eHealth Network –
24th eHealth Network Meeting

Minutes of Meeting
1 June 2023 (9:25 – 17:30)
2 June 2023 (9:30 – 12:55)

Participants

Commission Units & Agencies: DG SANTE C1, DG CNECT H3, DG CNECT R3, ECDC, eHMSEG.

Member States: AT, BE, CY, CZ, DE, DK, EE, EL, ES, FI, FR, HR, HU, IE, IS, IT, LT, LU, LV, MT, NL, NO, PL, PT, RO, SE, SI, SK.

Invited: Contractor (Infeurope/Mercury-97, Empirica); Private Experts (eHälsomyndigheten, ESZFK), TEHDAS, PATHeD-POTENTIAL Project Manager.

Day 1: 1 June 2023

The Co-Chairs welcomed the participants and extended their thanks to the Swedish eHealth Agency for hosting the meeting.

A new organisational process was introduced by which, a list of contact and photos will be shared in a secured environment accessible to eHN members with participants' consent. This list will be checked before each meeting. It was also suggested to use a collaborative message tool for event coordination.

The State Secretary to the Minister for Social Affairs of Sweden gave a welcome speech expressing the need for the ambitious reform of the digital infrastructure of the Swedish healthcare sector with a focus on quality healthcare for citizens as well as accessibility of relevant information for healthcare providers. The EHDS negotiations currently under the Swedish EU presidency are at the top of the presidency agenda. The SE presidency has presented a compromise text to the Member States. The two main purposes of the reform are to reduce the administrative burden for health professionals and improve patients' safety. The SE presidency hopes that the compromise text will be well received by Member States and wishes ES good luck with the presidency.

1. Interoperability

As per the mandates received at the 22nd eHealth Network meeting, the Semantic and Technical Interoperability Subgroups (Semantic and Tech IOP SG) provided an update.

1.1 Patient Summary

The Semantic SG was to assess the inclusion of a new code system in the Patient Summary guidelines for vaccine coding, as suggested in the EU Vaccination Card Study. The minor updates made intend to align the representation of vaccine medicinal products in the Patient Summary Guidelines with the ePrescription and eDispensation Guidelines as well as with the International Patient Summary. After careful deliberations, the Semantic SG opted to: support the vaccination use case to allow

specification of a coded element representing the vaccine medicinal product, to add the EMA Product Management Service (PMS) as the preferred code system, to not include further preferred code systems (i.e. NUVA) at this stage, and also addressed the security issue related to URLs as values of Patient Summary data elements in V3.3 of the Patient Summary Guidelines.

The eHealth Network adopted by consensus the release 3.3 of the Patient Summary guidelines.

Laboratory results and reports update

The mandate was given to clarify the concept of the "Laboratory Summary" present in the current Laboratory Result Reports Guidelines and provide a new version of the said Guidelines. The concept developed in version 1.0 of the Laboratory Result Reports Guidelines was considered redundant to the dataset and easy to misunderstand. Therefore, the Semantics SG recommended to remove the concept of the Laboratory Summary and any reference to it in the Guidelines and added examples from Member States illustrating possibilities on how to present laboratory results to a health professional of the clinical use case defined in V1.0 of the Guidelines.

Following discussions with stakeholders, the Semantics SG introduced additional improvements of 1.0 version which focused on: the minimisation of risk of misinterpretations of laboratory test results and their comparability, adding precision on narrative texts and recipient information (3 fields), adding supportive information on technical standards, and finally it addressed metadata elements in the dataset.

The clarification and improvements performed bring additional maturity to the content and facilitate the implementation of the guidelines, therefore the Subgroup on Semantics recommended to the eHN to adopt the release V1.1 of the Laboratory Result Reports Guidelines.

The eHealth Network adopted by consensus the release 1.1 of the Laboratory Result guidelines.

The Co-Chair advised to republish both the Patient Summary and Laboratory Result Reports Guidelines documents in order to increase their visibility and promote them to vendors and healthcare organisations.

EC added that currently an updated version of the eHN webpage is being prepared in order to facilitate easy access to all eHealth Network guidelines on electronic health data sharing.

1.2 Metadata problem assessment

The Semantic SG performed an assessment on the need and readiness for metadata guidelines. Building on X-eHealth outcomes, problem assessment states that given the growing challenge of the increasing amount of available data, additional tools are needed to facilitate data discovery and to support health professionals' efficient access to electronic health data. Metadata has the potential to address this challenge in a harmonised way across different use cases, raising the importance of alignment and consistency, while acknowledging the specificities of each guideline.

As a result, the following a 2-step approach was recommended consisting of:

- Step 1: handover to Joint Action 09 to prepare draft guidelines on metadata and submit them to eHN Subgroups for consolidation;
- Step 2: eHN Subgroups to consolidate the draft Metadata Guidelines and submit them for eHN adoption, taking into account whether a separate guideline for metadata is necessary or the topic can be included in the General Guidelines as well as the revision of all guidelines to streamline content aligned with the metadata work.

The eHealth Network endorsed the 2-step approach.

1.3 Hospital discharge report guidelines

In the compilation of the draft Hospital Discharge Report Guidelines, the SG took into consideration the following: the adoption of standards-based definitions as key concepts (ex: ISO); the inclusion of both workflows (Country A – Country B; Country B – Country A); the inclusion of a fully-fledged data-set, and specifications of cardinality and conformity (not included in current version for consistency reasons).

With the draft Hospital Discharge Guidelines prepared, the Semantic SG will now proceed with the second step: organising a stakeholder consultation at national level and EU-level respectively, focusing on use case description (Chapter 1) and guidelines (Chapter 2) as well as the question regarding whether a recommendation towards a minimum dataset is feasible.

The eHealth Network endorsed the approach of running a public consultation over the draft version of the guidelines and submitting them for adoption in the November 2023 eHealth Network meeting.

The Co-Chair assured the participants that MS will be supported by EC in this process.

1.4 Imaging Study and report guidelines

The Tech IOP SG was mandated to take the lead on Medical Images and Imaging Study and Report Guidelines. Draft Release 1 of the Guidelines has been prepared. It is now suggested to launch stakeholder consultations using this draft in a process similar to that planned for the hospital discharge report guidelines. Currently, the guideline identifies 4 use cases, the first of which is noted as a first priority (request and retrieval of medical images and imaging reports by health professionals treating a patient). The guideline also includes two data sets (one for medical images and the other for DICOM metadata), the basic data elements required for the cross-border exchange of medical images and imaging reports, as well as some possible architectural options the selection of which remains to be discussed with the eHMSEG.

The main standards being proposed for content representation are FHIR for imaging reports and for information on imaging studies as well as DICOM for imaging studies. For content transmission the proposal is to use FHIR REST API for imaging reports and for information on imaging studies and DICOM for imaging studies.

The Tech IOP SG recommended to organise stakeholder consultations at national and EU level, focusing on the use case description (Chapter 1), the Guidelines (Chapter 2), the datasets (Chapter 4), as well as the architectural and standardisation options to support the safe and interoperable exchange of medical images and imaging reports. Relevant SDOs will be included in the stakeholder consultation with a view to a future-proof architecture enabling exchange of images or other large files.

The eHealth Network endorsed the approach of running a public consultation over the draft version of the guidelines and submitting them for adoption in the November 2023 eHealth Network meeting.

The Co-Chair noted the important element of engaging stakeholders in the technical consultation and thus reassuring them that the work is based on best practice, building upon internationally recognised standards.

2. Updates from eHealth Network Subgroups

2.1 Semantic Subgroup update

In November 2019, the eHealth Network adopted the Common Semantic Strategy and mandated the Subgroup on Semantics to pursue the scope and goals established in this document.

The scope of this strategy is aligned with the European electronic health record exchange format (EEHRxF) (patient summary, ePrescription, laboratory results, medical imaging and reports, and hospital discharge reports). The strategy organises work in a 5-year overall plan (2020 to 2024) with an evaluation activity at the 4th year (2023) to analyse sustainability and the need for continuation of work.

Since their inception, the Subgroups have revised the Patient Summary Guidelines, the ePrescription/eDispensation guidelines, and the General guidelines. They have also finalised the first version of the Laboratory Results Reports Guidelines and contributed to the preparation and maintenance of the EU DCC Guidelines. Furthermore, the Subgroups assessed and prepared draft versions of the Hospital Discharge Report Guidelines, Imaging Studies and Imaging Report Guidelines as well as promoted the coordinated adoption of coding systems (SNOMED CT, ISO IDMP). Not initially on the agenda, the Subgroups also began assessing the need and readiness of Metadata Guidelines.

In view of these achievements, the Subgroups have established the capacity to develop and maintain eHN Guidelines as well as enabled resolution on semantic and technical interoperability issues across projects and functions.

The Semantic SG therefore recommended to continue with the achievement of its mandates until the end of the 5-year plan in 2024, namely the submission of the first version of the HDR Guidelines, Medical Images and Imaging Reports Guidelines, and the Metadata Guidelines to the eHN, to continue assessing the needs for updates on all Guidelines in collaboration with ongoing initiatives, and support the eHN transition to the EHDS.

The Semantic SG will undergo the election of a MS Co-Chair and Rapporteur in November 2023, which will be the third election as part of a two-year cycle. Considering the ongoing negotiations of the EHDS Regulation, the SG recommended not to formally conduct an evaluation exercise this year (2023), but rather to support the transition to the EHDS.

The eHN Co-Chairs commented on the importance to build upon the expertise and experience gained in the Subgroups for the future implementation of the EHDS and brought attention to prospective challenges such as the review of the EHR exchange format, encouraging applications for the next position of the MS co-chair.

2.2 Tech IOP update, including renewal of subgroup's mandate, model Rules of procedure document and election of subgroup's co-chair

The Tech IOP Co-Chair updated participants on the mandate update proposal, rules of procedure, and election of the Subgroup's new MS Co-Chair.

The Tech IOP SG was established in 2020 and began working on vaccination certificates and on the EU DCC in the end of 2020, with the biggest amount of work falling on 2021. In 2022, the SG continued refining the EU DCC and began considering its future use as well as looking into EU digital identity wallet possibilities in eHealth. In 2023, the group worked on the selection of standard for the new use cases in MyHealth@EU and is currently working on the medical images and imaging reports Guidelines.

The mandate created with the establishment of the Tech IOP SG was closely linked to COVID-19. The text of a new mandate was therefore redrafted with the general mandate proposal stating that the Tech IOP SG will abide to the following:

- Support the eHN in reaching substantiated decisions, strategies and measures on technical interoperability issues, to facilitate growth and innovation of the EU eHealth landscape;
- Provide expert policy advice on technical interoperability aspects and recommend on interoperability issues concerning MyHealth@EU and possible other European eHealth services. Also, to advise on harmonisation issues arising from different implementation strategies in the eHN and/or its MS either at cross-border, national or regional level;
- Work out strategies to improve adoption and implementation of interoperability standards in MS, including aspects such as technical obstacles, market readiness, suitability, costs, timeline, that will support the eHN to formulate a well-substantiated roadmap for future development;
- Find synergies in sharing best practices and assets related to interoperability in eHealth;
- Closely work together with the eHN Subgroup on Semantics.

The Tech IOP SG therefore proposed to continue its ongoing activities for 2023, such as the development of the medical images and imaging reports Guidelines (stakeholder consultation), monitoring the future of the EU DCC and supporting its uptake by the WHO through their Global Digital Health Certification Network (GDHCN), contribute to the governance paper of the eHN SGs, continue leading in the development of choices for technical standards, and act on emerging topics in ongoing and upcoming initiatives with strategic advice on technical interoperability to the eHN when so requested.

For 2024-2025, the activities are to be defined by the corresponding eHN Work Plans.

The Tech IOP MS Co-Chair asked the eHN to award the Subgroup a mandate of 2 years with an evaluation moment by eHN in June 2025. After the 2-year mandate, the eHN may or may not extend the mandate depending on the needs.

The EC eHN Co-Chair stated that the Commission fully supports the updated mandate proposal.

The Tech IOP SG Co-Chair proceeded with the topic of Rules of Procedure for the eHN Subgroups. As agreed in the joint meetings of the Subgroups in Uppsala (18-19 April 2023), the MS Co-Chairs of the Semantic and Tech IOP Subgroups have prepared a draft Rules of Procedure (RoP) document applicable to both eHN Subgroups and is now proposed to the eHN for adoption.

DISCUSSION:

AT raised concerns about the proposed RoP, stating that they are missing information leading to issues of transparency and communication. In particular, the supportive documentation they received did not include Version 7, and Version 9 was not communicated to eHN members. In terms of communication, AT asked for timely distribution of documents in adherence to the deadlines.

ES stated that the latest version of the agenda, including the information about the adoption of the model RoP was sent yesterday and suggested points for adoption to be explicitly stated in the agenda. ES was further concerned about the precedent that the proposed RoP may set for the future of governance in digital health. Furthermore, in article 6.1 of the proposed RoP, two calendar days are not considered enough time for MS to analyse the documents presented for adoption. Longer time period should be specified: e.g. 1 week. For example, with the current wording, documentation may be sent on Friday COB and expected to be adopted in a meeting on Monday. In article 10.1 of the proposed RoP, no time limit has been specified for COM to send the meeting notes. There should be a deadline of 2-3 working days (Brussels work calendar) to send the meeting minutes to MS. In fact, as it stands, the minutes are generated on-the-fly during these meetings and shared immediately after the meeting. This modification would put no burden on COM. Article 5.1 of the proposed rules of procedure states that “The Secretariat shall draw up the agenda, after consultation of the Chairs and rapporteur”. ES suggested that the propositions of individual MS should also, when possible, be

included in the agenda. The Rules of Procedure should reflect how the Subgroups currently function. Additionally, ES requested a confirmation whether EEA countries which are not part of the EU (i.e. Norway, Iceland, and Lichtenstein) have a binding vote in the eHN and its Subgroups, due to the incorporation of Commission Implementing Decision 2019/1765 into the EEA agreement: https://www.efta.int/eea-lex/32019D1765. This would be a very significant change in the decision-making of the eHN. As an example: if during the COVID-19 crisis the aforementioned countries had a binding vote, the eHN would have ended up with a different specification of the EU DCC (some relevant decisions were an almost 50/50 split), wherein some decisions were adopted because Norway and Iceland did not have a binding vote. Such modifications of the governance framework should be communicated to the MS in a transparent manner with a sufficient advance. ES also asked adoption of binding documents to be kept to a minimum in August, since many experts are on vacation during this time.

LU commented that they have the same concerns regarding timeframes as ES and AT. In article 6, LU suggested the current time limit of 2 days to be replaced by 5 days. In article 9, LU suggested to put a time limit of 5 days limit for sending comments in written procedure. In article 10, LU asked a maximum time limit of 5 days to be foreseen when requesting comments to the minutes. Regarding adoption process of deliberations, LU explained that in case of numerous abstentions, the adoption by consensus might impact future implementations and suggested considering options for the abstentions to be considered as such.

NL, PL, and FI supported the observations made by ES, AT and LU.

Taking into account that SG only prepares recommendations while eHN makes decisions, CZ supported proposed RoP without modification.

While SE recognised that the specific workflow of the Subgroups should be clarified in the RoP, they explained that all meetings are pre-planned and that the documents produced by the SGs' Task Forces (TF) are continuously available in their latest version for Member States on Confluence. Extending the timeframe for input might reduce the capacity of the TFs, disrupting their work. However, SE assured Member States that this does not reflect lack of transparency and recognised that this has to be made more evident in the RoP.

NO stated that their understanding of the incorporation of Commission Implementing Decision 2019/1765 into the EEA agreement is different than that of ES. They suggested to request a clarification of this matter from the legal perspective, which the Commission confirmed should be considered.

ES added that abstentions should not be considered as negative votes, as a negative vote should be explicitly stated as such. Otherwise, the decision-making process will be stalled. ES endorsed the need for a written clarification from the Commission regarding voting rights.

The Semantics SG MS Co-Chair clarified that the final decision for adoption of the subgroups' RoP is made by the eHN. She suggested differentiating between working documents and those for eHN submission, as extending the timeframe for working documents for discussion might hinder the work process of the Subgroups. The Semantics SG Co-Chair also reminded participants that it is volunteers who are working on the RoP document and therefore it can be challenging to generate them in a timely manner especially as a lot of input is received shortly before meetings. Finally, eHN members were asked whether deviation from the eHN RoP would entail a more independent formulation of the RoP for the two Subgroups.

The Tech IOP SG MS Co-Chair commented that the documents submitted to the eHN have to be submitted 3 weeks in advance. Regarding the SG meetings, new agenda items are continuously being added to the Tech IOP bi-weekly meetings. Nevertheless, the items remain on the agenda for months

and are visible to all. Furthermore, the documentation in the form of minutes and the chat provide transparency. Yet the Co-Chair agreed with his colleagues that some of these elements would have to be made more explicit in the RoP.

The eHN Co-Chair clarified that the version being discussed is Version 9 and that ES referred to an already commented-on version. It was also clarified that in article 6, it is referred to two working days and not calendar days. The Co-Chair confirmed that the Tech IOP SG receives a mandate to prepare and endorse documents, while the adoption of documents rests with the eHN. Longer timeframes for MS scrutiny should be assessed regarding their compatibility with the Tech IOP SG workflow.

It was decided that the Subgroups will address the comments at their next meeting and send out a new version to Member States.

With regard to the election of the new Tech IOP SG MS Co-Chair, the eHN was proposed to appoint Panayiotis Savva from CY (only candidate) to fill the position as Vincent van Pelt (NL) is stepping down. With no objections, the eHN appointed Panayiotis Savva as the new MS Co-Chair of the Tech IOP SG. The eHN Co-Chair called for candidates for the position of a rapporteur of the SG, and thanked the outgoing Co-Chair for his dedication to the Tech IOP SG and enabling the group to complete its mandates.

3. MyHealth@EU

EC presented the MyHealth@EU state of play, KPIs, and roadmap. There are currently 11 Member States connected, allowing health data exchange for Patient Summaries and ePrescriptions. These services will be expanded to include laboratory results, medical images and imaging reports, as well as hospital discharge reports from 2024-2026.

MS live now are:

- CZ EE ES FI FR HR LU MT NL PL PT

MS expected to join the MyHealth@EU are:

- 2023 : CY EL HU IE IT LT LV SE SI
- 2024: BG SK
- 2025: AT DE DK IS NO RO

Regarding the KPIs, on one hand, the number of ePrescription transactions shows a steady increase, while the number of Patient Summary transactions is currently stable. On the other hand, the number of hospitals connected show an increase from 2021 to 2023.

The MyHealth@EU roadmap aims for the full entry into force of the EHDS regulation (mandatory participation for all MS), the development of the Pilot on Patient Access enabling citizen access to their translated health data, the enhancement of existing services using EU DCC technology, as well as connecting more points of care for new MS joining MyHealth@EU services.

Regarding funding, direct grants have been made available under EU4Health. MS will soon receive feedback from HaDEA on the evaluation of their grant applications under EU4Health Work Programme 2022.

The main actions taking place on the primary use of data are represented by the proposed EHDS regulation (under negotiation) that provides long-term vision for MyHealth@EU, and the upcoming Joint Action on primary use (2023) which will also provide important support for the implementation of EHDS regulation. Member States are therefore invited to participate in the Joint Action to

contribute their input. In addition, the ongoing contract on Capacity Building, which is included in the roadmap, will provide MS an opportunity to exchange experiences related to the implementation of digital health services, thereby supporting them in strengthening their national infrastructures.

DISCUSSION:

The eHMSEG Co-Chair took the opportunity to extend her thanks for the support provided by the Commission as well as to the Romanian delegation for organising a technical bootcamp, and the SGs for the preparation of the Guidelines. The Co-Chair pointed to the need for better promotion of the new services to the end user at both national and EU level for better understanding and boost of MyHealth@EU use.

EE asked if there is intention to onboard third countries, as Ukraine has approached them for the possibility to join the infrastructure and pointed to the urgency to be able to exchange certain type of information.

FR noted that a solution for joining the EHDS is also required for micro-countries, such as Monaco, where health data exchange is challenging.

The eHN Co-Chair clarified that the question of third countries onboarding is still being checked internally in terms of technical feasibility as well as the appropriate legal and political frameworks.

ES supported the comment made by FR about micro countries and made the following additional comments:

1) The funding initiatives are fundamental to help the MS with the implementation of the EHDS.

2) The following information on each of these lines of work is desirable: 1) Scope; 2) Objectives (with a certain level of detail); 3) Deliverables (functional specifications that will be binding, technical specifications that will be binding, drafts of legally binding documents such as implementing acts, drafts of EU recommendations such as Commission or Council recommendations, exploratory technical R&D documents, non-binding policy documents, etc).

3) There should be a mapping for the relationship between these lines of work (in particular, between the deliverables).

4) Whenever possible, overlap between these lines of work should be avoided, while coherence should be maintained (i.e. contradictory or incompatible legal, technical or semantic specifications should be avoided).

Regarding the communication plan for MyHealth@EU, PT advised to devise a joint communication plan between Member States. NL and CZ fully supported PT proposal.

IE supported the need for a common communication plan and supported the comment made by the other eHMSEG Co-Chair, adding that those in the process of going live are being encouraged to share their communication plans as part of what they have done (Live) and will do (Going Live) in the eHMSEG community. As suggested by the eHN chair, this can be pushed forward at the eHMSEG level in advance of the next eHN meeting.

BE remarked that for reasons of privacy protection and compliance with GDPR it is necessary that exchange of personal data is encrypted end to end.

3.2 Overview of current means to build MyHealth@EU

Two mobile application projects are ongoing: POTENTIAL and PATHeD. Their purpose is to involve citizens in the management and control of their health data by adding new functionalities to the existing MyHealth@EU infrastructure.

Regarding PATHeD, stakeholder analysis is ongoing and the project is currently working on WP4 of functional and technical specification. The complete infrastructure of the pilot will be available at the end of year when citizens/patients will have access to the new services.

The stakeholder analysis resulted in the definition of 6 pillars of the coming development:

1. Power to the people: providing support to citizens
2. Focus on eID
3. Focus on the EU Regulation
4. Reuse2Advance: all developed artifacts will be reused
5. Communication-Dissemination-Education
6. MyHealth@EU infrastructure in the eHealth Ecosystem

The stakeholder analysis further identified important elements for involving the citizens towards closing the health gap, such as the development of chatbot, the selective disclosure of health data and the use of plain terms.

PATHeD focuses on displaying the Patient Summary on citizens' mobile devices translated into selected European languages for presentation to patients and health professionals. In particular, a mobile backend will be developed to connect national infrastructure along with OpenNCP servers to allow citizens to select any Member State language and provide the translated version of the Patient Summary. The project will end on 30 June 2024 with a test and evaluation of deployment of the mobile app in six Member States.

The eHealth Use Case of POTENTIAL will apply the new EUDI Wallet for ePrescription. The PID function will provide uniform patient identification method across pharmacies in Europe, and the wallet will store and display information of ePrescriptions that will be finalised in June. The retrieval of the eP/eD will be implemented through the MyHealth@EU infrastructure.

By the end of July, the following actions shall be completed: (1) the analysis of legal and business requirements to access online services, (2) the analysis of existing processes and technical implementations supporting access to online services, and (3) the identity matching and management of public authentic sources including the relying party integration. By the end of August, the scope of work will be updated and consolidated by use case leader and WP3 leader.

The project will be completed on 31 March 2025 with the evaluation of the pilot deployment of the EUDI Wallet application in nine Member States.

DISCUSSION:

ES proposed to consider having a discussion regarding emerging capabilities of new AI technologies, such as multilevel language models (i.e. machine translation capabilities between different languages).

4. Capacity Building on Primary Use of Health Data

A presentation on the **Capacity Building on the primary use of health data** was given to inform participants about the developments of the capacity building initiative. The Capacity Building ambition is to enable European countries to maximise their strengths, expertise and complementarity, while focusing on increasing the digital skills of their healthcare and management workforce in order

for countries and Europe as a whole to more effectively respond to increasingly complex challenges (i.e. rising healthcare demands, increased delivery complexity, health equity, and patient empowerment).

The challenges have been defined as the variation among countries in access to health data (e.g. development stage of healthcare digitalisation and limited capabilities of individuals in assessing and sharing their health data. On the other hand, the identified opportunities are the increased investments in digital health infrastructure and services, the planned further steps in the digital health transformation and the need to build new capacities (e.g. processes, resources, expert staff.)

The study objective is to facilitate the development and strengthening of skills and abilities of staff working on national digital health services. This is done by:

A. Identifying state of the art in key processes, resources, and infrastructures in digital health at national/regional/cross-border level and countries' needs for support in building their capacity for the primary use of health data
B. Implementing a twinning approach that allows EU countries to benefit from knowledge and best practices implemented in other EU countries with already proven successful outcomes, especially in the areas of digital transformation of health services
C. Facilitating cross-border interoperability between the national systems and the EU level, while avoiding fragmentation in the digitalisation process across Europe

The study approach encompasses 1) Capacity Building Requirements Catalogue (November 2022-April 2023); 2) Mapping and Pairing for launching knowledge exchange activities (May-June 2023); 3) Twinning Program Design (June-July 2023) and 4) Twinning Program Implementation (August 2023-May 2024).

The scope of the Capacity Building Catalogue is the essential capacities for the primary use of health data and it aims to provide a framework for mapping state-of-play for Member States with regards to their digital health journey, capture their existing capacities and enable countries to identify capacity areas in which countries can benefit from knowledge exchange via twinning activities and dedicated visits. The ultimate result is to help countries prioritise their efforts and investments.

The next step for eHN members is to revise and complete their Catalogue file. The study team is available for providing support and clarifications (email, dedicated meetings). Each MS will have their own file and is asked to complete the questionnaire.

DISCUSSION:

ES asked about the financing policies as part of the policy and organisational framework of the catalogue overview and whether the survey on the twinning approach is intended to be used for alternative purposes. The Contractor explained that there are indeed a series of questions for financing policies to help better understand MS capacities.

FR noted that the next steps should include a dedicated Task Force which would explore the implementation plan of ethical principles for digital health in more detail. Regarding the twinning approach, FR asked if there is a maximum number of countries able to participate in the initiative and how will the pairing decisions be made. Additional comments were made on the possibility to share the insights from the questionnaire related to the digital health across countries relevant for one of the key eHN Work Plan priorities. The Contractor responded that 45 different twinnings will be suggested depending on what MS provide in the catalogue and advised MS to provide transparent responses on their needs and what they can offer.

SE requested more time to be given for answering the questionnaire due to upcoming public holidays in July.

NO asked for clear definitions of concepts, such as national EHR. The contractor stated that the definitions can be found in the catalogue and the team is happy to offer support to the participants via email or call.

5. Presentation of the Swedish eHealth Agency

The Director General of the Swedish eHealth Agency addressed vital questions regarding eHealth and presented the agency's activities and goals. As the national eHealth contact point at the EU level, the agency provides digital solutions for health systems. The agency aims at developing legislation that supports technological innovations, accessible national infrastructure for healthcare providers, and data exchange. Currently, the SE government is working on several initiatives on achieving national digital infrastructure and the promotion of research and innovation. Ultimately, the Swedish eHealth Agency aims at cooperation at the national and EU level to make healthcare data available throughout the entire healthcare chain.

6. EU Funding Opportunities

6.1 Digital health actions under work programme 2023 of EU4Health (for information)

EU4Health is the EU's main programme investing in cross-border digital health infrastructures. In its 2023 work programme, it foresees EUR 26 million for the European Health Data Space. The grants for the enhancement of MyHealth@EU (including vaccination card services) are EUR 4 million, while the grants to support semantic interoperability are EUR 5.4 million. In the area of primary uses of health data, the following grants are included in work programme 2023:

- DI-g-23-75 Direct grants to Member States' authorities: increase health data semantic interoperability and build national capacity on health terminologies (EUR 5.4 million)
- DI-g-23-77 Direct grants to Member States' authorities: development and enhancement of MyHealth@EU services, including vaccination card services (EUR 4 million)

With the first action, EU4Health will support the increase of health data semantic interoperability by supporting Member States to join SNOMED International and/or to acquire or renew the annual licenses. With the second action, EU4Health will support pilots for the implementation, integration, deployment, and operation of Member State services in MyHealth@EU, taking advantage of widespread use of smartphones and QR code technologies, based on the example of EU Digital Covid Certificate, with a specific focus on vaccination card services.

The Member States are kindly encouraged to nominate competent authorities and affiliated entities for these actions. The nomination of a competent authority does not commit a MS to implement the action, but it is necessary for the submission of the proposal. The deadline for nominations is 15 September 2023. The tentative opening of the submission period is 16 October 2023, while the hands-on workshop organised by HaDEA and DG SANTE is scheduled for 19 October 2023. The deadline for the submission of proposal is 31 January 2024.

6.2 Current and future health-related calls under DIGITAL EUROPE

The DIGITAL EUROPE work programme 2023-2024 was published in April 2023. Currently, there are two open calls, on Genome of Europe and Federated European Infrastructure for ICU data, as part

of Data Spaces. A call for patient access to data which will be directly supporting the EHDS is currently under review and will be published in the amended Work Programme of 2024. The call deadline for Federated European Infrastructure for ICU data and the Genome of Europe is 26 September 2023. The third health-related topic in 2023 is a procurement action supporting a platform for advanced virtual human twin (VHT) models.

All the information regarding the work programmes can be found online: The DIGITAL Europe Programme – Work Programmes | Shaping Europe's digital future (europa.eu). The call document on Funding & Tenders portal is crucial in specifying details beyond the WP. In addition, a webinar on health-related Calls 2023 is planned for 20 June 2023 – the link to the webinar webpage is https://digital-strategy.ec.europa.eu/en/events/online-webinar-digital-europe-work-programme-2023-digital-health-topics

DISCUSSION:

FR asked whether the XpandDH project is also included in one of the Digital Europe work programmes. It was confirmed to be funded by Horizon Europe.

AT asked for elaboration on agenda point 6.1 and how the funding was distributed within the different projects.

EC clarified that:

- The PATHeD offers patient access to translated health data.
- POTENTIAL focuses on eP/eD use cases
- Upcoming grants on the use of EU DCC in MyHealth@EU focus on the vaccination card.
- On the question of funding, the cost specified is the total including the national contribution

6.3 Non-paper on funding under eHealth Network Work Plan 2023

After the adoption of the eHN Work Plan 2023, the next step is to adopt a non-paper on the funding issues in the next eHN meeting which could then be used to advocate toward relevant entities focusing on digital health implementation. An initial draft entitled "Financing challenges involved in transitioning and implementing the EHDS" has been reviewed by MS and is undergoing edits. The non-paper stresses the importance of the funding for implementing the EHDS in order to achieve its strategic objectives, notably around sovereignty, and to set an example for other sectoral data spaces to come. It also emphasises that Member States must be supported in their preparation and implementation trajectory to guarantee success, thanks to funding commensurate with the ambition, and thus avoid a disappointing launch and weak usage.

The current draft of the non-paper includes the following themes:

I. The European Health Data Space meets a European objective of sovereignty.
II. Establishing the European Health Data Space requires substantial investment in terms of preparation, harmonization, and implementation at both national and European level.
III. What funding instruments are currently available to accelerate digital health in the Member States?
IV. Direction to be taken.

The eHN MS Co-Chair explained that collectively identifying the relevant funding mechanisms and the necessary scale will ensure the sustainability and success of the EHDS in the future.

7. eHealth Network Work Plan 2023 Update

Five breakout sessions took place to discuss the 5 key priorities of the eHealth Network Work Plan 2023:

1) Identify the need for European funding for eHealth infrastructure for health data primary and secondary use of health data;
2) Achieve further technical common choices and formalize our process;
3) Implement European ethical principles for digital health;
4) Assess digital health deployment progress and best practices in EU Member States;
5) Cooperate more effectively, in preparation for the future EHDS board.

Within their discussions, the eHN Co-Chair encouraged participants to broaden their perspective in terms of identification of needs for the breakout sessions, to focus on horizontal policies, and to keep in mind the addressees and use of the non-paper on funding.

7.2. Plenary session to wrap up and agree on the next steps for the implementation of the eHealth Network 2023 Work plan follow up

Room 1 - Priority 1: Identifying the needs for European funding for eHealth infrastructure for health data primary and secondary use of health data

The group noted that the main expected milestone was the adoption of the non-paper by the next eHN meeting in November 2023. The discussion around the expected deliverables was focused on organising dedicated sessions to streamline various topics such as funding at both MS and EU levels, the incentivisation of MS to complete an impact assessment, the deployment of the necessary IT services for further development of the EHDS, as well as the digitalisation of health data and legislation related to it. Important factors to consider were noted to be financing mechanisms while key success factors rest in bringing awareness to MS and others about costs and obligations.

DISCUSSION:

The eHN Co-Chairs noted the need for more information on the costs of the EHDS. The EC also noted that the capacity building questionnaire could be insightful for assessing the funding needs on the MS level.

TEHDAS commented that they have also identified the need to harmonise the expectations of EU funding for the different topics (generic infrastructure, MS infrastructure, EHDS).

Room 2 - Priority 2: Achieve further technical common choices and formalize our process

The expected milestones were considered to be the creation of a Task Force for delivering decision process and harmonisation of the guidelines towards common elements, which has been already started. The group expects to deliver a decision process for technical choices by 30 November and will continue to prioritise collaboration and communication with other organisations and the general public as well as define and improve the work methodology in the Task Forces. The key success factors rest in the smooth transition between the X-eHealth project and JA09, the involvement of experts in relevant fields, and the transparency of the work process.

DISCUSSION:

EC noted that the common assessment for method standards is available online: https://joinup.ec.europa.eu/collection/common-assessment-method-standards-and-specifications-camss.

Room 3 - Priority 3: Implement European ethical principles for digital health

The group determined the inclusion of the ethical principles in the questionnaire/survey + catalogue, the consultation of citizens both at national and EU-level, the translation into EU languages as a prerequisite for the consultation, and the paper on end-user involvement as expected milestones. The expected deliverables are respectively the capacity building questionnaire to be completed in June 2023, the outcomes from the citizen consultation, the European Ethical principles translation into EU languages, and the end-user involvement paper which is to be initiated this summer and delivered in the next eHealth meeting. Regarding modalities, the group believes that the capacity building initiative and consultation of citizens will provide support and insight. They also consider selecting key information from ethical principles before the consultation to be useful in achieving effective communication as well as necessary to coordinate national and EU consultations, including consultation on related topics/initiatives. Furthermore, the use of EC translation services should be available as soon as possible to begin translation. The key success factors are viewed to be in the honest responses from MS for the effective implementation of the ethical principles in the capacity building catalogue as well as the consultation process.

Room 4 – Priority 4: Assess digital health deployment progress and best practices in EU Member States

The group expects the following outcomes: engaging in conversation beyond standardised questionnaires, understanding of success factors (e.g. moving from opt-in to opt-out, incentives, cultural factors), and using available monitoring mechanisms in MS. The discussion on expected deliverables indicated matching agile development with traditional/legacy governance as well as gap analysis (European surveys and national measurements). As a mode of work, the group believes in a mixed-method approach as primary data contexts can vary. Finally, the clear objective of what is planned to be achieved was seen as the key success factor.

DISCUSSION:

The eHN Co-Chair suggested creating and publishing a single web page of agency names working for eHealth as well as digital strategies at the EU-level in order to provide global visibility to the ecosystem.

PT commented on the measurement of digital health development and maturity. Firstly, it is important to clearly define the objectives for developing such an observatory, while taking into account the various ongoing initiatives for monitoring the development of digital health in different countries. EC and MS should work toward establishing a space for measurement activity and toward sustaining a digital health observatory. Telemedicine deployment in the different MS was given as an example of a digital health measurement domain that is lacking.

Room 5 - Priority 5: Cooperate more effectively, in preparation for the future EHDS board

The expected milestones in this group were defined as the collection of input from existing groups (eHN Subgroups, eHMSEG) on how to streamline future governing structures, the inclusion of input regarding ongoing work on governing structure of EHDS, and the enhancement of digital collaboration tool to facilitate work (Confluence) with possibility of calendars for better planning and possibilities for forums. Based on this, the group believes there should be a focus on delivering a paper on existing groups and lessons learned, enhancing Confluence, as well as to hold monthly meetings. To achieve this, the group suggests to create Task Forces, one for primary use and one for secondary use for technical issues, so as to enable discussions on how to address overlapping topics, separate between operational and strategic levels, avoid duplication of work, and facilitate communication. The group also defined as necessary to investigate funding models and conflicts of

interest by having financial leaders/experts. The discussion on the key success factors focused on the retention of knowledge/continuity of services and smooth transition between the different stages.

DISCUSSION:

The eHN Co-Chair suggested that MS along with EC generate a document on the 5 priorities discussed in the meeting in order to identify the next steps as well as the volunteer's responsibility for each priority, which will be then circulated among eHN members.

8. Digital Decade Program

The eHN members were updated on the progress in the monitoring advancement towards eHealth target of 100% citizens having access to electronic health records incorporated in the Digital Decade Program Policy 2030 adopted on 5 January 2023.

Digital Decade e-health composite score serves as a new DESI indicator in the Digital Public Services dimension. The first annual report is on the State of the Digital Decade (SDDR) with EU trajectories is currently still in preparation. Preparatory work included carrying out the study that incorporated regular collaboration with the eHN whose feedback was integrated in the designed methodology, indicator and sub-indicators composition and scope. The baseline data has been collected via a survey, which was verified and completed for 28 countries[1] on 31 March 2023.

Access to e-health records is measured as the nationwide availability of online access services for citizens to their electronic health records data (via a patient portal, or a patient mobile app) with additional measures in place that enable certain categories of people (e.g. guardians for children, people with disabilities, elderly) to also access their data, and the (actual coverage) percentage of individuals that have the ability to obtain or make use of their own minimum set of health-related data currently stored in public and private electronic health-record (EHR) systems. In order to capture the complexity of measuring citizens' access to digital healthcare services, four layers have been introduced composing the overall e-health composite indicator: 1) Implementation of electronic access services, 2) Categories of accessible health data, 3) Access technology & coverage, 4) Access opportunities for certain categories of people. Twelve sub-indicators are arranged in four layers that allow for thematic analysis of Member State progress in different aspects of 'citizens' access.

The EU-average on overall citizens' access to electronic health records reached 71%.

[1] Survey covered 27MS and additionally Norway and Iceland.
As Bulgaria replied to a survey at a later date, the data provided was included in the revised results and the presentation.

Day 2: 2 June 2023

9. WHO Presentation

WHO gave a presentation on their vision for personal health records. Driven by the Global Strategy on Digital Health (2020-2025), WHO's main objectives are to: promote global collaboration and advance the transfer of knowledge in digital health; advance the implementation of national digital health strategies; strengthen governance for digital health at global, regional, and national levels; and advocate for a people-centred health systems that are enabled by digital health.

WHO's strategy aims at reducing the burden of data reporting by identifying global standards for interoperability, enabling health data sharing by using a common digital health architecture, and supporting digital health transformation at national, regional, and cross-border levels by building a regulatory framework.

WHO focuses on digital personal health records by leveraging the SMART Guidelines methodology to digitise and scale provider-side and client-side solutions. However, the implementation of Personal Health Records (PHR) faces numerous challenges at the individual, national and global levels which can be tackled by a global trust network.

The launch of the Global Digital Health Certification Network (GDHCN) has been planned for 5 June, 2023. It will take up the EU DCC with shared values and principles, enabling the secure issuance and verification of health documents across members of the trust network. In short, the GDHCN is 100% Compatible with EU DCC Technical Specifications. It utilizes "transitive trust" to enable rapid onboarding, builds on EU open-source DCC Gateway, and its health content (verifiable digital health certificates) is separated from trust network infrastructure (PKI). Future APIs & use cases will be aligned to WHO SMART Guidelines (HL7 FHIR).

WHO's role in the GDHCN will be as a trust anchor whereby the public key provided by a country's credential authority is verified and distributed by the WHO to members of the trust network. Credentialed documents issued by any member can then be verified by any other member.

The first use case/domain of trust of the GDHCN's is the Digital Documentation of COVID-19 Certificates, which may be followed by the International Health Regulations, the WHO Academy, Routine Immunizations, and Patient Summary over the next years. The outlined role of the WHO is to establish technical and governance policies as well as an interoperable framework, develop common standards for health credentials, run the public key directory, monitor the onboarding process, ensure a secure platform that addresses security and data concerns, and lastly will be the custodian of the system.

The WHO is equipped to support national frameworks and provide guidance and support for regions and countries who wish to use the infrastructure of the GDHCN for their own use cases.

Regarding the timeline, in the first half of June, the WHO GDHCN Trust Network Gateway will go live, followed by a nightly sync of the EU DCC Gateway to the WHO TNG. However, the EU DCC will remain the authority for public keys and replicate updates. In the second half of June, key updates to EU DCC Gateway except for policy for security incidents will be put to a freeze and the WHO TNG will be authorised for public keys. On 30 September 2023, the WHO GDHCN will be eligible to expand to non-EU DCC participants.
The WHO looks forward to Member States' support to contributing expertise and building consensus around trust network leadership as well as engagement and feedback for providing governance, resources, guidance, and reviewing documentation including processes and workflows.

The eHN Co-Chair commented on the successful cooperative effort that has established the EU DCC as the building blocks of the WHO GDHCN which is to be now scaled up globally and expressed EC's eagerness to work with the WHO on future use cases.

DISCUSSION:

SI asked whether a harmonised semantic structure for the future use cases, in particular patient summary, will be in place to avoid issuing multiple patient summaries (e.g. MyHealth@EU, digital wallet, etc.).

The WHO confirmed that there are semantic issues in the patient summary in terms of which codes are being used, therefore challenges are to be expected. However, the FHIR implementation guide facilitated the mapping and interoperability across the different specifications and versions of QR codes in the instance of the DCC is expected to mitigate those semantic challenges in the future. Additionally, as the SMART guidelines will facilitate data representation, the defined data models can be grounded into clinical care or public health use cases and mapped to existing national systems.

EC added that there is no specification yet published for the GDHCN and Patient Summary and those will be most likely based on international standards already used in the EU Patient Summary with minor variations. EC anticipates that eHN work on the previous and future revisions of the Patient Summary Guidelines would be useful at this international level.

DE asked what role WHO envisions with respect to EU standards for personal electronic health records in the context of the global challenges of alignment of healthcare data sharing. DE also inquired about the future development of the EU DCC added services and the respective timeframes and resources. WHO clarified that the funding is provided by voluntary contributions and that WHO is working on identifying long-term resources. It was also explained that since COVID-19 no longer constitutes a public health emergency of international concern, the WHO does not foresee a need for changes to the COVID certificates and believes the governance process can be managed with the continued coordination with the eHN. With regard to the future use cases, a larger governance process will be required, which will be defined along with the other use cases over the next months. The WHO anticipates using the eHN as a potential model for defining of future governance policies and frameworks. Regarding the ICVP, the WHO is working on a proposal that ensures that the International Patient Summary includes all information necessary for the ICVP and noted that challenges in terms of equity issues might occur.

10. HealthData@EU

10.1 HealthData@EU pilot (for information)

EC presented an overview of its supporting actions for secondary use of health data in the EHDS.

In the timeframe 2021-2023, TEHDAS set the foundation and contributed to the proposal for a regulation on the European Health Data Space. The legislative proposal was published in May 2022, followed closely by the launch of a pilot phase for the infrastructure for secondary uses of health data, HealthData@EU. The pilot project builds on the TEHDAS suggestions and will run for the next 16 months to develop and test a smaller version of the infrastructure for HealthData@EU. This work will prepare for its uptake later at EU level. The project brings together health data access bodies, research infrastructures and the EMA and ECDC.

Following the pilot phase, a scale-up phase will begin and will in particular be supported by the direct grants for setting up health data access bodies. Projects funded under these grants are expected to run for 3-4 years and are intended to start by the end of 2023.

At the same time the Capacity Building initiative aims to support Member States to increase the skills of the people that will play an active role in the European Health Data Space. Additionally, the Horizon Europe programme includes a coordination and support action on the data quality and utility label.

Side by side with the scale up actions, a new joint action will be launched to prepare the grounds for implementation. The joint action aims to propose guidelines to support the implementation for the Regulation. The joint action should be launched in the beginning of 2024 and run until 2026.

The HealthData@EU pilot project is planned for 2 years with EUR 5 million in European funding. In order to test a beta version of the HealthData@EU infrastructure, a network of data platforms will be built and tested by concrete cross-border uses cases.

The project will essentially create a first version of the overall EHDS user-journey, covering data discovery, data permit request, data preparation, use of data, and finalisation.

WP5 works on building the technical infrastructure that allows the platforms in the network to exchange information and connect it to the EU central services. WP6 is working on the metadata standards, WP8 on data interoperability, WP7 on common contractual forms and procedures.

Within the first 7 months of the project, the following has been achieved: WP5 has delivered a proof of concept of the network; WP6 has finalised its landscape analysis of available metadata catalogue and has started to work on DCAT-AP validator; WP7 has finalised its landscape analysis of legal frameworks and is starting to work on the common data application form and conditions for data use; and WP8 has delivered first milestones on standards for data interoperability and will continue supporting use cases in terms of data quality and interoperability.

The next step in the project timeline is to report on the overall progress in the mid-term general assembly in October 2023. More information about the HealthData@EU pilot can be found on the project's website, LinkedIn and Twitter. Various opportunities for engagement are available, such as external advisory board and stakeholder meetings.

10.2 TEHDAS update (for information)

An update was provided on the study results and different work packages of the TEHDAS project between 2021 and 2023. A key element in building the EHDS, TEHDAS' objective was to develop principles of secondary use of health data and lay the ground for the legislative proposal.

In WP2 "Dissemination of secondary use of health data", the communication efforts for visibility have been successful with nearly 24.000 visitors to the TEHDAS website in 2022.

WP3 has been working on evaluation of the project plan and the final internal evaluation is currently being completed.

WP4 worked on "Outreach and Engagement with stakeholders" as well as on "Achieving long-term Sustainability". Project and policy forums have been organised to facilitate engagement. In the project's forums, EU projects working in the field have been invited to discuss relevant topics to secondary use of data. In the policy forums, all MS via the Ministries of Finance, Health, and Research were invited for discussions and consultations. the team is currently finalising the sustainability plan after conducting a preliminary study on the funding sources.

WP5 on "Sharing Data for Health" developed options for governance models and recommendations on national legislations for secondary use of health data.

WP6 worked on excellence in data quality and have been providing recommendations on standards on interoperability for data discoverability, semantic interoperability, and nodes communication

WP7 “Connecting the Dots”, provided options for the technical interoperability of the secondary use of health data and for fostering the participation of future users in the EHDS. External advisors from multiple domains contributed to the implementation of this work package.

WP8 on “Citizens” focused to obtain a better understanding of citizens’ attitudes towards sharing their health data, identifying ways to inform and empower citizens around the use of health data.

As a new joint action is in preparation, eHN members were encouraged to nominate competent authorities for the project before September 2023.

In the context of the ongoing preparation for the EHDS Board, the eHN Co-Chair called for discussions and knowledge exchange on the project among all Member States.

11. Update on Proposal for regulation on EHDS (for information)

An overview was provided on the status of the Proposal for EHDS Regulation.

Within the Council of the EU, the FR Presidency started the examination of the proposal in the first half of 2022, which was continued by the CZ Presidency. The latter concluded the first examination of the proposal and put forward the first Presidency compromise test for Chapters II and III. In 2023, the work continued under the SE Presidency who tabled several Presidency compromise texts on Chapters I and IV to IX. In May, they presented the second compromise proposal on the whole text.

Within the European Parliament, the ENVI and LIBE committees deal with the file in a joint committee procedure, with ITRE and IMCO being associated committees. ENVI/LIBE have drafted a report which was published on 10 February 2023. The deadline for the tabling the amendments was due 29 March 2023. The vote was held in IMCO and ITRE on 23 May 2023, and the vote ENVI/LIBE is foreseen for July 2023. The plenary vote is expected sometime in September 2023.

The eHN Co-Chair stated that EC continues to believe the Regulation should be adopted before the next European election and that it acts as a firm point of reference for the EHDS implementation.

DISCUSSION:

FR inquired about the planned timeframe to begin the trilogues.

EC responded that both co-legislators are aiming to have an agreement during the current EP mandate.

12. COVID-19

13.1 Update on the EU DCC (for information)

The next steps for EU DCC are to prepare its integration into the WHO GDHCN which launches in June 2023. Currently, there are ongoing pilots with multiple MS. Once the WHO Gateway is launched, the piloting will be extended to third countries. While COVID-19 is the first use case for the GDHCN, there are further possible uses for the system such as the digitisation of the International Certificate for Vaccination and Prophylaxis amongst others.

On 5 June, 2023 a proposal for a Council Recommendation will be adopted. The goal is to enable a smooth transition of EU DCC countries to the WHO GDHCN. In light of the EU DCC regulation expiry after 30 June 2023, the reactions from the MS, and the WHO’s declaration on 5 May that

COVID-19 no longer constituted a "public health emergency of international concern", EC has decided to go forward with a proposal for a Council Recommendation.

The Council Recommendation would focus on the following:

- To encourage MS to join the WHO Global Digital Health Certification Network
- MS should issue and accept certificates for international travel as needed, and
- To encourage the Member States to follow and participate in the further development of the WHO Global Digital Health Certification Network, such as its expansion to other diseases beyond COVID (e.g. the digitalisation of the yellow booklet or routine immunisation), or other possible uses in the health context.
- To enable the Member States to stay connected to the EU DCC Gateway for a transitional period to ensure continuity, including vis-à-vis third countries that connected to the EU DCC Gateway, and the smooth uptake of the system by WHO. Adoption of the proposal for the Council Recommendation is planned for 5 June.

Call for interest for piloting countries was sent to the eHealth Network members on 27 April, wherein 8 MS expressed interest to join the pilot. Those participating in Wave 1 (EE, ES, HR, LV, NL) have been already onboarded to the test environment, while those in Wave 2 (BE, SE), and Wave 3 (FI) are in progress – the waves overlapping. More MS are welcome to join the onboarding community. EC noted the application received by LT on 1 June.

Materials on the current state of play are available on the WHO GitHub: FHIR.WHO.SMART-TRUST\Home -FHIR v4.0.1 (worldhealthorganization.github.io).

DISCUSSION:

PL asked for confirmation on whether MS would need to devise their own legal basis on the national level in order to continue issuing certificates in the new infrastructure.

EC confirmed that all necessary measures should be adopted by MS to connect to the GDHCN, including, if necessary, adopting a legal basis at the national level to continue issuing certificates.

EE asked for clarification on what the launch on 5 June, 2023 comprises. It was clarified the launch entails the press release and the adoption of the proposal for a Council Recommendation.

NO revisited the question on the governance process and the need to establish a common agreement on how MS and EC should be involved in WHO's work, as the WHO does not have the same involvement structures/legal basis as the EC. NO also asked whether the public keys for the EU DCC will be transportable and whether the Commission or WHO take over these key or are they national responsibility.

EC explained that for the EU DCC there is backward compatibility. EC is in contact with the WHO on how to best proceed in the event of a COVID-19 use case in the future that may require updates (e.g. new vaccines). A proposal on new vaccine codes could be adopted from the eHN as the WHO is open to their support.

Regarding new use cases, it has not yet been defined how they are going to be shaped. However, EC is in direct contact with the WHO on defining new use cases and the first use case after COVID-19. On the question regarding the public keys, there is readiness to transport the keys for MS and third countries on the WHO level. Currently, the keys are in the EU DCC gateway and there is still time for discussion. eHN members have been asked about the proposal for automatic transfer of the keys in the Tech IOP SG meetings before and are welcome to provide their feedback on the issue.

PT remarked that due to a lack of formal communication with MS, the governance mechanism of the new gateway is unclear and thus a proposal to the respective MS governments cannot be made. PT insisted that the WHO and EC provide clear documentation and governance model.

EC explained that a distinction should be made between the different use cases. With regard to the COVID-19 certificate system, the EU DCC is taken-up by WHO at the global level in order to maintain readiness in case of future emergencies. WHO does not have established bodies for governing COVID-19 certificates and welcomes proposals from the eHN as well as other regions, such as Latin America and Asia. Nevertheless, MS are welcome to participate in the design process of the upcoming use cases, as future use cases model has not yet been shaped by the WHO.

Semantics SG Co-Chair urged MS to strongly engage with the eHN SGs as well as WHO's work considering that changes in the guidelines are to be expected throughout the alignment process with the WHO.

FR supported DE and PT comments and stressed that the need of clarity on a governance model has two different timeframes: (a) clarity on transition towards the WHO, and (b) clarity on the future governance. FR also asked for more information on the ethical framework of the infrastructure, the WHO Academy, and on the legal basis needed at national level. Regarding the key exchange and production of certificates, FR asked how MS should proceed with the key exchange management (centrally or by health professionals given that there might be a high number of keys per country to manage).

ES summarised that clarification is needed on the governance and the MS responsibilities. While ES participates in the pilot, they would appreciate quicker responses from the WHO technical support team.

DE asked whether the legal act that obliges MS to join the WHO will be enforced.

Finally, PT stressed the importance of clearly communicating the new gateway as a pilot initiative to be further developed and legally defined and governed.

Regarding governance, EC explained that the arrangements made are administrative and not legally binding, yet it is an important element in influencing the discussions on the next steps. Despite the areas of uncertainty, EC intends to continue negotiations with WHO to ensure continuity of EU values and standards at the centre of future use cases.

EC is to follow up with WHO to ensure more clarity is provided on the points commented as well as to ensure a possibility for MS involvement in the future development of the system. Regarding DE's comment on the possibility of legal act, it is currently a proposal for Council Recommendation which might be followed by a Regulation Proposal at a later stage depending on the situation.

eHN Co-Chairs commented that the more engagement MS initiate on the EU DCC uptake by the GDHCN, the more EC will be able to influence the future shape of the system. The next steps were summarised as: EC to launch discussion with WHO on a governance model; to follow up on the Council Recommendation; to clarify about the automatic transfer of keys from the EU DCC, and about the role of onboarded MS in the GDHCN.

13.2 Contact tracing apps (EFGS) (for information)

EC updated participants on the contaact-tracing applications and the EFGS. After the last MS were offboarded in February 2023, the EFGS has been discontinued and the ECDC is currently in charge of

the post-retirement activities. During its operational period, almost 80 million keys were exchanged across 19 countries with most of the traffic coming from DE.

The ECDC is currently working on the post-retirement activities to ensure the availability of the EFGS should it need to be reactivated.

Regarding the reactivation procedure, two scenarios have been identified: a COVID-like scenario and the New Health Threat scenario. In the former scenario, no major changes will be needed, while in the latter, the reactivation procedure might take longer.

13. Swedish Presidency presentation

The Swedish Presidency updated participants on their work in 2023. The main tasks of the Ministry of Health have been political priorities (pharmaceuticals, antimicrobial resistance (AMR), aging population), planned meetings (an informal EPSCO Health in June; a high-level meeting on AMR in March; two presidency expert conferences on health) and negotiations, such as the EHDS, SOHO, EMA fee negotiations. The EHDS negotiations under the SE Presidency have been chaired by the Ministry of Health and supported by the SE eHealth Agency and the National Board of Health and Welfare. 12 to 13 Working Party meetings have been planned focusing on secondary use, and compromise proposals will be presented covering the entire EHDS Regulation. In addition, the SE Presidency is currently working on a progress report to be presented at EPSCO in June and the hand-over process of the presidency to ES. Other agencies that have made contributions to the work of the SE Presidency are the Medical Products Agency, the TLV (authority for pricing and reimbursement of pharmaceuticals), Public Health Agency of Sweden, the Health and Social Care Inspectorate, and the National Board of Health and Welfare. The SE Presidency is in the process of concluding the current Trio-Programme and wishes the best of luck to the new Trio ES, BE, HU.

14. Spanish Presidency presentation

ES thanked the SE Presidency for their valuable work and expressed their anticipation in taking over the Presidency. They proceeded with giving a presentation on their national infrastructure on primary use as well as their strategy in preparation of their Presidency.

The components of the ES national infrastructure on primary use are the national Electronic Health Record Exchange System, the national and cross-border ePrescription/eDispensation system, and the national master patient repository. ES's implementation of the Patient Summary and ePrescription/eDispensation is an extension of the national services which were mapped to the primary use of the EHDS regulation.

The ES deployment of Patient Summary A/B allows sending information about most of the population and enables health professionals to retrieve information from other MS. In Wave 5/September 2023, 80% of ES population will be covered. Regarding the deployment of the ePrescription/eDispensation A/B, ES aims for 100% population coverage as well as full interoperability with other MS who have PS and eP/eD A/B available. EU funding of PS-A/B and eP/eD-A/B services has been secured for 100% of Spain's regions.

ES strategy on digital health envisage to have interoperable and intelligent EHRs advancing beyond the recording of assistance provided making patient interaction and control compatible with the use of their data through the incorporation of new technological capabilities and new data sources.

Concerning medical imaging, the digital transformation of diagnostic processes makes it possible to make information immediately available to health professionals regardless of their location. There is currently a national pilot based on FHIR and OpenEHR for Laboratory Results. Lastly, ES wishes to make use of virtual reality (augmented and mixed) as well as additive printing laboratories for prototyping and personalized healthcare devices and remotely managed robotic devices:

ES national strategy for digital health can be consulted at:
https://www.sanidad.gob.es/ciudadanos/pdf/Estrategia_de_Salud_Digital_del_SNS.pdf

A national conference and eHN Semantic & Tech IOP SG joint-meeting will be held in ES from 27 to 29 September 2023. Participants are welcome to both SG meetings and the joint-session at the national conference.

The meeting was adjourned. The next eHN meeting will be held on 28 November 2023, in Brussels.