

Two years plan of the eHealth Network meetings and sustainability

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| 2 | DIRECTIVE 2011/24/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 9 March 2011 on the application of patients' rights in cross-border healthcare |
| 3 | 25 April 2018 Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions on enabling the digital transformation of health and care in the Digital Single Market; empowering citizens and building a healthier society |

A note of vision from the eHealth Network Member State co-chair

Aligned with my candidacy a year ago for Member States co-chair of the eHealth Network I believe citizens should be empowered with the possibility to access their own health information anywhere, thus making health ICT interoperability in and between Member States crucial. It is also important to consider each Member State's particularities and respect data protection while recognising the faster speed of recent technological developments further increases our need to work together. By working interdependently through cultural diversity, every Member State can contribute significantly to this commitment while promoting mutual understanding. Moreover, sustainability of cross-border healthcare must be addressed and guaranteed under Union European projects and post Horizon 2020. Thus, the eHealth Network's contribution is crucial for promoting *eHealth in support for better health*.

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1. Executive Summary

The purpose of this document is to present the Member States eHN co-chair vision for the eHealth Network and consequently for eHealth in Europe for the period 2019 to 2020 including ideas for sustainability scenarios for eHealth post 2020. In this document you will find information about background and context, key drivers and vision on eHealth domain across the European level.

2. Background and Context

The European Union identified 35 different policy areas to improve the European citizens' life. Public health is one of them, and with this *the EU complements national policies to achieve shared objectives*¹. Thus, EU created instruments to implement the EU Health strategy, namely the third EU Health Programme, Horizon 2020 and Connecting Europe Facility. Therefore, and under the Directive 2011/24/EU², the eHealth Network was created, a voluntary network with main objectives to:

- (a) *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;*
- (b) *draw up guidelines on:*
 - i. *a non-exhaustive list of data that are able to be included in patients' summaries and that can be shared between health professionals to enable continuity of care and patient safety across borders; and*
 - ii. *effective methods for enabling the use of medical information for public health and research;*
- (c) *support Member States in developing common identification and authentication measures to facilitate transferability of data in cross-border healthcare.*

To achieve these objectives, recurrent meetings with nominated Member States/Countries (MS/C) representatives are held about twice a year. The nomination of the new MS co-chair happened in the 13th eHN meeting of 2018. This nomination represents an opportunity to look further in the definition of a new perspective for a joint vision on eHealth - in alignment with EU Directives, policy documents and joint cooperation within members states, industry and eHealth Stakeholders.

2.1 Major References as policy documents

- eHealth Action Plan 2012-2020: Innovative healthcare for the 21st century³
- Multiannual Work Programme 2018-2021⁴
- Digital Single Market Communication of 19 April 2016
 - The EU e-Government Action Plan 2016-2020⁵

¹ [The European Union – What it is and what it does](#)

² [DIRECTIVE 2011/24/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 9 March 2011 on the application of patients' rights in cross-border healthcare](#)

³ <https://ec.europa.eu/digital-single-market/en/news/ehealth-action-plan-2012-2020-innovative-healthcare-21st-century>

⁴ https://ec.europa.eu/health/sites/health/files/ehealth/docs/ev_20171128_co01_en.pdf

⁵ <https://ec.europa.eu/digital-single-market/en/news/communication-eu-egovernment-action-plan-2016-2020-accelerating-digital-transformation>

- Priorities of ICT standardization for the Digital Single Market⁶
- Communication of 23rd March 2017 from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on European Interoperability Framework – Implementing Strategy⁷
- Communication of 25th April 2018 from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on enabling the digital transformation of health and care in the Digital Single Market; empowering citizens and building a healthier society⁸
- Commission Recommendation of 6th February 2019 on a European Electronic Health Record Exchange Format⁹

These initiatives and their organization could be summarized on the Figure 1.

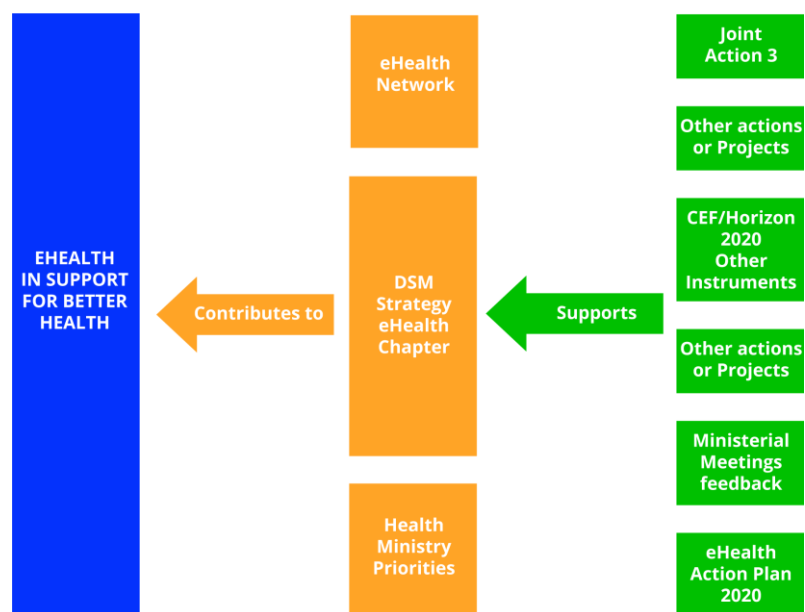


Figure 1 - MWP 2018 – 2021: EU eHealth strategic roadmap

Working towards a common approach on eHealth is a priority. Thus, the eHealth Network should joint efforts and work jointly with the parallel **five** Joint Actions of the Third EU Health Programme 2017 (Table 1). The key instrument for doing this is the Joint Action supporting eHealth Network in order to identify and address common issues for cohesive eHealth throughout Europe.

This process obviously includes the ongoing need for conversations with relevant EU-level stakeholders, this was the function of the DGs eHealth Stakeholder Group, now in a restructuring phase.

⁶ <https://ec.europa.eu/digital-single-market/en/news/communication-ict-standardisation-priorities-digital-single-market>

⁷ https://eur-lex.europa.eu/resource.html?uri=cellar:2c2f2554-0faf-11e7-8a35-01aa75ed71a1.0017.02/DOC_1&format=PDF

⁸ https://ec.europa.eu/health/sites/health/files/ehealth/docs/com2018_233_en.pdf

⁹ <https://ec.europa.eu/digital-single-market/en/news/recommendation-european-electronic-health-record-exchange-format>

Table 1 – Joint Actions under Health Programme 2017

| | |
|------------|--|
| JA-01-2017 | Joint Action on Health inequalities |
| JA-02-2017 | Joint Action – Innovative Partnership on Action against Cancer |
| JA-03-2017 | Joint Action on Vaccination |
| JA-04-2017 | Joint Action on preparedness and action at points of entry (air, maritime and ground crossing) |
| JA-05-2017 | Joint Action supporting eHealth Network |
| JA-06-2017 | Joint Action on Health Informatics towards a sustainable EU health information system that supports country knowledge, health research and policy-making |

3. Key Drivers

The three pillars related to eHealth in the Commission's Communication¹⁰ require the eHN's attention to both progress and monitor of their take-up. It will also be vital to align them with the MWP 2018-2021. This shall happen on a regular bi-annual basis.

The task assignment in the 13th eHN meeting to its Joint Action Supporting eHealth Network – eHAction is the expression of the Network's ambition to lead the way on key developments and to support Member States in core topics:

- Empowering People
- Innovative use of Health Data
- Enhancing continuity of care
- Overcoming implementation Challenges
- Integration on National policies and sustainability on eHealth
- The Electronic Health Record Exchange Format (EHRxF)
- A Common Semantic Strategy (CSS)

These topics together along with the extension of the accepted and implemented CEF use cases are key tasks. As for now, the implementations in CEF eHDSI are a major breakthrough in European co-operation, yet they need to be matured and extended both in the way of content and European uptake. Within the scope of Horizon 2020 or a sequel scheme not only these applications require attention but also other issues such as immunization systems, exchange of imaging, lab results and discharge reports. The eHealth Network will need to identify - with the help of the eHAction - what guidance, guidelines or frameworks are required in the different core topics previously defined.

¹⁰ [25 April 2018 Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions on enabling the digital transformation of health and care in the Digital Single Market; empowering citizens and building a healthier society](#)

It is already foreseeable that the practical implementation of these topics can be based on the current CEF policies as well as the related working schemes exemplified in the eHealth Digital Services Infrastructure (eHDSI). However, measures will have to be taken to further professionalize and accelerate the design, implementation and practical introduction of services on a larger scale. One means of supporting this would be to agree on:

- Choosing a number of new information blocks (elements containing information that serve more than one use case); (e.g. exchange of imaging, lab results and discharge reports/letters)
- Creating common semantic assets
- Creating and maintaining a roadmap on future features and use cases on Cross Border activities

This approach will help to go beyond the current concept of focusing on use cases. The EHRxF recommendation of the European Commission already leads in the right direction but requires more attention and dedication. With that in mind, Joint Coordination Process (JCP) could facilitate governance on these topics, but should have a broader scope and be well in alignment with MS strategies and specificities. To support the further elaboration of the baseline of the health information domains and specifications (such as Annex 1 of EHRxF), this way of working should be aligned with the general principles stated in the recommendation on electronic health record exchange format (EC EHRxF).

4. Vision

The cornerstone of the vision is to create a permanent dynamic – as much institutionalised as possible - for the various assets and services created for interoperable and cross-border eHealth services and needed for running them. Such assets need to be conceived, promoted, and aligned with the eHealth Network policy perspective. The eHealthNetwork priorities would therefore be clustered into 4 areas:

1. Promote and create conditions for ever more eHealth services at cross-border level
2. Develop and sustain common eHealth interoperability assets
3. Capacitate and give guidance to National eHealth Agencies
4. Support National Digital Networks

The usefulness, if not the necessity, of a strong eHealth Network should become evident as part of this eHN vision.

So far significant developments in European eHealth have led to the introduction of pilots and more recently to regular services. However, the maintenance of assets and the support and further development of services heavily depends on voluntary contribution and the acquisition of further funding. What is more, with the CEF induced separation into Generic Services, financed and operated by the MS and Central Services, accounted for the European Commission sustainability beyond certain cut-off dates is not assured, examples are the life-cycle of CEF and of eHN support actions. It's very important that EC, through there funds and projects allow MS to get coherency and cohesion on eHealth domain at national and European level.

It is important to understand that concerns do not only regard finance but also reliable operation and further development. Significant assets in legal, operational, semantic and technical domains have been accrued. It's critical that topics such as: security, secondary use of health data and

emerging technologies would play an important role in priorities of MS, because these are critical technological issues and of emerging relevance combined with somehow a policy vacuum. Yet many of them are bound to be orphaned if they are left without permanent responsibility and support. This is true although all parties involved both from Member States and Commission do their best to maintain, fund and run services.

The assets and services created for and needed for running cross-border eHealth services are complex, trans-sectoral and dynamic. None of the projects, DGs and other parties involved alone will be able to master all aspects of cross-border eHealth services. It is thus most important to ensure sustainability through a more close coordination.

A further relevant element of the vision for the eHealth Network is to increase interaction and co-operation with other European institutions. Table 2 analyses an initial set of organisations with varying membership and remit. Already individual activities, such as EU projects liaise with the one or the other of these organisations, yet the activities should be stepped up significantly:

Whenever relevant and adequate experts' presence of these organisations should be requested for guidance, alignment and to achieve a convergent strategy. The strategy of interaction is based on eHN priorities. The activities will, amongst other, be conducted by the Joint Actions, namely eHAction, by the process of stakeholders engagement.

Table 2 – eHealth Network stakeholders



5. The seven key Focus Areas

Overview

Taking in consideration the European Union policy areas, eHealth Network role and work done by European and International organisations in health or interrelated areas, seven additional key focus areas (Figure 2 and 3) are recommended to the attention of the eHealth Network for 2018-2021.



Figure 2 – Key focus areas

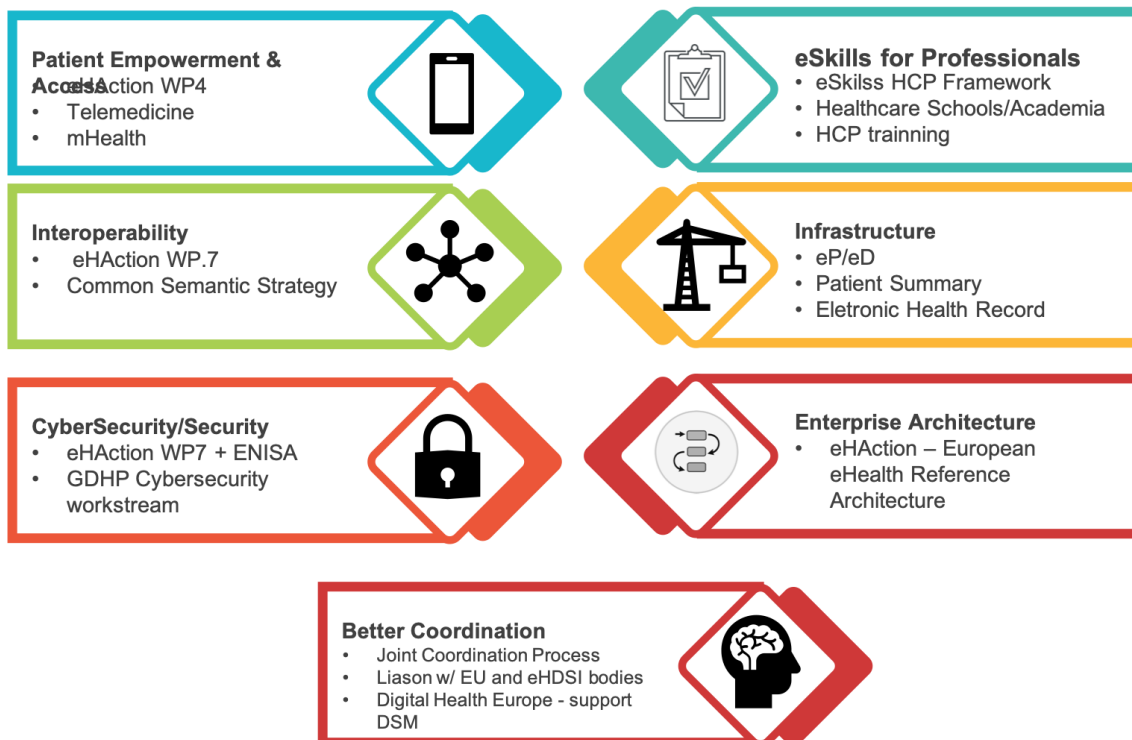


Figure 3 – Key Focus Areas

These seven priority areas are aligned with MWP 2018-2021 and consequently with eHAction workpackages and tasks, providing support to the eHN (Figure 4).



Figure 4 – Schematic overview of one of the four priority areas of MWP 18-21

5.1 Patient Empowerment & Access

Both Patient Empowerment and Patient Access place the patient in the focus of our considerations. Aligned with MWP 2018-2021 the eHealth Network's work priority area **Empowering People**, with focus effort on enabling citizens to take an active role in the management of their health, is addressing the subject in specific topics, as illustrated bellow, simultaneously address by eHAction under the **WP4 – Empowering people**.

It is planned that WP4 will prepare for eHealth Network adoption two initial key deliverables on:

- D4.1 Policy framework on patient empowerment
- D4.2 Policy proposal

The work is already well advanced. We are seeing light house developments in some of our countries and health systems. At a higher-level action and work from eHealth Action will relate to eHN via discussed deliverables already scheduled. The Netherlands provide the lead of WP4 and the country's advanced thinking may lead the way. However, the current remit of the WP as stated in the project's Grant Agreement may well need to be extended: *"Addressing citizens as individuals who should take an active role in their health care process"* does not only encompass educating and enabling citizens and patients but also to change our own thinking and eventually our positioning as MS/C and as eHN.

Clearly patient empowerment is part of a larger development towards citizens' enabling and enacting in more than just one domain. Patient access is just one, although a critical element of empowerment. It is in eHealth Network responsibility to enable and safeguard patient information and also to ensure that patient information is correct, logical and that it cannot be corrupted, neither by the source, nor during transmission or by the recipient. This is the direct link to the security and cybersecurity topic discussed below.

Putting the citizen in the driver's seat is not a very new concept but it is also not yet mainstream and in particular not in health. We have to address legal, operational and security matters as much as practicalities, usability and added value aspects. In the early phase of the Artificial Intelligence hype we should bundle our activities with other domains. eHN should look for project and funding options to enable ourselves and the citizens. For the sake of efficiency but also to make sure our vital aspects are regarded eHealth should not try to cover the entire subject all by itself.

5.2 eSkills for Professionals

Even if we find the "solution" to uptake and progress in the multiple domains of the eHealth at national and European level, we will face challenges with the workforce, namely healthcare professionals. ICT technologies are evolving so fast, making disruptive changes on the way that people work and provide care delivery. Emergent technologies disrupt the healthcare business model and government need to retain the workforce, for this reason its important that we equipping healthcare professionals with the e-skills required to performed a better threatment to citizens

Its important that national authorities and education sector (e.g DG Education, Medical Schools, HCP chambers), have a clear understanding of how common standards or frameworks can be exploited as part of a structured methodology to develop the eSkills necessary to support eHealth in the different professional groups in healthcare.

5.3 Interoperability

Similarly to the challenge of putting the patient at the centre, also in interoperability and infrastructure domains we need to look beyond the close loop. For example, there is already another "Joint Action on Health Information towards a sustainable EU health information system that supports country knowledge, health research and policymaking" that we may want to target and interact with. We need to wider our radar scope towards other CEF domains and more importantly to the new Digital Europe programme.

5.4 Infrastructure

Both topics, interoperability and infrastructure, go hand in hand. We are already seeing extensive activities in the semantic domain and regarding use cases. It takes more time to work on the existing use cases ePrescription/eDispensation and Patient Summary than expected. This is in a way good news: As MS now work in all detail on the live implementations of cross-border data exchange inconsistencies of national implementations become more visible than before. This calls for compromises in the short run but primarily for enhanced efforts to improve interoperability. In turn we need both increased national efforts but also new ways of achieving interoperability by looking at enhanced coding and structuring schemes.

The structures that eHN created during the 2nd Joint Action - JAsEHN together with some support from DG SANTÉ are progressively providing new and improved contents and methodologies. Yet these activities are chronically underfinanced and depend heavily on voluntary contributions of our

countries. What is more: The work needs proper management, continuity, documentation, and accessibility. Again, this is currently achieved or at least aimed at - with temporary, voluntary and volatile measures.

We thus need to ensure that the tremendous amount of work that we have already invested is maintained and enriched. It is key that we achieve this through a permanent “home” for cross-border eHealth implementations. It needs to cover the maintenance and further development of structural and semantic interoperability and the support of day to day operations alike. With adequate Member States’ right to have a say in it an eHealth branch of an eGovernment Decentralized Agency should be the solution to go for. In the meantime, it may be necessary to create another sub-group of eHN.

The introduction of new use cases has already begun. The Commission has triggered EHRxF as a possible new application. eHealth Network is currently supporting it with our existing fragile structures assigned by the eHAction, yet once the Commission recommendation is out we need to ensure both CEF and Digital Europe (DE) funding.

The concept of CEF is that of centralized and decentralized (national or regional) infrastructures. The Central Services of CEF are coined eHDSI (eHealth Digital Services Infrastructure) and localized at DG SANTÉ. While the DG undertakes significant efforts to provide these services successfully the future after the ending of CEF is foreseen with the Digital Health Europe programme. However, processes and demands are likely to be different and require more coordinated action in future. This situation has to be dealt with as it is not acceptable that Member States are asked to implement services that rely on central functionalities of which the future is unclear. We need to analyse how more robust solutions – like a future eGovernance/eHealth Agency - could become the provider of the Central Services in the future.

With the eIDAS Regulation electronic (IDentification, Authentication and trust Services), the General Data Protection Regulation (GDPR) and other relevant legislation in place the hitherto stand-alone solution for cross-border data exchange inherited from eSOS is now obsolete. We now depend on support infrastructure like eIDAS nodes. eHealth is thus becoming more and more one application in a universe of applications which depend on similar and partly identical information sources and primarily national infrastructures, such is the vision and should be the increasing scope CEF/ DHE building blocks approach.

5.5 Cybersecurity/Security

This key focus areas can be logically grouped into two main domains with the subject “security and cybersecurity” being a critical hinge between the conceptional and structural patient orientation of the patient empowerment and patient access and the implementation aspects of the interoperability and infrastructure.

While this is not discussed here as a focus area we should consider that in reflection of the MWP 2018-2021 focus **Implementation challenges and impact** the eHAction has an entire work package dedicated to support the implementations called WP7 - Overcoming Implementation challenges.

As in MWP 2018-2021, the priority area **Overcoming Implementation challenges** addresses transversal issues crossing the other four categories, namely **Data Protection and Data Security**.

Digital Single Market and modernisation of health care require building trustable environments for health information systems and technologies, as the exposure to risk changes and health data is the new currency, **security** and **cybersecurity** are essential on the rethinking of the eHealth strategy.

Therefore, eHN MS co-chair believes that for the UE Member States/Countries common security measures and standards for health care must be communicated and implemented, with transversal and cross-sectorial governance and strategic organisation by building robust secure information systems, by creating collaborative responses to threats and sharing best practices implementation, with prevention and training, by the cooperation of universities, industry and academia for a sustainable development, and governments promotion of digital literacy.

EU eHealth CSIRT

Cyber security risks contribute to a complex and diverse risk profile, that governments, national competence centers and healthcare organisations must manage with appropriate responses and coordination among national stakeholders based on local constraints; These risks cannot be addressed in isolation, e.g. regional or national risk.

Currently, there is minimal sharing of information related to cyber threats specific or critical to health domain, and that which exists is based on individual relationships between national competence centers and healthcare organisations countries, rather than formal agreements that support fast and effective sharing of key information.

The development of formal sharing agreements and protocols will increase the understanding of the cyber threat landscape and deliver the following benefits:

- improve the response to cyber security incidents
- reduce resource impacts for implementing good security processes
- support the development of a unified view of good cyber security practices for the healthcare sector

Computer security incident response teams (CSIRTs) are a key component of protecting the digital community from cyber threats. Cooperative CSIRTs can deliver improved incident response, due to a shared understanding of threats and response actions, but there is currently no united approach across the global health sector for incident response. The creation of a EU CSIRT for the health sector, would enable the sharing of skills and resources in an industry where there is an internationally recognised skills shortage. This would improve the ability of all EU countries to improve their cyber abilities, regardless of their current maturity, in the adoption of digital health technologies.

5.6 Enterprise Architecture

Most of the solutions developed in the eHealth environment depend on each other to survive, or only really provide value to end-client (citizen, patient, health professional) when they are interconnected. Mapping and understanding this interdependencies is significantly enhanced with a Reference Architecture for eHealth, based on the Enterprise Architecture (EA) framework aiming the interoperability of eHealth in Europe.

An architecture is a formal description of a complex whole, and of the principles that are applicable to the development of that whole and all its components. Such description must include the pillars to the final design as such. The “whole” can be an organization or a chain, or equally a single information system or a network as an enterprise architecture is used as an instrument through

which to steer a project when steering the individual components alone would not lead to the desired result.

Architecture is the construction of the language, components, their interrelationships, and the principles and guidelines governing their design and evolution over time. A reference architecture is a generalized architecture of a solution, based on best-practices on a particular aspect. The goal of a reference architecture is reusability: it can help eHealth programs in to reduce duplication, increase shared services, upsurge a common planning of the eHealth synergies, close performance gaps, and promote the empowerment of European eHealth strategy and goals.

The reference architecture and recommended standards ensure that communication and interoperability can be performed in a simple and efficient way that facilitates quality and efficiency of services within healthcare providers at the European eHealth environment.

5.7 Better Coordination

One of the most relevant activities at the EU level, is to ensure proper alignment among the different European countries, EU projects/directives, national needs and capabilities, industry drivers, governance and business model and reimbursement. For that reason, we need to ensure a high-level cooperation among different MS/C in order to promote cooperation and cohesion in the several activities defined at the eHN. Political agenda and emergent technologies play an important role, to set up the speed of the ecosystem, although it is important to ensure governance and alignment.

This 2 years plan points to the ever more pungent need for governance, enterprise architecture thinking, and an holistic approach to eHealth at EU level. Initiatives like, an approved 5 years Common Semantic Strategy, the Joint Coordination Process, as well as, efforts under the tasks of WP 8 for sharing of national strategies as well as pós 2021 scenarios are key to achieving a more coordinated and efficient process of achieving our common goal, more interoperability in eHealth for better health in Europe.

Until we achieve a global vision and integrated governance, the meetings of the eHealth Network are our best pace-maker, and its agendas, and the topics covered should guarantee we do not deviate too much from the intended path.

6. eHealth Network Landscape themes/topics

In order to achieve a holistic view about the seven key areas on eHealth and healthcare information systems, it is crucial to keep in mind which themes and topics came and will arise to eHN with the integration of these new concepts.

Until now, the eHN has been working with crucial health themes to improve people's lives among the EU, facilitating the cohesion among MS/C. For that, it is indispensable look for actual new subjects and themes that reflects the European citizens necessities in a complex environment. The eHN has been working hard on the strategic themes since their foundation on 2012. For a better understanding, we propose a themes classification according their priorities on four points B1, B2, B3 and C1 (please, see the annex 2 for the all themes view):

- The B1 group has been worked and evolve the eHN management issues, policy, past Joint Actions, the actual eHAction and the eHDSI subtopics. The B1 themes are considered with high priority and have a defined strategy to be discussed.
- The B2 themes can be faced as the new priorities for the eHN and they actually are approached on a secondary eHN scenario but shows a high importance to be integrated on the next years. These themes evolve, but not only, some subjects as telemedicine, EU Stakeholders involvement, Joint action on vaccination, big data, artificial intelligence, genomics and etc.
- The B3 represents some themes ad-hoc that are suggested to be discussed on the eHN and can be faced as some reference on next scenarios.
- The C1 themes represents new directives EU policy proposal, new calls and funding mechanisms, are from EC interesting that expects validation and endorsement from eHN.

These subjects (B2, B3 and C1) should be considered with high importance for a strategic alignment to eHN. Take these themes in mint will support a clear vision of the actual relevant topics for health. With this scenario, is possible a better MS/C articulation to integration and will guarantee the eHN sustainability and health field among the European Union.

7. Considering the Way(s) Forward

The extent and direction of future activities is considered below with a small number of potential scenarios on which the Member States could embark on. It is the nature of scenarios that they are not put into praxis one to one, yet they can serve as a powerful tool for thought and as a means for creating conditions that can move us forward. Table 3/annex 3, develops some scenarios for helping understand choices.

Between 2008 and 2010 [CALLIOPE](#) networked the main European eHealth related projects and activities to “...(1) deliver a Roadmap to achieve eHealth Interoperability...; (2) formulate a proposal for updating the 2009 Commission Recommendation on Interoperability of Electronic Health Record systems...” Ten years later main recommendations of the projects covered by the CALLIOPE networking activity have not (yet) been transposed or at least not fully. Ten years later some of them may also be considered either outdated due to new or different developments or because they do not seem to be promising or achievable. Key considerations are reflected in the table below. Repetitive topics and cornerstones are:

- The necessity for permanent structures for governance, (semantic) interoperability and the maintenance thereof
 - several years down the road we also require permanent structures for the operation and governance of live services
 - for our CEF deployment we have identified and implemented a significant number of structures and measures in the legal, organizational and technical domains at the European Commission. The mostly centralized structures are as yet fragile and do not have the capacity for permanent operations
- Semantic activities in support of CEF operations remain primarily with the MS/C primarily on a voluntary basis, partly with the support of the eHAction. The CALLIOPE suggested roadmap to provide general semantic interoperability remains to be completed

Definitely the work on Joint Coordination Process is key to achieving overarching governance.

8. European Financing Schemes and Sustainability Beyond 2020

The current eHDSI is based on the CEF scheme providing partial funding and support and operational facilities provided by the European Commission. Three Directorate Generals are involved in eHealth: DG Santé, DG CNECT, and DG Digit. While this provides a broad knowledge base and various competences, it also requires dedicated and demanding attention by the Member States participating in the cross-border exchange, partly through voluntary work or the Joint Action supporting the eHN.

CEF will come to an end in 2020 and it will be an important task of both the EC and the member States through the eHN to ensure the permanent availability and further development of the eHDSI. As yet there is no sequel scheme to CEF in place and it needs to be analysed by the eHealth Network if the current scheme of having a partial responsibility of DGs with insufficient contractual relations between those and the MS is future-proof.

Ultimately only an independent body covering all relevant aspects can ensure the permanent attraction and usefulness of cross-border services. The eHN MS co-chair believes that this body should be a Decentralized European Agency. Analysis shows that none of the existing European Agencies could cover the topics relevant for eHealth and it is thus an important task for the eHN to conceive, propose and have implemented all relevant responsibilities for Digital Health in a new Decentralized European Agency.

There are movements towards establishing such a new Decentralized European Agency for eGovernance aspects. eHN should target activities to shape this new agency as a functional instrument towards the end of CEF support for eHDSI. For this it is necessary that the eHN dedicates an appropriate body to pursue the case in co-operation with all relevant EU bodies and the Commission.

Although the origin of the eHealth Network always reminds us to take into account the applicability of the Directive 2011/24/EU perhaps another sustainability measure is to look more intensely beyond outskirts of Europe. This is not only because of mobility outside the EC's borders but also and primarily because the work of relevant SDOs is global and in particular driven by the US. We should thus go beyond occasional joint projects and put a stronger and regular co-operation on the agenda. In the future the EHDA could also play a role in this.

Towards the end of Horizon 2020 and at the eve of future EC schemes it is advisable that we collect demands and developments in MS and from elsewhere and transform them into R&D items rather than just reacting to schemes being set up by the Union. The Commission's Communication and its three pillars related to eHealth and DG CNECT's invitation to work on the EHRxF can be considered a stepping stone in the right direction.

Abbreviations

| Acronym | Description |
|-------------|--|
| BEUC | The European Consumer Organisation |
| CEF | Connecting Europe Facility |
| CEN/CENELEC | European Committee for Standardization/European Committee for Electrotechnical Standardization |
| CSS | Common Semantic Strategy |
| DE | Digital Europe |
| DG CNECT | Directorate-General for Communications Networks, Content and Technology |
| DG Digit | Directorate-General for Informatics |
| DG Santé | Directorate-General for Health and Food Safety |
| EC | European Commission |
| ECDC | European Centre for Disease Prevention and Control |
| eHAction | eHealth Action |
| eHDSI | eHealth Digital Services Infrastructure |
| eHN | eHealth Network |
| EHRxF | Electronic Health Record Exchange Format |
| EMA | European Medicines Agency |
| ENOPE | European Network on Patient Empowerment |
| epSOS | Smart Open Services for European Patients |
| EU | European Union |
| GDHP | Global Digital Health Partnership |
| GDPR | General Data Protection Regulation |
| ICT | Information and Communications Technology |
| JAsEHN | Joint Action to support the eHealth Network |
| MWP 18-21 | Multiannual Work Programme 2018-2021 |
| OECD | Organisation for Economic Co-operation and Development |
| SDO | Standards Developing Organisation |
| WEF | World Economic Forum |
| WHO | World Health Organisation |
| WP | Work Package |

ANNEXs

Annex – 1: Multi-domain

L

Multi-lateral Agreements and Bilateral agréments (e.g. eHDSI Agreement)

Uptake of legal directives such GDPR, NIS eIDAS

eHN Implementation decision

New Business Cases and models for Cross-Border Healthcare

O

Cross Border cooperation among MS/C

Guidelines for eHealth Nacional Competences Centers

Definition of Policy Cooperation based with “real” data and EU needs (e.g Localware and Peopleware)

Promote better semantic interoperability in the EU

S

Alignment of eHealth standards

Convergence between ways MS/C document clinical processes

Define new strategies for mapping and translate data, such (NLP)...

Allow sufficient flexibility to provide structured and coded data from the national and Cross-border infrastructure while, at the same time, enabling the explore of new services.

T

Evolve national infrastructure and systems

Improve interoperability at Local and National level, that use common standards (such HL7 or IHE)

Promote CyberSecurity at national and local level

S

EU guidelines for CyberSecurity (D7.3.)

EU Common approach on cybersecurity threads; Protection measures and capacity building

Shared and Integrated prevention, education and awareness

Annex – 2: eHealth Network Landscape themes

| Priority Classification | Project/ Entity/ Area of Relevance | Topics to be addressed | eHealth Network meetings | | | | | | | | | | | | | | | | | | | | |
|-------------------------|--|--|--------------------------|-----|------|-----|------|-----|------|-----|------|-----|------|-----|------|-----|------|-----|------|-----|------|-----|---|
| | | | 2012 | | 2013 | | 2014 | | 2015 | | 2016 | | 2017 | | 2018 | | 2019 | | 2020 | | 2021 | | |
| | | | May | Nov | May | Nov | May | Nov | May | Nov | June | Nov | May | May | May | Nov | June | Nov | May | Nov | May | Nov | |
| B1 | eHN | Rules of Procedure eHN | ■ | | | | | | | | | | | | | | | ■ | | | | | |
| | | Network's objectives and Multiannual Work Programme | ■ | | | | | | | | | | | | | | | | | | | | ■ |
| | | Preparatory work for new Multi-annual Work Program of the eHealth Network | | | | ■ | ■ | | | | | | | | | | | | | | | | ■ |
| | | Appointment of Member State chair | | | | | ■ | | | | ■ | | | | ■ | | | | | ■ | | | |
| | | EU strategy and activities on digital health – presentation of the proposals & tour de table | | | | | | | | | | | | | ■ | | | | | | | ■ | ■ |
| | | Implementing Decision | | | | | | | | | | | | | | | | | ■ | | | | |
| | | Strategic priorities for the eHealth Network for the period 2012- Presentation of EU initiatives on eHealth | | ■ | | | | | | | | | | | | | | | | | | | |

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|-------------|------|--|-----------------------|--|--|---|---|---|--|---|---|---|---|---|--|---|---|---|---|---|---|---|
| | 2014 | Work on ePrescription under article of the Directive 2011/24 | █ | | | | | | | | | | | | | | | | | | | |
| | | eHealth Action Plan 2012-2020 | █ | | | | | | | | | | | | | | | | | | | |
| | | The Connecting Europe Facility 2014-2020 | █ | █ | | █ | █ | █ | | | | | | | | | | | | | | |
| | | The ICT multistakeholders platform on standardisation | █ | | | | | | | | | | | | | | | | | | | |
| | | EU eHealth strategy towards 2020 | | | | | | | | | █ | | | | | | | | | | | |
| | | eHN Legal subgroup | | | | | | | | █ | | | | | | | | | | | | |
| | | eHN Joint Action (JAseHN) | | | | | | | | █ | █ | █ | █ | █ | | | | | | | | |
| | | National eHealth Strategies | | | | | | | | █ | █ | █ | █ | █ | | | | | | | | |
| | | Implementation of the Digital Single Market strategy | | | | | | | | | | █ | | | | | | | | █ | █ | █ |
| | | eHAction | WP4 Empowering People | D4.1 Policy Framework on Patient Empowerment | | | | | | | | | | | | | █ | █ | █ | | | |
| D4.2 Policy | | | | | | | | | | | | | | | | █ | █ | | | | | |

| | | | | | | | | | | | | | | | | | | | | | |
|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|--|
| on Action against cancer | | | | | | | | | | | | | | | | | | | | | |
| Joint Action on preparedness and action at points of entry (air, maritime and ground crossing) | | | | | | | | | | | | | | | | | | | | | |
| Joint Action on Health Informatics towards a sustainable EU health information system that supports country knowledge, health research and policy-making | | | | | | | | | | | | | | | | | | | | | |
| European Oncology | | | | | | | | | | | | | | | | | | | | | |

Annex – 3: Scenario exercise

Table 3 – Proposed Scenarios

| | Scenarios | | |
|------------------------|--|--|--|
| | Scenario 1 - Continue as before | Scenario 2 - Focus on Principal Matters | Scenario 3 - Separate Strategy and Operations |
| Strategy | Trust that the current work of the eHN and its interrelations are sufficient. Continue to monitor and accompany new developments in health, influence EC law and rulemaking. Guide and support MS in aligning eHealth strategies and implementations and promote interoperability. | The eHN has set important pillars for the future. Frameworks and Guidelines are showing the way forward. Based on these activities the eHN works towards leaving practical implementations and operation of cross-border services to the European Commission, the Member States and interested parties. SDOs are entrusted with the further development of the underlying structures and mechanisms. | Gain a certain level of control over principal developments and actual implementations. To achieve this, professionalize all necessary elements of eHealth in a dedicated body while fully maintaining Member States' interest. |
| Outcome by 2025 | Further improvement of MS co-operation and interoperability. Continuation and extension of cross-border services with central services not being under controls of MS. | The eHN is focussing on principal matters, Member States are significantly relieved from voluntary contribution related to practical implementations at the price of reduced influence. Cross-border services may be running sufficiently, yet with little control by the eHN | eHN continues to address and decide upon all principal matters of eHealth. A European Agency is taking care of overseeing and developing further working elements such as semantics, operations, X-border developments and takes care of operations. |
| Pros | Progress in the running and development of regular cross-border services | eHN is focussed on decision making of principal matters on the high level for which it has the competence embedded | Cross-border services are permanently developed supervised and operated by a European Agency. Operations and finance are permanently secured |
| | Continuous MS and EC interaction and alignment | On a working level Member States have reduced efforts, Joint Action supporting the eHN can limit their efforts to supporting the then limited activities of eHN | eHN focuses on the principal developments and sketches the broad lines |
| Cons | Voluntary alignment and restricted control over the production elements limits the extent and quality of data exchange | Vastly reduced influence on the implementation and running of cross-border services | Member States can focus much more on the national and legal aspects. Their cross-border implementations are based on a stable European governance model |
| | SDOs and industry are not sufficiently related to the eHN's intentions | Dependence on developments and changes within the Commission, control over SDOs in particular beyond Europe very limited | Setting up a European Agency requires commitment and significant effort on the side of the MS |
| | New main drivers in eHealth can at best be supported but not influenced and moderated at an early stage | eHN may lose contact with the Member States' needs and requirements on principal matters and real-life implementations | eHN needs to rethink its remit and activities. Member States need to adjust working with a party that by definition needs a degree of independency |