**21st eHealth Network meeting Summary Report**

**1-2 June 2022**

Location : PariSante Campus, 2 - 10 Rue d'Oradour-sur-Glane, 75015 Paris, France

Participants : Representatives of DG SANTE, DG CNECT, DG RTD, Members of the eHealth Network from the Member States

Chairs:

Andrzej Rys, Director for DG SANTE.B, European Commission

Ron Roozendaal, Director for the Ministry of Health, Welfare and Sports, the Netherlands

## 1. European Health Data Space

The Commission presented the legal proposal on the European Health Data Space (EHDS), which was adopted on 3 May 2022 together with a Communication. It explained the policy context, including the European strategy for data where several common data spaces were announced. EHDS is the first one. In addition, there is a need to maintain the momentum after the work on the EU Digital Covid Certificate during COVID pandemics. Several challenges were identified during the preparatory work, including the difficulty for patients and health professionals to access health data in the context of healthcare as well as for researchers and policy makers in the context of their activities. Therefore, 3 main objectives were identified: a) empower individuals to have access and control over their health data; b) unleash the health data economy; and c) ensure a consistent framework for data reuse.

The Commission reminded that this initiative is not taken in isolation but in the context of other EU initiatives and legal acts, such as the European Health Union, GDPR, DGA/DA, EU cybersecurity framework, Artificial Intelligence Act and Medical Device Regulation. It also explained the preparatory work, including an open consultation and several supporting studies, as well as the 3 policy options identified in the impact assessment (from low to high intensity regulatory interventions). The medium intensity regulatory intervention was identified as the preferred option with the most important benefits with regards to the costs.

The Commission detailed the choice of the 2 legal bases (article 16 and 114 TFEU) and the scope of the EHDS proposal: a) strengthening individuals' rights to access their health data; b) providing rules for EHR systems; and c) defining rules for secondary use. This is supported by the mandatory participation in 2 infrastructures for primary use (MyHealth@EU) and secondary use (HealthData@EU). In addition, the new governance framework (the EHDS Board which will replace the current eHealth Network), the funding of the EHDS and the expected benefits for the different stakeholders were presented.

Next steps are the negotiations which takes place in the Council and the Parliament as co-legislators. While the proposal is currently available in EN, FR and DE, the other languages should be available shortly.

## 2. COVID-19 Coordinated actions

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### 2.1 European Digital COVID Certificate

The Commission presented the state of play of the European Digital COVID Certificate system. Currently the system is used by 67 countries and has essentially set a global standard. More third countries are in the pipeline of joining the system.

A number of modifications have been introduced to the system since the last eHealth Network meeting, partly as a response to the Omicron variant. Delegated and implementing acts were adopted in order to formalise these changes. The Commission continues to monitor the development of the pandemic in order to propose further changes if needed. One of the changes that was introduced due to security reasons is the revocation system. Countries are currently onboarding to this revocation system.

Discussions are ongoing with WHO and G20, which are working on the development of digital health trust frameworks. They are also developing a pilot for a universal verifier app. The Commission is following these developments.

At the same time, discussions are ongoing about other use cases in which the EU DCC technology and approach could be used. One of such possible use cases is ePrescription, which could be included in the EUDI Wallet. On this, there will be a presentation later during the day.

### 2.2 Contact tracing applications and the European Federation Gateway Service

The Commission presented the state of play of contact tracing applications across the EU and the European Federation Gateway Service (EFGS). The rollout of these apps and of the EFGS was achieved in a record time. This was an immense coordination effort between the Commission and Member States, which allowed to move from an early problem analysis to the deployment of a full EU-wide solution in 6-7 months. This was the basis for the cooperation afterwards in the context of the EU Digital COVID Certificate.

Early in the pandemic, the eHealth Network adopted an EU toolbox which set out the foundations of a common pan-European approach to contact tracing and warning apps. The work of the eHealth Network focused after that on interoperability and led to the design of an interoperability gateway, the EFGS, to ensure the exchange of contact tracing keys across borders. The EFGS was deployed by the end of September 2020. The EFGS has since October 2020 managed to connect 19 national contact tracing apps (out of 22). With the favourable evolution of the pandemic in spring 2022, several Member States have been offboarded from the EFGS, with 12 remaining connected as of early June 2022.

With the Omicron variant, the traffic of keys reached an all-time maximum in March 2022, with over 700 thousand keys uploaded to the EFGS on a single day. This shows the relevance of the EFGS. The traffic of keys has since decreased, but still remains higher than before the Omicron variant broke out.

The mandate of the ECDC will be strengthened under the European Health Union and broadened to include digital contact tracing and their interoperability. With this prospect, the operations of the EFGS

were transferred successfully to the ECDC in April 2022. We would like to thank the ECDC team for their good cooperation, and Member States for their support.

Proper performance monitoring and measuring public health effectiveness of digital contact tracing apps is difficult given the privacy-preserving technology that they rely on. The Commission launched a study on lessons learned, best practices and epidemiological impact of the common EU approach on digital contact tracing apps. The relevant work groups of the eHealth Network, and associated experts, are being consulted in the context of this study. It is expected to be finalised in autumn 2022.

## 3. MyHealth@EU

### 3.1. Update on MyHealth@EU (eHDSI Dashboard)

The Commission presented an update on MyHealth@EU development. There are 10 Member States that are live, and all other Member States + Norway and Iceland have applied to launch the development in order to connect to the infrastructure. Currently the system supports ePrescription and Patient Summary services. There is also an upcoming pilot project on Patient Access and further use cases developed by the X-eHealth project (laboratory results and reports, medical images and reports, hospital discharge reports, information on rare diseases), support for which should be added in the next waves.

The Commission has prepared a dashboard summarizing the state of play and upcoming development of the infrastructure. The dashboard is available to all Member States and is being constantly updated.

### 3.2. Development of new services (X-eHealth, Vaccination Card, ESSPASS and the successor to X-eHealth)

<u>X-eHealth</u>

SPMS introduces the X-eHealth project that develops the necessary elements to expand the MyHealth@EU infrastructure with services such as lab results, medical images, Hospital Discharge Reports and the PS for rare diseases. SPMS stressed the importance of involving stakeholders, including healthcare professionals, to develop services that will align with their needs.

X-eHealth will produce change proposals for MyHealth@EU. The project collaborates with eHDSI communities, work groups and policy owners. It also involves stakeholders like citizens, hospitals, Member States decision makers.

The laboratory results domain will require a very dynamic maintenance model for semantic artefacts. On hospital discharge reports, there are many cross-border scenarios, and discussion on these is ongoing.

The project is going to hold an Interoperability Award event on 27 October 2022. Applications have been received from FR, BE, AT, DE, DK, SI, CY, NL, and PT. There will be also technical events, such as a hackathon on 7-9 June 2022. The X-eHealth project is also looking into the EHDS proposal.

A question was asked, whether the project is working with ERNs. Answer: yes, and the project is also working on refining the PS guidelines.

Question: are there changes needed to the project because of the EHDS proposal? Answer: There are some aspects related to governance and sustainability, on which the project will need to focus more. Also secondary use needs to be considered.

*Vaccination card*

COM (HaDEA) presented the outcomes of the EU vaccination card feasibility study. The study was launched before the COVID pandemic. The feasibility study has delivered the proposal on options (feasibility analysis and recommended path to implementation). The report has been already approved and validated.

The card has two formats, physical and digital. The study has prepared possible layouts and tested them with citizens. Infrastructure needed for a vaccination card is similar to that established for EU DCC, but in addition there are connections to MyHealth@EU and possibly other infrastructures. There are many benefits that have been identified for the vaccination card, including better preparedness for future pandemics.

A possible path for implementation is through a pilot project involving a few pioneering Member States. In addition to technical infrastructure, a joint effort would be needed to develop a common unified nomenclature for vaccines. Such a feasibility pilot should involve diverse countries in order to test and accommodate for possible differences between Member States. It should develop reference implementations and run demonstrators.

ES commented that there are challenges in data repositories, as information is often not coded or there are other data quality challenges. ES believes that offline is a better approach than online. This is however a good initiative, and ES would be interested to participate. ES further asked, is there financial support, how countries can participate?

CZ commented that a use case description would be very useful.

COM answered that a unified nomenclature of vaccines is a good basis, but of course further work would be needed. Quality of information could be improved gradually, in a similar way how it was done for COVID vaccination. On pilot, COM would need to understand the interest of Member States. This information could be then fed into the possibility of exploring funding opportunities. On the use cases, Patient Summary is one of them, and the vaccination card approach is compatible with it. On the legal part, some language in EHDS proposal on vaccination card is existing already. Funding opportunities are being explored.

NL asked to clarify: what are use cases. COM clarified that there are in fact multiple use cases, including sharing of vaccination data through MyHealth@EU, use of vaccination data in schools, but also for travel. WHO is looking at the digitalization of a vaccination card. Chair added that a broad picture should be considered.

*EU social security pass (ESSPASS), pilot project*

COM (EMPL) presented the ongoing work, which is part of the European Pillar of Social Rights. The goal of ESSPASS is to provide a digital solution for the verification of social security documents such as portable documents and EHIC. There are 9 portable documents + EHIC in the scope. The pilot is starting with Portable Document A1 (for posted workers). INPS (IT) and DG EMPL are co-leading the project for

PD A1. 13 countries are involved in the project. IT, DE and FR are involved in technical activities. The pilot is to be concluded by the end of 2022, and decisions to extend the pilot would be taken in 2023.

In the pilot, a person is issued with a digital PD A1 document, and a labour inspector from another MS is checking and verifying the document. The EESSI infrastructure is used as part of the process. By 2023, 21 key administrative procedures should be fully online, according to the SDG regulation and social security coordination.

The proposal for a European Digital Identity Framework is currently being negotiated. As part of it, an EU Digital Identity wallet is being developed. Verifiable credentials such as PD A1 could be stored in such a wallet.

The infrastructure for ESSPASS utilizes Blockchain to ensure the verification of credentials and check them for possible revocation. The legal framework is social security coordination rules (Regulations 883/2004 and 987/2009). Ad-hoc group of the Administrative Commission on the coordination of social security systems on the digitalization of the EHIC has been established.

ES commented that there is difference between patient identification and citizen identification, which are often not directly linked in MS. Digital divide should be prevented, therefore the digital system should be optional. ES further asked how in the blockchain-based infrastructure the right to be forgotten is to be handled?

IE commented that the digitalization of EHIC could be done in an extremely simple way using the EU DCC infrastructure and asked whether this is being considered.

BE commented that a much better-integrated approach is needed. An integrated view is needed instead of establishing multiple different infrastructures. EHIC is a good example, and it could be implemented using EU DCC technology. Better coordination would be beneficial for the EU citizens instead of competition between different approaches.

COM (EMPL) answered that in social security there are also some additional identifiers, they should be handled, and this is similar to what is done in the healthcare domain. Digital divide should be tackled at the legal level. Verifiers also need better tools to verify the documents. The right to be forgotten is a long-standing question in the blockchain domain, which is addressed in the scope of EBSI. No private data is written on the blockchain, so there is nothing to be erased. Infrastructures should be designed based on business requirements, meaning that one size does not necessarily fit all. Some features could be developed on top of blockchain.

COM (CNECT) thanked Member States for the work on EU DCC. A key factor for success was trust. Simplicity and ease of use were other key factors. Citizens should be in control of their own data. The main driving factor was the need for a specific use case. For the EUDI wallet, eHealth use cases are extremely important. COM thanked the people working on its development, in particular the eHN Technical IOP SG.

COM (CNECT) further added that the digital twin programme is progressing. Two infrastructures are being developed, one on cancer images, and one on genome data.

<u>Intervention by CNECT.H Director</u>

DG CNECT Director H intervenes on the important work achieved by the EUDCC. Key to this success has been the trust framework and to make it simple. CNECT emphasises the importance of building the eID solutions and the eID wallet solutions in the area of digital health. CNECT Director also refers to 1MG and the Cancer plan.

### 3.3. eID Wallet

The Commission explained that the new framework for the European Digital Identity (EUDI) creates a great opportunity for the European Health Data Space in the primary uses of health data. Under the proposed new framework for the EUDI, Member States will offer citizens and businesses digital wallets that will be able to link their national digital identities with proof of other personal attributes, e.g. driving license, diplomas, bank account, health data. A key aspect in developing a common toolbox (publication by October 2022) is the development of use cases, including in health.

Today, this access is still limited, whereas by 2030, all citizens should have access to electronic medical records according to the Commission's 2030 Digital Compass. In health, the EUDI wallet can be an important enabler to overcome today's limited access and control of people to their health data. It could allow people to easily request access to a number of health-related documents (patient summaries, e-prescriptions, laboratory results, etc.), and to decide when to share and with whom, and for which purpose, while keeping track of all accesses to their health data. Based on the mandate of the eHealth Network on 30 March 2022, the technical interoperability group is developing an integrated vision for digital health (ePrescriptions) and eIDAS and is in close contact with the eIDAS working group.

Holding and sharing ePrescriptions data directly by citizens themselves is proposed as a first use case for the EUDI wallet in health, which would complement very well with MyHealth@EU for eDispensation data. A call for proposals (EUR 37 million) dedicated to large-scale pilots for the EUDI wallet are open for Member States to apply until 17 August. Digital health is a possible use case, therefore the Commission encouraged Member States to participate and offered its support for coordinating the action.

Several Member States highlighted the need to apply to this use case the ethical principles that were agreed by the eHealth Network. The Commission indicated that the ethical principles are horizontal, that they can be applied to this and other use cases, and that the trust framework of the EU Digital COVID Certificate (DCC) could be reused in the context of the large-scale pilot for health.

### 3.4. Joint controllership presentation

The EC presented the upcoming project regarding a "Draft Data Protection Impact Assessment" for the operation of eHDSI for MyHealth@EU. During the presentation at hand, it was mentioned that some of the MS using the eHDSI have already conducted or intend to conduct a DPIA in order to identify and address any risks derived from the processing of health data in the eHDSI. Under GDPR terms, the EC acts as processor in the context of MyHealth@EU and specifically, provides the eHDSI in order to facilitate the exchange of the health data and the MS act as controllers. The EC will provide support for an external contractor to assist MS in fulfilling their obligations by preparing a "draft" model DPIA. Through this project, the intention of the EC is to support the MS to conduct a DPIA or to complement the existing DPIAs in order to fulfil the obligations stemming from the GDPR while ensuring and strengthening the security of the system and the health data processed. The "draft model DPIA" developed by an external

contractor will assess the risks deriving from the processing of health data and will be made available to the MS that act as controllers.

The upcoming Draft DPIA will check the overall operation of the system and it is likely that there will be the need to update the existing DPIAs of the MS. Also, it was stated that the DPIA will include 1. the overall description of the eHDSI and its purposes, 2. Legal Compliance Check List (e.g. general principles of data protection and legal basis), 3. Description of Data Subjects Rights and Personal Data Categories, 4. Description of IT and Security Measures, 5. Risk Assessment and specifically, the Identification of the Risks deriving from the processing of health data of the eHDSI, including the means of addressing them and finally, 6. Actions that should be taken and resulting From the DPIA. The EC is currently drafting the terms of reference for the contractor that is going to materialize the project in question.

**4. Capacity building (for information)**

***FR study on Digital Health in Europe***

The French Presidency introduced the concept and objectives of FR study on Digital Health in Europe. For the French presidency it was important to avoid any additional burden to eHealth network members and therefore they decided to take a contractor in order to prepare a ground for EU Digital ethical principles. Further, the French presidency explained the steps which were taken during the study. They underlined that all Member States comments were taken into account and the last version has been sent out to Member States. It was followed by the presentation of the main results of this study and creation of country profiles; the full version of the report is being finalised. The French presidency stressed that the study is a snapshot of the situation in the Member States.

***Digital Decade monitoring***

COM (DG CNECT) presented the update on the state of play of the Digital Decade monitoring framework in the area of eHealth. COM explained the background: Communication 'Digital Compass: The European Way for the Digital Decade' where the Commission sets out targets to be reached by 2030 with 4 main goals, where under the digitalisation goal it was agreed that all citizens have access to their electronic health records. Further COM explained the process of the establishment of the monitoring system. COM will use existing monitoring results - according to a recent study published by the Commission, Interoperability of Electronic Health Records (EHR) in the EU study, 26 countries generally provide their citizens with online access to EHR data by law; the access to health information for citizens has been facilitated nationwide in 17 countries and 6 countries report ongoing pilot projects. However, COM does not have complete data on the situation in Member States. Therefore, currently COM is working on developing the methodology for all the targets, incl health target. During the meeting COM presented possible indicators, available indicators in MS and the timeline of process. Further consultations: 09. – 10. 2022, conducting survey on missing data: 12.2022 – 02. – 03. 2023.

**5. Secondary use of health data (for information)**

The coordinator of the Joint Action TEHDAS provided an overview of the state of play of the ongoing work. Work in TEHDAS is organised in different work streams, namely: governance, data quality, infrastructure,

citizen engagement, data altruism, sustainability. All TEHDAS deliverables are available in the TEHDAS website - https://tehdas.eu/. The following outcomes were mentioned as particularly meaningful: explanation on why is a specific case in data legislation, barriers of cross-border sharing of data for secondary use and options to overcome these, identification of relevant standards for semantic harmonisation, data quality features that can be legally bound, overall federated architecture. Regarding next steps, the TEHDAS is currently looking for ways on how to support Commission and Member States over the next phase of the EHDS regulation proposal. Next event 14-16 June TEHDAS Stakeholder Forum in Helsinki.

**6. eHN subgroups progress (for adoption and discussion)**

**6.1 Subgroup on Semantics**

General guidelines

The eHealth Network subgroup on semantics submitted for adoption the version 3 of the eHealth Network General guidelines introducing the following enhancements:

- Clarified the interplay between General Guidelines and the use case specific guidelines, as well as removed outdated statements and references;
- Clarified the legal basis for the eHealth Network Guidelines, improved interplay with GDPR and other health interoperability requirements;
- Removed the duplication with Organisational Framework for NCPeH and removed project specific guidelines;
- Reinforced guidelines towards common terminology practices, such as the addition of the preferred code systems approach.

The eHealth Network adopted, by consensus, the version 3 of the eHealth Network General guidelines. The guidelines will be published (publicly available) in the coming weeks.

ePrescription guidelines

The eHealth Network subgroup on semantics submitted for adoption the version 3 of the eHealth Network ePrescription guidelines addressing some of the limitations faced during real world operation of cross-border ePrescriptions exchange and strengthen semantic interoperability of electronic prescriptions. Main improvements in the new version:

- Change in the name of the guidelines reflecting the scope of prescription and dispensation
- Introduction of Preferred Code systems acknowledging that ISO IDMP implementation is still ongoing and not yet complete
- Removing project specific guidelines to allow for a wider use of the guidelines within the future EHDS

The eHealth Network adopted, by consensus, the version 3 of the eHealth Network ePrescription guidelines. The guidelines will be published (publicly available) in the coming weeks.

Laboratory results guidelines

The eHealth Network subgroup on semantics submitted for discussion (and possible adoption) the version 1 of the eHealth Network Laboratory Results guidelines addressing the following use case:

- Sharing Laboratory Results of a patient from his country of affiliation (Country A) with a healthcare professional in the country of treatment (Country B) in two scenarios: 1) Sharing of individual reports or 2) Sharing of laboratory summaries, including results from multiple reports, e.g. a cumulative list

From the discussion at the eHealth Network there was a remark about too many mandatory fields. It was clarified that these fields are recommended, not mandatory.

It was agreed that the eHealth Network Laboratory Results guidelines should be submitted for adoption, by written procedure, until the end of June 2022.

Sub-group on Semantics work plan

The eHealth Network endorsed the work plan, until eHealth Network fall 2022 meeting, proposed by the subgroup on Semantics. The following work items were agreed:

- Conduct a minor update of Patient Summary guidelines, to ensure consistency with new guidelines;
- Evaluation of the outcomes from X-eHealth to prepare the ground for upcoming guidelines on hospital discharge reports and medical imaging and reports;
- Proceed with supporting EU DCC guidelines update.

The eHealth Network endorsed the work plan proposed by the subgroup on Semantics and requested to the subgroup to, additionally, analyse the semantic aspects of the vaccination card project.

**6.2 Update from the Technical IOP SG**

The eHealth Network subgroup on Technical interoperability informed to have started discussions related to the interoperability repository/workspace and the use of eID in health, in particular looking at the reuse and extension of the EU DCC trust framework. The EU DCC process generated important lessons for upcoming implementation projects: importance of a common sense of urgency, whole system in the room, standards based and open source, international collaboration works, strength through diversity, reuse of building blocks and focus on use cases instead of technology.

The subgroup will have a face-to-face meeting on 7 June 2022 in Brussels to identify potential next work items, subject to agreement of the eHealth Network. One possible work item is to prepare a strategic proposal concerning the **selection of standards and technologies** to be used for the implementation of new use cases in MyHealth@EU (lab results, medical images, hospital discharge reports), building on the outcomes of the X-eHealth project.

**6.3 Enhancement of MyHealth@EU service using EUDCC technology**

The eHealth Network subgroup on Technical interoperability prepared a description of the use case on ePrescription that could be implemented through the EU Digital Identity Wallet. The document also outlines the contents of a QR code representing the ePrescription or giving access to an ePrescription list. The subgroup prepared data and messaging specifications for MyHealth@EU, which could be used for MS-to-MS integrations, also including the eDispensation part. The subgroup proposes to use similar technology, to the one used in EU DCC, for the digital signature of the QR code contents. The same technology can also be used for other use cases as access to a vaccination card or an international patient summary.

Under Digital Europe Work Programme 2021-2022, at least 4 large scale pilots will be launched to test the deployment of the European Digital Identity Wallet in priority use cases, including health. Member States in the eHealth Network are invited to consider the implementation of the ePrescription use case as described by the Technical Interoperability subgroup as part of the Large Scale Pilot of the EU Digital Identity Wallet.

In its meeting on 7 June, the subgroup will discuss the evolution of the EU DCC trust framework, including its possible use for other use cases; interoperability of digital health trust networks; new functionalities for the new X-eHealth specifications and possible development of an interoperability workspace/repository.

Regarding the EUDI Wallet ePrescription use case, the proposed next steps are: 1) the subgroup on Technical Interoperability finalises the EUDI Wallet ePrescription use case documentation and submits it for written adoption, and 2) work is continued on the technical details needed as guidance for a Large Scale Pilot (ideally till end of June), following the proposed collaborative approach.

**7. French and Czech presidencies**

The Czech team presents the agenda of the CZ presidency. The focus will be on oncology, vaccinations, rare diseases, the situation in the Ukraine and Global Health. On digital health, the CZ presidency will work on interoperability, patients' access to data and the ethical principles.

The French team presents the work of the FR presidency. The EHDS legal text has come out, so we were fully aware that this would be an outstanding period of time to have the French presidency. Also coinciding with the French presidential election. The three priorities of the French government were to relaunch, to defend values and to build a sense of belonging. These were also translated to the work on digital health, through the Ethical principles, the standards in nomenclature (e.g. SNOMED) and the work on the French national infrastructure. Also, the EUDCC are rooted on our common values. The harmonisation of medical devices is important to promote the single market. The French are also working with the CZ and SE colleagues towards this development in the area of HTA.

**4.3 Capacity building**

SANTE explains the call for tender has closed and now the contractor will be selected. First phase will be the development of a catalogue of minimal essential requirements. These will be discussed in the eHN. After developing the catalogue, the contractor will perform a mapping exercise to determine where

Member States stand. Then the contractor will organise expert visits where best practices can be shared amongst Member States.

**8. European Ethical principles: implementation strategy and next steps (for adoption)**

The French team explains that ethics is one of the three pillars of EHDS, next to the security and interoperability. 16 principles have been agreed upon in collaboration with the Member States. A conference was held February 2. January 26 it was adopted by the eHN, October-November there will be a first consultation of the ecosystem. End of 2022 would then see the principles communicated towards citizens. The aim is to promote trust in the services, to promote wide use by citizens. The self-assessment grid results will be shared in the end of June. Then there will be work on a best practices compendium. The supportive document is for adoption. AT, SE and NL had reservations to adopt due to the very short timeline in which the document was shared ahead of the eHN meeting. AT also stressed the importance of art 6 (eHN Rules of Procedure) which states deadlines to be respected. FR asks to see this as another step in a process, where the document is open to further improvement in the future. DE proposes to adopt for now and discuss implementation in following meetings. CY says forgetting the document would be a big failure. SANTE states that the next phase, where the work on ethics would also be shared with stakeholders, it would be good to support the DE proposal. ES, IT, PL wish to see the proposal adopted. NL proposes to follow the DE suggestion, add in the document it's a living document, put this on the agenda for a longer period time. AT will abstain. The documents (supporting document and self-assessment grid) are adopted. Results to be discussed end of June. Global state of EU, not results by MS.

**9. European Ethical Principles Digital Health formal signature + picture**

A picture is taken in the hallway of PariSante Campus of all participants at the eHN meeting.

**10. Future governance model for eHealth in the EU**

<u>Presentation of proposal for improvement of eHealth Network Coordinated Actions</u>

The Member States co-chair reflects on the future governance model and role of eHN in light of the EHDS proposal. After leaving the crisis mode, there is a need to discuss the mandate of the coordinated actions and propose a multi annual work plan. The Member States co-chair suggests to build upon the successful cooperation of the eHN on EUDCC and EHDS projects in order to ensure that the eHN still fulfill the needs of the MS and of its mandate. A multi-annual work plan model is proposed in order to define what should be achieved, how it could be achieved and which resources are needed to achieve these goals. It would involve identifying which activities and sub groups are needed and what they should focus on. Based on adopted multi-annual work plan, coordinated actions would monitor progress on the planed work and assign it to subgroups which would provide regular feedback. It is thus proposed that pool of experts are created to work on the multi-annual work plan and eHN work switch to a more project based system

Presentation of the future governance model for EHDS in the EU

SANTE presents the future governance model envisaged in the proposal for the EHDS Regulation. The cooperation between Digital Health Authorities will continue at the European level and with the EHDS proposal, it is planned for such cooperation to be improved and to include Health Data Access Bodies which are involved in regulating the secondary use of health data. With the EHDS proposal, there will be a shift from a voluntary network to a more formal compulsory board with an expanded list of attributed tasks. The proposed EHDS Board would also allow other relevant stakeholders/expert to participate to activities of the Board.

The proposal also introduces two Joint Controllership groups tasked with managing the development and operation of the necessary cross-border infrastructure required by the EHDS framework. The Commission will provide a secretariat but most of the elements related to the operation of the two groups will be set out in the rules of procedures adopted by those groups.

In addition, Member States represented in expert groups or committees will be involved in designing the necessary implementing and delegated acts required to setup the EHDS framework. Relevant stakeholders will play an important role in designing these implementing and delegated acts. For delegated acts, the Commission will prepare and adopt them following consultation of expert groups composed of representatives of all Member States. Citizens and other stakeholders can provide feedback on the draft text of a delegated act during a four-week period. And once the Commission has adopted the delegated act, Parliament and Council generally have two months to formulate any objections. If they do not, the delegated act enters into force. For implementing acts, the Commission must consult, prior adoption, a committee where all the Member States are represented. Citizens and other stakeholders can provide feedback on the draft text of an implementing act for four weeks before the relevant committee votes to accept or reject it.

The Commission confirms that the proposed model is based on a standard typical system proposed in other legislative proposals and that the EHDS Board is planned in continuing and enlarging the work currently done within the eHN.

Outcomes of the break-out sessions where the EHDS governance is discussed:

The first group raised concerns that the work is not really focused on the real stakeholders, like patients and healthcare providers. There is opposition to the idea of Joint Controllership. There are also concerns about too heavy administrative burdens and lack of national support and resources. There is support for empowering patients, harmonization of standards, an EU terminology server and the need for Member States to decide common goals.

The second group had uncertainty about the future functioning of EHDS. There was a need for supporting newcomers to be able to onboard new members with a set of materials. EHDS requires an adequate governance framework. There should be a balance between top-down and bottom-up decision making. The evolution of the eHMSEG should be considered carefully.

The third group would like to see deadlines respected better in communicating documents ahead of the meeting. There was also support for an EU digital health agency to ensure continuity. There is concern that with EHDS the Member States would no longer have a clear seat at the table. Patients and other stakeholders should also be heard. There is concern that the EU would take decisions and the member states would have to implement these. There is concern that there is a lack of experts to achieve the implementation speed. There is a need to coordinate national efforts in the same field at European level. Also, some Member States expressed concerns that the European services are not being used a lot. There should be more focus on the benefits of European collaboration and the business case.

In the fourth group, it was suggested to separate primary and secondary use in EHDS. Importance was given to a good balance between the roles of Member States and the Commission. The continuity of the current structures and work could be threatened by the change in governance. The transition should be planned early enough. Work should be prioritised given the limited resources. Given the need to transition MyHealth@EU processes, a 12 month period is foreseen in the EHDS proposal. Some expressed the need for a subgroup on capacity building. The French ethical principles were seen as an instrument to promote trust in EHDS. On infrastructure, the point was made that European Cloud vendors do not always respect European sovereignty. There should also be sufficient resources for Member States to enable EHDS in a sustainable way. Key words were capacity, sustainability, balance and flexibility.

**11. Preparation of implementation for primary use of health data under the EHDS (for discussion)**

The Commission presented the EU funding sources that are available to Member States to support the implementation of the European Health Data Space (EHDS). EU4Health will be the main source of funding for the EHDS infrastructures, together with Digital Europe Programme (DEP). In its 2021 and 2022 work programmes, EU4Health already supports the development and establishment of the EHDS with a substantial initial contribution of almost EUR 110 million, with approximately EUR 33 million in 2021, and EUR 75 million in 2022.

In its 2022 Work Programme, EU4Health includes EUR 30 million in direct grants for Member States to connect to MyHealth@EU and expand its coverage and services. This is a very substantial amount for EU4Health, and it is a “once-in-a-programme” opportunity. Additionally, a new joint action will be launched to support the internal market dimension of the EHDS, including the certification of EHR systems and wellness applications. EU4Health will also support an infrastructure pilot project for the secondary use of health data (HealthData@EU), the set-up and connection of health data access bodies, the uptake of international standards by Member States, actions on capacity building and other preparatory actions, as well as a pilot project for the access of patients to their health data through MyHealth@EU.

DEP, Horizon Europe and Connecting Europe Facility (CEF) include actions in their scope that will further support the implementation of the EHDS. Additionally, activities in the area of digital health are also eligible under the Recovery and Resilience Facility (RRF), the European Regional Development Fund (ERDF), the European Social Fund + (ESF+), the Technical Support Instrument (TSI) and Invest EU. Each

programme pursues its own specific objectives and is bound by specific rules. Therefore, it is vital for the success of the EHDS to make an effective use of the available funds.

During the breakout sessions, several Member States indicated that they are interested in applying to the grants that are available under EU4Health in 2022 but also expressed that they require support from HaDEA and the Commission. The Commission explained that it is ready to provide support and guidance on these funding opportunities. A follow-up discussion will be organised together with HaDEA to tackle Member States' questions.

Outcomes of the break-out sessions where the EHDS funding opportunities are discussed:

Group 1 discussed their intentions to apply for the funding schemes. Some countries were willing to apply, but found it difficult given the bureaucracy and the perceived lack of outcome-based deliverables. Participants asked for support in establishing Digital Health Authorities as well as expertise on the development of use cases. Also, the limited national resources were mentioned as part of the difficulties to find national co-financing means.

Group 2 had many questions about the scope of the Joint Action and connections to the X-eHealth project. Also, there were questions regarding the link to the New use cases work group of eHMSEG. There were suggestions to include social care related aspects to the Joint Action and the importance of involving Standards Development Organisations. A number of participants indicated their interest to participate in the Joint Action. Some indicated the lack of national resources as a barrier to being able to participate.

**12. AOB**

The Commission mentioned the election for the position of MS co-chair of the eHN will take place in November during the next eHN meeting. According to the rules of procedures, this is a mandate of 2 years. MS will be invited to express their interest.

**13. Conclusions of the meeting**

The eHN co-chair thanked everyone for the fruitful discussion. The next meeting is scheduled on 7 November 2022 in Brussels.