisation in which eHealth cooperation currently takes place in the EU, towards achieving sustainability in cooperative practices:
  - Organisational sustainability upholding eHealth policy cooperation would promote unblinkered work practices that allow agile responses. These are crucial features to face unexpected events like the COVID-19 pandemic.
- Security, safety and privacy must be addressed at the general health data circulation level:
  - Interoperability guide and cybersecurity meta-guide to help to navigate the EU guidance documents (NIS Cooperation Group and ENISA).
  - feedback and further engagement from user community is fundamental to elaborate and validate publishing content.
  - facilitate consultations with relevant EU groups, such as the advisory eHealth Stakeholder Group.
- Facilitate succession planning (smoother transition)
- Create a framework to promote awareness among relevant stakeholders, such as patient groups, industry, academia, medical professions, etc.
- Develop an EU level strategy towards a common vision to cover the access to and exchange of health data for healthcare provision, research, policy-making and regulatory activities.

B – Establishment of a Centralised Portfolio Management Office

Following on from our extensive discussion with stakeholders, it appears that a centralised portfolio management office, guided by and accountable to the eHN, to run and help manage day-to-day aspects of the eHealth ecosystem, including funding streams, should be established.

This would mean the establishment of a designated structure/team, with a citizen-centric approach, to coordinate and manage a sustainable eHealth ecosystem, to include but not limited to:

- Centralised repository to hold:
  - Directories of resources (e-registry),
  - Semantic assets including data dictionaries,
  - Glossaries and other information sources (virtual health libraries),
  - Common online platforms and tools,
  - Relevant published documents, results and achievements from previous eHealth activities,
  - Shared knowledge base, including best practices is essential to promote the alignment of the different levels of digital transformation between the Member States;
- Align political priorities with technical implementation, through an established framework:
  - Identify key aspects of the relationship between policy and process to ensure interoperability and ultimately patient safety, in a strategic, cohesive and transparent way;
- Promote a joint agenda for EU Digital Services among decision-making and technical bodies;
- Facilitate risk mitigation and consensus among the Member States;
- Function as an observatory to investigate alternative policy options on EU and global initiatives, for example, the WHO, OECD, EU/US, EU/China;
- Establish a common online platform that supports Member States and Commission in observing and evaluating actions:
  - improve the governance of (some) funded initiatives to achieve common goals;
  - portfolio management;
- Promote awareness among relevant stakeholders, such as patient groups, industry, academia, medical professions, etc:
  - strategic information campaigns;
- Extend digital skills curricula to cover digital health skills, such as, supporting ESCO;

C – Recommendations to support existing/building Networks

Deepen the relation between stakeholders and Member States to include, but not limited to, CEN, eHealth Stakeholder Group, NDHN, ReRIF, and advisory eHealth Stakeholder Group.

Address not only the political component, but also emphasise the field value of having these structure for high sharing of best practices.

- Leverage the existing networks;
  - Community of practice (i.e. learning community):
    - Closer relationships with stakeholders so as to achieve a vibrant and functional ecosystem;
    - Bottom-up approaches allow for better respect for local conditions, stakeholder engagement, close to the field innovations and better usage;
    - Healthcare domain professionals and their networks are the key experts to enlist to influence national and European policy for post-2021 cooperation. Collaboration among these experts, the eHealth Network Members and National Contact Points for cross-border eHealth can work to maintain and sustain the progress made and the potential for healthcare system interoperability and semantics integration.
- National competence centres coordinating local and domain specific activities with the Portfolio Management Office (top-down), linking that with Communities of Practices activities (bottom-up):
  - Clear assignment of responsibility to avoid duplication of effort.

D – Recommendations for National Action

It is important that Member States ensure that the eHealth agenda is ultimately embedded in national policy through measures that prioritise eHealth and all its benefits.

Actions that are not politically sustainable advance a current agenda item at the expense of future support.

- Adopt Ability-Motivation-Opportunity Framework to help citizens gain control of their health and achieve empowered behaviour (D4.3 – Policy Proposal on People Empowerment);

- Member States should be encouraged, via national dialogue, to leverage existing frameworks and roadmaps, to address:
  - new use cases: interoperability assets;
  - legal challenges: leverage existing frameworks (eIDAS);
  - the common principles for practical governance of big data (D5.3);
  - skills: competence framework;
  - draw up a national roadmap to establish the necessary legal agreements and plans, taking into account the EU centralised roadmap;
- Enhance national capacity to embed eSkills competences into professional development criteria at all levels of Health science education:
  - e-skills framework with a minimum set of learning objectives, recognised CPD, expansion and mobility programmes;
  - Extends digital skills on primary and secondary curricula cover digital health skills.

Summary / Conclusions

Significant investment has been made in eHealth in recent years with a particular emphasis placed on delivering the values and objectives set out in the Multiannual Work Programmes.

The considerable work already achieved by Member States in eHealth, cross-border healthcare and health information policy has only been enhanced through participation in various EU actions/initiatives. Participation at a European Level has also been of direct benefit to driving improvements in the current healthcare systems in Member States. This offers huge potential for the advancement of Member State eHealth policy objectives.

➢ Sustainability, national policies and nine core elements

The deliverable focuses on the concept of sustainability as it applies to Member State cross-border relations in the field of digital health. Political, strategic and operational sustainability (technical design and implementation) are reviewed following the results of several workshops held within eHAction stakeholders, Member States and Health Professionals. Some description work also includes the joint actions and initiatives undertaken by the several Member State's health ministries and their contribution to constructing a framework for continuous improvement of healthcare systems as well as organisational sustainability upholding eHealth policy cooperation.

Specific core elements are investigated as fundamental components to structure and maintain the eHealth ecosystem running, addressing different key topics such as patient empowerment and access (taking an active role in the health care process), eSkills for professionals (digital health), interoperability (EHRxF), infrastructure, cybersecurity. But also, enterprise architecture (roles, processes and management of operations), coordination and governance model, data-driven innovation and legal challenges to advance a common EU legal framework.

- **Framing a Sustainable Post 2021 Policy Cooperation**

To propose elements for preparing the continuity post-2021 of the cross border policy cooperation, and integration of its results in national policies, five main topics are described as follows: organisational commitment, building networks, raising awareness, financial support and legal landscape. Those topics gather multiple suggestions, ranging from concepts to practical matters.

'Organisational Commitment' focuses on building the right instrument for achieving organisational goals in eHealth, such as implementing National Digital Health Networks, Global Observatories, Communities of Practice, Common eHealth Repository, Health-in-All-Policies, and Common Platforms. 'Building Networks' centralises concepts and practices to ensure collaboration between stakeholders, while 'Raising awareness' promotes knowledge and understanding among citizens, healthcare professionals, at policy and strategy levels. The last two topics include an overview on 'Financial Support' and a reflection on the 'Legal Landscape' of this post-2021 policy cooperation frame.

- **Four clusters of recommendations:**

The deliverable puts forward a set of recommendations aimed at setting the best course of action for post-2021 eHealth policy cooperation in the EU, following the conclusion of the JA supporting the eHN. Four overarching clusters of recommendations are proposed for action, therewith functions/processes to direct cross-border health policy cooperation towards sustainable transformation.

The first cluster (A) of recommendations is designed to the eHealth Network, supported by the European Commission. Some key recommendations are:

- Organisational sustainability upholding eHealth policy cooperation would promote un-blinkered work practices that allow agile responses;
- Facilitate consultations with relevant EU groups, such as the Advisory eHealth Stakeholder Group;
- Develop an EU level strategy towards a common vision to cover the access to and exchange of health data for healthcare provision, research, policy-making and regulatory activities;

The second cluster (B) of recommendations focuses on the establishment of a Centralised Portfolio Management Office, guided by and accountable to the eHN, to run and help manage day-to-day aspects of the eHealth ecosystem, including funding streams. It elaborates on the approach to design (citizen-centric) and manage such a structure.

The third cluster (C) of recommendations develops the existing and building networks configurations and guides on how to deepen the relationship between stakeholders to include other parties. It addresses not only the political component, but also emphasises the field value of having these structure for high sharing of best practices.

The fourth cluster (D) of recommendations is meant for National Action, ensuring that the eHealth agenda is embedded within Member State national priorities and policies, sustaining the benefits of a broader collaboration and leveraging current investments and existing infrastructure.

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