eHEALTH NETWORK RECOMMENDATION

for the

Development of National Digital Health Networks in the EU Member States

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Purpose of this document

The idea of National Digital Health Networks (NHDNs) was first put forward in the Commission's EEHRxF Recommendation of 2019, as a valuable instrument to promote greater interoperability of cross-border health data. From this recommendation, the initial concept of NDHN was expanded through an intense process of discussion in the eHN and eHN subgroups meetings and exchanges of information between Member States. The eHAction members, based on the inputs received, have elaborated a set of recommendations aimed at supporting the development of NDHNs.

In this sense, and by representing the considered views of all contributors and some examples of already existent NDHNs, this document presents a first step towards the development of a governance framework that Member States could use in setting up a NDHN. NHDNs are needed to ensure that all relevant national bodies and stakeholders are connected. This better develops digital health inside member states as well as supports EU policy efforts to achieve national and cross-border interoperability as NHDNs can be better communicate, follow-up and leveraged such efforts.

A NDHN aspires to create a positive impact on national (e)Health ecosystems in terms of information exchange and capacity building. As national governments all strive to improve healthcare services quality and reduce health inequalities in access by EU citizens, a NDHN aims to contribute to better coordination of national activities, advance evidence-based policymaking, and stimulate the development of interoperability in eHealth so that new services could sustainably emerge (EEHRxF).

The present recommendation was designed with the purpose of presenting the eHN with a more concrete view of a prototypical NDHN, its principles, structure and main bodies that can be recommended as a reference model. It does not intend to explain how exactly each MS is to accomplish such structures, as that is an internal Member State decision. Nonetheless, a clear overview of all governance in Member States and a common understanding of what we want to achieve, supported by the development of a common frame of reference, could act as a first step forward for comprehensive NDHNs to be created and interoperate with those of other MS.

CONTROL PAGE OF DOCUMENT		
Document name		eHealth Network recommendation for the Development of National Digital Health Networks in the EU Member States
Work Package		WP1 - Coordination
Dissemination level		PU
Status		Final
Author(s)		
Country	**Organisation**	**Name**
Portugal	SPMS	Henrique Martins; Diogo Martins; Anderson Carmo; Miguel Santinhos
Beneficiary(ies)		SPMS

REVISION HISTORY – eHealth Network recommendation for the Development of National Digital Health Networks in the EU Member States				
Version	**Date**	**Author**	**Organisation**	**Description**
0.1	02/08/2019	Henrique Martins	SPMS	First version of the document.
0.2	15/09/2019	Diogo Martins; Anderson Carmo	SPMS	Improvement of the document and inclusion of the section “NDHNs principles”.
0.3	05/10/2019	Henrique Martins; Diogo Martins; Anderson Carmo	SPMS	Contribution of an example of NDHN: “Portugal and local level engagement”.
0.4	21/10/2019	Roger Lim	MINVWS	Contribution of an example of NDHN: “The Dutch Health Information Council”.
0.5	24/10/2019	Sari Palojoki	STM	Contribution of an example of NDHN: “Findata and Secondary Use of Data”.
0.6	29/10/2019	Sarah Murphy	IEDoH	Contribution of an example of NDHN: “Ireland and Formalization of partnerships with academia on eSkills for healthcare professionals”.
0.7	01/11/2019	Priit Tohver	SM	Contribution of an example of NDHN: “a multi-stakeholder approach to eHealth strategic development plan”.
0.8	17/01/2020	Diogo Martins; Anderson Carmo	SPMS	Revision of the document after inclusion of examples of NDHNs.
0.9	05/03/2020	Henrique Martins; Anderson Carmo	SPMS	Revision of the document.
0.10	16/03/2020	Isabella Webber; Niklas Kramer; Priit Tohver; Csizmadia István	Sozialministerium; BMG; SM; AEEK	Comments on the document in order to align with a common EU view.
0.11	25/03/22020	Anderson Carmo	SPMS	Compilation of the comments on the document.
0.12	27/03/2020	Henrique Martins; Diogo Martins	SPMS	Review of the document and comments.

REVISION HISTORY – eHealth Network recommendation for the Development of National Digital Health Networks in the EU Member States				
Version	**Date**	**Author**	**Organisation**	**Description**
0.13	20/04/2020	Miguel Santinhos	SPMS	Restructuration of the document.
0.14	18/06/2020	Diogo Martins; Anderson Carmo	SPMS	Comments and update of the document.
0.15	20/07/2020	Anderson Carmo; Miguel Santinhos	SPMS	Reviewed document considering the received comments.
0.15a	07/09/2020	Hugo Agius Muscat	MFH	QM review of version 0.15
0.16	09/09/2020	Anderson Carmo	SPMS	Revision of the document after QM review.
0.17	13/01/2021	Anderson Carmo; Miguel Santinhos	SPMS	Restructuration of the document accordingly eHN comments.
0.18	10/02/2021	Roger Lim; Stergiani Spyrou; Philipp Schardax	MINVWS; 3rd-RHA; ATNA	Comments on the document after LC meeting.
0.19	17/03/2021	Anderson Carmo; Miguel Santinhos	SPMS	Revision of the document accordingly the received comments.
0.19a	20/03/2021	Hugo Agius Muscat	MFH	QM review of version 0.19.
0.20	25/03/2021	Diogo Martins; Anderson Carmo; Miguel Santinhos	SPMS	Revision of the document after QM review and update of content.
0.21	14/04/2021	Leonhard Kamper; Diogo Martins; Anderson Carmo; Miguel Santinhos	ATNA; SPMS; SPMS; SPMS	Update of the document accordingly the received comments from the eHAction Leadership Council members.
1.0	05/05/2021	Anderson Carmo; Miguel Santinhos; Leonhard Kamper;	SPMS; SPMS; ATNA;	Final revision of the document taking into account the comments received from EC and eHAction Steering Council meeting.

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Executive Summary

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. At the same time, new needs are arising, such as to better bridge digital health information between research and healthcare, to secure data exchange processes and enhance data-driven innovation.

Acknowledging this, the 2019 Commission's recommendation on a *European Electronic Health Records exchange Format* brought forward two instruments that can help fostering greater interoperability for cross-border health data exchange – National Digital Health Networks (NDHN) and a Joint Coordination Process.

This document represents the outcome of the eHN subgroup discussions on the development of National Digital Health Networks. Its purpose is to present a possible vision on how such an instrument could be understood and what features it should encompass. It cannot to harmonize how the Member States should organise their bodies and stakeholders nationally, as this is a matter of national responsibility under the EU Treaties. But to bring a collection on principles that Member States could refer to, when organising their own NDHN according their national needs and competences.

Furthermore, it aims to help the Member States in the setting up of 'interoperable' national networks that can operate in an interconnected manner, between Member States as well as between them (and its national health related bodies).

This being said, the following recommendations aim to:

- Support the Member States to formulate decisions on the establishment of bodies or functions relevant to the development of a fruitful national eHealth ecosystem, if these do not already exist;
- Map and consolidate the possible interdependencies and synergies between the different nodes of a National Digital Health Network in order to further improve its functioning, as well as collaboration with National Digital Health Networks from other EU Member States.
- Encourage the development of a common frame of reference to which all partners in the EU Digital Health ecosystem can refer when they think and act vis-à-vis national level topics regarding eHealth.

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Acronyms

Acronym	Description
AI	Artificial Intelligence
CSS	Common Semantic Strategy
ECDC	European Centre for Disease Prevention and Control
eHDSI	eHealth Digital Service Infrastructure
eHMSEG	eHealth Member States Expert Group
EEHRxF	European Electronic Health Record Exchange Format
EMA	European Medicines Agency
eHN	eHealth Network
ENISA	European Union Agency for Cybersecurity
EU	European Union
GP	General Practitioner
GDPR	General Data Protection Regulation
JCP	Joint Coordination Process
MoH	Ministry of Health
NCPeH	National Contact Point for eHealth
NIS	Network and Information Systems
NDHN	National Digital Health Network

Glossary

Governance – In this document, the word governance denotes an organisational arrangement (horizontal and vertical) amongst nodes which, based on their functions and characteristics, influence, support and enact policies and decision-making concerning a national digital health transformation towards a sustainable development on health.

National eHealth Ecosystem – This document defines a national eHealth ecosystem as a large community of actors (people, workforce, organisations, institutions and authorities) that are linked for the purpose of healthcare provision, innovation and health advancement, and interact mainly within national borders. A national eHealth ecosystem enacts a continuing process of interaction between actors, that due to its own singleness, generate systemic dynamics that shape national needs and strategies under the responsibility of each Member State.

Nodes (Network) – Based on the visual image of a network, this document defines nodes as a set of interconnected actors that interact with one another continuously, consequently giving shape to a national health ecosystem, which in turn, is hierarchised under the corresponding authority.

Introduction

Not all Member States have a unique national eHealth agency, and those that do have one, have very different competencies, legal attributions and scope of action. Such heterogeneity is only natural due to the organic development of each national eHealth ecosystem[1] and its changing nature.

By recognising the different degrees of digital transformation in national health systems and its relationship with a European interoperable eHealth ecosystem, EU Member States' ambition to deepen their technical-scientific cooperation to advance the sector culminated, on 6 February 2019, in the official publication of the *Recommendation on a European Electronic Health Electronic exchange format*[2] (EEHRxF) by the European Commission.

In this recommendation, the role of governance is again emphasised as a critical step towards the implementation of interoperable solutions. A Joint Coordination Process was deemed necessary, as well as the 'setting up' of National Digital Health Networks for the Member States. The European Commission Recommendation already pointed out some aspects, in detail the text reads:

> ***National digital health networks***
>
> *6) To enhance the interoperability and security of national health systems and support the secure exchange of health data across borders, each Member State should set up a national digital health network involving representatives of the relevant competent national authorities and, where appropriate, regional authorities dealing with digital health matters and the interoperability of electronic health records, and security of networks and information systems, and the protection of personal data. In particular national digital health networks should involve the following:*
>
> *(a) the national representative of the eHealth Network;*
>
> *(b) national, or regional, authorities with clinical and technical competence for digital health matters[3];*
>
> *(c) supervisory authorities established under Article 51 of Regulation (EU) 2016/679;*
>
> *(d) competent authorities designated pursuant to Directive (EU) 2016/1148.*
>
> *7) The results of discussions or consultations of the national digital health networks should be transmitted to the eHealth Network and to the Commission.*

In order to achieve an interoperable European ecosystem (e.g. '*100% availability of medical records'*)[4], national activities and demands should be aligned with European initiatives. That is, to achieve something at the EU level, that is a national competence, having the right governance/organisation at the national level (NDHN) is fundamental to ensure that all relevant national bodies/stakeholders are connected, and can be engaged and mobilised to reach common goals.

[1] See Terms of Reference section for definition. For more information see: https://ec.europa.eu/health/sites/health/files/ehealth/docs/ev_20190611_co922_en.pdf
[2] For more information: https://ec.europa.eu/digital-single-market/en/news/recommendation-european-electronic-health-record-exchange-format
[3] This document considers it important to emphasise the role of semantics in eHealth when discussing clinical technicalities.
[4] Europe's Digital Decade: digital targets for 2030. For more information access: https://ec.europa.eu/info/sites/info/files/communication-digital-compass-2030_en.pdf

Therefore, it is clear that arising governance/coordinative requirements cannot be achieved without the strong involvement of Member States and national stakeholders. Having such national arrangements in place, a NDHN would generate a substantial impact on the implementation of interoperable solutions at the national level, hence paving the way for high levels of interoperability at the EU level.

How can NDHN impact European interoperability?

National Digital Health Networks can foster European interoperability in three ways:

1. Build an interoperable network of networks

To support and improve the connection and communication between the different networks at national and EU level, leading to an efficient exchange of health information (avoiding duplication of work) and eHealth interoperability.

A NDHN can streamline health information services in place, (ePrescription/eDispensation & Patient Summary), and support the development and deployment of new information domains, as put forward in the EEHRxF (e.g. laboratory results, medical image reports, hospital discharge letter and records on rare diseases).

With this in mind, the outcome of having a network of national networks in the EU would generate gains in eHealth interoperability by facilitating communication and promoting general and continued applicability of eHealth solutions/tools. Moreover, it can also help to leverage the recommendations/guidelines produced in the context of technical cooperation in eHealth in the EU[5].

As for the relationship between NDHNs and the eHN, the former represents a national (autonomous) organisational structure in which the representative of the eHN plays a major role in its functioning and development. In particular, by acting as an interconnector between national ecosystems spheres and the EU realm (cross-border). In this regard, a network of the networks would arise as a result of continued interaction between representatives of the national structure/ecosystems (NDHNs) and European cooperation (eHN). Figure 1 presents the relationship between the Member State eHN representative, the NDHNs and the topics that this network intends to support.

[5] By way of example, the leverage of eHAction's Recommendations and guidelines for IT Management on implementing interoperability actions in healthcare organisations (D7.1). http://ehaction.eu/wp7-overcoming-implementation-challenges/

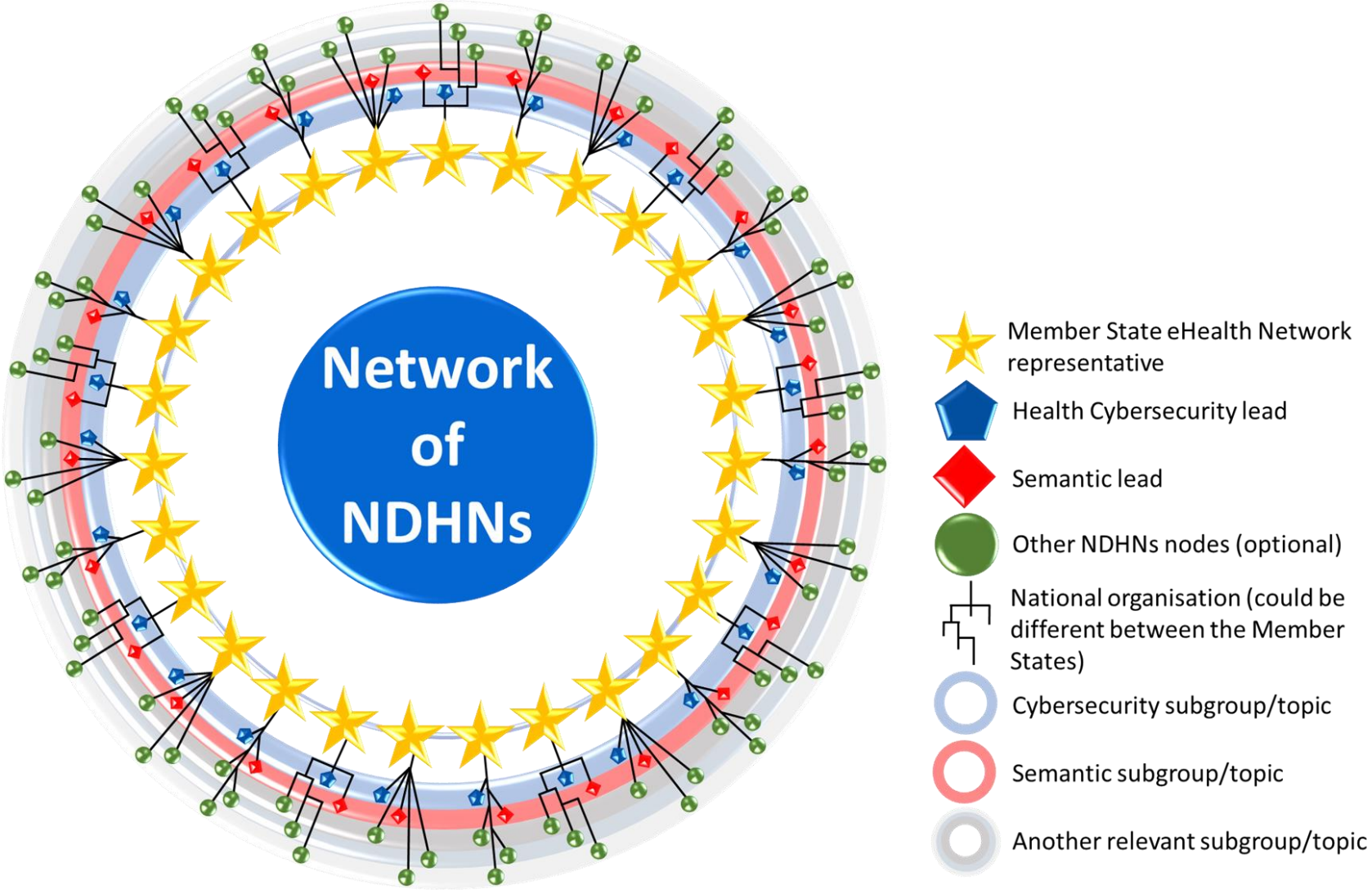

Figure 1: NDHNs relationshiop with eHN and the supported topics.

2. Facilitate benchmarking and knowledge sharing between Member States

Having NDHNs set up (i.e. knowing which are the different governance structures in the Member States) would allow all relevant national bodies/stakeholders to develop plans on how to make improvements or adapt specific best practices, based on the lessons learned from the other Member States, as well as encouraging benchmarking as a tool for identifying weaknesses and promoting further developments/innovation.

Such organisational features can contribute to increased awareness and understanding of eHealth pursuits, just as to support continuous monitoring of ongoing eHealth activities towards achieving sustainable processes in eHealth policy cooperation.

3. Bridge needs of primary health data use with needs of secondary health data usage

To best tackle societal health challenges, when developing national healthcare strategies, Member States would gain leverage from having both timely access and integrated insight on people's health data conditions. By bridging the needs of primary use of health data with needs of secondary use, Member States would stand better placed for delivery of better healthcare outcomes, as well as promoting health research and evidence-based policymaking, tailored to their national context. Moreover, national eHealth ecosystems could gain leverage as well from the innovative potential of re-using health data for multiple purposes.

Having outlined three potential impacts of setting up of NDHNs, it is also important to emphasise that the existing fragmentation of digital standards and the limited digital interoperability between healthcare systems poses a significant challenge for eHealth policy cooperation in the EU, hence to the development of the European Health Data Space (EHDS).

NDHNs would act as a valuable instrument to achieve better coordination between national governance structures, ultimately addressing the barriers hindering data use and re-use, in particular those related to infrastructure, interoperability, data quality and standards in the health field. Moreover, NDHN could also reinforce the security of the personal data exchange within and between the national health ecosystem, therefore increasing the safety of personal data space. Following this line of thought, NDHNs could also feed into the ongoing work towards the EHDS; namely, the bodies/functions put forward in the Commission's proposal on a horizontal framework[6] for the development of common European data spaces would benefit from having an interconnected organisational structure at the national level for eHealth.

In this regard, building capacity in the Member States is fundamental to mitigate the existing fragmentation among and within them. Making the most of funding opportunities is, therefore, key to advance interoperability implementation across the Member States (i.e. access, sharing, use and reuse of health data). In order to accomplish a functional and fruitful eHealth ecosystem, particular emphasis must be given to streamlining national capacities (e.g. infrastructures, professionals, citizens and health data).

Paving the way for Europe's Digital Decade means, at the current stage, establish the appropriate organisational/co-operation framework nationally (NDHN), and to strengthen the elementary

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

foundations for long-term sustainable and inclusive growth (capacity building). In this sense, funds such as CEF (Connecting Europe Facility) and NextGenerationEU through the RRF (Resilience and Recovery Facility) are directly related with the improvement of capacity building among the Member States. They can be used as a direct source of investment to support the development of the eHealth interoperability and co-ordination, digitalise public administration services/systems and reskill citizens and professionals. The Commission has started, through DG SANTE, but can further develop the necessary initiatives to capacitate Member State's national agencies. E.g., such initiatives could be the basis for a funding programme specifically target to support the identification of nodes and to promote the implementation of the NDHNs.

This document shall serve as a reference point for the Member States and help to create policy pressure, intending to establish better coordination mechanisms aimed at supporting national digital health strategies to improve eHealth services already in place and to develop new services as stated on the EEHRxF recommendation.

1) Setting the Ground for Digital Health Networking

Table 1 in this section presents a set of important nodes[7] to achieve better procedural coordination in digital health dynamics. Emphasising, once again, the Member States' heterogeneity with regard to digital transformation, the nodes[8] in presented in Table 1 aim to facilitate the processes of co-creation and decision making[9] by clarifying competences between nodes horizontally and the national authority vertically.

Table 1 – Nodes within a modern approach to Digital Health Networking

Secondary data usage function / institution	As society moves towards big data analysis and artificial intelligence (AI) usage in health, in response to increasing challenges in the national health system, it becomes crucial for Member States to make explicitly clear which is the institution/organisation responsible for leverage of secondary use of health data towards achieving better and faster research and innovation outcomes. The information on how analyses this kind of data, such as good practices, should be exchanged between the Member States and NDHN group towards a kind of standardisation on the data format in order to support the machine learning algorithms used for such secondary big data analysis. It is important to ensure that data protection and privacy principles are always respected.
Cybersecurity in Health	Since the main purpose of this document is to establish networks as a means to achieve better coordination and sharing, cybersecurity plays a crucial role when it comes to ensuring that information circulates accurately and securely. Furthermore, the NIS Directive[10] states that 'critical services' shall have cybersecurity monitoring; eHealth fits clearly in this category.
Public Health Authority and National Competence Centres	While there may be more than one agency/body with public health functions in a Member State, there is generally one public health authority which interacts with WHO on behalf of that Member State. Moreover, the National Competence Centres can play a valuable role in promoting the digital transformation in the health sector by cooperating with European counterparts. As public health functions become increasingly digitalised, it is advisable that these entities play a role in the eHealth ecosystem.
Agencies / Ministries supporting national research initiatives	Increasingly researchers ask for health data, as well as research into health informatics, as well as healthcare provision, requiring not just data, but eventually, digitally-enabled organisational changes, in health management research.

[7] See glossary to access the 'node' definition (page 3).
[8] The following examples are not exhaustive but serve to illustrate how different actors are relevant for a modern approach to digital health networking at the national level.
[9] Mainly technical-scientific processes.
[10] https://ec.europa.eu/digital-single-market/en/network-and-information-security-nis-directive

	Alignment of national research agendas with that of digital health is therefore key to faster eHealth solution adoption and also to the study of its benefits.
eHealth Agencies	The eHealth services are provided, in many Member States, by eHealth Agencies in association or under direct responsibility of the Ministry of Health. These agencies use innovative technology to support the health sector needs with services such as ePrescription, Patient Summary, Telehealth, and are working on the development of new services as stated in the EEHRxF recommendation. eHealth agencies are a key driver on the integration/development of the national health ecosystem and plays a central role on decision making policy of health ecosystems. Therefore, crucial to foster a sustainable national health ecosystem.
Initiatives related to Personalised Genomics / Precision Medicine	Efforts to support genomics use as well as some of its promises like precision medicine are a concern in many Member States; linking to datasets is only one concern. Impactful interventions will require the capacity to go back to subjects and healthcare processes and inject/include that which has been researched/learned into practice, decision-making and ultimately patient care. Such linking requires these parties to be part of the eHealth ecosystem more and more.
National CIOs, AI agencies and super-computing	Digital is not a health matter, but a whole-of-government approach to this is key. Areas like personal digital ID are often catered for by national level agencies. Artificial intelligence strategies are coming out in many countries in a trans-sectoral manner, and both funding as well as some computing (like super-computing capacity) make sense in a cross-domain fashion. Linking healthcare sector organisations, their digital health efforts, is thus key to ensure that health is not left behind.
National Semantic Assets	It should be worked upon in the eHN Subgroup on Semantics that semantic assets be established on the national and cross-border levels. The semantic basis is very important to standardise data sharing and achieve an unambiguous language. This approach should be seen in a complementary way with EHRxF, electronic identification and eHealth Reference Architecture.
Patient representative organisations	Patient organisations are important partners for good policy making. These platforms offer a patient perspective crucial to be taken into account when developing structural level policies.
Stakeholder groups & Innovation	Since the health sector strongly relies on information to solve problems, a multi stakeholder forum would act as a valuable asset to foster an innovate national health ecosystem.

To achieve better procedural coordination, it would be important that NDHNs play a facilitator role; i.e. an NDHN should ensure that the output of EU level recommendations/decisions is followed up, in a way that reaches out to national nodes, ultimately promoting the awareness of strategies and visions for national actions. Alignment with key European stakeholders could be valuable to promote national interoperability. To name a few stakeholders:

- European Medicines Agency (EMA),
- European Union Agency for Cybersecurity (ENISA),
- European Centre for Disease Prevention and Control (ECDC),
- eHDSI CEF services,
- Other European initiatives (e.g. 1+ Million Genomes)

Such a link between national nodes and EU activities could be achieved through an intense review process of the national activities, followed by mapping with the EU activities on these diverse scenarios. The identification of the similar activities among the Member States at EU level could enhance the development of those initiatives by the exchange of experiences, best practices and lessons learned, improving the evolution of such activities and, in an ideal scenario, drive discussions towards a common approach for next steps regarding each node/activity.

Only by connecting the dots can a Member State achieve coherent organisational interoperability between digital services.

Notwithstanding, striving for stakeholder engagement stands as well as a critical step towards enacting more inclusive decision-making. In this sense, the arrangement of NDHNs would certainly benefit if associations, clusters and enterprises would have a means to interact.

1.1 What could NDHNs strive for?

The following section presents five compelling reasons for the usefulness of having a commonly agreed approach to NDHNs and conveying that to Member States:

I. Build an interoperable network of networks

a. Enhance interoperability through national eHealth ecosystems

b. Increase coordination and cooperation through an EU-wide Network of NDHNs

The development of ecosystem of networks should be fostered following European Commission and Member States/countries recommended guidelines, approved in the eHealth Network (eHN) or to be elaborated after the approval of these recommendations, taking in account the operational realm of each national eHealth arrangement whilst promoting the alignment of all specific topics/functions with other national counterparts.

It is also important to highlight the synergistic effect of bringing together people at the same level of responsibility (e.g. eHN organised workshops for semantics and cybersecurity), which demonstrates the usefulness of the existence of similar functions in all Member States.

I. Facilitate benchmarking and knowledge sharing between Member States

a. Similar nodes[11] for delivering national eHealth ecosystem insights

[11] This document defines a homologous node as a body/function that appears in different national health ecosystems and may not be similar in structure but shares the same purpose.

b. Fostering efficiency through reduce of cost and avoid duplication of work

II. Strive for inclusiveness

a. Create favourable conditions for enhanced interoperability at the national and cross-border levels
b. Deliver guidelines and support eHN decision-making

III. Support Member States in developing eHealth strategies

a. A governance model as a major step towards achieving better coordination and outcomes
b. Official documents clarifying principles, goals, priorities, capabilities and processes
c. Ensure stakeholder engagement and clarify nodes processes

IV. Promote development of the European Health Data Space

a. Establish a national digital space to advance health data exchange services, and enhance research and innovation outcomes
b. Foster a competitive Digital Single Market for health, duly considering the differences between commercial products and health data
c. Link secondary use of data with both research strategies and educational programmes in order to improve people empowerment regarding digital health literacy

1.2 First Step towards the setting up of a NDHN

To help Member States formulate decisions about establishment of bodies or functions relevant to the development of a fruitful national eHealth ecosystem, primary work should be placed on two levels:

- At the national level:
  - To determine any organisational challenges that the supporting governance structure (NDHN) should address, considering that each Member State has different interests, structures and organisations.
- At the European level:
  - To study and understand the differences between the eHealth ecosystems in Member States, and hold discussions to achieve a common understanding on this approach.

Such work should ultimately deliver a common frame of reference[12] to which ecosystem actors can refer when thinking and acting vis-à-vis national level topics in eHealth.

[12]The idea of a common frame of reference requires further discussion. Nevertheless, its main purpose is to have a 'benchmark/guideline' document stating a way forward for NDHN developement and alignment.

Nonetheless, as it is up to each Member State to decide on how to involve stakeholders, as well as to complete the NHDN framework; this document mainly focuses on a concept of principles whose purpose is to support the development of a framework for enhanced national interoperability and governance.

2) National Digital Health Networks Principles

The general principles listed in Table 2 intend to stimulate each NDHN in their country, that should follow them and set up the network according to their national ecosystem needs and strategies.

This section aims to provide the crucial recommendations for the development of NDHNs.

Table 2 – General principles

Organisational Autonomy	Member States autonomy for the national organisation of the nodes within their NDHN is a legal prerequisite for all our actions enshrined as (even primary) EU law in Art. 168[13] para. 7 of the Treaty on the Functioning of the European Union and reading as follows: "Union action shall respect the responsibilities of the Member States for the definition of their health policy and for the organisation and delivery of health services and medical care. The responsibilities of the Member States shall include the management of health services and medical care and the allocation of the resources assigned to them. The measures referred to in paragraph 4(a) shall not affect national provisions on the donation or medical use of organs and blood."
Minimum required set of nodes	Those coming out of existing EU legislation, such as the *General Data Protection Regulation*[14] (GDPR), and the *Directive on security of network and information systems*[15] (NIS Directive). Moreover, the natural dynamics of national and European ecosystem legislation workflows (e.g. recommendation, regulations and directives) should, once deemed necessary by each Member State, and by formal means, be included in the NDHN scope of action.
Inclusiveness-by-design	When creating or reshaping the NDHN, this process itself should be inclusive towards stakeholder engagement.
Common inter-Member State 'Interface' functions	Having common 'functions and/or interface nodes' allows the linking to all other National Digital Health Networks and respecting common bodies/functions.
Patient engagement mechanisms	Not just occasional online consultations, patient engagement processes should be part of the dynamics of all elements of the NDHN as well as of the governance and dynamics of the network.

[13] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A12008E168
[14] For more information: https://gdpr-info.eu/
[15] For more information: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016L1148&from=EN

Data-driven collaboration	Collaboration to aggregate, curate, improve quality and protection of health data, is key to building new usages of data which is often located in multi-organisational matrix.
Proactive engagement of other Member States for collaboration and sharing	Member States should seek to reach out and collaborate in the many aspects of digital health in ways that are useful for their strategies at national level, incorporating common policies adopted/endorsed by the eHealth Network, but not waiting for EU-funded collaboration mechanisms only. Multilateralism is preferred to bilateralism as a principle, but that should not exclude useful and effective bilateral collaboration that takes common principles and policies into account.
Explicit processes and bodies for engaging national stakeholders	Making processes and bodies responsible for engaging national stakeholders explicit avoids unnecessary criticism of 'exclusion' at critical decision points at national level; it allows non-involved stakeholders that think they are relevant to come forward and link to digital health agendas, and also allows sharing between Member States in a challenge that world-wide is considered a largely unresolved issue in eHealth.

Bearing in mind the original concept, as stated in the European Commission Communication, and recognising the fact that several Member States already have some sort of 'network', the purpose and scope of National Digital Health Networks differ according to the strategy as well as needs of each country. Notwithstanding, it is possible to recommend elements of a proper National Digital Health Network as:

a. Strongly recommended;
b. Additionally desirable.

This being said, the following list is better interpreted as sample scenario towards establishing a functional and added-value NDHN model.

Strongly recommended elements of a NDHN
1. *The national representative of the eHealth Network* 2. *National eHealth agency (with roles of eHealth strategy definition/direct dependence on Ministry of Health/other Government sectors; eHealth guideline emission capacity; provision of eHealth services)* 3. *Supervisory authorities established under Article 51 of Regulation (EU) 2016/679 – this is the national data protection authority* 4. *Competent authorities designated pursuant to Directive (EU) 2016/1148 – this is their national or sectoral cybersecurity agency* 5. *National body representative for semantics in health, and the formalisation of the respective Member State representative at the eHN Subgroup for Semantics, as set in the Joint Coordination Process* 6. *National body/function of national technical interoperability definitions in health and the formalisation of the Member State representative for the eHN Technical Subgroup, as put forward in the Joint Coordination Process*

7. *National competence centres – can promote a valuable role in promoting the digital transformation in the health sector in accordance with the national needs.*
8. *The authority or organisation responsible for the National Contact Point for eHealth (NCPeH)*

It is relevant to consider a minimum set of nodes that should exist and are 'stable and similar' so they can interact with their counterparts in all other Member States/countries.

Additional desirable elements of a NDHN

1. *National medical drug/devices agency or equivalent, as identified to EMA/European Commission* [16]
2. *National public health authority, as identified to the European Commission and ECDC* [16]
3. *Health data usage agency/competence centre, with capacity to aggregate and manage secondary use of data, both at national and at EU level* [17]
4. *National body responsible for coordinating EU funds distribution and applications* [18]
5. *National eIDAS node responsible agency, and/or national eID authority*
6. *National-level agency or research institutes responsible for AI/robotics strategy also with the relation to health if there is any*
7. *Regional/Federal (country dependent) organisations that play role in designing/implementing National eHealth strategy*
8. *Agency with the role of verifying and controlling the quality of healthcare provision*
9. *National Telehealth Centre/agency with national responsibility for developing telehealth*
10. *Body or organisation responsible for national level genomics and related fields*

If other bodies exist, perhaps from non-health sectors, due to other EU regulations or trends, these can be seen as additionally recommendable nodes that should be included at some point, ideally from the onset

[16] These two features are very likely to already exist in different ways and formats, depending on each Member State arrangement. What is relevant for the sake of digital health development is that these elements are networked with the remaining, examples such as National ePrescription or common cybersecurity strategy makes it obvious that eHealth agencies and other more obvious elements, need to articulate with, often quite well established, agencies/bodies with the areas of medicines or devices. Only by these means will Precision Public Health be attainable in Member States, and more broadly at EU level.

[17] EU level features need to be further defined, along the lines of common agreements on the creation of an EU health data space.

[18] The articulation with body/agency responsible for coordinating EU funds is critical for the implementation of the recommendations on funding and interoperability approved by the eHealth Network in June 2019. Obviously, there cannot be a widespread use of digital identity in health without technical and policy cooperation of the relevant parts of government that, in the vast majority of Member States, are part of national eID and digital identity in general. If in existence, and as AI and robotics is one of the complex new emerging realities, it makes sense to seek out the active engagement of any formalised body/agency with those functions at national level. Last, but certainly not least, if the Return on investment (ROI) of eHealth, but more so the 'health value' or 'health outcomes' improvement from digital investments is to be calculated, as well as the risks of digital inclusion in care processes are to be followed-up and mitigated, the straight collaboration with bodies or agencies having these functions at the Member State Ministry of Health seems equally recommendable.

3) NDHNs general terms of reference

This section provides a brief introduction on how the purpose and structure of NHDNs could be defined and developed. It aims to support Member States with a non-exhaustive basis for making future decisions on the development of NDHNs, in accordance with national needs, conditions and stakeholders, under the responsibility of each Member State.

I. Purpose and vision

The purpose and vision of each National Digital Health Network is very likely to be different according to each Member State strategy and vision for its digital health development. The following should be thought of as pointer ideas, insofar as a NDHN should, as a minimum and in varying ways, attempt to address the:

a. Promotion of national as well as international interoperability of eHealth systems;
b. Development and promotion of usage of the EEHRxF and other outcomes of European governance (e.g. Common Semantic Strategy, Joint Coordination Process, etc.), as a way to mature an interoperable eHealth ecosystem and improve/provide eHealth services;
c. Foster a balanced approach to digital health for direct patient care and innovative use of health data;
d. Ensure the broadest participation possible of all relevant parties in the evolution of digital health;
e. Encourage sharing of best practices towards improving access, quality and sustainable health and care services.

II. Scope

The exact scoping and definition of goals and activities to be fulfilled by such a NDHN is key for the one responsible to implement it nationally. Hence, NDHNs should make clear that their realm of action is in accordance with their national eHealth ecosystem needs and strategies, notwithstanding the promotion of the EEHRxF, the European Health Data Space and digital health more broadly.

a. Establish a clear scope and mandate;
b. Elaborate a national implementation guide.

III. Objectives and link to national eHealth or digital health strategy

It is useful that a National Digital Health Network is not just something that is formalised and ‘exists’ in a Member State. Giving it objectives, as well as measurable attainment goals and an interlinkage with national eHealth strategy, stands as desirable towards reaching governments goals, which will ultimately benefit every actor within the ecosystem.

In order to achieve such success, particular attention should be paid at an early stage to sharing good practices in order to develop national implementation guides that will, to a certain degree, support the development of other NDHNs.

a. Define goals and objectives that can be measured and monitored;
b. Activities and action plan to be performed by defining a specific time-period.

IV. How they operate/governance

It is the competence of the Member States to organise how their NDHN operates. Whether there is a high or low degree of formalisation, and whether there is a formal governance process in place.

Having this in mind, it is useful to consider how parts of these NDHNs relate with common efforts in EU, for example in eHDSI/eHMSEG participation, common semantic work, technical interoperability, cybersecurity and secondary use of health data. On this basis, it is therefore helpful to assume these 'functions' mirror to some extent the operational processes that are conceived for the Joint Coordination Process.

4) Suggestions for NDHN Layers

National networks can be organised into levels. To help Member States/countries conceptualise and formalise their NHDNs. **It does not aim to be at all prescriptive but rather illustrate possibilities.** Having some common national-level dynamics can allow better sharing of national experiences.

The following suggestions are aimed at helping to identify critical interoperability factors for national networks to link with each other and with EU-wide initiatives.

- **What should NDHNs support?**

NDHN should be able to provide the relevant support to the following desirable outcomes:

a. Active engagement in multiple aspects of the EEHRxF Joint Coordination Process;

b. Ensure the implementation of the eHealth investment guidelines approved by eHN in June 2019, and explore other funding opportunities for Digital Health;

c. Support, develop and innovate cross-border services via eHDSI;

d. Ensure effective cybersecurity national and transnational cooperation and coordination;

e. Provide expertise, guidance and active work on common semantic challenges[19];

f. Explore digital ethics, in AI and telehealth, but also more broadly;

g. Ensure a fruitful ecosystem and flexible standards and architectures to ensure there is always an innovative attitude and that infrastructures are future-proof;

h. Innovative use of data for the purposes of research and education[20].

[19] Perhaps the biggest challenge for eHealth in the EU in a 10-year outlook.
[20] This outcome should be linked to the European frameworks for a common electronic identification and an eHealth reference architecture.

- **Possible three layers of NDHNs**

To help think about how these NDHNs can be formed and made dynamic, ensuring easy multi-level collaboration even cross-border, it may be advisable to have a similar minimal framework, for example a three-level one:

i. National level

An advisory function, through a Digital Health Advisory Board, can help channel in a positive and constructive manner the feelings and needs of different professional boards, and/or patient advocates. The creation of a cross-sectoral cybersecurity forum may seem a redundancy to other fora, but taking into account the relevance, specificity and still novel nature of the topic, it may have value in itself. Furthermore, ideas regarding an ethical advisory council for health information and digital health are taking shape (see Annex 1, section 4 for more information).

ii. Regional / Federal level: highly country dependent

Depending on the size of the Member State, it may be a good idea to create intermediate levels. There is of course no optimal size or arrangement. It seems obvious that the arrangements where healthcare is coordinated almost entirely at the regional level that digital networks exist at that level, which can be wired into a national network of networks, i.e. in this case the NDHN, as a dual-level arrangement. However, it is important consider that some areas, such as semantics and data protection, should stay on the same level, preferably a high national level.

iii. Local: within each organisation

In each hospital, large general practice or group of primary care practices, it makes sense to foster a 'digital health roles and responsibilities' approach; for certain domains (e.g. cybersecurity), having clear and formalised roles is considered essential for success by many. Such is the case for appointing a CISO (Chief Information Security Officer).

A clinical lead, be it a person, or a team, is also found to be of great use if fast adoption and uptake of eHealth is to be incentivised. These serve as a 'localisation' function of guidelines, standards, purposes and, when they exist, new digital services.

5) NDHN Implementation and National Strategies for eHealth

How and when Member States choose to create or formalise their respective National Digital Health Networks is of course a matter of national competence. Annex 1 gives examples of how some Member States are dealing with aspects of national networking of the different elements of their ecosystem.

These are of course not NDHN, but rather pieces of that complex puzzle. They serve, however, to illustrate the ways by which Member States are already addressing some aspects regarded as relevant. They are not exhaustive nor obviously the only relevant ones.

- **Formalisation**

While at first it seems obvious that setting up a governance and enhancement framework is best done in a formal/legal way, sometimes informality is key to the development of a progressively effective network. Also, hybrid solutions may exist, where some components/elements of the network have been formally inscribed and their relationship and decision making about eHealth and Digital Health topics clarified – into a governance model, while retaining other functions/elements in an informal collaboration outer circle.

- **Follow-up and performance review for NDHN**

If possible, it is equally recommended to Member States to consider how to monitor/review the performance of the NDHN, to see if they are working and serving their purpose.

6) Recommendations

This section intends to present a set of (non-exhaustive) recommendations to support Member States in the implementation of their NDHN, according to national competence, needs and strategies.

1. **National Action: Identify the possible interdependences between the nodes of NDHN.**
    a. Map and consolidate the possible interdependences/synergies between the different nodes of a NDHN:
        i. Carry out an intense process review of national activities followed by mapping with EU activities in these diverse scenarios;
        ii. Assess the issues that Member State structural/governance organisation need to address;
    b. Promote a multi-stakeholder forum that further enacts inclusive decision-making (e.g. associations, clusters and enterprises):
        i. Make sure that all relevant national bodies/stakeholders are connected, and can be activated and mobilised in the NDHN activities;
    c. Adopt/affiliate the nodes of the national health network that make sense, taking into account the level of maturity perceived by the Member State:
        i. The presented NDHN structure can be used by the Member States either as a referential framework to identify national nodes or a strategical referential to organise eHealth-related nodes.
    d. Support capacity building in the Member States.

2. **EU Cooperation: Identify similar nodes in the NDHN among the different Member States:**
    a. Identify similar activities among the Member States at EU level that could enhance the exchange of experiences, best practices and lessons learned;
    b. Improve the evolution of such activities and, in an ideal scenario, drive discussions towards a common approach for next steps regarding each node/activities.
    c. Clarify competences between nodes horizontally and the national authority vertically, in order to facilitate the processes of co-creation and decision making:
        i. Make explicitly clear which is the institution/organisation/team responsible for each Node competence (e.g. leveraging secondary use of health data);
    d. Study and understand the differences between the eHealth ecosystems in the Member States.

3. **Promote better procedural coordination.**
    a. NDHNs as a facilitator between Member State and EU level activities:
        i. Ensure a connection between the recommend elements of a proper NDHN;
    b. Promote the establishment of better coordination mechanisms aimed at supporting national digital health strategies;
    c. Support the follow-up of EU-level recommendations in a way that reaches out to national nodes knowledge:
        i. Ensure a link with the eHN subgroups, such as Semantic and Technical.

ANNEX 1 – Examples of Member State domestic approaches towards Digital Health

1) Findata and Secondary Use of Data

In Finland, a separate law was laid down in May 2019 on the secondary use of health and social data. The purpose of the Act on the Secondary Use of Health and Social Data[21] is to facilitate the effective and safe processing and access to the personal social and health data for steering, supervision, research, statistics and development in the health and social sector. The Act also aims to guarantee an individual's legitimate expectations, as well as their rights and freedoms when processing personal data. Finland's national legislation corresponds with the EU's General Data Protection Regulation.

The new Act will facilitate the elimination of overlapping administrative burden related to the processing of permits, smoother and faster processing of permits, smoother collation of data from different registers, easier and more efficient use of valuable social and health materials in research and development activities, and clearer knowledge management by service providers and parameters for this. Moreover, the Act facilitates the Finnish Institute for Health and Welfare's data access rights and the legislative basis for the national registers that the institute is responsible for will be adjusted so it is in accordance with the requirements in the General Data Protection Regulation.

The Act includes provisions on the data permit authority and its duties. A data permit authority, Findata, grants data permits when data is needed from numerous different controllers or when data is saved in the Kanta service and or the data in question is register data from private social welfare and healthcare service providers. A centralised system for the administration of information requests and data permits will be built for communication between the permit authority and the applicant, as will secure user environments and user interfaces for the supply of data. This will ensure the better protection of privacy for individuals and the secure use of data. The data permit authority operates at the Finnish Institute for Health and Welfare, separately from the institute's other activities.

Knowledge management is one of the grounds for secondary use of data. Information, including that on customers' well-being and the use of services and costs, can be used to support the management of social welfare and healthcare services. There has previously been no clear legal basis for the collation of data, which is required for knowledge management. Necessary collation of information for the purpose of management from the service provider's own registers is possible without authorisation by a permit authority.

2) The Dutch Health Information Council

The Netherlands created a National Health Information Council. A public-private partnership, including patients, doctors, nurses, other health professionals, insurers, hospitals, care institutions, general

[21] For these purposes: the secondary use of health and social data means that the customer and register data created during health and social service sector activities will be used for purposes other than the primary reason for which they were originally saved.

practitioners and governments, or as we call it 'the whole system in a room', with the Ministry of Health, Welfare and Sports (chairing the Health Information Council) in the role of mediator between all the stakeholders and also as law maker providing both carrots and sticks to speed up and force electronic exchange of data in healthcare. Together, we have set ambitious but achievable outcome goals: improving medication safety, promoting patients' access to their medical data, enabling safe data exchange and improving the quality of data. One-time registration at the source and multiple re-use. To reach these goals we need mutual agreed-upon standards for information exchange.

The MeetUp events:

During the MeetUp events of the Health Information Council, patients, health professionals, policy makers and ICT-solution providers meet each other. During the MeetUps the participants can follow dozens of workshops and get inspired to work towards a more durable health information system in the country. The MeetUp events take place twice a year at the Ministry of Health, Welfare and Sports. Every MeetUp has its own theme on topics that concern both health and ICT.

Chief Medical Information Officers (CMIO) Network:

The network aims to increase the knowledge of its members (Chief Medical Information Officers) by providing a platform for sharing experiences. Also by bundling common interests and needs, the network positions itself as a central point of contact for healthcare stakeholders, such as the Ministry of Health, NICTIZ, Federation of medical specialists, and IT suppliers, in order to realise innovations or optimisations.

The association tries to achieve this goal by:

1. Organising symposia, on-line forums, presentations and networking opportunities;
2. To act as a fully mandated discussion partner for healthcare stakeholders;
3. Collaborate with other (international) organisations that have the same goal;
4. Promotion for the role of CMIO.

The CMIO network comes together for a face to face meeting thrice a year.

Chief Experience Officer (CEO) Council:

In the context of working patient included, we give several experience experts the possibility to join us in discussions on topics which they find interesting. We facilitate the possibility to get input from the CEOs (might become CXO) to get insight on which topics they want to be involved in. In September 2019 we have, for instance, organised a speed date between the CEOs and policy makers in the Ministry of Health, Welfare and Sports for this purpose. CEOs are enabled to co-read on policy letters to make them more understandable, especially on information policy related topics; but they are free to use their expertise on all kinds of topics. From CEOs it is expected that they provide their expertise based on their own experience, as opposed to the opinion of a company or organisation.

At the moment we have group of 65 CEO experts. New people can apply to become CEO through the website or per email. The Ministry of Health, Welfare and Sports will then invite them for an interview to get an understanding on where their interests lies and more importantly whether there are any physical limitations to be considered.

3) Ireland and formalisation of partnerships with academia on eSkills for health professionals

Since the publication of the eHealth strategy in 2013, Ireland has been actively engaging with academia to progress the digital skills agenda for health professionals. Networking in order to align change and service improvement at national and local levels is essential to enabling eSkills in the health service and supporting professionals to operate in a modern digitised environment.

HISI Declaration on eSkills

As part of the eHAction Task 6.3 on eSkills for Professionals, the eHAction HISI Declaration was signed in November 2018 at the Healthcare Informatics Society of Ireland Conference by four academic institutions (University College Cork, Dublin City University, Galway Mayo Institute of Technology, University College Dublin), the Department of Health, Irish Computer Society and SPMS. Signing the declaration signified support from academia, Government and Europe to facilitate the development of eSkills and a prioritised focus on equipping current and future health professionals with these skills to drive the wider deployment of eHealth.

Partnering with Academia on Digital Health and Innovation

The Digital Academy and Open Innovation Directorate at the Health Service Executive, Ireland's largest public healthcare provider, has developed a Masters Programme in Digital Health Transformation, in collaboration with the University of Limerick and working with other academic partners including Dublin City University, Maynooth University, Trinity College Dublin and University College Cork. The Masters programme, already launched, aims to equip health professionals with the skills, knowledge and abilities to explore healthcare ecosystem developments, to facilitate collaboration and knowledge sharing and lead transformational innovations in a healthcare environment.

Trinity College Dublin (TCD), partnering with Health Innovation Hub Ireland, has also developed a Postgraduate Diploma to stimulate a culture of innovation in Irish healthcare, which will be a key catalyst in transforming innovation within the Irish healthcare landscape and making a measurable difference in how healthcare will be delivered in the future.

HSE Digital Skills Programme for Professionals

The Health Service Executive (HSE) has also collaborated with the Department of Communications, Climate Action and Environment to launch a programme for staff to guide staff through eSkills, utilising the digital tools they already have access to and to build on their digital literacy skills.

4) Portugal and local level engagement

In other to foster local adoption and local to national close cooperation, in Portugal, all public healthcare providers (all hospitals and hospital centres, as well as groups of family practices – so called ACES) are formally invited to create at their level:

1. CLICs – 'Comissões locais de informaticação clínica' /Local Clinical 'Informatisation' Committees: multi-professional groups of staff members and a board member, with the responsibility to foster, facilitate and liaise with all national initiatives in eHealth;
2. PITs – 'Promotores Internos de Tele-Saude'/ telehealth internal promoters: this is a person responsible for the development and use of telehealth solutions, ideally not an IT staff member, but rather a doctor or nurse. These are the link persons to the National Telehealth Centre;
3. Cybersecurity roles: all link with the national health cybersecurity team which is in SPMS; three roles have been outlined in different levels of formalisation:
    a. RNO – Responsável por Notificação Obrigatória / Compulsory Notification (of cyber incidents) responsible: mandated by MoH order
    b. CISO – Chief Information Security Officers: recommended
    c. CRSI – 'Comites de Risco e Segurança da Informação' /Information security and risk commitees: desirable
4. Innovation Leads: these are people with a special interest in robotics and advanced technologies for smart hospitals and such; they serve as the one person link to our Robotics Unit at national level.

Regular quarterly meetings between national-level units responsible for the eHealth strategy and the CLICs ensure alignment of local activities with national priorities; for example, the paperless NHS project. Likewise PITs are called for regular meetings, and telehealth related events, by the National Telehealth Centre staff, and in similar manner the SPMS Cybersecurity Unit maintains contacts and fosters training and awareness sessions to RNOs, CISOs and CRSIs, as well as emits documents and guidance on their functioning. The Robotics and Advanced Technology Unit of SPMS works with the innovation leads as 'match maker' to industry and academia parties interested in doing projects in the NHS.

5) Estonia – a multi-stakeholder approach to eHealth strategic development plan

The Estonian eHealth Strategic Development Plan was drafted through a multistakeholder approach. On 3 July 2014, the Government of the Republic decided to set up an eHealth Task Force, to develop a strategic development plan for Estonian eHealth until 2020, including the development of a vision for eHealth until year 2025. The Task Force included representatives of the Ministry of Social Affairs, the Ministry of Economic Affairs and Communications (which is among other things responsible for cybersecurity) and the Ministry of Finance, with the relevant state institutions of the area of government. The Task Force also included representatives from other health-related agencies, healthcare providers, patients and industry. Stakeholders were the Estonian Health Insurance Fund, Estonian Medical Association, Estonian Hospitals Association, Estonian Association of Information Technology and Telecommunications, Estonian Family Doctors Association, NGO Estonian Chamber of Disabled People, Technomedicum of Tallinn University of Technology, Faculty of Medicine of the University of Tartu, and the Estonian Service Industry Association. Other unaffiliated experts of various fields were also included in the preparation of the strategy. Following its adoption, a multi-stakeholder council was established to oversee the implementation of the strategy, and parts of the

implementation – such as the more industry facing aspects – were legally delegated to working groups outside of the Ministry of Social Affairs.

IT Development Council for Family Medicine

Lately, Estonia also established the IT Development Council for Family Medicine. The main goal of the council is to ensure, that the planning, development and implementation of digital solutions in family medicine takes place in cooperation between all stakeholders. In the council all IT planning, development, implementation, issues as well as needs are discussed among members, which includes representatives from both the family doctors' society and family nurses' societies, the enterprises providing their software solutions, the national health information systems centre and the health insurance fund. This council is led by the Ministry of Social Affairs.

Having the societies of family doctors and nurses involved in the IT planning, development and implementation stages allows to achieve a better balance between end-user needs, private sector ambitions as well as strategic public sector plans/goals. In addition, in time this helps to induce better IT capacities in the societies to set the demand and formulate the needs of healthcare providers/specialists, who otherwise might be too fragmented, small and uncoordinated to mobilise sufficient needs or formulate coherent needs for digital solutions. This allows the societies to become a better, useful, but also more influential partner to the enterprises providing the necessary software solutions and to the public sector implementing new digital services.