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PART 4/4

COMMISSION STAFF WORKING DOCUMENT

IMPACT ASSESSMENT REPORT

Accompanying the document

PROPOSAL FOR A REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on the European Health Data Space

{COM(2022) 197 final} - {SEC(2022) 196 final} - {SWD(2022) 130 final} - {SWD(2022) 132 final}

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ANNEX 12: EVALUATION OF ARTICLE 14 OF DIRECTIVE 2011/24/EU (CROSS-BORDER HEALTHCARE DIRECTIVE)

1 INTRODUCTION

1.1 Purpose and scope

This evaluation has been launched in January 2021 as part of the Commission's work on the European Health Data Space (EHDS). It is a back-to-back exercise which informs the Impact Assessment on the EHDS that has been developed in parallel.

The evaluation has been performed in accordance with the European Commission's Better Guidelines[1] and builds on the Study on Health Data, Digital Health and Artificial Intelligence in Healthcare (hereinafter also "the Study"), carried out by a consortium led by Open Evidence[2], and other sources as indicated throughout the document.

The Cross Border Healthcare (CBHC) Directive[3] (hereinafter also "the Directive") seeks to facilitate access to safe and high-quality care across borders as well as to promote the cooperation on healthcare between EU Member States, including cooperation on the use of information and communication technology in health (eHealth). This evaluation focuses on the provisions of the Directive related to eHealth[4], such as the cross-border cooperation and exchange of information on eHealth among the competent national authorities, the establishment of the eHealth Network (eHN) and patients' rights in relation to health records.

Article 14 of the Cross Border Healthcare Directive sets up a voluntary network connecting national authorities responsible for eHealth designated by the Member States (eHealth Network). The eHealth Network facilitates cooperation among the Member States authorities on various issues, in particular on interoperability of the national information and communications technology systems and cross-border transferability of electronic health data in cross-border healthcare, on sharing of health data between Member States and empowering citizens to access and share their own health data. It also facilitates the exchange of good practices concerning the development of different digital health services, such as telemedicine, m-health, or new technologies in the area of big data and artificial intelligence. However, other Articles also influence on the deliverables on digital health: Article 3(d) for the rules on telemedicine; Article 4(2)(f), 5(d) on the access to a written or electronic medical record for patients that have received treatment; Article 11 on the recognition of prescriptions issued in another Member State

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[1] https://ec.europa.eu/info/law/law-making-process/planning-and-proposing-law/better-regulation-why-and-how/better-regulation-guidelines-and-toolbox_en

[2] Lupiáñez-Villanueva, F., Gunderson, L., Vitiello, S., Febrer, N., Folkvord, F., Chabanier, L., Filali, N., Hamonic, R., Achard, E., Couret, H., Arredondo, M. T., Fernanda Cabrera, M., García, R., López, L., Merino, B., Fico, G. (2022). *Study on Health Data, Digital Health and Artificial Intelligence in Healthcare*, Publications Office of the European Union. https://op.europa.eu/en/publication-detail/-/publication/179e7382-b564-11ec-b6f4-01aa75ed71a1/language-en

[3] Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare, OJ L 88, 4.4.2011, p. 45–65: EUR-Lex - 32011L0024 - EN - EUR-Lex (europa.eu)

[4] This covers mainly Article 4.2 (f), Article 5 (d), Article 11.2 (b) and Article 14 of Directive 2011/24/EU.

The Commission also adopted implementing measures necessary for the establishment, management and transparent functioning of this network, which are taken into account in the present evaluation.[5]

The Cross-Border Healthcare Directive was adopted more than ten years ago. This evaluation assesses the effectiveness, efficiency, coherence, relevance and EU added value of the EU digital health system. The time period falling within the scope of this evaluation covers the period from the adoption of the Directive (2011) until the present day in the 27 Member States.

2 BACKGROUND TO THE INTERVENTION

2.1 The problem

The rapid uptake of new technologies and digital tools have the potential to offer relevant evolving solutions for health and healthcare services and products, providing the possibility to overcome the current main challenges of the different national healthcare systems. The ability of healthcare providers and patients to communicate effectively with each other is one of these challenges and requires the facilitation of the provision of digital health services in a cross-border setting. EU citizens have the right to access healthcare (including through digital means) in any EU Member State, as well as to be reimbursed for care abroad by their home country, within the limits provided for by the applicable EU legislation.

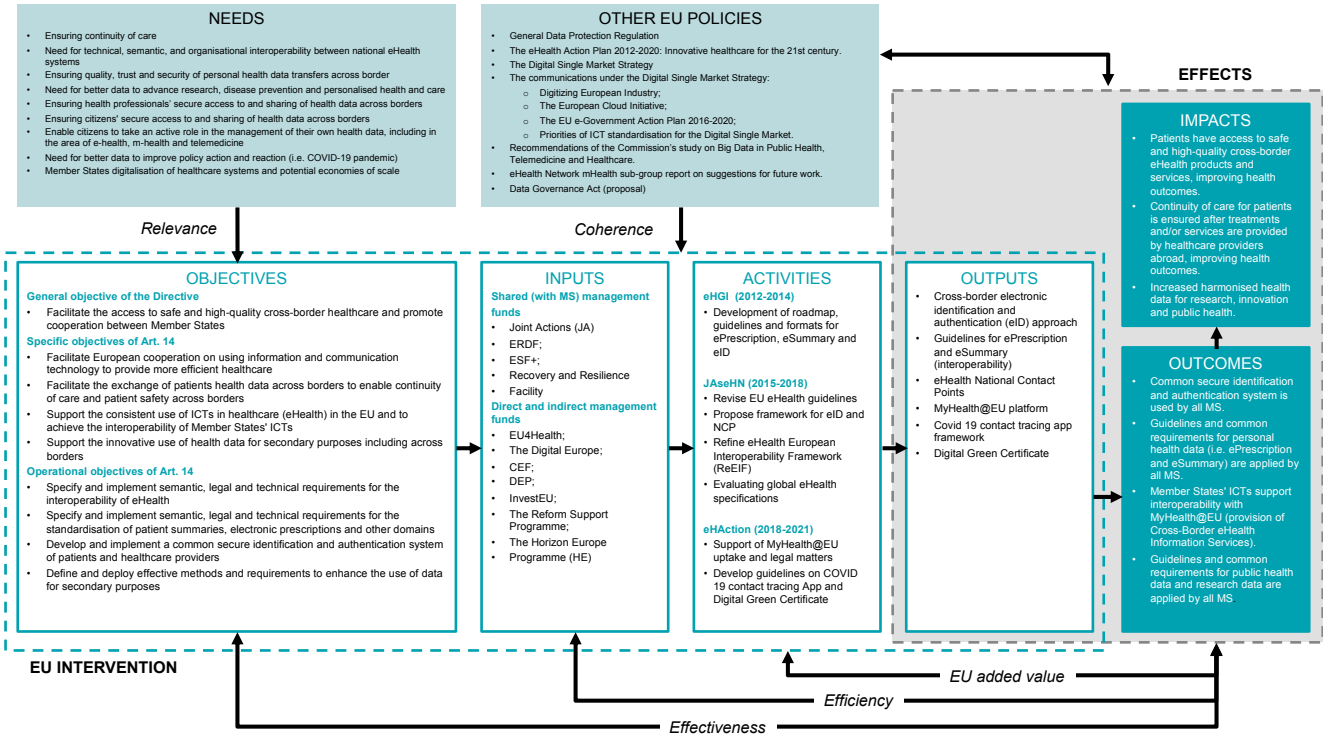
2.2 Description of the intervention

Overview of the intervention logic

For illustrative purposes, the approach through which Article 14 of the Cross Border Healthcare Directive operates has been summarised in the intervention logic provided in Figure 1. It presents an overview of the sequence of the intervention, from its needs and objectives to the inputs, activities, outputs, impacts and other relevant EU policies affecting the intervention.

[5] In particular, the Commission Implementing Decision 2019/1765 of 22 October 2019 providing the rules for the establishment, the management and the functioning of the network of national authorities responsible for eHealth, and repealing Implementing Decision 2011/890/EU (C/2019/7460), that is also part of this evaluation.

Figure 1. Intervention logic framework



Objectives of the Cross Border Healthcare Directive

The Cross Border Healthcare Directive sets out the conditions under which a patient may access healthcare in another EU Member State and be reimbursed and clarifies issues concerning the responsibility of the Member States for ensuring quality and safety of cross-border healthcare and provision of information concerning cross-border healthcare. In addition, it aims to foster European cooperation on healthcare in specific areas, including in the area of eHealth under the Article 14.

Objectives of the provisions on eHealth

"*The Union shall support and facilitate cooperation and the exchange of information among Member States working within a voluntary network connecting national authorities responsible for eHealth designated by the Member States*" (Article 14 of the Cross Border Healthcare Directive). This resulting eHealth Network[6] has the following general objectives :

- facilitate cooperation in the European Union (EU) in the use of information and communication technology (ICT) to provide more efficient healthcare;
- facilitate the exchange of patients' health data across borders to enable continuity of care and patient safety;

[6] https://ec.europa.eu/health/ehealth/policy/network_en

- support the consistent and interoperable use of ICTs in healthcare and achieve the interoperability of ICT between Member States;
- support the innovative use of health data for secondary purposes including across borders[7].

To achieve these objectives the eHealth Network aimed to (1) specify and implement semantic, legal and technical requirements for the interoperability of eHealth and (2) develop and implement standards for patient summaries, electronic prescriptions and other domains (as part of the interoperability of electronic health records), and (3) to develop other EU-wide interoperable infrastructures and applications in the area of health. To do so, the network had to develop and implement a common identification and authentication system allowing patients and healthcare providers to exchange health data. This was enabled by the eHealth Digital Service Infrastructure (eHDSI) launched in 2017, which has been named MyHealth@EU. Furthermore, the eHealth Network aimed to (4) define and deploy effective methods and requirements to enhance the use of data for secondary purposes.

The mandate of the eHealth Network was defined rather broadly in the Directive. This enabled the eHealth Network to intensify its collaboration on new subjects in the context of the public health COVID-19 crisis and, in this particular context, to achieve increased standardization at Member States level and cross-border interoperability (e.g. for COVID-19 contact tracing and warning applications and EU Digital COVID Certificates). The expected achievements of the collaboration through the eHealth Network was the increased interoperability of the respective national eHealth systems and seamless cross-border exchanges of health data between the Member States participating in the eHealth Network (in particular through the exchanges of electronic Patient Summaries and ePrescriptions via MyHealth@EU) in order to ensure appropriate continuity of care of patients even if this care was provided across borders. In addition, the eHealth Network was expected to contribute to achievement of greater harmonisation of health data among the Member States and consequently for better use of this health data for the purposes of research, innovation and informed decisions of health authorities.

2.3 Points of comparison

As the Directive entered into force in 2011, the points of comparison for the evaluation are the situation prior to its implementation. The impact assessment accompanying the proposal[8] did not provide sufficient quantitative data on the situation at the time, nor enough information on the expected outcomes. For these reasons, the baseline has been developed in the Study.

A study from 2008[9], highlighted that while patient data were stored electronically in many European General Practitioner (GP) practices and that computers were available in most GP

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[7] Lupiáñez-Villanueva, F., Gunderson, L., Vitiello, S., Febrer, N., Folkvord, F., Chabanier, L., Filali, N., Hamonic, R., Achard, E., Couret, H., Arredondo, M. T., Fernanda Cabrera, M., García, R., López, L., Merino, B., Fico, G. (2022). *Study on Health Data, Digital Health and Artificial Intelligence in Healthcare*, Publications Office of the European Union. https://op.europa.eu/en/publication-detail/-/publication/179e7382-b564-11ec-b6f4-01aa75ed71a1/language-en

[8] Commission staff working document - Accompanying document to the proposal for a Directive of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare - Impact assessment, COM(2008) 414 final.

[9] https://op.europa.eu/en/publication-detail/-/publication/7d72981d-f924-4977-a032-37361bb8b4b3

consultation rooms, use rates of electronic connections to other healthcare providers were low as were the use rates in the area of electronic transfer of patient data.

Administrative patient data were stored electronically in 80% of the EU27 GP practices. In some countries, usage rates were below the 50% level (Greece, Romania, Lithuania), going down as far as 26% (Latvia). The highest use rates were found in Finland and Hungary (100%), Estonia (98%), Denmark and the Netherlands (97%) and Sweden (96%). While computers were found in the consultation room of 78% of the European GP practices, they were not always used during consultation with a patient: 66% of the practitioners did so, while in 12% of the practices the computer was not used while a patient was present.

About 21% of European GP practices connected to other primary care providers, i.e. other GPs. Between GP and hospitals and specialist practices there was a noticeable gap. While about one fifth of GP practices connected to hospitals, only somewhat more than one tenth (12%) did the same with specialist practices. Connections to pharmacies were considerably less frequent (used by about 7% of the practices). Medical data were transmitted digitally to care providers or other professionals by 10% of the EU27 GP practices, ePrescription was practiced by 6% of the EU27 GP practices.

The implementation of the provisions related to eHealth was initially aimed to improve the interoperability of eHealth across Member States[10]. However, it is very important to note that at the time of the adoption of the Directive, Member States had low use rates of electronic connections and electronic transfer of patient data within their systems. Since this initial exercise, other benchmarks have been conducted[11] showing an increase in the digitalisation of health systems over time, including an increased interoperability within each Member State and to less extent between Member States.

Interoperability of digital health services systems

Prior to the Directive, lack of technical and semantic interoperability of digital health services systems was identified as a major obstacle for realising the social and economic benefits of eHealth in the EU and a source of market fragmentation in eHealth.

ICTs in health and standards used in Member States were often incompatible. Although some digital health registries were already available at national or local level, the different systems were not always interoperable at national level and even less in a cross-border healthcare setting.

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[10] As well as patients and healthcare providers' safe access to the transferred health data.

[11] Codagnone, C., and F. Lupiáñez-Villanueva.(2011) "A Composite Index for the Benchmarking of eHealth Deployment in European Acute Hospitals Distilling reality into a manageable form for evidence-based policy Strategic Intelligence Monitor on Personal Health Systems phase 2 (SIMPHS 2)." JRC-IPTS EUR 24825

Sabes-Figuera, Ramon, and I. Maghiros. (2013) "European hospital survey: benchmarking deployment of e-Health services (2012–2013)." *European Comission*

Codagnone, C., and F. Lupiañez-Villanueva. (2013) "Benchmarking deployment of eHealth among general practitioners. Final report." European Union. Luxembourg. Publications Office of the European Union: European Commission. Directorate-General of Communications Networks. Content & Technology.

Lupiáñez-Villanueva, F et al. (2018) Benchmarking Deployment of Ehealth Among General Practitioners: Final Report European Union. Luxembourg. Publications Office of the European Union: European Commission. Directorate-General of Communications Networks. Content & Technology

Therefore sharing of health data for continuity of care nationally, but also after seeking health services abroad, were often carried out in a manual fashion by requesting hard copies and translations of patient summaries to the respective healthcare providers.

In terms of **concrete targets**, the eHealth Network has set in the eHDSI Monitoring Framework that:

- By end 2020, 8 Member States should be interoperable with MyHealth@EU
- By end of 2020, 12 operational ePrescription services[12] (A and B) and 20 operational Patient Summary services (A and B) should be available.

Identification and authentication system

A few EU financed projects[13] started testing the possibility to share certain digital health data (patient summary and ePrescription) and started to develop a framework for cross-border electronic identification and authentication (eID). The results of these initiatives constituted a starting point for the development of the eHealth Network activities although they have been revised multiple times since then.

Guidelines and requirements for personal health data

At that time, no network or other cooperation structure was in place to deal with the complex set of framework conditions, organisational structures and implementation procedures required to achieve and maintain national and cross-border interoperability of digital health services. In 2008 the Commission adopted the Commission Recommendation on cross-border interoperability of electronic health record systems (2008/594/EC)[14], in which it identified technical, semantic, and organisational interoperability as essential to build and ensure interoperable digital health services that could ensure continuity of care. This Recommendation was intended to contribute to data quality, trust and security of personal data.

Guidelines and requirements for public health and research data

Furthermore, quality pan-European health data for secondary purposes (research, innovation and public health) were very limited due to national fragmentation. Some exceptions can be found in few key areas such as rare diseases, where the European Union has supported since 2007 ad-hoc projects under the Seventh Framework Programme[15].

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[12] It is considered a separate service when a Member State acts as a sending country (Member State of affiliation or "Country A") and when it acts as a receiving country (Member State of treatment or "Country B").

[13] Examples:

- epSOS (Smart Open Services for European Patients): Cross-border health project epSOS: What has it achieved? | Shaping Europe's digital future (europa.eu)
- STORK (Secure identity across borders linked 2.0): https://ec.europa.eu/cefdigital/wiki/display/EIDCOMMUNITY/STORK+Project

[14] https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:190:0037:0043:EN:PDF

[15] https://ec.europa.eu/info/research-and-innovation/research-area/health-research-and-innovation/rare-diseases_en

3 IMPLEMENTATION / STATE OF PLAY

3.1 Description of the current situation

Implementation of the relevant provisions of the Directive

There were no significant delays in terms of the formal implementation of the Article 14. The Directive entered into force in March 2011 and the first meeting of the new eHealth Network established on the basis of Article 14 took place already in May 2012, with the participation of all the Member States.

Financial investments

In terms of financial investments, EU financial instruments managed by the European Commission (and its agencies) and co-funded by Member States in some cases have supported the activities carried out by the eHealth Network. These include the financing of Joint Actions and grants from the Connecting Europe Facility (CEF)[16].

Joint Actions were the main instrument financing the eHealth Network activities, which are co-financed by Member States and the Commission. The financing of the Joint Actions has increased overtime: € 2 503 791 for the first Joint Action (2012-2014), € 4 000 000 in the following Joint Action (2015-2018) and € 4 499 963 in the last Joint Action (2018-2021). In addition, while the Commission contributed to slightly over 50% of the financing of the first Joint Action, the Commission increased its contribution to 60% of the total budget in following two Joint Actions, the rest being paid by Member States. The eHealth Network carried out its activities based on the priorities set out in its Multiannual Work Plan (MWP). Each of the MWPs covered the periods corresponding to the periods of the three Joint Actions.

The European Commission also provided direct financial support to 25 Member States[17] in the area of eHealth through the Connecting Europe Facility (CEF), amounting € 31.5 m in between 2015 and 2020. CEF funds in eHealth are used to support, among others, cross-border services at MyHealth@EU platform (formerly known as eHealth Digital Service Infrastructure).

Priorities and outcomes of the eHealth Network activities

(a) Patient Summary and ePrescriptions

Two electronic cross-border health services are currently progressively introduced in the Member States and exchanged through the MyHealth@EU platform: Patient Summary and ePrescription. Patient Summary enables healthcare providers to access patient's essential health information (part of the electronic health record) in their own language when the patient comes from another Member State. ePrescription allows EU citizens to retrieve their medication in a pharmacy based on the prescription issued in another Member State.

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[16] https://ec.europa.eu/inea/en/connecting-europe-facility

[17] Among these, 22 Member States received support from the CEF for cross-border exchanges of ePrescription and patient summary through MyHealth@EU, namely: Austria, Cyprus, Czech Republic, Germany, Estonia, Greece, Finland, France, Croatia, Hungary, Ireland, Italy, Luxembourg, Malta, Portugal, Sweden, Belgium, Spain, Lithuania, Netherlands, Poland, Slovenia.

The eHealth Network aimed at defining guidelines and formats for Patient Summary and ePrescriptions. This was achieved during the first Joint Action (2012-2014), as the eHealth Network produced and adopted the first guidelines:

- on a non-exhaustive list of data to be included in patient's summary;
- for cross-border electronic exchange of patients' summary data set;
- on the interoperability of ePrescriptions.

During this period, the activities of the eHealth Network were also supported by the work of the epSOS project[18]. The epSOS project was a European large-scale pilot testing the cross-border sharing of certain health data: a summary of a patient's most important health data in case of unplanned care (Patient Summary) and the electronic prescription (ePrescription).

These guidelines have been further refined (and updated when applicable) during the two following Joint Actions. An example is the "Guideline on Electronic exchange of health data under the Cross-border Directive" adopted in 2016[19].

(b) EU infrastructure (eHDSI/MyHealth@EU)

In order to enable services for cross-border health data exchange, the Commission developed a platform "eHealth Digital Service Infrastructure", which was launched in 2017 and later renamed as "MyHealth@EU". The platform was based on the conceptual framework previously developed by the epSOS project.

Therefore, the work of the eHealth Network first aimed at defining the prerequisites and key elements necessary to the establishment and deployment of the platform. In total, 15 policy documents of different nature were elaborated by the JAseHN Joint Action. Among them, key outputs developed and adopted by members of the eHealth Network are the guidelines used for the participation in MyHealth@EU:

- The Agreement between National Authorities or National Organisations responsible for National Contact Points for eHealth (NCPeHs) on the Criteria required for the participation in Cross-Border eHealth Information Service adopted in 2017[20]. Based to this agreement, Member States can join the NCPeHS and exchange health data cross borders, if it is set out in national law.
- The governance and operating principles of the NCPeHs have been outlined in the Guideline on an Organisational Framework for eHealth National Contact Point adopted in 2015. Based on this guideline, the NCPeH constitutes a Member States' communication gateway providing the interface between the national infrastructure and the EU network of other Member States' NCPeH, as well as with the central EU services. When a patient is travelling abroad, NCPeHs can either act as the country of affiliation (i.e. the country holding information about a patient, where the patient can be univocally identified and where the personal data may be accessed; Country A) or as the country of treatment (i.e. the country where cross-border healthcare is provided or a pharmacy is visited; Country B).

[18] https://digital-strategy.ec.europa.eu/en/news/cross-border-health-project-epsos-what-has-it-achieved
[19] https://ec.europa.eu/health/sites/health/files/ehealth/docs/ev_20160607_co05_03_en.pdf
[20] https://ec.europa.eu/health/sites/default/files/ehealth/docs/ev_20170509_co06_en.pdf

This resulted in the deployment of the MyHealth@EU infrastructure, and in the 2017 Council Conclusions on Health in the Digital Society[21], enabling the exchange of eHealth information services for the Member States participating in the eHealth Network, and approving the role of the NCPeHs.

In addition and during the third Joint Action (2018-2021) the main activities of the eHealth Network aimed at supporting the deployment of MyHealth@EU[22], as well as other aspects such as interoperability of electronic health records (in line with the Commission Recommendation on Electronic Health Record Exchange Format[23]), cybersecurity, e-identification, capacity building, empowerment of patients via tele-health.

- ***Outcomes of the above-mentioned activities (a) Electronic Health Records, ePrescriptions and (b) MyHealth@EU)***

Although the guidelines and common requirements for personal health data (i.e. ePrescription and Patient Summary) and guidelines and formats for Member States' ICTs interoperability with MyHealth@EU were adopted by the eHealth Network members, these have been implemented only partly so far:

- By the Q3 2021, **9 Member States reached interoperability with MyHealth@EU and joined the system of cross-border health data exchanges[24]**, which means that they can exchange ePrescriptions and/or Patient Summaries among themselves. Appendix IV summarises the services that are currently supported by the MyHealth@EU platform and the countries that are interoperable.
- In the early Q4 2021 there were **11 unique pairs of Member States, which were able to exchange the ePrescriptions (country with A[25] and country B[26])** and **21 unique pairs of Member States able to exchange Patient Summary (as country A and country B) services**[27]. This means that the eHMSEG decision to start new services exchange was issued after 64 unique tests on Production Environment Testing (each country is obliged to test each service with every available country).
- In terms of **hospitals** that enabled MyHealth@EU services as Countries of Treatment**, 3 Member States already provide a full national coverage (Luxembourg, Czechia, and Croatia)**. In addition, in **Malta**, only one of the two hospitals present in the country (Mater Dei Hospital on the island of Malta) enabled the service. Nevertheless, since the other hospital is located on the island of Gozo, where only 8% of inbound tourists spend at least one night, the actual coverage in terms of cross-border healthcare is rather high. In the case of **Portugal**, only a minority of hospitals (5 out of 247) enabled MyHealth@EU services.

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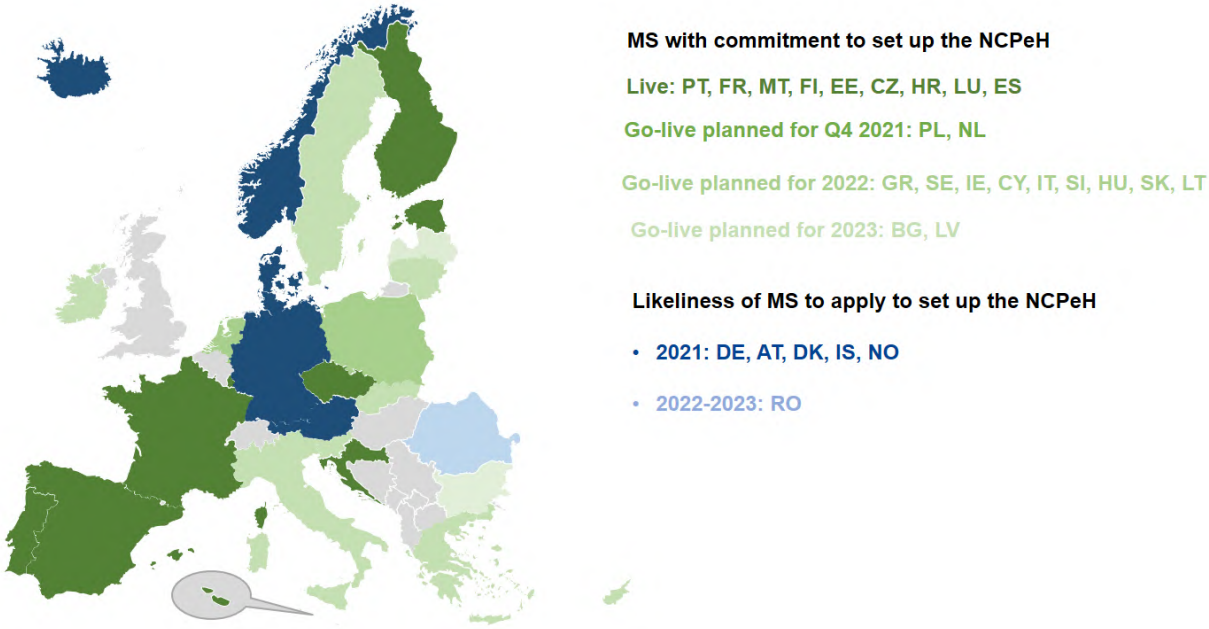
[21] https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2017:440:0003:0009:EN:PDF
[22] https://webgate.ec.europa.eu/fpfis/wikis/x/Zt7zN
[23] Commission Recommendation on a European Electronic Health Record exchange format (C(2019)800) of 6 February 2019: https://digital-strategy.ec.europa.eu/en/library/recommendation-european-electronic-health-record-exchange-format
[24] https://ec.europa.eu/health/ehealth/electronic_crossborder_healthservices_en
[25] Country of affiliation
[26] Country of treatment
[27] https://webgate.ec.europa.eu/fpfis/wikis/x/g-zzN

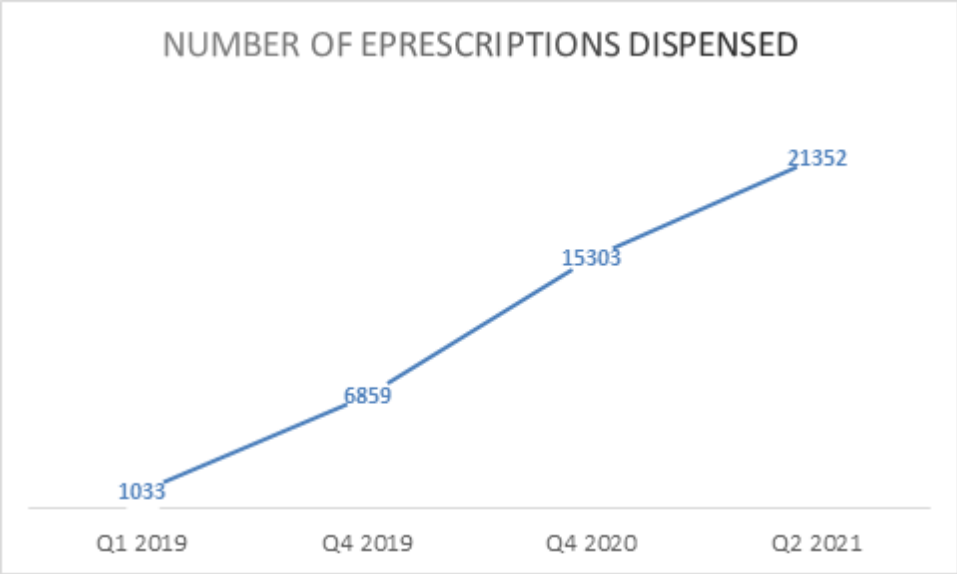
- In terms of **pharmacies** that enabled MyHealth@EU services as countries of treatment, **3 Member States** already **provide a full national coverage** with 100% of pharmacies enabling the services (Estonia, Croatia and Finland). On the other hand, in the case of **Portugal only one pharmacy** (of the 2972 present in the country) was reported to have enabled MyHealth@EU services.

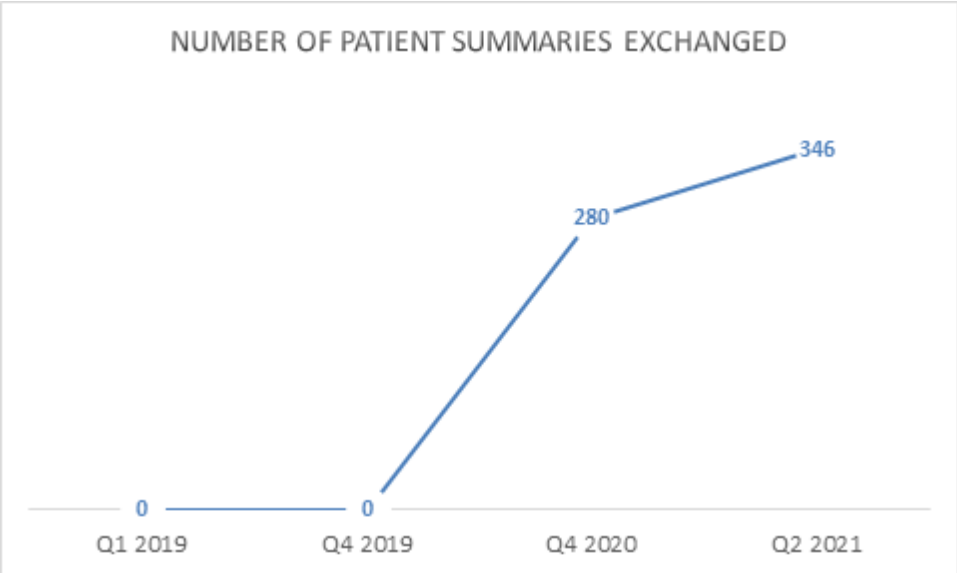


This results in a growing level of platform usage between 2019 and 2021, period during which the first data have been recorded (Figure 2).

- **21 352 ePrescriptions were dispensed to the patients by the end of Q2 2021**. The vast majority of ePrescription exchanges and dispensations happened between Finland and Estonia.
- There are still relatively few **exchanges of Patient Summaries, (346 by the end of Q2 2021**) and no clear pattern can be identified among participating Member States.

Figure 2. MyHealth@EU usage: number of ePrescriptions dispensed and Patient summaries exchanged





Source: EC[28]

(c) Security / electronic identification and authentication (eID)

The eHealth Network also aimed at developing the necessary guidelines and format for the electronic identification and authentication (eID) of citizens and businesses in the EU. The eHealth Network produced and adopted in 2017, among others, guidelines called "Policy paper on eID specific framework for eHealth"[29] and further updated them subsequently.

[28] https://webgate.ec.europa.eu/fpfis/wikis/x/g-zzN
[29] ev_20170509_co04_en.pdf (europa.eu)

The activities of the eHealth network in this area built on the STORK 2.0 project[30] and previous STORK framework for cross-border eID of citizens and businesses[31]. The STORK 2.0 project provided solutions allowing citizens to identify themselves across-borders by using identity-related data from authentic and reliable sources (attribute providers) or to represent other natural or legal persons, in the context of different business domains.

- **Outcomes of the activities related to a common eID approach**

Although the work on eID in eHealth is far from recent as early projects started in 2008 (epSOS and STORK), it has not yet been fully implemented in the currently operational MyHealth@EU services. At the EU level, there is no mainstream standard used. Identification of patients as part of the MyHealth@EU services is based on paper or plastic ID documents and national authorities can define and use their own identification mechanisms. In addition, 5 Member States do not employ the identification means according to the Regulation on electronic identification and trust services (eIDAS Regulation)[32], 3 Member States lack unique patient identifiers and 2 Member States lack health care staff identifiers[33].

(d) Mobile health

During the period of the second Joint Action, the eHealth Network activities aimed at developing a common framework and principles for the safe use of m-health apps. mHealth apps refer to health and wellbeing mobile applications and services which support self-management and measure vital signs such as heart rate, blood glucose level, blood pressure, body temperature and brain activity and are used by citizens. As Member States were setting up schemes and criteria to assess these apps, providing guidance to professionals and consumers, or seeking to integrate these apps into mainstream healthcare provisions, the eHealth Network started working on a coordinated approach at EU level addressing these challenges.

- **Outcomes of the activities related to m-health**

A dedicated subgroup of the eHealth Network focused on m-health[34] and produced, for example, a report on national mHealth strategies [35]. The objective of the report was to collect experiences on approaches in dealing with mobile health apps, to identify common challenges and recommend possibilities for future collaboration among Member States. This report is based on the responses received to the survey conducted among the sub-group members provides an overview of the existing strategies, activities and perspectives on mHealth in the Member States.

(e) Use of health data for secondary purposes

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[30] https://ec.europa.eu/cefdigital/wiki/display/EIDCOMMUNITY/STORK+2.0+Project
[31] https://ec.europa.eu/cefdigital/wiki/display/EIDCOMMUNITY/STORK+Project
[32] Regulation (EU) No 910/2014 of the European Parliament and of the Council of 23 July 2014 on electronic identification and trust services for electronic transactions in the internal market and repealing Directive 1999/93/EC, OJ L 257, 28.8.2014, p. 73–114: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2014.257.01.0073.01.ENG
[33] Thiel, R., Lupiáñez-Villanueva, F., Deimel, L., Gunderson, L. and Sokolyanskaya A. (2021). eHealth, Interoperability of Health Data and Artificial Intelligence for Health and Care in the EU. https://ec.europa.eu/newsroom/dae/redirection/document/79897
[34] ev_20170509_co09_en.pdf (europa.eu);
[35] ev_20161121_co22_en.pdf (europa.eu)

Besides the activities of the eHealth Network related to the primary use of health data for the purposes of delivering healthcare to patients described above, one of the aims of the eHealth Network was also to define and deploy effective methods and requirements to enhance the use of health data for secondary purposes. This refers to reuse of health data for purposes other than delivery of healthcare, such as medical research and innovation, informed decisions of health authorities in the area of public health or regulatory activities in the health sector.

- **Outcomes of the activities on secondary use of health data**

The activities carried out by the eHealth Network related to the secondary use of health data were very limited and no specific outcomes can be identified. Other EU initiatives (often funded through Horizon 2020 and Horizon Europe) did support projects dealing with the reuse of health data for research and innovation.

Appendix II provides a detailed description of all the activities and outputs of the eHealth Network for the periods covered by the different MWPs.

3.2 Overview of the impacts of the Directive's provisions related to eHealth

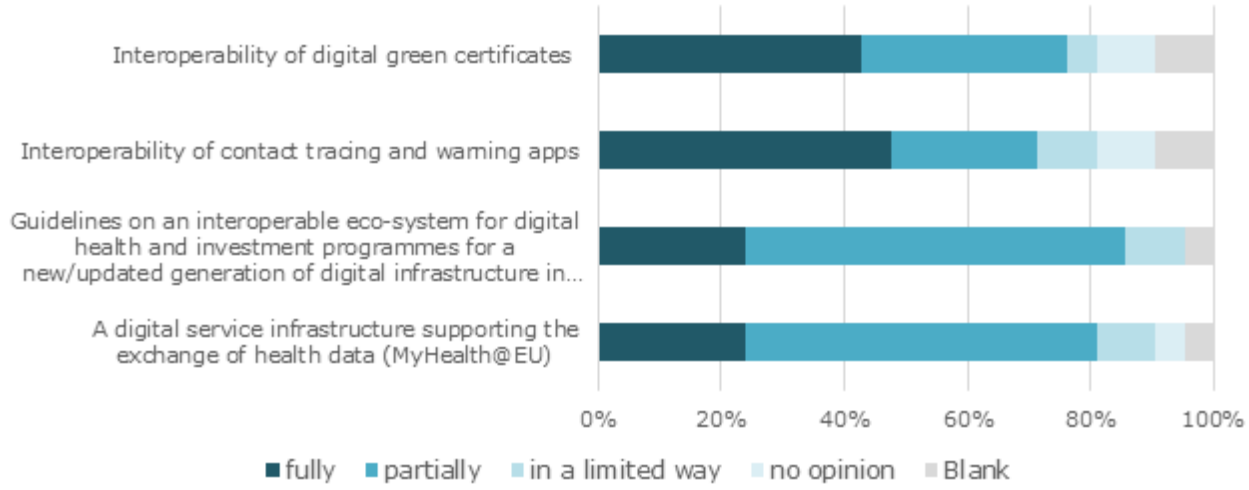
The box below summarises the expected impacts associated with the outcomes of the eHealth Network activities and other Directive's provisions related to eHealth, in particular with regard to healthcare provision and patient mobility but also with regard to research and innovation.

Box 1. Expected impacts

- Patients have access to safe and high-quality cross-border eHealth products and services, improving health outcomes.
- Continuity of care for patients is ensured after treatments and/or services are provided by healthcare providers abroad, improving health outcomes.
- Increased harmonised health data for research, innovation and public health.

When in 2021 eHealth Network members were enquired about the achieved impacts, different opinions emerged (Figure 3). More than half of the respondents believed that they only partially achieved a digital service infrastructure supporting the exchange of health data (MyHealth@EU) as well as guidelines on an interoperable eco-system for digital health and investment programmes for a new/updated generation of digital infrastructure in Europe. While almost half of the respondents believed that they fully developed interoperability of contact tracing and warning apps as well as of EU DCC.

Figure 3. Self-assessment of eHealth Network members of achieved objectives of Article 14 (a)



Survey Question: In your opinion, to what extent did the eHealth Network achieve the above-mentioned objective of Article 14 (a) set out in the legislation "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", by delivering: (n=19)

Access to cross-border healthcare

There are essentially two cross-border healthcare situations: (1) cross-border healthcare that becomes necessary during a temporary stay outside of the patient's home Member State (hereinafter "unplanned healthcare")[1]; (2) planned cross-border healthcare received in a Member State other than the patient's home Member State where the patient purposely seeks healthcare abroad.[2]

In the case of unplanned healthcare, the European Health Insurance Card (EHIC) proves the entitlement of the insured person to necessary healthcare treatment during a temporary stay in a Member State other than the competent Member State. Furthermore, there is an overall constant increase in patient mobility across Europe in the case of unplanned healthcare. In 2019, a total of 2,679,756 forms/claims were issued across Europe, for a total amount paid by the competent countries to the countries of treatment of € 1,280,450,122[36].

In addition, requests for information on cross-border care received by National and Regional Contact Points in 2019 accounted to 115,459 across the EU28, Norway and Iceland. More than half of the Member States received less than 1,000 requests. Estonia, Lithuania, Poland and Sweden stand out in receiving over 10,000 requests for information each. The 2019 data also show an

[1] With regard to the reimbursement of this type of cross-border healthcare, this is primarily addressed in Regulation (EC) No 883/2004 of the European Parliament and of the Council of 29 April 2004 on the coordination of social security systems.

[2] This type of cross-border healthcare can be reimbursed either based on the Cross-Border Healthcare Directive or on the Regulation (EC) No 883/2004.

36 https://ec.europa.eu/social/main.jsp?pager.offset=10&advSearchKey=ssc_statsreport2020&mode=advancedSubmit&catId=22&doc_submit=&policyArea=0&policyAreaSub=0&country=0&year=0

increase in requests for information since 2018. However, this is due to the fact that Sweden reported data for 2019, which in previous years was not possible. If the data from Sweden is excluded from the analysis, the total number of requests for information remains relatively stable between 2018 and 2019 (95,565 in 2018 and 95,689 in 2019). However, some countries did see significant variation between the years[37].

Furthermore, the 2019 data demonstrated the number of requests for reimbursement of cross-border healthcare costs under Directive 2011/24/EU. 23 Member States reported having received a total of 283,719 requests for reimbursement. Of these, 85% were granted, with 11% being refused and less than 1% withdrawn.

Access to cross-border eHealth products and services

Available evidence[38] show that when available, electronic health records are often only accessible locally, or at the regional level. In terms of patients' access to safe and high-quality cross-border eHealth products and services, the use of MyHealth@EU is still very limited in absolute terms. Although EHRs exist in two-thirds of Member States, by the end of 2020 only 7 Member States offered services (Patient Summary and/or ePrescriptions) on the MyHealth@EU platform.[39] All together, these 7 countries account for 32 997 906 people which represents only 7.38% of the overall EU population[40] that can access at least some of MyHealth@EU services.

In addition, two thirds of countries detail measures for technical interoperability and exchange measures in their legislative framework. 18 study countries indicate that data sharing of EHRs across national borders is permitted by law.

However, the level of alignment between national and EU-level initiatives on eHealth is limited. 9 Member States indicate to not refer to EU-level guidelines and documents on the Patient Summary and ePrescription/eDispensation in national policy documents and 19 do not refer to these resources in legislation documents. Seven countries do not have a standalone technical interoperability strategy. 17 countries have implemented an interoperability strategy focusing on semantics through a national terminology centre.

Medical prescriptions in electronic format are currently used in almost two-thirds of the Member States.

Improved continuity of care across borders

The low use of the MyHealth@EU so far and the limited cross-border patient mobility overall also affect any potential impact on the improved of continuity of care for patients after treatments and/or services provided by healthcare providers abroad. Given the relatively low level of platform usage and cross-border mobility, no major impacts on national healthcare systems could be observed. In general, according to Azzopardi-Muscat (2018), the Cross-border healthcare directive did not have so far a major transformative effect on national health systems.

Patients' empowerment and enhanced digitalisation of Member States' healthcare systems

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[37] https://ec.europa.eu/health/sites/default/files/cross_border_care/docs/2019_msdata_en.pdf
[38] Den Exter (2015)
[39] During 2021, one more Member State joined the exchanges at MyHealth@EU.
[40] EUROSTAT 2019 data

It is also important to consider to whether the relevant provisions of the Directive contributed to patients' empowerment and to what extent changes in the digitalisation of Member States' healthcare systems and the level of interoperability can be attributed to the activities of the eHealth Network. A detailed analysis of the digitalisation at national level has been carried out in the study conducted for the European Commission by Empirica and Open Evidence[41] and the main findings are summarised below.

Although enabling citizens to take an active role in the management of their health was included among the topics to be addressed in the last Joint Action supporting the eHealth Network, the impact of the relevant Directive's provisions on the access of patients to their electronic health records was limited as no outputs impacting this area were produced:

- Only a handful of countries provides electronic formats when ensuring the right to receive a written or electronic medical record of the treatment(Article 4.2 (f) of the Directive) and the right to have remote access to or have at least a copy of patient's medical record (Article 5 (d) of the Directive). Only 4 Member States have rules to provide digital access to a copy of the medical record/s for patients affiliated to their healthcare system seeking cross-border healthcare in another Member State (Croatia, Czechia, Greece and the Netherlands). Finland is planning to implement such rules over the upcoming three years. More details are available in Appendix VII.
- In terms of rules to provide digital access to a copy of the medical record/s of received treatment/s for patients affiliated to a different healthcare system that used cross-border healthcare in their Member States, only three countries provide such rules (Germany, Greece and the Netherlands) and three are planning to do so over the coming three years (Czechia, Finland and Poland). More details are provided in Appendix VIII.

In terms of citizens' control over their personal health data and patients' empowerment:

- citizens cannot choose which healthcare professional or other party can access their EHR in 12 study countries;
- GPs often act as 'data gatekeepers', allowing additional parties to access a patient's EHR, while in other countries the technical readiness of health data systems is not yet advanced enough to realise this option;
- Most study countries specify conditions for alteration and archiving of electronic health data but only around one third allow patients to correct data entered in their EHR by themselves;
- In terms of awareness actions and citizen information campaigns, 23 study countries claim to actively promote EHR system uptake and utilisation;
- 17 study countries have organised access to health information for citizens, with 6 Member States reporting ongoing pilots. Patient access to health data is not a reality in 3 Member States
- Access to EHR data via an online portal is by far the most common mode of access, with 4 study countries reporting they offer mobile access and 2 study countries still use paper print-outs
- In 18 study countries citizens can manage EHR data access at the document level

[41] Thiel, R., Lupiáñez-Villanueva, F., Deimel, L., Gunderson, L. and Sokolyanskaya A. (2021). eHealth, Interoperability of Health Data and Artificial Intelligence for Health and Care in the EU. https://ec.europa.eu/newsroom/dae/redirection/document/79897

This analysis has shown that 80% of the study countries have adopted national legislation on EHRs, on data safety and technical security measures less than five years ago.

While 26 study countries generally provide their citizens with access to EHR data by law, there are still some limitations as only 20 study countries have a law requiring that citizen can have access to their personal health data independent of place and technology.

Uniformly, one-third of study countries indicate that their eHealth policy is not integrated into general healthcare policy and that it does not contain planning measures for patient safety and quality of care, suggesting that eHealth policy is somewhat isolated in the respective countries.

The abovementioned study made also the following findings on organisation at Member States' level:

- 27 study countries have set up a competent authority for eHealth;
- 24 study countries report that competent authorities aim to facilitate semantic and technical interoperability;
- 18 study countries report that competent authorities translate international standards into the local language;
- 16 study countries have a forum similar to the National Digital Health Network envisaged by the European Commission;
- Most study countries have not yet implemented a terminology server;
- 4 Member States do not have a fully functioning EHR system.

3.3 The eHealth Network's contribution to the fight against the COVID-19 pandemic

Exchange of personal health data in times of pandemic: legal & technical gaps

As a consequence of the COVID-19 pandemic, **the need to exchange specific personal health data to manage and reduce public health risks and guarantee the free movement of persons across the EU became a key priority for the Commission.** However, no previous guidelines, infrastructure or governance mechanisms existed at EU level to address specific needs in times of a public health emergency.

New eHealth objectives in the context of a pandemic

The Commission therefore leveraged the potential of the eHealth Network to bring together Member States' experts in order to address these issues. The specific objectives of the eHealth Network in this context were **to support development and interoperability of contact tracing in the EU** by enabling the interoperability of contact tracing mobile applications (apps) and **support the development and interoperability of EU Digital COVID Certificates (DCC)**.

The expected outcomes of the related ad-hoc activities were that information about public health risks and contract tracing is available to citizens across the EU, while specific personal health data of citizens is available wherever they travel across the EU.

A high level of investments made by the European Commission and Member States

The types of investments considered in this analysis are twofold; they cover the funding provided by the European Commission in the new pan-European eHealth services delivered, as well as the human capital needed (especially at national level) to carry out these tasks.

The European Commission invested **€12.9 m** in the work related to the interoperability of contact tracing apps, especially by the creation and deployment of an infrastructure (the European Federated Gateway Service). The European Commission invested **€53 732 m**[42] in the development and introduction of the DCC.

In addition, an important amount of **human capital from Member States** has been invested in these activities. eHealth Network members met in a plenary setting on a weekly basis (through online meetings), while before the COVID-19 pandemic the Network organised plenary meetings twice a year only. Technical and semantic working groups also set-up additional meetings, with the most relevant groups meeting up to 5 times a week. Although no data are available on the overall Man-Days (MD) invested by Member States in these activities, the stakeholders consulted generally agreed that the commitment varied among the national members of the eHealth Network. A total of 254 online meetings have been organised from the beginning of the COVID-19 pandemic until June 2021. Considering that a meeting lasts in average 1 hour, and includes the participation of one representative per Member State, around 857.25 MD are estimated to have been invested in participation in eHealth Network meetings alone. This does not take into account human capital required for additional activities at national level to produce the different digital infrastructures and applications.

Providing an EU-wide rules and platform for the interoperability of contact tracing apps

As Member States were starting developing mobile apps to support contact tracing, the European Commission with the support of the eHealth Network took measures to support the development and deployment of national COVID-19 contact tracing apps beyond national borders and enable their interoperability. A contact tracing app is a tool which would allow app users to take appropriate action (such as testing or self-isolating) after being informed of having been potentially exposed to the virus through proximity to another user of this application, who has reported a positive diagnosis.

The eHealth Network supported:

- the development and adoption by Member States of a **Common EU toolbox** for Member States on mobile applications to support contact tracing[43];
- the development and adoption by Member States of **interoperability guidelines** for approved contact tracing mobile apps in the EU[44];
- the creation of the European Federation Gateway Service (EFGS), a **European digital infrastructure** that enables the exchange of personal health data across borders between the national contact tracing apps;
- the agreement on other technical specifications for the mobile apps and the European digital infrastructure.

This work resulted in the adoption by the European Commission of an Implementing Decision in July 2020[45], which puts forward specific rules for the cross-border exchange of data between

[42] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52021PC0130
[43] https://ec.europa.eu/health/sites/health/files/ehealth/docs/covid-19_apps_en.pdf
[44] https://ec.europa.eu/health/sites/health/files/ehealth/docs/contacttracing_mobileapps_guidelines_en.pdf

national contact tracing and warning mobile apps with regard to combatting the COVID-19 pandemic. It also lays down provisions on the role of the participating Member States and of the Commission for the functioning of the EFGS for the cross-border interoperability of the apps.

So far there has been a high level of uptake of the guidelines, as by the end of July 2021, 20 apps out of 22 existing apps in the EU have been developed following the guidelines and can potentially support interoperability. 19 apps were already interoperable with the EFGS. More details are provided in Appendix V.

However, their impact is limited by the unequal pick-up rates of these apps across EU countries. The apps connected to the EFGS were downloaded over 70 m times. From mid-October 2020 to mid-September 2021, Member States exchanged 6.7 m keys of users that tested positive through the EFGS. Assuming each user uploads 10 keys, this means that the EFGS transmitted, across borders, information from around 670 000 users that tested positive to alert other European users of their high-risk contact.

Enabling the development and interoperability of EU Digital COVID Certificates

Efforts of the eHealth Network in 2021 focused on supporting the creation of interoperable EU Digital COVID Certificates (EU DCC) based on the Regulation (EU) 2021/953[46]. **An EU Digital COVID Certificate** is a digital proof that a person has been vaccinated against COVID-19, has recovered from COVID-19 or has a negative test result. It seeks to lift lockdown measures such as the ability to travel across borders or access to certain services at national level.

The eHealth Network supported:

- the development and adoption by Member States of guidelines on verifiable vaccination certificates (basic interoperability elements)[47];
- the agreement on a minimum dataset of COVID-19 citizen recovery interoperable certificates[48];
- the creation of a trust framework composed of national infrastructures and back-end and an EU gateway, that enables the interoperability of EU Digital COVID certificates[49].

This work resulted in the adoption by the European Commission of an Implementing Decision in June 2021, which sets out technical specifications and rules of the implementation of a framework for EU DCC[50]. This framework entered into applicable on 1 July 2021 across the EU[51].

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[45] Commission Implementing Decision (EU) 2020/1023 of 15 July 2020 amending Implementing Decision (EU) 2019/1765 as regards the cross-border exchange of data between national contact tracing and warning mobile applications with regard to combatting the COVID-19 pandemic, OJ L 227I, 16.7.2020, p. 1–9: https://eur-lex.europa.eu/eli/dec_impl/2020/1023/oj

[46] Regulation (EU) 2021/953 of the European Parliament and of the Council of 14 June 2021 on a framework for the issuance, verification and acceptance of interoperable COVID-19 vaccination, test and recovery certificates (EU Digital COVID Certificate) to facilitate free movement during the COVID-19 pandemic, OJ L 211, 15.6.2021, p. 1–22: https://eur-lex.europa.eu/eli/reg/2021/953/oj

[47] https://ec.europa.eu/health/sites/default/files/ehealth/docs/vaccination-proof_interoperability-guidelines_en.pdf

[48] https://ec.europa.eu/health/sites/default/files/ehealth/docs/citizen_recovery-interoperable-certificates_en.pdf

[49] https://ec.europa.eu/health/sites/default/files/ehealth/docs/trust-framework_interoperability_certificates_en.pdf

All Member States have issued and are able to verify the certificates (for vaccination, recovery or tests) of the other Member States. By September 2021, 30 EU and EEA countries and 13 third[52] countries were are connected to the EU gateway enabling EU Member States to check in a simplified manner the COVID certificates issued by these third countries. Additional third countries are expected to join the process too. More details are provided in Appendix VI.

The results are positive, as over 460 million certificates have been issued by September 2021. This number is even higher in countries that put measures requesting the use of DCC for accessing other types of services such as events, etc. In practice, the certificates issued in a Member State can be used in others, not only when travelling across borders but also for national use when requested to access other types of services, and contributed to the lifting of measures restricting travels in a coordinated manner.

4 ANALYSIS AND ANSWERS TO THE EVALUATION QUESTIONS

4.1 Analysis and evaluation

Effectiveness

The eHealth Network developed guidelines for the identification of patients and healthcare professionals to enable cross-border exchange of health data in the framework of MyHealth@EU, and specified semantic, legal and technical requirements for the standardisation of patient summaries and ePrescriptions. Guidelines and standards on ePrescriptions and Patient Summary were implemented in the MyHealth@EU platform. More services are planned to be covered by the platform, such as medical images, laboratory results and hospital discharge letters. While the platform can facilitate the exchange of patients' health data across borders to enable continuity of care and patient safety across borders, its uptake has been so far limited to 8 Member States. Since many Member States so far have not implemented the developed standards and guidelines, lack of interoperability of digital health services systems remains one of the major obstacles to access to safe and high-quality cross-border healthcare. According to the finding of the study supporting this evaluation, one of the reasons behind the relatively low adoption of the platform lies in the voluntary nature of the eHealth Network that had no binding mandate towards Member States as well as the voluntary participation of the Member States in MyHealth@EU. Nevertheless, in quantitative terms, the volume of information exchanged on the platform was higher than the targets set by the eHealth Network in the eHDSI Monitoring Framework[53]. As the number of Member States taking up the platform will increase[54], so will the effectiveness of the platform. Ensuring a higher up-take level of the platform will increase the impact in terms of patients' access to safe and high-quality cross-border eHealth products and services, as well as continuity of care for patients receiving cross-border healthcare or benefitting from free movement within the EU.

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[50] https://eur-lex.europa.eu/eli/dec_impl/2021/1073/oj

[51] Between 1 July and 12 August 2021 there was a phase-in period to allow Member States that were not ready to issue the new certificate to use other formats.

[52] EU Digital COVID Certificate | European Commission (europa.eu)

[53] https://webgate.ec.europa.eu/fpfis/wikis/x/g-zzN

[54] It is expected that by 2025 all Member States will be connected to MyHealth@EU.

The eHealth Network did not directly support patients in accessing their health data in other Member States. Although the MyHealth@EU platform can support these evolutions, as of today only 4 Member States have in place national rules requiring digital access to a copy of the medical record/s for patients affiliated to their healthcare system seeking cross-border healthcare in another Member States and 3 Member States provide digital access to a copy of the medical record/s of received treatment/s for patients affiliated to a different healthcare system. The lack of eHealth Network activities in the area combined with the low level of priority of the issue within the Member States resulted in a very low level of effectiveness.

When it comes to the support of national digitalization of healthcare, interoperability and access of patients to their health data, progress has been made at national level since 2011. It is difficult to attribute this directly to the work of eHealth Network (except for the progress made in the area of COVID-19 contact tracing apps and EU Digital COVID certificates), as not all the Member States implemented eHealth Network guidelines at national level. Despite the fact that the General Data Protection Regulation (GDPR) has specific provisions on the access of data subjects to their data and portability of this data, eHealth Network took limited measures at EU level to implement these provisions. Nevertheless, some measures were taken at national level[55].

- 26 Member States generally provide their citizens with access to electronic health record data by law.
- 18 Member States indicate that data sharing of EHRs across national borders is permitted by law.
- 27 Member States have a digital health authority, with different tasks related to interoperability, security, data protection, tele-health and m-health.
- 24 Member States report that competent authorities aim to facilitate semantic and technical interoperability.

Also, some Member States implemented the Commission Recommendation on Electronic Health Record Exchange Format, complemented by the eHealth Network investment guidelines[56], as well as the eHealth Network recommendation on National Digital Health Networks[57] developed with the support of eHAction. The eHealth Network had, for a very long time, mainly a political or strategic profile in view of the fact that its members represented mostly the ministries of health. The eHealth Member States Expert Group (eHMSEG) was established as a permanent subgroup of the eHealth Network in relation to specific tasks related to MyHealth@EU. Only recently, with the creation of the semantic and technical subgroups, the technical expertise has been brought forward more strongly, allowing for technical discussions on digitalisation to feed directly the main decisions of the eHealth Network. Whilst a subgroup of the eHealth Network on m-health recommended to set up an assessment framework that would support Member States in their work in this area, the temporary character of this group did not ensure a proper follow-up and is not reflected, for

[55] Thiel, R., Lupiáñez-Villanueva, F., Deimel, L., Gunderson, L. and Sokolyanskaya A. (2021). eHealth, Interoperability of Health Data and Artificial Intelligence for Health and Care in the EU. https://ec.europa.eu/newsroom/dae/redirection/document/79897

[56] eHealth Network Guidelines to the EU Member States and the European Commission on an interoperable eco-system for digital health and investment programmes for a new/updated generation of digital infrastructure in Europe: ev_20190611_co922_en.pdf (europa.eu)

[57] eHealth Network Recommendation for the Development of National Digital Health Networks inn the EU Memmber States: eHAction_eHN-Recommendations-National-Digital-Health-Networks-_-for-adoption_19th-eHN.pdf

example, in any guidelines of the eHealth Network in this area. In any case, as the eHealth Network guidelines were voluntary, their impact on national development was rather limited and the effectiveness of eHealth Network actions was low.

Innovative use of health data has been developed during the COVID-19 crisis (i.e. Contact tracing apps, EU Digital COVID Certificates), guaranteeing the free movement of persons and allowing and promoting public health through digital means. This had a positive impact on the public health of the Union, providing crucial new tools in times of a public health crisis. These tools also helped to lift Member States temporary restrictions to the free movement of people, supporting the protection of an EU citizenship right. The digital infrastructure on contact tracing apps based on the Commission Implementing Decision (EU) 2020/1023 and on the guidelines of the eHealth Network was built on a voluntary approach (not all the Member States developed such apps and two Member States developed centralised approaches different from the general decentralized approach taken by the majority of the Member States). However, the eHealth Network managed to bring important coordination at EU level and changes at national level, done in rather similar way in several Member States. Such national and European transformation was even more visible for the EU Digital COVID Certificate, which had a strong legal basis (a Regulation (EU) 2021/953 based on free movement of persons legal basis which was adopted in extremely short time). Given the very high level of expertise brought forward in the semantic and technical subgroups of the eHealth Network and the coordination role of the eHealth Network plenary, Member States managed to deploy in few months an EU wide infrastructure, with a strong national rollout. The Commission also provided a strong support for EU interoperability. Therefore, on actions related to the public health crisis the effectiveness of the eHealth Network was very high.

In terms of **secondary use of health data**, no actions have been taken to boost secondary use of health data in research. In this area **the eHealth Network was not effective**. Some eHealth Network members explained the lack of action in the area as the result of several factors. On the one side, the prioritisation of developing ePrescriptions and patients' summary together with the infrastructure to run such services across Member States (MyHealth@EU) took most of the capacity not allowing to focus on other topics. On the other side, up until 2020 the issue was lacking political support at Member States level and given the voluntary structure of the network, that represented an obstacle to moving forward in the area. The digital health agencies, represented in the eHealth Network had in many cases a national mandate focused on the use of data for healthcare. While no activities on secondary use of data were carried out by the eHealth Network, other EU initiatives (often funded through Horizon 2020 and Horizon Europe) did support the reuse of health data for research and innovation. A relevant example is the work carried out in the field of rare diseases[58]. Therefore, some impacts have been reached in the area, but they were not linked to effective eHealth Network activities.

Since the adoption of the Directive in 2011, the need for better management of data for policy making, research and innovation purposes has been recognised by some Member States. This resulted in the set-up of different new national institutions such as Health Data Access Bodies or national health institutes (e.g. Findata, French Data Hub, etc.). The need for action in this area is also reflected in the work on the European Health Data Space that became one of the priorities of the Commission and is supported, among others, through a new Joint Action (TEHDaS). With the

[58] https://ec.europa.eu/info/research-and-innovation/research-area/health-research-and-innovation/rare-diseases_en

setting up of a European Health Data Space, THEDAS future activities are likely to impact the amount and availability of harmonised public data for research, innovation and public health across the Union. Within the scope of secondary use of data, it is important to note that the entry into application of the GDPR brought not only a framework to guarantee safe processing of personal data, but also provided a framework for secondary use of personal data. Reasons of public interest in the area of public health, such as protecting against serous cross-border threats to health or ensuring high standards of quality and safety of health care and of medicinal products or medical devices (on the basis of Union or Member State law) have been considered by the GDPR (Article 6(1)(e) and 9(2)(i) GDPR).

- *Conclusions regarding Effectiveness:*

As of today, after almost 10 years of activities, the effectiveness of the eHealth Network action has been rather limited and concentrated in enhancing the use of health data for primary use in the context of cross-border healthcare and more recently in promoting public health. More specifically, most of the activities focused on drafting guidelines for **ePrescriptions** and **patient summaries** and to support the development of the **MyHealth@EU infrastructure** to enable electronic cross-border health services. The MyHealth@EU platform has been implemented in 8 Member States so far. Member States with decentralised healthcare systems and lower levels of digitalisation appeared to have a lower level of readiness to implement the tools developed in the context of the eHealth Network activities. The platform currently supports two services (ePrescriptions and Patient Summaries), use of which has exceed the expected targets as set in the eHDSI Monitoring Framework (KPIs)[59]. In the future the platform may be used to extend the number of services provided and could constitute a starting point for the development of the European Health Data Space for primary use of health data. The very limited activities in the areas of patients' access to their health data, telemedicine and secondary use of data resulted in a very low effectiveness in these areas.

While the eHealth Network recommended Member States to use the standards and specifications from Electronic Health Record Exchange Format in procurements, in order to build interoperability, their real uptake was limited and the outcome remains very fragmented.

Following the outbreak of the COVID 19 pandemic in Europe, the eHealth Network provided support in developing interoperability for the **contact tracing apps** as well as supported the development of an interoperable **EU Digital COVID Certificate**.

However eHealth Network activities in the field of mHealth were limited only to the above-mentioned actions on contact tracing apps and EU digital COVID certificate.

Support from the eHealth Network to Member States in developing effective methods for enabling the use of medical information for public health and research was not effective. Some general documents on big data were produced by the eHealth Network, but they were not followed up by additional specific implementing actions. At the EU level, some relevant activities in the area have been carried out by research projects funded by the Commission. Since February 2021, the establishment of the TEHDaS Joint Action has reinforced the EU intervention in the area. The Data

[59] https://webgate.ec.europa.eu/fpfis/wikis/x/g-zzN

Governance Act and the forthcoming European Health Data Space initiative will be important policy instruments in this area.

Efficiency

As a general rule, the benefits of EU interventions are expected to justify the costs they generate, although those who bear the costs do not always reap the benefits. This is a common situation in the health domain, where final beneficiaries are supposed to be citizens and patients. Furthermore, due to a lack of accounting of man-days and other inputs, it was not always feasible to quantify exactly the costs sustained by certain stakeholders. Nevertheless, this section seeks to identify the factors that are driving these costs and benefits and how these factors impacted the activities of the eHealth Network.

In terms of costs, the major contributors to eHealth Network activities have been the European Union and the Member States. The European Commissionwas a major contributor to the different Joint Actions. The table below summarises the European Commission's financial contribution to the Joint Actions supporting the eHealth Network since its creation.

Table 1: Financing of eHealth Network Joint Actions

	European Commission	Member States	Total JA budget
eHGI JA (2012-2014)	EUR 1 001 895 (50% of total budget)	EUR 1 001 895 (50% of total budget)	EUR 2 003 791
JAseHn (2015-2018)	EUR 2 400 000 (60% of total budget)	EUR 1 600 000 (40% of total budget)	EUR 4 000 000
EHAction (2018-2021)	EUR 2 699 989.67 (60% of total budget)	EUR 1 799 985.38 (40% of total budget)	EUR 4 499 963

Source: European Commission

Overall the European Commission provided more than €6 m in Joint Actions since 2012. The Commission has increased greatly its contribution from the first to the second Joint Action while its contribution has increased only slightly from the second to the third Joint Action. Member States, have also co-financed a sizable percentage of the budget for the first and second Joint Action. The Joint Action budgets covered:

- Support for development of policy documents to support the different priority areas identified in the MWPs
- The dissemination of content produced within Member States and Stakeholder Groups;
- The dialogue with relevant EU eHealth stakeholder groups and standardisation organisations;
- In addition, the European Commission ensured the eHealth Network secretariat, the preparation and reimbursements of eHealth Network meetings, its subgroups and of the meetings of the eHealth Stakeholders Group.

The financial inputs that contributed to the work of the eHealth Network, were not limited to the already mentioned Joint Actions and support provided from the Health Programme, but included also the CEF which supported the development of the MyHealth@EU and the initial elements used

for the set-up of primary data standards and interoperability. For the purpose of this analysis, other grants and projects that were generally linked to the development of eHealth in Europe, but not to the implementation of the eHealth Network specifically, have been excluded.

As mentioned above, the Commission supported the development of the **MyHealth@EU platform** mainly via the Connecting Europe Facility (2015-2020). Between 2015 and 2020, the Commission managed approximately EUR 31.5 million funds for eHealth activities.[60]

The CEF funds have contributed to development and running of the MyHealth@EU platform by supporting the National grants for setting up National Contact Points for eHealth, Management and governance of the platform, Requirements and specifications, Configuration services, Terminology services, Test and Audit services, NCPeH Reference Implementation, Operations orchestration, Hosting.

The Commission also provided support from the financial instruments implementing the main research and innovation programmes (i.e. FP7, Horizon 2020, Horizon Europe, etc.). Over the years, these grants co-financed several projects relevant for the activities of the eHealth Network.

Before the setting up of CEF, different projects already started to build the groundwork to deliver digital cross-border eHealth services, by defining eID formats, as well as formats and frameworks for the digital exchange of Patient Summaries and ePrescriptions. The most relevant projects funded by EU are summarised in the following table:

Table 2: EU projects on cross-border eHealth services preceding CEF

	Topic	Budget	EU contribution
epSOS	Patient Summary and e Prescriptions	EUR 38 008 793	EUR 17 999 000
STORK & STORK 2.0	Cross-border authentication and identification (eID)	EUR 26 453 042 € 18 655 793	EUR 13 073 335 8 762 939
EXPAND	Deploying cross-border eHealth services	EUR 989 988	EUR 989 988
e-SENS	Deploying cross-border eHealth services	EUR27 358 005	EUR 13 678 995
Total		EUR 111 465 621	EUR 54 504 257

Source: European Commission

As highlighted in the previous two tables, Member States have also financially contributed to Joint Actions and projects. Furthermore, according to the stakeholders involved in the study, particular effort was required by the 8 Member States that are already operational on MyHealth@EU to join

[60] As of 2021, funding of activities in these areas will largely move under the EU4Health Programme.

the platform. Furthermore, there are significant differences across Member States that need to be considered.

Financial support to some Member States has been provided by the European Commission to offer technical support to design and implement structural reforms. These are targeted, time limited projects, which usually take place at the request of a Member States. Technical support includes context specific study visits and best practice exchange between the Member States/Regions. Digital health is one of the areas where technical support is provided. For example, support was provided to Croatia for development of the 2021-2027 Croatian eHealth Strategic Development Plan and Croatian eHealth Business Implementation Plan 2021-2022. Bulgaria, Belgium, Estonia, Greece and Slovenia also receive support to develop their eHealth strategies and future proof ICT governance frameworks. Czechia received technical support for the creation and implementation of the national eHealth centre. The eGovERA project (eGovernment Enterprise Reference Architecture) also received support and has developed expertise in the area of eHealth.

On top of these financial inputs, **additional human capital** has been invested to ensure the execution of the eHealth Network activities. This includes especially the time spent by national experts and representatives, who on top of participating in semi-annual meetings, also organised and carried out their work in thematic sub-groups. Unfortunately, upon request no information was provided on an estimation of these costs. As a result, it was not possible to gather evidence on the estimation of the overall Man-Days (MD) invested by the different Member States. Nevertheless all stakeholders agreed that the commitment varied greatly among the eHealth Network members, hinting that some Member States invested far more than others. Furthermore, according to eHealth Network members, more sub-groups and frequency of meetings and activity was carried out since the start of the COVID 19 pandemic. As summarised in the Appendix IX, a total of 330 online meetings have been organised since the start of the COVID 19 pandemic until June 2021. Considering an average of 1 hour per meeting and the participation of one representative per Member State, we can estimate around 990 MD invested since the start of the pandemic until June 2021 on meetings alone (without considering the investments carried out nationally to produce and sponsor the different digital infrastructures and applications). Detailed overview of the number of eHealth Network meetings organised in the relevant period is provided in Appendix IX.

The voluntary cooperation structure of the network resulted in different levels of commitments and investments from Members that could be justified by different Member States' priorities as well as different level of readiness to adopt the developed tools and guidelines.

In addition, Member States that already implemented the MyHealth@EU platform such as Finland and Estonia already had very **digitalised healthcare systems at the time they joined the platform**. On top of that, the population of both countries is concentrated in the capital regions of Helsinki and Tallinn respectively. Separated by the 65-kilometre-wide Gulf of Finland, the twin-city region of Helsinki-Tallinn is already a **highly integrated region** with relevant mobility flows across the gulf. These pre-existing conditions are likely to have played an important role not only in gathering the political support needed to adopt the MyHealth@EU platform, but also to be the two regions with the highest frequency of exchange of cross-border data. Furthermore, as highlighted by Portuguese representatives, having Portugal already a **centralised national health data system**, made it easier (and relatively cheaper) for the country to adopt all the standards required to uptake the MyHealth@EU platform compared to countries such as Spain, Germany and Italy with regional systems that already present interoperability issues within the countries.

Although the MyHealth@EU infrastructure is up and running, its adoption by Member States is so far limited to 8 Member States. Nevertheless, the exchanges on the platform have exceeded the targets set by the eHealt Network for 2019 and 2020. Compared to the 2011, Member States have now at their disposal a platform to exchange health data (ePrescription and eSummary) with other Member States in a secure and trustworthy manner. As more Member States will join the platform, more beneficial the tool will be for the countries that have already implemented it.

Limited commitment by Member States within a voluntary cooperation structure played an important role in limiting the effectiveness of the investments carried out in the area since 2011. The COVID 19 pandemic brought a change in policy focus and commitment by Member States. Whilst it is acknowledged that there has been an increase in the number of meetings and therefore human resources invested in the activities of the eHealth Network during the COVID-19 crisis in 2020 and 2021, the amount and quality of activities and concrete outcomes delivered within this short timeframe in the field of contact tracing apps and EU Digital COVID Certificate, are a proof to the fact that when there is political convergence and support among the different stakeholders of the voluntary network and, ideally, a stronger legal basis, the efficiency of the eHealth Network can increase greatly. From the beginning of 2020, the eHealth Network developed guidelines that supported the development of 19 interoperable contact tracing apps across the EU, as well as the development of the EU Digital COVID certificate launched across the EU in July 2021. It is important to note that in the case of the EU Digital COVID certificate, the initiative was legally based on a regulation[61], while in the case of the MyHealth@EU platform, the cooperation was carried out mainly within a voluntary cooperation framework. This was probably another factor that increased the effectiveness of the activities carried out for the EU Digital COVID certificate.

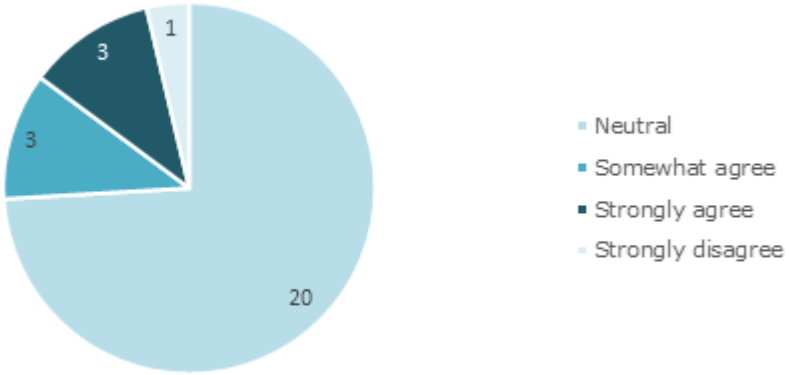
Appendix X summarises in detail the different costs and benefits by stakeholder group.

It is important to highlight that, when enquired, none of the eHealth Network members was able to quantify the costs and benefits provided by the participation to the network, although the majority believed the network to be run in a cost-efficient manner. Future administrative procedures to participate to the eHealth Network activities should improve the accounting of the different costs (i.e. Man-Days, national investments, etc.) to allow for a better ex-post estimation of the costs carried out.

When Member States were enquired about the extent to which the eHealth Network activities contribute to a more cost-efficient development of cross-border digital health resources, the large majority did not have any strong position. The figure below summarises the results of the survey.

[61] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52021PC0130

Figure 4. To what extent do you agree that the eHealth Network support contributes to a more cost-efficient development of cross-border digital health resources



(n=27)

Source: Author's elaboration

- *Conclusions regarding Efficiency:*

The lack of data collected for certain cost categories (MD and national investments to implement developed tools) resulted in difficulties in assessing the costs incurred by the different stakeholders. Nevertheless, the analysis of the activities carried out against the input and resources provided by the Commission and the Member States suggests that there is scope for improvement with regard to the efficiency of the routine activities of the eHealth Network. So far only 8 Member States have implemented the MyHealth@EU platform and within these 8 Member States, the number of healthcare providers that are connected to the MyHealth@EU platform through NCPeHs also differs significantly.

However, the eHealth network proved to be fairly efficient in times of political convergence following the COVID 19 pandemic outbreak when it delivered high-quality concrete results and solutions within an extremely short period of time, in particular on contact tracing apps and EU DCC.

Different levels of commitment by different Member States are partially linked to different national priorities as well as different levels of readiness to introduce digital solutions. When Member States were enquired about the extent at which the eHealth Network support contributes to a more cost-efficient development of cross-border digital health resources, the large majority did not have any strong position.

As more Member States implement the developed tools and platforms, the more efficient their development and maintenance will be. Currently, all Member States are expected to implement the MyHealth@EU platform by 2025.

Relevance

Barriers to exchange patient's health data across borders to enable continuity of care and patient safety across borders are still present. Digitalisation can support the continuity of care across

borders, an important aspect for those who spend time abroad for business or leisure purposes. In terms of relevance, while some issues such as the development of eID, the MyHealth@EU platform and common guidelines for patients summary and ePrescriptions have been addressed, most of the initial needs and objectives remain relevant as barriers to interoperability remains. Only 7 Member States have implemented the MyHealth@EU platform so far. In addition, Nalin (2019) identified several barriers towards the actual adoption and implementation of data exchange initiatives, namely;

- Not all EU Member States are aligned with the JASeHN agreement (and the IDAS regulation)
- Different consent mechanisms exist among Member States
- Lack of standard EHR systems in Member States.
- Different implementation of EU regulations among Member States[62]
- Different information workflows among National Infrastructure and healthcare organisations
- Lack of harmonisation in rules, processes, and safeguards
- National Contact Point for eHealth deployments in Member States are still in early stages
- Lack of the budget to address security aspects by healthcare organisations.

The recent COVID 19 pandemic has highlighted more than ever the relevance and need of a more integrated and interoperable European eHealth system. Facilitating the exchange of patients' health data across borders to enable continuity of care and patient safety across borders remains highly relevant. In terms of semantic, legal and technical requirements for the interoperability of eHealth improvements have been made. The MyHealth@EU platform is up and running and is able to support cross-border transfer of health data (ePrescription and Patient Summary).

In the future, the same platform especially after the eID system will be integrated could be used to support other health services and enhancing accessibility to new cross-border digital health services such as tele-medicine, tele-health and tele-monitoring.

The **eHealth Action Plan 2012–2020 – Innovative healthcare for the 21st century**[63] evaluated the development of eHealth and defined the main objectives. In 2012, despite the economic crisis, the telemedicine market was booming, at an annual rate of 18.9% between 2010 and 2011. However, the complexity of the European legal framework was already a heavy burden. Most of the obstacles hampering the deployment of eHealth at the time are still not addressed:

- lack of awareness of, and confidence in eHealth solutions among patients, citizens
- and healthcare professionals;
- lack of interoperability between eHealth solutions;

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[62] Regulation 2014/910/EU and Regulation 2016/679/EU

[63] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, eHealth Action Plan 2012-2020 - Innovative healthcare for the 21st century; COM/2012/0736 final: https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A52012DC0736

- limited large-scale evidence of the cost-effectiveness of eHealth tools and services;
- lack of legal clarity for health and wellbeing mobile applications;
- inadequate or fragmented legal frameworks including the lack of reimbursement schemes for eHealth services;
- high start-up costs involved in setting up eHealth systems;
- regional differences in accessing ICT services, limited access in deprived areas.

The four actions defined to address these barriers were

- Achieving wider interoperability in eHealth Services;
- Supporting research, development, innovation and competitiveness in eHealth;
- Facilitating uptake and ensuring wider deployment of eHealth;

Promoting policy dialogue and international cooperation on eHealth at global level.

The use of common standards for health data transferred across borders through one platform could potentially also be relevant in the future to better grasp new technologies such as the use of Big Data and Artificial Intelligence in the field of healthcare.

Finally, supporting the pooling of the EU's data resources and to facilitate their use for research, innovation and policy making (secondary use of data) remains a major need that the eHealth network was not able to address. Not only enhancing secondary use of data (Article 14(b)(ii) of the Directive) remains a major need, but further reflection is needed on how to coherently address this issue with the different EU policies implemented. To ensure better secondary use of data, some Member States have set up different governance structures and strategies. The need to enhance secondary use of data resulted in the 2019 announcement of the Commission's work towards creation of a European Health Data Space[64], which is supported by the TEHDAS Joint Action. Secondary use of data solutions being developed under TEHDAS would help promote the use of health data for research, which would support research for the improvement of healthcare, taking away current existing barriers for the secondary use of health data.

- *Conclusions regarding Relevance:*

Digital solutions for healthcare can increase the well-being of millions of citizens and radically change the way healthcare services are delivered to patients, if designed purposefully and implemented in a cost-effective way.

The **digitalisation of healthcare has actually increased the need for greater interoperability and data flow** also in the context of tele-health and mHealth. This is also a need for the secondary use of data, which has only been recently started to be tackled by the TEHDaS Joint Action.

Coherence

First, this section analyses to what extent the provisions related to eHealth are coherent internally.

[64] https://ec.europa.eu/health/ehealth/dataspace_en

In terms of patients' access to data, ad-hoc electronic medical record/summary of the treatment received supporting the continuity of care across borders have rarely been implemented, nor is required by Articles 4 and 5 of the Directive. While the Directive does not impose an obligation on Member States to ensure issuing of electronic copies of medical records/treatment received, a potential revision of the Directive could consider the possibility to foster more remote access to medical record in the context of cross-border healthcare.

At the same time, whilst eHealth Network issued guidelines supporting the implementation of the Commission recommendation on European Electronic Health Record Exchange Format and national interoperability, their voluntary status limited their impact on national interoperability.

This section also analyses the coherence of the eHealth provisions with other key EU policies, especially with regard to **the GDPR and the work on the digital Single Market** (the Commission Communication on Digital Transformation of Health and Care, The Data Governance Act, EU e-Government Action Plan)**, the needs emerging as part of the pandemic, and finally with national structures put in place for secondary services.**

The work of the eHealth Network and especially the activities related to the primary use of health data via the MyHealth@EU platform has been brought forward in full respect of the applicable data protection rules and the GDPR in particular. The Commission adopted in 2019 the Implementing Decision 2019/1765 providing the rules for the establishment, the management and the functioning of the network of national authorities responsible for eHealth. This Implementing Decision has clarified the responsibilities of the relevant national authorities or other designated bodies as controllers of personal data they process through the MyHealth@EU. On that basis the Member States authorities should clearly and transparently allocate the responsibilities between them as controllers. The Implementing Decision also clarified that the Commission acts as the data processor for patients' personal data processed through MyHealth@EU.

The Communication on a Digital Single Market Strategy for Europe[65], which was adopted in 2015, includes eHealth and telemedicine under the section on "Boosting competitiveness through interoperability and standardisation". Based on the work carried out within the **Digital Single Market Strategy for Europe**, and more specifically the **EU e-Government Action Plan 2016-2020** communication[66] as well as the communication on the priorities of ICT standardisation for the Digital Single Market adopted in 2016, in 2018 the EC published a **Communication on Digital Transformation of Health and Care[67]**. The communication identified three priorities for future action:

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[65] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions: A Digital Single Market Strategy for Europe. COM/2015/0192 final: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A52015DC0192

[66] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions: EU eGovernmeny Action Plan 2016-2020 Accelerating the digital transformation of government. COM/2016/0179 final: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52016DC0179

[67] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on enabling the digital transformation of health and care in the Digital Single Market; empowering citizens and building a healthier society. COM/2018/233 final: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM%3A2018%3A233%3AFIN

- **Citizens' secure access to their health data**, including across borders, enabling citizens to access their health data across the EU;
- **Personalised medicine through shared European data infrastructure**, allowing researchers and other professionals to pool resources (data, expertise, computing processing and storage capacities) across the EU;
- **Citizen empowerment with digital tools** for user feedback and person-centred care using digital tools to empower people to look after their health, stimulate prevention and enable feedback and interaction between users and healthcare providers.

The proposal for a Regulation on European data governance (**Data Governance Act**)[68], is the first of a set of measures announced in the **2020 European strategy for data**[69]. The Data Governance Act aims to foster the availability of data for use by increasing trust in data intermediaries and by strengthening data-sharing mechanisms across the EU. The Data Governance Act refers to the sectoral data spaces, including in the health sector, and should be complemented in the health domain by creating a harmonised framework for health data exchanges, the **European health data space (EHDS)** for primary and secondary use of health data. The objectives of the Data Governance Act are therefore coherent with the objectives of the provisions of the Cross-border healthcare directive concerning eHealth. However, as mentioned above, in the area of secondary use of health data the implementation of these objectives by the eHealth Network was rather limited.

The eHealth Network activities set out in its MWPs have been largely coherent with the policy evolution that took place over the last few years and set out in the Digital Single Market Strategy, and more specifically the **EU e-Government Action Plan 2016-2020**. However, contrary to the guidelines set forward in the "eHealth Action Plan 2012–2020-Innovative healthcare for the 21st century", only limited activities have been carried out by the eHealth Network in the field of telehealth (only few policy documents developed by the eHAction Joint Action). In the field of mHealth the eHealth Network seems to be more aligned with the objectives of the eHealth Action Plan 2012-2020 as it set up a temporary working group, which delivered recommendations on mHealth, including on guidelines for evaluating tele-health applications. However, their follow-up and implementation was limited at the end of the mandate of this group.

The COVID-19 pandemic brought an increase of the activities in the area of m-health and public health (contact tracing apps and EU Digital COVID Certificates) and the digital solutions developed in this light seem to be coherent with Member States policies and infrastructures developed to fight the COVID-19 pandemic.

As already mentioned, so far the majority of the activities of the eHealth Network only focused on primary use of health data while only limited activities were carried out in the field of **secondary use of data**, partly due to the fact that the institutions participating in the eHealth Network may

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[68] Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on European data governance (Data Governance Act), COM/2020/767 final: EUR-Lex - 52020PC0767 - EN - EUR-Lex (europa.eu)

[69] Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions: A European strategy for data, COM/2020/66 final: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52020DC0066

have not been the ones responsible for the secondary use of health data at the national level. As demonstrated above, the Commission supported financially several projects in the area of secondary use of health data through various funding programmes, but there seems to be insufficient or very limited coherence of this work with the work of the eHealth Network.

There are different governance structures and strategies for managing health data in the Member States, with a particular focus on reusing data for research purposes. These include national agencies or bodies authorized to grant permits for the use of data already collected for another specific purpose, as well as any other mechanisms for providing access to health data for research and public policy purposes, including by means of initiatives to further enhance data altruism. There are currently thirteen data governance bodies at a Member States level that currently have a central role within their Member State for providing access to health data for research. However, these bodies often existing in parallel to other bodies and data controllers that are entrusted with similar responsibilities or are providing similar services within the Member States. The ongoing Joint Action TEHDAS can help to address these existing incoherencies.

The evolution of national agencies specialised in secondary use of data and Health Data Access Bodies means that there are new actors and stakeholders that need to be engaged to ensure the coherent development of the future European Health Data Space and aligning the respective national policies in this area. The current structure of the eHealth Network was not able to promote cooperation between Member States in the field of secondary use of health data, nor was it able to engage with these new institutions. Therefore, to ensure the implementation of the European Health Data Space in its entirety a different structure should be developed to ensure the appropriate coordination of the work on secondary use of health data.

Moreover some other stakeholders such as health insurers, representatives from the medical device and pharmaceutical industry flagged during the consultation activities (interviews) that they were not invited to monitor and provide input to eHealth Network's activities in a systematic way, although they represent key players in healthcare. These stakeholders have been invited to several meetings of the eHealth Network in the past years on an ad-hoc basis but better engagement with eHealth Network activities could be further considered.

- *Conclusions regarding Coherence:*

In terms of coherence, the eHealth Network has been, at least on its intentions reflected in the MWPs, coherent with the policy evolution that took place over the last few years, especially with the development of the Digital Single Market Strategy, and more specifically the EU e-Government Action Plan 2016-2020. However, some areas were rather neglected, such as telehealth and eHealth. Member States national policies were not always aligned with eHealth Network activities and that may partially explain the current low pick up rates of some of the tools developed (i.e. MyHealth@EU platform). The recently launched **TEHDaS Joint Action focusing on use and reuse of health data and involving new actors in the process,** should help **to ensure better coherence with** Member States' policies and initiatives carried out at the national level. That would be in line with the requirement of the Directive for the eHealth Network to develop guidelines on effective methods for enabling the use of medical information for public health and research. The current situation calls for expanding the cross-border services offered to include secondary use of health data to develop the planned European Health Data Space.

EU added value

Healthcare is a national competence in the EU, as Member States have the primary responsibility for organising and delivering health services. Therefore EU action must complement national policies and encourage cooperation between Member States (Article 168 of the TFEU). EU intervention contributes only where Member States cannot act individually or where coordination is the best way to move forward.

While looking at activities and results, the evaluation assessed changes which can reasonably be argued are due to the EU intervention, over and above what could have been expected from national actions by the Member States.

According to Azzopardi-Muscat et al. (2018) the impact of the Directive (EU) 2011/24 varies between countries and is smaller in countries where a large degree of adaptation had already taken place in response to the European Court of Justice Rulings[70]. Nevertheless, most of the reforms analysed did not addressed eHealth issues.

Regarding eHealth and the cross-border exchange of health data for healthcare, it would be hard to imagine the development of a platform such as MyHealth@EU without EU intervention. According to the different experts interviewed (external experts as well as some eHealth network members), Member States showed different levels of involvement in the different eHealth Network initiatives that is reflected in the varying up-take rate of the platform ranging from the early adopters to the Member States that have not yet even indicated their intention to join the exchanges via MyHealth@EU. In terms of interoperability and eID, the Member States with regional healthcare systems (i.e. Spain, Germany, Italy), still suffer from lack of national interoperability and may not consider the EU level interoperability neither as a priority nor as an opportunity to foster national interoperability within the country. Furthermore, given the relatively low volume of cross-border healthcare, compared to healthcare provided to national patients, when it comes to developing formats for ePrescriptions and Patient Summary some countries would have had less incentive to factor in the interoperability across the EU.

Having an established network in place played an important role in reacting quickly to the COVID 19 pandemic by setting up common standards for contact tracing app and COVID certificates and establishing a European infrastructure to enable interoperability. The COVID 19 pandemic stressed the need to coordinate and ensure better flow of health data across Europe and demonstrated greatly the added value of the EU action in the area of digital health.

When it comes to secondary use of health data, the involvement of new national agencies and Health Data Access Bodies will be crucial to develop better data usage for research and policy making. The limited activity of the eHealth Network in the field of secondary use of data provides an example of insufficient coordination and common action among Member States. This could be partly improved by the setting up of the TEHDAS Joint Action but a potential long-term solution could be to have two different networks, one focusing on primary use of data and involving the stakeholders currently involved in the eHealth Network and the second one focusing on secondary use of data and involving Health Data Access Bodies as well as national data agencies. The two networks would need to be interconnected and well coordinated to avoid duplication and ensure

[70] The analysis was carried out in seven EU Member States. Namely: Belgium, Estonia, Finland, Germany, Malta, Poland and The Netherlands.

common use of certain tools and formats such as eID. Together, the two networks would provide the two pillars on which to build the future European Health Data Space, ensuring the control of citizens over their own personal health data and the use of data for medical diagnosis, public health and research. However, attention should be paid to the extent that the TEHDAS replicates the same path taken by the eHN.

- *Conclusions regarding EU added Value:*

In terms of evaluating the EU added value of the intervention, the result is mixed. While there are clear potential benefits of the cross-border collaboration on eHealth and digital health, the number of healthcare providers and patients that can actually take advantage of this possibility is currently low although increasing. This is due to the continuing insufficient interoperability across the different national systems, but also due to a relatively low demand for cross-border healthcare compared to national demand. While the EU contributed to the development of common standards for ePrescriptions, Patients Summary and eID, the pick-up rate in the Member States remains low for the time being, although it should improve in the years to come. Furthermore, while the political support of most Member States for greater interoperability have been fairly low since the establishment of the Network, the outbreak of the COVID 19 pandemic not only brought the greater effectiveness of the network when there is political convergence, but it also highlighted **EU added value of having an integrated system that can enable effectively the use of medical information for public health and research**.

5 CONCLUSIONS

The present evaluation was carried out more than 10 years after the adoption and entry into force of the Cross Border Healthcare Directive and its provisions related to eHealth. The Directive provides that that Member States work within a voluntary network connecting national authorities responsible for eHealth designated by the Member States. In this regard, the eHealth Network has been operational for more than a decade. The analysis carried out above, and in particular the voluntary nature of actions, indicates that the effectiveness and efficiency of the eHealth Network actions has been rather limited and its routine activities were restricted to enhancing the use of health data for primary purpose in the context of cross-border healthcare (primary use of health date). As shown in the analysis carried out, the advancements in eHealth in recent years call for a more coordinated action at EU level. The MyHealth@EU platform has been so far implemented only in 8 Member States and the platform currently supports two services (ePrescriptions and Patient Summaries). The low and slow uptake is partly related to the fact that the Directive, whilst establishing the right of patients to receive a written record of the treatment carried out, does not require this medical record to be provided in electronic form (see Article 4(2)(f) and Article 5(d)). Currently, most Member States are expected to implement the MyHealth@EU platform by 2025. Only when more Member States will implement the MyHealth@EU platform and the developed tools, their use, development and maintenance will become more efficient across the EU.

Nevertheless, following the outbreak of the COVID-19 pandemic in Europe, the eHealth Network provided effective and efficient support in developing and implementing two important initiatives and digital infrastructures within an extremely short period of time: the contact tracing apps for the EU's fight against COVID-19 as well as supporting the development of interoperable EU Digital COVID-19 Certificate. These activities provided important contributions to achieving objectives related to protection of public health, interoperability of applications and free movement of persons. Therefore while eHealth network actions related to the routine operations regarding health data for primary use in the context of cross-border healthcare presented some limitations in terms of

efficiency, the eHealth network proved to be very effective and efficient in times of public health crisis and political convergence following the COVID-19 pandemic outbreak.

With regard to the use of health data for purposes of research, innovation, policy making and regulatory decisions of health authorities (secondary use of health data), it can be concluded that the eHealth Network activities were limited and not very effective. Some non-binding documents on big data were produced by the eHealth Network, but they were not followed up by further specific actions and implementation of these guidelines in practice remains very limited. This lack of effectiveness was also related to the fact that few members of eHealth Network had at national level tasks related to secondary use of health data, while some Member States set up different bodies to deal with this file. Most of these new bodies participate in the Joint Action TEHDaS. However, neither the Joint Action TEHDaS, nor the numerous funds provided by the Commission to support the secondary use of health data have insufficiently been realized in coherence with eHN activities.

Based on the abovementioned analysis the following measures may be considered further in order to address the identified issues and gaps.

To ensure the development of the European Health Data Space for both primary and secondary use of health data, the current structure of the eHealth Network does not appear to be appropriate anymore as it is not able to address in particular the needs related to the secondary use of health data in an effective and efficient manner. Its revision or adaptation could be therefore considered. Options to address the limitations related to the voluntary nature of the eHealth Network should be further considered and taken forward in the future initiative on the European Health Data Space, especially in order to support the creation of a digital single market in the health sector.

In order to achieve higher acceptance of the outputs and more efficient coordination with the stakeholders involved, the eHealth Network activities should be better coordinated with the different stakeholders and existing activities including:

- Projects directly affecting the eHealth Network's objectives and supported, for example, through the Digital Europe Programme, Horizon Europe or EU4Health programmes;
- Health Data Access Bodies and national health institutes (and in particular with the TEHDAS Joint Action);
- Industry and other non-governmental organisation representatives.

Further actions are also needed to facilitate the access of health data to patients, ensuring the control of citizens over their own personal health data and the use of data for medical diagnosis and treatment (primary use), but also for research, innovation and policy making (secondary use). A potential solution could be making the data on the MyHealth@EU platform accessible and available to patients and at the same time extending the number of services available on the platform to all healthcare providers in the Member States.

In order to ensure secure and efficient access to and use of patient's data on the MyHealth@EU, the efficient implementation and uptake of the developed eID format on the MyHealth@EU platform and its binding adoption and application by Member States should be ensured. Binding measures in this area could be considered.

The objectives mentioned in Article 14 of the Directive on secondary use of health data require stronger intervention from the European Commission. The development of a European

infrastructure should be considered, along with the strengthening of the legal base for the use of health data for secondary use and stronger coordination of activities relating to the various investments in this area under e.g. Horizon Europe.

Furthermore, in order to better achieve the availability and accessibility of electronic health records, the repeal of the provisions in the Directive related to digital Health, especially its Article 14 is considered in order to strengthen digital access to patient's data. This could incentivise the application of rules to provide digital access to a copy of the medical records for patients affiliated to their healthcare system seeking cross-border healthcare in another Member State, as well as a copy of the medical record(s) of received treatment(s) for patients affiliated to a different healthcare system that used cross-border healthcare in another Member States. This could also potentially contribute to enhanced interoperability of applications available in the Member States and therefore to the strengthening of the Digital Single Market.

The COVID-19 pandemic has highlighted and emphasised the importance of access to and availability of public health and healthcare data beyond the Member States borders. However, progress on these issues seems to be hindered by the absence of binding or compulsory standards across the EU and consequently limited interoperability. Addressing this issue would not just benefit the patients, but also contribute to the achievement of the Digital Single Market and lowering the barriers to the free movement of digital healthcare products and services.

In order for the Member States to achieve the identified policy objectives they need to make efforts to build sufficient capacity and infrastructure nationally to implement the measures agreed and adopted at the EU level. The support for the Member States in this area is currently available, for example, from the Recovery and Resilience Facility (RRF). The support for the capacity building provided by the RRF should target in particular the Member States with lower levels of readiness in adopting the different tools already developed (such as the MyHealth@EU). Member States would need to remove legal barriers for the exchange of health data across borders.

Finally, another issue identified during the evaluation concerns the difficulties to quantify or even estimate the inputs provided by the Member States for the activities of the eHealth Network. To ensure better future evaluation of the activities carried out in the area, Member States and the eHealth Network members should consider keeping record of financial and non-financial inputs (including quantification of human resources involved) provided for the eHealth Network activities.

The findings of the evaluation confirm that the abovementioned issues should be further considered and addressed as part of the initiative on development of the European Health Data Space.

Appendix I: Evaluation matrix

Criteria	Research questions (RQ)	Indicators	Source
Application of Art. 14 and accompanying acts (A16)	• How effective was the setting up of the eHealth Digital Service Infrastructure in stimulating interoperability and cross-border exchange of health data?	• Number of Countries with Operational NCPeH • Number of transactions between Countries	• eHDSI Monitoring Framework (KPIs)
	• To what extent was the intervention of the eHealth Network effective in stimulating the use of health data for research and policy making?	• Number of publications using health data generated as a result of eHealth Network activities • Number of policies and initiatives using health data generated as a result of eHealth Network activities	• Desk research
	• To what extent was the intervention of the eHealth Network effective in stimulating the primary and secondary use of health data?	Primary use of data: • Number of ePrescriptions exchanged • Number of Patient Summaries exchanged • Number of Operational eP-A services • Number of Operational eP-B services • Number of Operational PS-A services • Number of Operational PS-B services Secondary use of data: NA	• eHDSI Monitoring Framework (KPIs)

Criteria	Research questions (RQ)	Indicators	Source
	• To what extent was the eHealth Network effective in supporting the use of health data for medical diagnosis and treatment, public health (including planning, provision of healthcare, management of health or social care systems and services, regulatory purposes, certification of medical devices, protecting against cross-border health threats) and for scientific or historical research and innovation?	• Number of publications using health data generated as a result of eHealth Network activities	• Desk research
	• What were the factors that influenced the observed achievements and to what extent?	• Factors affecting the up-take rate of the developed tools and guidelines	• Focus Group • Interviews
	• Which factors hindered the attainment of the objectives and to what extent? How do these factors link to the actions carried out under Article 14? To what extent were there external factors that influenced the results?	• Factors affecting the up-take rate of the developed tools and guidelines	• Focus Group • Interviews
Effectiveness (A17)	• To what extent were the objectives reached, as they were set out in Article 14 (2) of the Directive?	• Number of information exchanged • Number of guidelines produced on patient's summary and medical information for public health and research	eHealth Network deliverables
	• What were the qualitative and quantitative effects of the eHealth Network on the cooperation and exchange of information between MS? How were these effects achieved?	• Adoption of guidelines on ePrescription, patient's summary and eID • Number of Countries with Operational NCPeH • Number of transactions between Countries • Number of services offered on the	eHDSI Monitoring Framework (KPIs)

Criteria	Research questions (RQ)	Indicators	Source
		MyHealth@EU platform	
	• To what extent can they be attributed to the eHealth Network, e-Prescriptions and Patient Summaries, European Electronic Health Record exchange format, etc.?	• Number of ePrescriptions exchanged • Number of Patient Summaries exchanged	eHDSI Monitoring Framework (KPIs)
	• How effective was the setting up of the eHealth Digital Service Infrastructure in stimulating interoperability and cross-border exchange of health data?	• Number of Operational eP-A services • Number of Operational eP-B services • Number of Operational PS-A services • Number of Operational PS-B services	eHDSI Monitoring Framework (KPIs)
	• To what extent was the eHealth Network instrumental to deliver sustainable economic and social benefits of e-health systems? To what extent was the eHealth Network instrumental to achieve a high quality of trust and security, enhance continuity of care and ensure access to safe and high quality healthcare?	• Number of e-health agencies in Member States • Member States with legislation in the area of electronic health records • Member States implementing electronic health records • Member States implementing Electronic Health Records Exchange Format to ensure the interoperability of health data	Desk research
	• To what extent was the intervention of the eHealth Network effective in stimulating the use of health data for research and policy marking?	• Number of publications using health data generated as a result of eHealth Network activities • Number of policies and initiatives using health data generated as a	• Desk research

Criteria	Research questions (RQ)	Indicators	Source
		result of eHealth Network activities	
	• To what extent was the intervention of the eHealth Network effective in stimulating the primary and secondary use of health data?	Primary use of data: • Number of Countries with Operational NCPeH • Number of transactions between Countries Secondary use of data: NA	eHDSI Monitoring Framework (KPIs)
	• To what extent was the eHealth Network effective in supporting the use of health data for medical diagnosis and treatment, public health (including planning, provision of healthcare, management of health or social care systems and services, regulatory purposes, certification of medical devices, protecting against cross-border health threats) and for scientific or historical research and innovation?	• Number of publications using health data generated as a result of eHealth Network activities	• Desk research
	• What were the factors that influenced the observed achievements and to what extent?	• Factors affecting the up-take rate of the developed tools and guidelines	• Focus Group • Interviews
	• Which factors hindered the attainment of the objectives and to what extent? How do these factors link to the actions carried out under Article 14? To what extent were there external factors that influenced the results?	• Factors affecting the up-take rate of the developed tools and guidelines	• Focus Group • Interviews
Efficiency (A18)	• To what extent have the actions carried out under Article 14 been realised in a cost-effective way?	• Costs of Joint Actions • CEF funds • Costs of DG RTD projects directly related to eHealth Network activities • MD of eHealth Network members	• eHealth Network Joint Action budget • CEF budget • Relevant DG RTD projects' budget

Criteria	Research questions (RQ)	Indicators	Source
		• MS cost of implementation of developed tools • DG REFORM capacity building budget • Estimated benefits for the EU, Member States, Patients, HCP, Researchers, Industry. • Funding for digitalisation under EU and national funds	• Accounting of MD spent (currently not monitored) • Accounting of funds invested by MS in implementing the tools developed (currently not monitored) • Estimation of benefits: https://ehealth-impact.eu/
	• Looking closely at both the costs and benefits of Article 14 as they accrue to different eHealth stakeholders, how efficient has the implementation of Article 14 been for each type of stakeholder (citizens, patients, healthcare professionals, policy makers, researchers, companies (pharmaceutical sector, AI) etc.)?	• Analysis of costs and benefits	• Funding for digitalisation under EU and national funds • Survey
	• To what extent are the costs justified and proportionate given the effects observed/objectives achieved/ benefits obtained in general? How proportionately were the costs of the intervention borne by different stakeholder groups taking into account the distribution of the associated benefits?	• Costs of Joint Actions • CEF funds • Costs of DG RTD projects directly related to eHealth Network activities • MD of eHealth Network members • MS cost of implementation of developed tools • Funding for digitalisation under EU	• eHealth Network Joint Action budget • CEF budget • Relevant DG RTD projects' budget • Accounting of MD spent (currently not monitored)

Criteria	Research questions (RQ)	Indicators	Source
		and national fundsDG REFORM capacity building budget • Estimated benefits for the EU, Member States, Patiens, HCP, Researchers, Industry.	• Accounting of funds invested by MS in implementing the tools developed (currently not monitored) • DG REFORM funds invested on capacity building • Estimation of benefits: https://ehealth-impact.eu/
	• If there are significant differences in costs (or benefits) between MS, what is causing them? How do these differences link to the intervention?	• MD of eHealth Network members • MS cost of implementation of developed tools • DG REFORM capacity building budget • Estimated benefits for the EU, Member States, Patiens, HCP, Researchers, Industry.	• Accounting of MD spent (currently not monitored) • Accounting of funds invested by MS in implementing the tools developed (currently not monitored) • DG REFORM funds invested on capacity building • Estimation of benefits: https://ehealth-

Criteria	Research questions (RQ)	Indicators	Source
			impact.eu/
	• What factors influenced the efficient functioning of the intervention and to what extent? What factors hindered it and to what extent? What is the connection between these factors and the actions laid out in Article 14?	• Regulations linked to eHealth Network activities	• EUR-Lex • MWP
	• Which factors influenced the cost side and which ones influenced the benefit side? To what extent? To what extent were these factors linked to the intervention described in Article 14? To what extent were there external factors that influenced the results?	• Internal and external factors affecting the efficiency of the developed tools and guidelines	• Focus Group • Interviews
Relevance (A19)	• To what extent are the objectives and provisions of Article 14 still relevant, considering current needs and how they have evolved since the adoption of the Directive?	• Revision of intervention logic needs and objectives	• The intervention logic developed in this report should be used as a baseline
	• How relevant is Article 14 to EU citizens? How did the Article contribute to supporting citizens to access their own health data and ensure portability of these data?	• Mapping of rules to provide digital access to a copy of the medical record/s for patients affiliated to a healthcare system seeking cross-border healthcare in another Member State • Mapping of rules to provide digital access to a copy of the medical record/s of received treatment/s for patients affiliated to a different healthcare system that used cross-border healthcare in another Member State	• Tables developed for this report should be used as a baseline (based on countries self-declaration in survey)

Criteria	Research questions (RQ)	Indicators	Source
	• To what extent the provision of Article 14 are relevant for the secondary use of health data (for policy making, regulatory purposes, research and innovation)?	• Analysis of the needs relevant for the secondary use of health data and the objectives of Article 14	• Desk research • Interviews • Focus Groups
	• To what extent have the original objectives proven to be appropriate to facilitate the cooperation and exchange of information between MS?	• Level of achieved objectives and observed impacts	• The results of this study should be used as a baseline
	• How well adapted is Article 14 to subsequent technological or scientific advances (e.g. the use of Big Data and Artificial Intelligence in the field of healthcare)?	• Analysis of the needs evolution inked to technological change and the objectives of Article 14	• Desk research • Interviews • Focus Groups
	• To what extent does Article 14 facilitate both the processing of health data for treatment (e.g. through the eHealth Digital Service Infrastructure and the National Contact Points for eHealth), and further compatible processing of health data for research and policy-making?	• Analysis of MWPs and subsequent activities carried out	• Desk research • Interviews • Focus Groups
Coherence (A20)	• To what extent are the provisions of Article 14 coherent with wider EU policy and with the European Health Data Space (especially the use of data for medical diagnosis, public health (including planning, provision of healthcare, management of health or social care systems and services, regulatory purposes, approval of medical devices, protecting against cross-border health threats) and for scientific or historical research and innovation)?	• Documentation and overview of other EU policies have been collected • Objectives • Activities and outputs carried out	• Additional stakeholder/expert inputs on coherence with other EU policies should be collected
	• To what extent is the cooperation described in art 14 coherent with other activities supporting the access to health data, interoperability, tele-health, m-health,	• Amount of activities aimed to implement Electronic Health Record Exchange Format	• eHealth Network deliverables

Criteria	Research questions (RQ)	Indicators	Source
	Electronic Health Record Exchange Format?	• Amount of activities aimed to implement m-health, tele—health	
	• To what extent is the cooperation described in art. 14 coherent with other Networks/cooperation possibilities which have similar objectives (especially for the use of data for policy making, research and innovation – e.g. Findata, French Data Hub, etc.)?	• Amount of activities on cooperation with other networks	• eHealth Network cooperation with other networks
	• To what extent is Article 14 coherent with international obligations?	• Amount of activities on international cooperation	• eHealth Network deliverables on international cooperation
	• To what extent is the eHealth Network coherent internally (e.g. there is coherence between its actions/activities/tasks)?	• Analysis of MWP	• MWP
	• To what extent is the eHealth Network able to implement the European Health Data Space in its entirety, as requested by the mission letter of Commissioner Kyriakides?	• Analysis of Output with respects to the European Health Data Space objectives	• This report can be used as a benchmark
	• To what extent can Article 14 and the eHealth Network ensure that citizens have control over their own personal health data?	• Discussion on policy evolution (GDPR) and on Article 4.2 (f) and Article 5 (d) of the directive.	• Focus Groups
EU added value (A21)	• What is the added value produced by the provisions of Article 14, compared to what could reasonably have been expected from the MS acting in the absence of the network at national or regional level?	• If common identification and authentication measures and platform running cross-border services would have been developed without eHealth Network. • If yes, it would have been more or less effective.	• Study Survey

Criteria	Research questions (RQ)	Indicators	Source
	• What would be the most likely consequences of stopping the eHealth Network/ repealing Art. 14?	• If common identification and authentication measures and platform running cross-border services would have been developed without eHealth Network. • If yes, it would have been more or less effective.	• Study Survey
	• How should the eHealth Network and Article 14 be modified to increase their impact, especially in the light of new technological developments and the use of data, including for digitalisation, access of citizens and control over their data, interoperability, provision of digital health services (e.g. m-health, tele-health), but also scientific research, policy making, reporting, protecting against cross-border health threats etc.?	• Discussion on new technological trends, digitalisation, control of citizens over their data, interoperability, provision of digital health services (e.g. m-health, tele-health), cybersecurity and use of data for research, policy making and regulatory purposes (secondary use of data)	• Focus Groups
	• How should the tasks of the eHealth Network and Article 14 be modified to increase their impact, especially in relation to setting up the European Health Data Space, supporting digitalisation, ensuring the control of citizens over their own personal health data, interoperability, provision of digital health services (e.g. m-health, tele-health), and the use of data for medical diagnosis, public health (including planning, provision of healthcare, management of health or social care systems and services, regulatory purposes, approval of medical devices, protecting against cross-border health threats) and for scientific or historical research and innovation)?	• Discussion on policy evolution and on Article 4.2 (f) and Article 5 (d) of the directive.	• Focus Groups

Appendix II: Multiannual Work Plan activities and outputs of the eHealth Network

Multiannual Work Plan (MWP) 2012-2014 (eHGI JA)

Objectives	Activities	Outputs
Adopt common measures on eIdentification and authentication for eHealth under the Cross Border Healthcare Directive, art.14	Policy paper "Conclusions on eID EU Governance for eHealth Services" - May 2012	Common identification and authentication measures based on national solutions to support electronic transferring of data in cross-border healthcare settings.
	eID & Authentication practices for eHealth in the EU Member States based on a questionnaire - November 2012	
	Position paper on the Commission proposal for an eID Regulation - May 2013	
	Road map giving a strategic approach to common measures on eID for eHealth under Directive 2012/24/EU and analysis of its implications (Risks, legal challenges, cost, benefits) - November 2013	
	Development of Common identification and authentication measures based on national solutions to support electronic transferring of data in cross-border healthcare settings.	
Addressing semantic and technical barriers to interoperability	Discussion paper on semantic and technical interoperability - November 2012	Guidelines on semantic and technical interoperability
	Semantic and technical interoperability roadmap (stepwise approach and intermediary milestones) - May 2013	
	development of Guidelines on semantic and technical interoperability	

Addressing legal barriers to interoperability, including data protection issues	Network's report on the Commission proposal for a Regulation on data protection November 2012	Guidelines on legal interoperability
	Legal Interoperability Roadmap for cross border exchange of electronic Health Records and ePrescriptions -2014	
Guidelines on patients' summary set of data for cross border electronic exchange, under the Cross border Directive	Non-exhaustive data set for patients' summary that can be exchanged across borders - November 2013	Guidelines on non-exhaustive list of data to be included in patient's summary
	Guidelines on technical and semantic interoperability of the selected data set, including the coding, classification and terminologies set and their semantic transformation process in a multilingual environment - 2014	Guidelines for cross-border electronic exchange of patients' summary data set
Guidelines on interoperability of ePrescriptions (art 11 of the Cross border Directive)	Discussion of the Network on interoperability of European and national databases for medicinal products - November 2012	Guidelines on interoperability of ePrecriptions
	Roadmap on interoperability of electronic prescriptions - 2013	
	Discussion paper on guidelines for electronic prescriptions - May 2014	
Sustainability	Development of recommendations on the governance of the Connecting Europe Facility (CEF) – May 2013	Recommendations on the governance of the Connecting Europe Facility (CEF)

Objectives	Activities	Outputs
Interoperability and standardisation;	Trusted eHealth National Contact Points. Propose an organisational framework to prepare, establish and govern eHealth National Contact Points in the scope of cross border care services deployed under the Connecting Europe facilities work plan.	Organisational Framework for National Contact Points for eHealth and several specific policy papers serving as the main basis for the preparation, deployment and operation of the National Contact Point for eHealth
	Electronic Identification for eHealth. Activities include the elaboration of an eID specific framework for eHealth representing an agreement primarily under the scope of the eID Regulation. This shall also include a set of common identification, authentication and access measures based on national solutions to allow trusted electronic transfer of patient data in cross-border care. Further activities refer to the elaboration of guidelines on the interoperability of electronic professional registries and reports on notification of national eID under the scope of the eID Regulation.	• (Legal) Agreement between National Authorities or National Organisations responsible for National Contact Points for eHealth on the Criteria required for the participation in CrossBorder eHealth Information Services • Organisational Framework for National Contact Points for eHealth and several specific policy papers serving as the main basis for the preparation, deployment and operation of the National Contact Point for
	Update & revision of EU eHealth Guidelines: Update and revise guidelines for Patient Summary, ePrescription and Patient Registries, which have been developed following former projects and been adopted by the eHN (except the Patient Registries guideline). The updating and revising process is necessary to ensure that requirements from the Member States and other stakeholders (incl. the input gathered by WP6) are taken into account for the development of further revisions. The aim is to maintain and provide a set of guidelines to foster semantic interoperability for cross-border exchange and to inform about the Member States' plans for national implementations.	

Objectives	Activities	Outputs
	Alignment of standardisation	eHealth • Refined eHealth European Interoperability Framework (ReEIF)
Exchange of Knowledge;	Analysis of the implementation of eHealth guidelines: The implementation analysis reflect various conditions in the Member States concerning the eHealth infrastructure in terms of legal, organisational and technical prerequisites for full guidelines adoption.	• (Legal) Agreement between National Authorities or National Organisations responsible for National Contact Points for eHealth on the Criteria required for the participation in Cross Border eHealth Information Services • Refined eHealth European Interoperability Framework (ReEIF)
	Development of legal interoperability in a cross-border context: This task concentrates on the creation of a sustainable legal basis for cross-border exchange of personal health data.	
Assessment of implementation;	Sharing of National eHealth Strategies and Action plans	9 Documents on assessment of Member States policies and guidelines implementation
	Secondary use of Health Data: This task focused on: • The pros and cons of the use of cloud computing in health, • Publication of a code of conduct on how to handle secondary use of health data. • Recommendation on de-identification of data for secondary use.	
	• Research on added value of eHealth Tools: This task explored and reported on the most up-to-date studies on the added value of eHealth services to health services	
Global	Participation, Liaison and Influence in global eHealth: This task is divided into the	6 Documents on main eHealth

Objectives	Activities	Outputs
cooperation and positioning.	following sub-tasks: • Overview of OECD studies on eHealth and core outcome • Prepare for preparatory convergence meetings to coordinate input before WHO and OECD meetings on eHealth • Information paper on main eHealth activities outside of the EU	activities outside of the EU and global eHealth specifications
	Evaluation of global eHealth specifications	

Objectives	Activities	Outputs
Empowering people: enabling citizens to take an active role in the management of their health;	mHealth and health apps reliability. • Perform desk research including input from a consultation round with external stakeholders and input from JAseHN, and other projects. In addition, investigate ways to motivate or create incentives for patients to participate in their healthcare process by adopting and using mHealth services. • Analyse the findings and define a common understanding on the subject. • Develop a state of play/positioning report (common framework for the assessment/endorsement of health apps) with regard to mHealth and health apps reliability in relation to Patient Empowerment. • Participation to workshops to implement the MWP and coordinate dissemination activities.	Develop a common framework and principles for facilitating safe and reliable use mHealth apps.
	Patient access and use of data. • Perform desk research; input from the consultation round with external stakeholders, JAseHN and other projects. In addition, investigate ways to motivate or create incentives for patients to participate in their healthcare process by accessing and using their health data. • Analyse the findings and define common understanding on the subject • Develop a state of play/positioning report with regard to patient access and use of data in relation to Patient Empowerment. • Participation to workshops to implement the MWP and coordinate dissemination activities.	Synergetic and coherent approach to patient access, sharing, and reuse of health data in the EU.
	Digital health literacy of patients. • Starting with desk research including input from the consultation round with external stakeholders and input from JAseHN and other projects. In addition, investigate ways to motivate or create incentives for patients to participate in their healthcare process by increasing their digital health	Increase digital health literacy for EU-citizens by sharing best practices and tools

Objectives	Activities	Outputs
	literacy. • Analyse the findings and define common understanding on the subject • Consult existing coalitions, such as https://ec.europa.eu/digital-single-market/en/national-local-coalitions • Develop a state of play/positioning report with regard to digital health literacy in relation to patient empowerment. • Participation to workshops to implement the MWP and coordinate dissemination activities.	
	TeleHealth. • Perform desk research including input from the consultation round with external stakeholders.	Facilitate the adoption of telehealth taking available evidence into consideration.
Innovative use of health data: exploring the use of health data to develop knowledge for healthcare policy and other purposes;	Mapping, awareness raising and policy relevant actions on innovative use of big data in health. • Compile policy relevant documentation including the EU Study and the effects of GDPR and review Member States/C policy level efforts on governing big data in health. • Also assess the implications of FAIR data principle. • Identify obstacles preventing Member States/C policies from being replicable either in another Member States/C or on EU level and investigate how to overcome these. • Provide an initial set of enabling actions for the information of the eHN by translating recommendations of the EU Study into operationalized solutions that can be communicated for increased awareness.	Increase awareness on the possible impacts, challenges, risks and directions of Big Data in healthcare.
	Sharing and learning best practices on European level. • Define and use methods to identify underlying needs and barriers experienced by stakeholders (pros	Common vision and priorities for innovative use of

Objectives	Activities	Outputs
	& cons) affecting efficient and effective sharing of best practices in order to reach the objectives of the WP and the JA. • Investigate already formalized cross-border use cases such as European Reference Networks for rare diseases as well as practical solutions in R&D including analytics in order to identify new possibilities for innovative use of big data on the European scale, to assess feasibility of network optimization to cross-border IT infrastructure and data flow management and to enhance interdisciplinary and openness, the most potential usage and stakeholders that could benefit.	data in healthcare.

	Towards an attempt to define common principles for practical governance.
	
	• Make available guidance on practical governance for eHN and Member States.
	• Provide a framework for the implementation of common principles for practical governance of big data including privacy protection and security aiming at improving health data transferability across borders with a special focus on data to be used in public health, research and quality assurance in healthcare on a European scale.
	• The guidance will include guidance on implementation of data access and focus on helping Member States to utilize the potential of harnessing new opportunities arising from big data and improved data analytics capabilities, as well as from personalized medicine, use of clinical decision support systems by health professionals and use of mobile health tools for individuals to manage their own health and chronic conditions, in order to:
	  ○ facilitate preparation of actions to improve the comparability, accuracy and reliability of health data and to encourage the use of health data to enable more transparent and patient-centred health systems focusing on health outcomes and evidence-based health policy and decision-making, as well as to promote data-driven innovation;
	  ○ to enable the use of health data for research and innovation, in full compliance with data protection requirements and FAIR data principle;
	  ○ apply network optimization to cross-border IT infrastructure and data flow management;
		Common principles to facilitate the development of innovative use of data projects at European Level.

Objectives	Activities	Outputs
	○ foster patient-centred interoperability; ○ improve service effectiveness for the individual patient in which benefits are experienced locally; ○ enhance interdisciplinary and openness that removes barriers between data sources and infrastructure to provide 'fit for purpose' data platforms.	
Enhancing continuity of care: improving the uptake of cross-border eHealth services;	Support of MyHealth@EU uptake. Support countries through eHMSEG for long term policy development in MyHealth@EU by facilitating the uptake of current use cases PS and eP/eD and especially the new European Reference Networks use case and by shaping an overall roadmap for MyHealth@EU use cases and additional features for a sustainable and continued usage of the NCPeH.	Full exploitation of the CBeHIS services.
	Support of legal MyHealth@EU matters. Support countries through eHMSEG by facilitating the national implementation of the MyHealth@EU legal environment (including but not limited to the eIDAS regulation, GDP regulation, NIS directive and the Agreement between National Authorities or National Organisations responsible for National Contact Points for eHealth on the Criteria required for the participation in Cross-Border eHealth Information Services) by providing a forum for sharing expertise, problems and solutions and by synthesising shared elements into an MyHealth@EU legal report for an non-lawyer audience.	Identifying and developing new use cases and the sustainability of MyHealth@EU.
	eSkills for Professionals. Support countries through eHMSEG by developing a process to ensure that the eSkills necessary to gain full advantage from the implementation of European eHealth Strategies and cross-border healthcare services, identifying current challenges and appropriate actions that can be taken to build the necessary eSkills framework for healthcare professionals.	Equip healthcare professionals with eSkills for eHealth services.
	Implementation of the Electronic Health Record Exchange Format	Investment guidelines on the implementation of the Electronic

Objectives	Activities	Outputs
		Health Record Exchange Format National Networks for the implementation of EEHRxF
Overcoming implementation challenges: addressing transversal enabler issues crossing the abovementioned categories.	Recommendations on how to implement interoperability guidelines in large health-care organisations. Interoperability has long been identified as the fundamental facilitator of communication, exchange and use of patient information between healthcare providers, hospitals, government, insurers etc., especially in the context of cross-border health services. During the past decades various standards have been developed regarding messaging (HL7, DICOM, ASC-X12, IEEE 1073 etc.), terminology (ICD-10, ICD-11 which is due by 2018, LOINC, SNOMED CT etc.), documents, conceptual frameworks, application and architectures, both for syntactic interoperability, and for semantic interoperability. Nevertheless, and despite the efforts, interoperability is still considered as an "open field" in the healthcare ecosystem, especially when striving to provide cross-border health services. The aim of this task is to exploit any previous work in the field of interoperability as described in the Digital Agenda, the eHealth Action Plan, the "Refined European eHealth Interoperability Framework" (reEIF), the epSOS project, SemanticHealthNet, JAseHN and more, in order to facilitate patients' rights in cross-border healthcare. All previous work will be combined to produce recommendations for IT Management on how to implement interoperability guidelines in large healthcare organisations (e.g. hospitals). The main purpose is to align all work done about various EU regulations/common frameworks and provide it to IT Management of hospitals for implementation. The deliverables of this task will provide recommendations, guidelines to facilitate implementation of the interoperability framework by hospital IT management staff taking into consideration the recommendations included in the new European Interoperability Framework (EIF). Hospital experts will contribute to this task with F2F	Interoperable digital infrastructure (software and hardware) of healthcare providers using a common format for cross-border exchange of health data.

Objectives	Activities	Outputs

	Workshops.
	The task will be implemented in the following steps:
	
	• Review of previous work, interoperability frameworks and standards that can be implemented from the IT departments in healthcare organisations
	• IT challenges in implementing interoperability in/ between large healthcare organisations
	• Recommendations, guidelines and priorities for IT Management on implementing interoperability actions in healthcare organisations.
	• Interoperability guidelines for hospital IT management staff in the following cases:
	  o Software supply
	  o Software building
	  o Software deployment	

	Data protection. This task will focus on the GDPR implementation and its implications in cross border healthcare. The aim of this task will be to share best practices and approaches on data protection at national level. Situation regarding data protection and the new requirements GDPR brings in eHealth. It is proposed to implement the topic in 5 steps: 1. Review of the GDPR topic in general and view of its impact on the healthcare stakeholders. 2. Characteristics of main points and requirements of GDPR adoption in the healthcare sector. 3. Proposal of the set of relevant recommendations/policies for successful completion of GDPR adoption in the healthcare sector. 4. Sketches of collaborative instruments for related information and education in current and future dealing with GDPR topic in the healthcare settings. 5. Foresight – vision and mission - of the future fulfilment and development of the GDPR. The task is motivated by both urgent needs for correct GDPR adoption in the healthcare sector and	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.

Objectives	Activities	Outputs
	the utilization of GDPR potential for comprehensive respecting human rights for the healthcare provision practice in long-term run. In topics No. 2, 3 and 5 the cooperation with public interest groups (patient and healthcare professionals' organisations) will be actively sought and utilized.	
	Data and systems security. The aim of this task is to create a common Framework for cyber security for eHealth systems	

Appendix III: CEF funding for eHealth

year	Indicative budget spent (EUR)	Call ID
2015	7.5 million	CEF-TC 2015-2
2017	9 million	CEF-TC-2017-2
2018	5 million	CEF-TC-2018-4
2019	5 million	CEF-TC-2019-2
2020	5 million	CEF-TC-2020-2
2015-2020	**31.5 million**	-

Source: Innovation and Networks Executive Agency (INEA)

Appendix IV: eHealth services availability across EU Member States

Doctors from the countries below:	Number of Hospitals (% over total)	can access health data of citizens coming from:
Croatia	80 (100%)	Czechia (Sept. 2019), Malta (Feb. 2020) and Portugal (Feb. 2020)
Luxembourg	4 (100%)	Czechia (Jun. 2019), Malta (Dec. 2019)
Malta	1 (50%)	Portugal (Feb. 2020)
Portugal[71],[72]	5 (2%)	Malta (Jan. 2020)
Czechia	37 (100%)	Croatia (Dec. 2020)
Health data of citizens from the countries below:	**can be consulted by doctors from the countries below, using the Patient Summary:**	
Czechia	Luxembourg (Jun. 2019), Croatia (Sept. 2019)	
Malta	Luxembourg (Dec. 2019), Portugal (Jan. 2020), Croatia (Feb. 2020)	
Portugal	Malta (21 Feb. 2020), Croatia (Feb. 2020) and Luxembourg (March 2020)	
Croatia	Malta (17 Dec. 2020), Portugal (17 Dec. 2020), Czech Republic (21 Dec. 2020)	
ePrescriptions of citizens from countries below:	**can be retrieved in pharmacies in:**	
Croatia	Finland (August 2020), Portugal (August 2020)	
Estonia	Finland (June 2020), Croatia (August 2020)	
Finland	Estonia (January 2019), Croatia (September 2019), Portugal (August 2020)	
Portugal[72, 73]	Estonia (June 2020), Finland (August 2020), Croatia (August 2020)	
Pharmacists of countries below:	**Number of Pharmacies (% of total)**	**can dispense ePrescriptions presented by citizens from:**
Croatia	1147 (100%)	Finland (September 2019), Estonia (August 2020), Portugal (August 2020)

[71] https://www.sns.gov.pt/sns-saude-mais/cuidados-de-saude-no-estrangeiro-2/
[72] https://www.spms.min-saude.pt/a-minha-saude-na-europa/

Estonia	500 (100%)	Finland (January 2019), Croatia (March 2020), Portugal (June 2020)
Finland	819 (100%)	Estonia (June 2020), Portugal (August 2020), Croatia (August 2020)
Portugal	1 (0.03%)	Finland (August 2020), Croatia (August 2020)

Source: https://ec.europa.eu/health/ehealth/electronic_crossborder_healthservices_en

Appendix V: Mobile contact tracing apps in EU Member States

Countries	App	Interoperable - is this app potentially interoperable?	Interoperable - can this app already talk to another app?
Austria	Stopp Corona App	Yes	Yes
Belgium	Coronalert	Yes	Yes
Bulgaria	Not foreseen	-	-
Croatia	Stop COVID-19	Yes	Yes
Cyprus	CovTracer-EN	Yes	Yes
Czechia	eRouška	Yes	Yes
Denmark	Smittestop	Yes	Yes
Estonia	HOIA	Yes	Yes
Finland	Koronavilkku	Yes	Yes
France	TousAntiCovid	No	-
Germany	Corona-Warn-App	Yes	Yes
Greece	Under development	Yes	-
Hungary	VirusRadar	No	-
Ireland	COVID Tracker	Yes	Yes
Italy	Immuni	Yes	Yes
Latvia	Apturi Covid	Yes	Yes
Lithuania	Korona Stop LT	Yes	Yes
Luxembourg	-	-	-
Malta	COVIDAlert	Yes	Yes
Netherlands	CoronaMelder	Yes	Yes
Norway	Smittestopp	Yes	Yes
Poland	ProteGO Safe	Yes	Yes
Portugal	StayAway COVID	Yes	No
Romania	-	-	-
Slovakia	-	-	-
Slovenia	#OstaniZdrav	Yes	Yes
Spain	Radar Covid	Yes	Yes
Sweden	-	-	-

Source: European Commission[73]

[73] https://ec.europa.eu/info/live-work-travel-eu/coronavirus-response/travel-during-coronavirus-pandemic/mobile-contact-tracing-apps-eu-member-states_en

Appendix VI: Member States and third countries effectively connected to the EU Digital COVID Certificate Gateway

(15 September 2021, Panama not visible on the map)

Source: European Commission[74]

[74] https://ec.europa.eu/info/live-work-travel-eu/coronavirus-response/safe-covid-19-vaccines-europeans/eu-digital-covid-certificate_en

Appendix VII: Member States with applicable or planned rules to provide digital access to a copy of the medical record/s for patients affiliated to the Member State's healthcare system seeking cross-border healthcare in another Member States

	Yes/Planned*/No		Yes/Planned*/No
Austria	No	**Italy**	No
Belgium	No	**Latvia**	No
Bulgaria	No	**Lithuania**	No
Croatia	Yes	**Luxembourg**	No
Cyprus	No	**Malta**	No
Czechia	Yes	**Netherlands**	Yes
Denmark	No	**Poland**	No
Estonia	No	**Portugal**	No
Finland	Planned	**Romania**	No
France	No	**Slovakia**	No
Germany	No	**Slovenia**	No
Greece	Yes	**Spain**	No
Hungary	No	**Sweden**	No
Ireland	No		

**Planned within the next three years*

Source: Country survey results

Appendix VIII: Member States with applicable or planned rules to provide digital access to a copy of the medical record/s of received treatment/s for patients affiliated to a different healthcare system that used cross-border healthcare in that Member State

	Yes/Planned*/No		Yes/Planned*/No
Austria	No	**Italy**	No
Belgium	No	**Latvia**	No
Bulgaria	No	**Lithuania**	No
Croatia	No	**Luxembourg**	No
Cyprus	No	**Malta**	No
Czechia	Planned	**Netherlands**	Yes
Denmark	No	**Poland**	Planned
Estonia	No	**Portugal**	No
Finland	Planned	**Romania**	No
France	No	**Slovakia**	No
Germany	Yes	**Slovenia**	No
Greece	Yes	**Spain**	No
Hungary	No	**Sweden**	No
Ireland	No		

**Planned within the next three years*

Source: Country survey results

Appendix IX: Number of meetings of the eHealth Network 2012-2021

Total number of eHealth Network meetings 2012- 2021		
YEAR	eHealth Network, eHealth sub-groups, eHDSI/eHMSEG, eHealth JA, eHealth Stakeholder Group, CBHC Committee	**COVID-19** - Contact tracing and EU DCC related
2012	2	0
2013	2	0
2014	9	0
2015	16	0
2016	20	0
2017	22	0
2018	13	0
2019	17	0
2020	7	116
2021	7	200
	115	**316**
Total number of meetings B3 - 2012-2021	**431**	

Appendix X: Overview costs and benefits

	European Commission		Member States		Citizens		Healthcare Professionals	
	Qualitative	Quantitative / monetary	Qualitative	Quantitative / monetary	Qualitative	Quantitative / monetary	Qualitative	Quantitative / monetary
Costs								
Direct costs	Low	€6 m in JAs since 2012 € 1.2 m - Health budget for meetings organisation MD:NA	Low	€4.4 m in JAs since 2012 MD: NA	-	-	-	-
Indirect costs	Medium	€ 31.5 m € 54,5 m	Medium	European Commission research projects: € 57 m Implementation of MyHealth @EU solution: NA Development of tracing apps: NA	-	-	-	-
Benefits								
Direct benefits	Better monitoring of cross border healthc	-	Better monitoring of cross border healthcare for policy	-	Patients have access to safe and high-		Caregiving is simplified.	

	ar for policy making at the EU level.		making at the Member States level. Better public policy making and management of public health and epidemiological measures (tracing app and digital pass)		quality cross-border eHealth products and services, improving health outcomes. Continuity of care			
Indirect benefits	Support freedom of movement across the Union	Number of temporary restrictions in the different Member States	-	-	Lifting of temporary restrictions of free movement.	Number of temporary restrictions in the different Member States	Less administrative burden.	-