eHealth Network

Multiannual Work Programme

2018-2021

"eHealth in support for better health"

The eHealth Network is a voluntary network created under article 14 of Directive 2011/24/EU. It provides a platform for Member States' competent authorities responsible for eHealth and is scientifically and technically supported by a Joint Action.

-Adopted by consensus on 28 November 2017, Brussels-

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1. Executive Summary

During the 10th eHealth Network Meeting on 21 November 2016, the Members agreed to set up a sub-group that worked on developing a new Multiannual Work Programme (MWP) for the years 2018-2021. The sub-group kicked off on 27 January 2017 and submitted a first draft of the MWP to the eHealth Network for discussion at the 11th eHealth Network Meeting on 9 May 2018. On XX November 2017 the final version of the MWP was submitted to the eHealth Network as an attachment to the personal invitation. The eHealth Network will decide on the adoption of the MWP at its 12th Meeting on 28 November 2017.

The MWP identified four main priority areas on which the eHealth Network's activities for the coming years will be focussed. Each priority area contains topics that are relevant to current and upcoming policy developments. These topics will be further concretised in specific actions and initiatives. The main priority areas and the related topics are the following:

A. Empowering people
    1. mHealth and apps reliability
    2. Patient access and use of data
    3. Digital health literacy of patients
    4. Telehealth
B. Innovative use of health data
    1. Awareness raising of using Big Data in healthcare
    2. Develop common vision of innovative use of data on healthcare
    3. Governance and methodologies for Big Data
C. Enhancing continuity of care
    1. Stimulating and supporting the adoption of CBeHIS
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    3. Data protection and data security
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The eHealth and digital health sector is continuously evolving at a rapid pace. At the same time policy on digital health is taking shape at EU and national level. Therefore, the MWP allows flexibility for amendments in order to accommodate these future developments in eHealth and digital health policy.

2. Preamble

In accordance with article 6(1) of Commission Implementing Decision 2011/890/EU, the eHealth Network decided at its 10th meeting to set up a sub-group for drafting its new Multiannual Work Programme (MWP) for the period 2018-2021. The eHealth Network discussed the first draft of the MWP during its 11th meeting in Malta.

The eHealth Network, in accordance with article 6(2) of Commission Implementing Decision 2011/890/EU, will decide on the adoption of the MWP at its 12th meeting on 28 November 2017. After adoption, the MWP will come into effect as of 1st January 2018.

The following eHealth Network Members volunteered to contribute to this sub-group: Portugal, The Netherlands, Estonia, Greece, Finland, France, Germany, Croatia, and Poland. The sub-group meetings were accompanied by a JAseHN[1] observer to ensure the link between of the work of the Joint Action and the eHealth Network. Furthermore, the sub-group meetings were chaired by the European Commission and supported by the eHealth Network Secretariat.

The sub-group commenced with a kick-off on 27 January 2017 and held four meetings on 7 March 2017, 12 April 2017, 14 June 2017, and 13 September 2017.

3. Background

The MWP is based on the main EU policy documents related to eHealth and builds on the results of work undertaken under the previous MWPs, as well as relevant JAseHN deliverables.

a. Major references

- The eHealth Action Plan 2012-2020: Innovative healthcare for the 21st century[2].
- The Digital Single Market Strategy: eHealth (Telemedicine) is mentioned under the section *Boosting competitiveness through interoperability and standardisation*[3].
- The communications under the Digital Single Market Strategy: there were four European Commission Communications published on 19 April 2016 of which in particular the last two included actions on eHealth:
    - Digitizing European Industry[4]
    - The European Cloud Initiative[5]
    - The EU e-Government Action Plan 2016-2020[6]

[1] Joint Action supporting the eHealth Network: http://jasehn.eu/
[2] https://ec.europa.eu/digital-single-market/en/news/ehealth-action-plan-2012-2020-innovative-healthcare-21st-century
[3] http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1447773803386&uri=CELEX:52015DC0192
[4] https://ec.europa.eu/digital-single-market/en/news/communication-digitising-european-industry-reaping-full-benefits-digital-single-market
[5] https://ec.europa.eu/digital-single-market/en/news/communication-european-cloud-initiative-building-competitive-data-and-knowledge-economy-europe
[6] https://ec.europa.eu/digital-single-market/en/news/communication-eu-egovernment-action-plan-2016-2020-accelerating-digital-transformation

- Priorities of ICT standardisation for the Digital Single Market[7]
- Recommendations of the Commission's study on Big Data in Public Health, Telemedicine and Healthcare[8].
- eHealth Network mHealth sub-group report on suggestions for future work[9].

Other documents used as input for defining the priorities and topics in the MWP:

- Recommendations of the Commission's study on Big Data in Public Health, Telemedicine and Healthcare[10.]
- eHealth Network mHealth subgroup report on suggestions for future work[11].

b. Previous Multiannual Work Programmes

Since its inception in May 2012, the eHealth Network had worked under two Multiannual Work Programmes:

- **1st MWP 2012-2014:** the priority of the first MWP was set on the implementation of article 14(b) of Directive 2011/24 regarding de development of guidelines. The eHealth Network, with the support of the eHealth Governance Initiative had adopted the Patient Summary guideline in November 2013 and the ePrescription guideline in November 2014. Furthermore, it had set the agenda for further developments on i.e. eID and the data protection.
- **2nd MWP 2015-2018:** the second MWP built forth on the achievements of the first MWP. The second MWP identified 4 main priority areas: 1) Interoperability and standardisation, 2) Exchange of knowledge, 3) Monitoring and assessment of implementation, 4) Global cooperation and positioning. The eHealth Network adopted new releases of the Patient Summary and ePrescription guidelines as well as making progress in the context of building an eHDSI.

[7] https://ec.europa.eu/digital-single-market/en/news/communication-ict-standardisation-priorities-digital-single-market
[8] https://publications.europa.eu/en/publication-detail/-/publication/5db46b33-c67f-11e6-a6db-01aa75ed71a1
[9] https://ec.europa.eu/health/sites/health/files/ehealth/docs/ev_20161121_co22_en.pdf
[10] https://publications.europa.eu/en/publication-detail/-/publication/5db46b33-c67f-11e6-a6db-01aa75ed71a1
[11] https://ec.europa.eu/health/sites/health/files/ehealth/docs/ev_20161121_co22_en.pdf

4. Scope

The scope of the MWP is in conformity with the objectives of the eHealth Network as outlined in article 14 of the Cross-Border Healthcare Directive 2011/24/EU[12].

> *The objectives of the eHealth network shall be 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 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.*

5. Stakeholder interaction

A close cooperation with different stakeholders is essential in achieving the objectives of the eHealth Network. The eHealth Stakeholder Group https://ec.europa.eu/digital-single-market/en/ehealth-experts, the advisory expert group to the European Commission, had been consulted to provide input in the MWP.

The first draft of the MWP was sent to the Members of the eHealth Stakeholder Group in preparation for their meeting on 29th April 2017 where it was presented. The Members of the eHealth Stakeholder Group were given until mid-May 2017 to provide the sub-group with comments. To standardise the input from the eHealth Stakeholder Group, a commenting form was provided. The stakeholders' feedback was received and proper analysed and brought into the discussions of the subgroup.

6. EU eHealth strategic roadmap

The objective of MWP is to give strategic direction to the activities of the eHN, pointing to concrete outcomes to be achieved in the period 2018-2021. Those outcomes would result from multiple actions to be driven by several actors and supported by different instruments.

[12] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:088:0045:0065:en:PDF

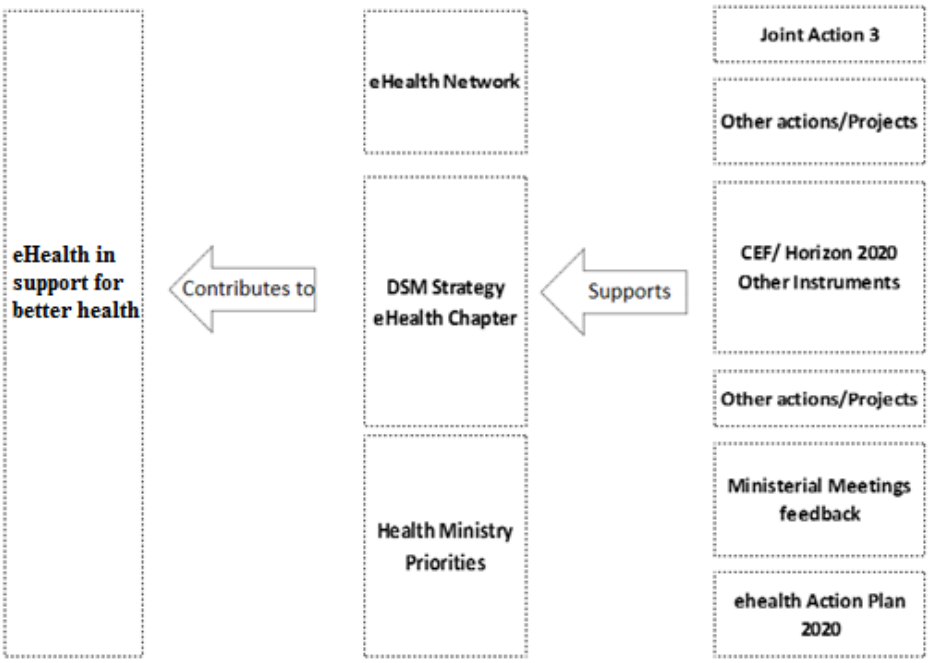

Illustration 1: eHealth in support for better health

7. Main priority areas

The MWP has four priority areas on which the eHealth Network will focus its efforts:

A. Empowering people: enabling citizens to take an active role in the management of their health;
B. Innovative use of health data: exploring the use of health data to develop knowledge for healthcare policy and other purposes;
C. Enhancing continuity of care: improving the uptake of cross-border eHealth services;
D. Overcoming implementation challenges: addressing transversal enabler issues crossing the abovementioned categories.

The following schematic overview aims to illustrate in the agreed four priority areas. Each of the priority areas will be contain specific topics.

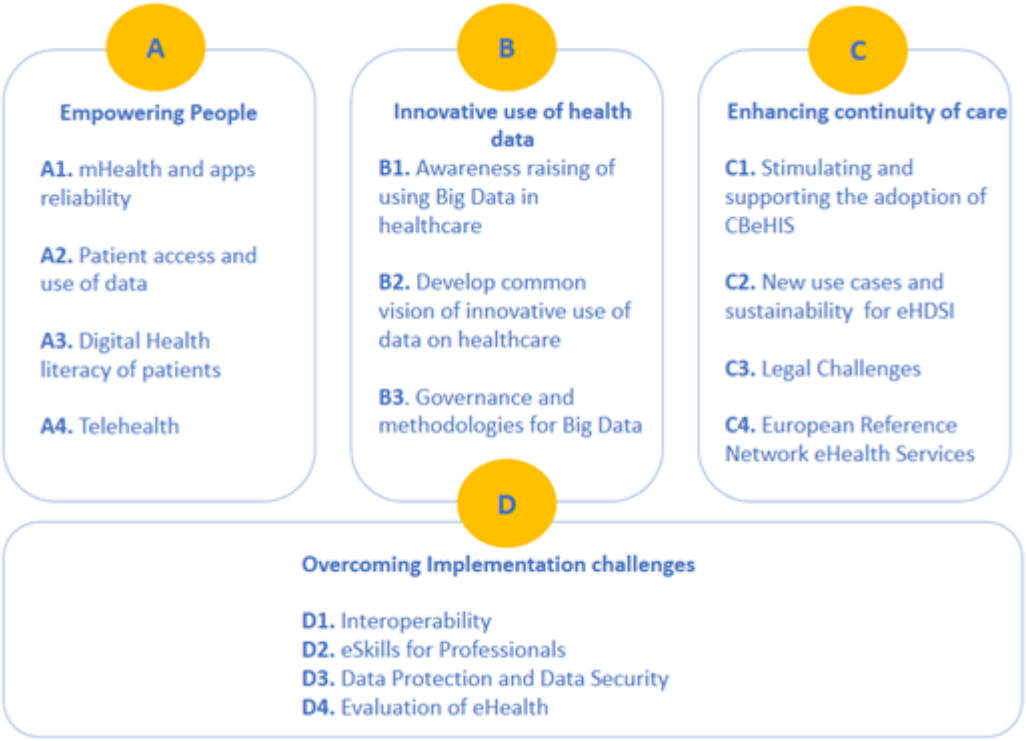

Illustration 2: schematic overview of the priority areas and their included topics

A. Empowering people

eHealth/ mHealth can be a means for better integrated and personalised health care, with greater focus on disease prevention and on the promotion of health and wellbeing. ICT can promote patient empowerment through the use of mHealth apps, patient access to and control over sharing of his/her own health data between healthcare providers. On the other hand, digital tools can also be used to manage chronic conditions and improve access to healthcare through telemedicine services, including remote and self- monitoring. However, the concerns related to the quality and reliability of those tools and to the readiness of patients and health systems to adopt them, need to be addressed properly.

Empowering Patients as a priority area:

Many EU Member States are facing the same challenges of an ageing population and rising numbers of people with one or more chronic diseases. In the future, more people will require care or support.

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

Expected achievements:

The strategic goal is to work towards the implementation of patient-centred health information solutions in all EU Member States. This means that:

- People are better informed and have better guidance and access to high quality mobile health applications which they can trust, use, and recommend;
- People are better supported in accessing healthcare through the use of high quality telehealth/telemedicine services regardless of whether they live in remote or urban areas;
- People have easy and secure access to their health data and they are enabled to enter data to their personal health record(s);
- People are better equipped to control and manage the use of their health data, including the possibility to allow the sharing of their health data between service providers as well as for research and innovation purposes in a secure and protected way.

Topics under this priority area and expected outcome:

A.1 mHealth and health apps reliability
Expected outcome: Develop a common framework and principles for facilitating safe and reliable use mHealth apps.

There are a large number of lifestyle and wellbeing apps (mHealth apps) available with no clear evidence on their quality and reliability. This raises the concerns about the ability of patients to properly assess the effectiveness of mHealth apps. In several countries, initiatives are ongoing to set up schemes and criteria for mHealth apps assessment, to provide guidance to professionals and consumers on “good apps”, or to integrate them into mainstream healthcare provisions by linking them to health information systems. Given the rapid developments and the need for a coordinated approach, it is important to closely follow the deployment of mHealth solutions in healthcare and to reinforce the cooperation among Member States, with the support of the European Commission, in order to achieve a common (flexible) framework for app quality and security assessment.

A.2 Patient access and use of data
Expected outcome: Synergetic and coherent approach to patient access, sharing, and reuse of health data in the EU.

Giving patients' insight in their own medical history (electronic health records) will allow them to better manage their own health. Since the added value of eHealth/mHealth solutions correlate with the availability of health data, it is indispensable that the data flow between patients and healthcare professionals is stimulated, under the condition that data sources are trusted and data protection and

security requirements are met. The challenges on how patient generated data could be linked to clinical data should be addressed. Furthermore, patients need to be in control over their own health data and it is essential to provide them transparency on its collection and use. They should also be given the possibility to decide on sharing their data between different service providers to potentially benefit from a holistic approach of their healthcare. A synergetic and coherent approach to patient access, share, and reuse of health data is the aim in the EU, taking the Member States' competencies and room for manoeuvre into consideration.

A.3 Digital health literacy of patients

Expected outcome: Increase digital health literacy for EU-citizens by sharing best practices and tools

For the appropriate use of eHealth/mHealth it is also important to improve digital health skills and to raise public awareness about the benefits and risks related to the use of these solutions, assuring useful usage of digital data from patients. Digital literacy refers to the skills required to achieve digital competence. For citizens to benefit from digital tools it is essential to be sufficiently digitally literate, by sharing best practices among Member States.

A.4 Telehealth

Expected outcome: Facilitate the adoption of telehealth taking available evidence into consideration.

Telemedicine services allow patients to interact with health professionals remotely for consultation or diagnostic purposes. It improves the access to healthcare not only for people with reduced mobility but also for those living in remote areas. Telemedicine services allow self-monitoring and remote monitoring by health professionals, potentially preventing further escalation of existing chronic conditions through early detection. This reduces unnecessary visits to doctors and potentially lower healthcare costs, positively contributing to the sustainability of health systems.

B. Innovative use of health data

The healthcare sector is a data-intensive industry generating large volumes of data. There has been tremendous growth in the range of information that is being collected, such as clinical, genetic, behavioural and environmental data from an array of devices including electronic health records, genome sequencing machines, patient registries, social networks and smartphone applications that monitor patient health.

The use of large volumes of health data could unlock great potential in the healthcare sector. Powerful data analytics can discover patterns that will lead to new prevention, diagnostic and therapeutic avenues; can help remove inefficiencies in care processes and reduce waste; and help make better management and clinical decisions that will improve the performance of health systems (e.g. in terms of procedures, quality of care, patient safety and patient outcomes).

The phenomenon of big data is still new and there is much uncertainty on how to go forward on benefiting from big data on the practical level. On the policy level it is important to strengthen the awareness of the possibilities and to highlight the potentially beneficial impacts of big data in health.

Innovative use of health data as a priority area:

Secondary use of data and big data can provide value for research, teaching, managing and planning healthcare systems. It can also be a great opportunity for the development of personalised medicine, the improvement of the effectiveness of medicine, efficiency of health systems, and continuity of care.

However, an EU approach for sharing expertise but also raising the awareness of the potential benefits of the secondary use of health data is lacking.

Expected achievements:

- Strengthen the awareness of the possibilities and potentially beneficial impact of big data in health by identifying best practices;
- Develop frameworks and common principles for realising the added value of big data in health;
- Support the creation of good governance principles, practices and methods in handling use of health data, including big data.

Topics under this priority area and expected outcome:

B.1 Awareness raising of using Big Data in healthcare
Expected outcome: Increase awareness on the possible impacts, challenges, risks and directions of Big Data in healthcare.

The focus should be on raising awareness with patients and policy makers on the use of Big Data in healthcare. It needs to be transparent to patients on how, when and for which purpose their data is being used and to the healthcare professionals as well.

B.2 Develop common vision of innovative use of data in healthcare
Expected outcome: Common vision and priorities for innovative use of data in healthcare.

Study prospective use-cases concerning the potential diverse and innovative use of data in order to evaluate the benefits and constrains, and define common priorities to plan and develop further actions and competences. There are many good examples of Big Data use in healthcare. In the study on *Big Data in Public Health, Telemedicine and Healthcare*[13] commissioned by DG SANTE in 2016, a mapping exercise was done on examples of Big Data use in healthcare. However, clear criteria are needed to define which use cases of Big Data use in healthcare have the best potential to improve the sustainability of healthcare system and provide examples for benchmarking.

B.3 Governance and methodologies for innovative use of health data, including big data
Expected outcome: Common principles to facilitate the development of innovative use of data projects at European Level.

The use of big data with best practices of good governance on handling big data complying to current regulations and at the same time bringing patients at the centre of the digital health should be promoted. Common approaches are needed to create enabling conditions for data integration and analysis in a secure environment, as well as to achieve necessary scale for advanced data analytics, for example in the field of genomics and personalised medicine. Another field for common work should be improving data infrastructure, analytics and decision support to predict, prevent and control serious cross-border health threats. The sharing of best practices on how issues concerning privacy, protection and security, transparency around criteria and automatic processes/algorithms in the use of Big Data in healthcare – technical and governance – are being addressed nationally or at European level is necessary. The focus will be about facilitating the innovative use by designing and testing appropriate methods and governance.

[13] https://publications.europa.eu/en/publication-detail/-/publication/5db46b33-c67f-11e6-a6db-01aa75ed71a1

C. Enhancing continuity of care

The cross-border exchange of data supports cross-border healthcare and with that supports the continuity of care and the right of Europeans citizens to choose your own healthcare provider. In the last years efforts, have been made to define and pilot services that enable this paperless and secured data exchange. At this moment, the first eHealth Cross Border eHealth Information Services (CBeHIS) are being prepared to go live in three waves from 2018 through 2020.

There is still a lot of work to be done to grant adoption at national, regional and local levels, namely assuring the establishment of necessary legal agreements, enhancing uniform and effective communication plans, promoting change management, defining adequate IT service management procedures and monitoring/evaluating the CBeHIS services implementation, operation and benefits realization.

Other objectives under this topic are the clarification of common criteria and the priorities for new services, and to study at a strategic level what should be the next services to implement in CBeHIS. Also, it is important to ensure the deployment of a stable and secure legal environment for cross-border data exchange, with an optimal implementation at each level (national, regional, local). The promotion of the definition of a European eHealth Architecture Vision and the clarification on the relation between eHealth services and correspondent building block (e.g. eDelivery, eID, eSignature) at national and regional implementation are needed.

Finally, ensure the proper alignment between CBeHIS and European Reference Network based on adopted framework and guidelines, based on agreed standards, avoiding divergent parallel unnecessary or inconsistent development and optimising the resources.

Enhancing continuity of care as a priority area:

It is crucial to ensure that the conditions that are needed to provide and expand eHealth services are met. The implementation of the services can only be fully achieved if all stakeholders (local, regional and national) become aware and are ready pick up their role in the overall process.

Expected achievements:

- Wide adoption of CBeHIS services, including overcoming the current difficulties on achieving legal interoperability;
- Financial and operational Sustainability of CBeHIS;
- Clear view on how to proceed on the development of other CBeHIS.
- Aligned architectures between eHDSI, ERNs and the future use-cases

Topics under this priority area and expected outcome:

C.1 Stimulating and supporting the adoption of CBeHIS
Expected outcome: Full exploitation of the CBeHIS services.

Stimulate and support the Member States to connect their National Contact Points to CBeHIS allowing the exchange of building blocks, guaranteeing interoperability between countries and at national level, widening services and enhancing the continuity of care.

C.2 Explore the need and conditions for the new use-cases, aligned with the eHDSI principles
Expected outcome: Identifying and developing new use cases and the sustainability of eHDSI.

In the coming years, based on clear documented need, new use-cases for the CBeHIS should be identified and discussed. Furthermore, Member States should be supported in the process of adopting these new use-cases in the CBeHIS at national, regional and local levels (communication, prioritization, change management), on the promotion of IT management services and service legal agreements. Also, the implementation of new use-cases will be monitored to assure the smooth operation of the CBeHIS and its sustainability.

C.3 Legal challenges
Expected outcome: Stable and reliable implementation of the provisions of a common legal framework.

Ensure the deployment of a stable and secure legal environment for cross-border data exchange, with optimum implementation and smooth evolution at each level (national, regional and local) over time.

C.4 European Reference Network eHealth services
Expected outcome: Consistency between the eHealth services and the European Reference Networks architecture and improved interoperability.

Ensure that the architecture of ERNs is interoperable and consistent with the architecture deployed for the eHDSI.

D. Overcoming Implementation challenges

This topic is about developing, implementing and deploying consistent eHealth enablers based on as interoperability, security, competencies and evaluation agreed common frameworks.

The EU faces challenges in providing interoperable eHealth services. One objective under this topic is to improve interoperability by promoting the use of common standards to facilitate the exchange data at European Level and develop a strategy on European Semantic Interoperability.

A high level of data protection and data security is another precondition for eHealth promotion. The GDPR raises challenges from an organisational, legal and technical point of view, which should be addressed through proper coordination and collaboration initiatives.
Another major issue is to address the lack of appropriate skills to implement the digital transformation in health sector. Besides, it is crucial to define a framework for the proper evaluation of eHealth and, the support the exchange of knowledge on the development on new health business models supported by innovative technologies of eHealth.

Overcoming implementation challenges as a priority area:

Interoperability of eHealth services remains an important topic in the EU. Despite the fact that much work has been done to improve interoperability, challenges remain in terms of practical application and reinforcing the compliance to common European and international standards. Continued work is needed on all four aspects of interoperability: 1) technical, 2) semantic, 3) organizational, and 4) legal.

Furthermore, upcoming EU legislation e.g. GDPR, NIS Directive, eIDAS Regulation, will have an impact on the implementation of cross-border eHealth services. Clarity on the ramifications of these EU legislations are needed to ensure legal interoperability and to take into account specific needs and requirements in the health sector

Expected achievements:

This category will contribute to:

- Build confidence in the wider adoption of eHealth services and solutions and encourage the uptake of new technologies;
- Enable the authentication of the parties concerned and the secure exchange of trusted health data among diverse systems;
- Promote the use and consistent operationalization of appropriate frameworks for eHealth;
- Increase the strategic coordination of ICT standardization, foster the collaboration among all interested parties;

- Overcome obstacles in the consistent application of existing eHealth standards and promote the EU-wide adoption and use of appropriate methods to increase the semantic interoperability across borders;
- Promote data protection and data security;
- Promote e-competencies among health care professionals;
- Promote evaluation eHealth services best practices.

Topics under this priority area and expected outcome:

D.1 Interoperability of digital healthcare infrastructure
Expected outcome: Interoperable digital infrastructure (software and hardware) of healthcare providers using a common format for cross-border exchange of health data.

Current work on eHealth standards and the interoperability of the digital infrastructure in healthcare systems will be continued. Moreover, in order to foster the cross-border exchange of health data, the eHealth Network should investigate the development of a common standard/format that builds forth on existing guidelines. Also, it is necessary to exchange information and best practices of governance models.

Furthermore, the eHealth Network will provide guidance to support healthcare providers in keeping their digital healthcare infrastructure up-to-date enabling them to exchange health data. A first exercise would be to investigate the needs of healthcare providers and align existing and forthcoming policy with them.

D.2 eSkills for Professionals
Expected outcome: Equip healthcare professionals with eSkills for eHealth services.

In order to better equip healthcare professionals with the necessary eSkill, an eHealth skills framework should be operationalised through the design and reuse of common training content and tools at the EU level. This should be based on common agreed principles, and collaboration working towards bringing together national and European healthcare professional organisations and medical specialists, and reduce profile and competency gaps through multiple initiatives, namely awareness campaigns, academy cooperation, eLearning tools, MOOC, among others.

D.3 Data Protection and Data Security
Expected outcome: Increase trust in eHealth by overcoming the implementation challenges of the relevant EU legal frameworks on data protection, security, authentication of the actors, and privacy.

The key objective is to provide transparency and clarity on the effects of relevant EU legislations, such as GDPR, eIDAS Regulation, and the NIS Directive, on the implementation of eHealth services and to align the implementation approaches in different Member States. Communication between the eHealth Network and the Article 29 Working Party (later the European Data Protection Board) and the Commission towards and EU-wide coordinated implementation of the GDPR are needed.

Furthermore, it is essential to monitor the possible amendments to the Agreement between National Authorities or National Organisations responsible for National Contact Points for eHealth.

D.4 Evaluation of e-Health
Expected outcome: Improved transparency and evidence-based evaluation on the progress, results and impact of eHealth adoption.

It is essential to define a framework for the proper evaluation of the impact of eHealth adoption (quantitative and qualitative, at patient and system level, with external and internal assessments) and to agree on common criteria and indicators to monitor the progress in the adoption of digital health services. Knowledge exchange on the development of new or reengineered health business models will support the application of innovative technologies and methodologies.

8. Aligning the MWP with future developments in eHealth and digital health

In order to maintain its relevance by ensuring that it is in line with the most recent developments in eHealth and digital health policy at EU and national level, the MWP allows flexibility for amendments after adoption.

Proposals to amendment the MWP can be initiated - with the approval of the eHealth Network co-chairs - by Members of the eHealth Network, sub-groups of the eHealth Network, Joint Action that supports the eHealth Network, or the eHealth Network Secretariat and should be submitted to the eHealth Network for adoption.

9. List of abbreviations

Acronym	Description
CEF	Connecting Europe Facility
CBeHIS	Cross-Border eHealth Information Services
GDPR	General Data Protection Regulation
DSM	Digital Single Market
EC	European Commission
eD	eDispensation
eHDSI	eHealth Digital Service Infrastructure
eHN	eHealth Network
EHR	Electronic Health Records
eID	Electronic Identity
eIDM	Electronic Identity Management
eP	ePrescription
EU	European Union
ICT	Information and Communication Technology
JA	Joint Action
MS	Member State
MWP	Multiannual Work Programme
NCP	National Contact Point