Deliverable 4.2

Policy and Project Forums report

Engaging with national and international stakeholders and initiatives.

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0 Document info

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1 Executive summary

TEHDAS work package 4 (WP4) aimed to reach out and engage with national and international stakeholders, to reflect on their needs and expectations for the future European Health Data Space (EHDS). In particular, task 4.2 set up two different Forums to engage with the relevant stakeholders with regards to the EHDS: Policy Forums and Project Forums. Four Policy Forums and four Project Forums were organised between May 2021 and December 2022.

This document presents the methodology used to invite participants and develop the discussion topics for each Forum. Regarding the Project Forum, an open call procedure was initially used, in which relevant projects/initiatives were invited to apply. Thereafter, more projects/initiatives continued to be identified, and the Project Forum was actively promoted on the TEHDAS communication channels. By contrast, the Policy Forum was an invite-only event, bringing together policymakers designated by ministries of health, ministries of research, and ministries of economy or finance. The invitations were distributed through the health attachés in the Council of the EU, who forwarded them to the ministries of health, research and finance in their respective countries. This also ensured that the invitations reached countries not in the TEHDAS consortium, as well as those within it.

This document then presents the key discussion points from all the Project and Policy Forums. The aim of the Project Forums was to incite dialogue and collaboration between different EU projects working on health data sharing and secondary use. The discussions generally followed the format of the themes of the different TEHDAS work packages (WPs): data governance, data quality and interoperability, technical infrastructure, and citizens' engagement. In general, there was good discussion between projects.

The Policy Forum aimed to bring together policymakers representing different ministries and countries, to incite cross-ministerial and cross-border discussions. The topics of the Policy Forum included the countries' expectations and needs for the EHDS, and views on financial sustainability and funding of EHDS, among others. In general, the Policy Forum was well-received by the representatives, who noted that it provided an informal discussion venue to learn from each other. It was noted that the Policy Forum also indirectly supported several member states in the national processes around the EHDS regulation and increased awareness of the EHDS.

Finally, this document presents the next steps to continue the work initiated by the Project and Policy Forums.

2 Introduction

The Joint Action (JA) Towards the European Health Data Space (TEHDAS), helps EU Member States (MS), Associated Countries (AC) and the European Commission (EC) to develop and promote concepts for the secondary use of health data to benefit public health and health research and innovation in Europe.

More specifically, work package 4 (WP4) aims to reach out and engage with national and international stakeholders, to reflect on their needs and expectations for the future European Health Data Space (EHDS). This work underpinned the legislation on the EHDS.

WP4 engages with stakeholders at different levels to ensure their opinions, needs, and expectations are considered in the development of the EHDS. One of the engagement activities by WP4 was the setup of two Forums providing discussion platforms for two stakeholder groups: EU project representatives and policymakers.

The Project Forum brought together representatives from EU projects and initiatives working with health data and on the secondary use of health data, as well as health-related research infrastructures. The aim of the Project Forum was to present the TEHDAS activities to European experts and initiatives, initiate collaborations and learning, and ensure that TEHDAS builds on already existing results and expertise.

The Policy Forum was set up to bring together representatives from three ministries from MS/AC. Ministries of health, ministries of research, and ministries of economy or finance were included, given their respective relevance to the EHDS. The aim of the Policy Forum was to bring together representatives of these three ministries, to encourage cross-border and inter-ministerial discussions, reflecting on the needs and expectations of the EHDS from the perspective of diverse policy makers. The Policy Forums also explored views on the economic sustainability of the EHDS.

Throughout the duration of TEHDAS, four Policy Forums and four Project Forums took place. This document presents the minutes and a summary of the discussions in the Forums. The full sets of minutes from all the Forums are included in the Annex 2 and Annex 3 respectively.

3 Methodology

3.1 The Project Forum

Call for participation and selection procedure for Project Forum

On 1 March 2021, a call for participation was launched by the TEHDAS coordination team through the TEHDAS website, to join the Project Forum, Stakeholder Forum, and the different advisory groups of TEHDAS. The call was open for three weeks. For the Project Forum specifically, any interested EU project/initiative or research infrastructure could apply to join. The interested projects/initiatives applied by filling in a survey to provide relevant information for which forum or advisory group they wish to join. The questions for the open call included four general questions and one specific question for the Project Forum.

The general questions from the open call:

1. Which groups or perspectives do you represent that are related to the European Health Data Space?
2. How does the development of the European Health Data Space impact you?
3. What experience and knowledge do you have that is relevant to the TEHDAS Joint Action?
4. How can you contribute to the TEHDAS Joint Action?

Specific WP4 added question:

1. Do you represent a project or an EU initiative that has experience in the secondary use of health data operating across and within European countries? Please provide details of your project or initiative.

The open call rendered more than 100 applications from different projects/initiatives with experience in the secondary use of health data operating across and within European countries. All projects/initiatives that applied were invited to the first Project Forum. This open call procedure was used for the first Project Forum to ensure that the appropriate audience were invited. However, the number of projects was not limited.

It is important to note that after the open call, the team continued screening the landscape for new projects and initiatives to be included. In addition, a snowballing approach was used for the subsequent Project Forums: participants were allowed to forward the event to relevant contacts in their network, and the Project Forum was actively promoted through the TEHDAS social media channels.

Selection of topics of each Forum

Four Project Forums were held throughout the TEHDAS JA. The selection of topics for discussion was a collaboration between the WP4 team, the TEHDAS Work Package Leads (WPLs) and the European Commission (EC).

It was important that the topics of the TEHDAS work packages (WPs) were represented during the discussions. During the planning of each Forum, a preparatory meeting with the WPLs took place, in which the WPLs were able to present any specific topic they would like to discuss or suggest a project/initiative to present to share experiences. Furthermore, the WPLs were able to provide any specific questions to put to the Forum participants, if specific input was helpful. As such, the topics also evolved with time, in line with the progress of TEHDAS and evolutions in the landscape (e.g., the publication of the EC's proposal for the EHDS regulation). The specific topics discussed in each Project Forum are outlined in the Results section.

Finally, at the end of each Project Forum, an online survey (using the online tool Mentimeter) was launched to ask the attendees to evaluate the Forum and suggest topics for the next Forum.

3.2 The Policy Forum

Invitation for Policy Forum

In contrast to the Project Forum, the Policy Forum was an invite-only event, as the objective was to bring together policymakers to incite cross-ministerial and cross-border discussions.

To reach as many MS/AC as possible and select the right representatives to join the Policy Forum, multiple channels were used. A standard invitation was prepared and signed by the Scientific Director of Sciensano, the TEHDAS partner responsible for the organisation of the Project and Policy Forums. In the invitation, ministries were asked to designate and provide contact information of two persons to attend the Policy Forum. To complement the invitation, a one pager describing the overall objectives of TEHDAS and of the Policy Forum was developed. The invitation and one pager can be found in the Annex 1.

In terms of dissemination, invitations were first sent to the partners of the TEHDAS consortium to be forwarded to their network and contacts at the different ministries. Secondly, invitations were sent to all countries' health attachés in the Council of the EU, to forward the invitation to the appropriate representatives in their countries. This ensured the invitation also reached MS/AC who are not part of the TEHDAS consortium.

Selection of topics of each Forum

Four Policy Forums were held throughout TEHDAS. The selection of discussion topics was a collaboration between the organisers, the TEHDAS WPLs and the EC. The topics for the Policy Forum followed a logical progression in line with the EHDS regulation developments.

During the planning of each Forum, a preparatory meeting with the WPLs and representatives from the Directorate General for Health and Food Safety (DG SANTE) took place. This was important to align the developments both at TEHDAS activities level, as well as the developments of the EHDS proposal for regulation. Specific topics were selected in agreement and evolved accordingly. WPLs provided specific topics they could present to the ministries to inform them of TEHDAS's ongoing activities. Multiple presentations were also provided by the EC at different stages of the EHDS proposal.

To facilitate the discussion, surveys were prepared and sent to the representatives before each Forum. The survey questions served as preparatory material for the ministry representatives and were also used to guide the discussions during the Forums. The survey questions were the following (see table 1):

Table 1: Preparatory questions sent to the participants prior to each Policy Forum

Policy Forum number	Preparatory survey questions
Policy Forum #1	1. What are your expectations of the European Health Data Space (EHDS)? 2. How do you think the European Health Data Space (EHDS) can benefit your ministry? 3. Please give us an example of successful data exchange and use across sectors in your country. Why has it been successful?
Policy Forum #2	1. National single information point:

	a. What do you think a national single information point is or should be? (Ref. Art.8 of the Data Governance Act) b. How would you estimate the feasibility of having a single information point in your country? c. Do you have a similar structure already existing in your country? Or are you in the process of developing this? 2. User's journey for the EHDS: a. As a user, what services would you expect the European Health Data Space (EHDS) to provide (data discoverability, data accessibility and/or data analysis)?
Policy Forum #3	1. National contact point a. What progress has been made in the last 6 months regarding the national contact point for the EHDS for secondary use in your country? As defined in the legislative proposal under "Definitions" in chapter 1, article 2." 'national contact point for secondary use of electronic health data' means an organisational and technical gateway enabling the cross-border secondary use of electronic health data, under the responsibility of the Member States;" b. Is there an already established national contact point for the EHDS for secondary use in your country? if yes, who or which authority or institute is it? 2. Financial sustainability for the EHDS for secondary use a. In your opinion, what funding models could be considered for the financial sustainability of the EHDS for secondary use, in the long-term? (Feel free to provide existing examples of such models.) b. What do you think of the possibility to implement a fee policy for the users of the EHDS for secondary use (e.g., researchers and policy makers)? Would this be feasible in your country? 3. Multi-country data application requests and mutual recognition a. What do you think of the concept of mutual recognition within the EHDS for secondary use? Refering to mutual recognition in case of multi-country data access application requests (Article 54 of the legislative proposal)
Policy Forum #4	1. National contact point a. What progress has been made in the last 6 months regarding the national contact point for the EHDS for secondary use in your country? As defined in the legislative proposal under "Definitions" in chapter 1, article 2." 'national contact point for secondary use of electronic health data' means an organisational and technical gateway enabling the cross-border secondary use of electronic health data, under the responsibility of the Member States;"

	b. Is there an already established national contact point for the EHDS for secondary use in your country? if yes, who or which authority or institute is it? 2. Needs for implementation of EHDS for secondary use a. From your perspective as Ministries, what are the needs in your country to start implementing the EHDS for secondary use? b. Have you applied for direct grants for capacity building to fulfil those needs? What do you plan to use them for? c. Have you had discussions with different stakeholders in your country (e.g. data holders, data users, etc.) with regards to the EHDS implementation, how it will affect them, their needs and expectations? If so, please provide further information.

At the end of each Forum, an online survey (using the online Mentimeter) was launched to ask the attendees to evaluate the Forum and suggest topics they would like to discuss or be further informed about during the next Forum.

3.3 Results

After each Forum, TEHDAS issues a news article to provide an overview of the discussions that took place during the Project and Policy Forums. The full minutes of all Project and Policy Forums have been included in Annex 2 and 3. For data protection reasons, all participant names have been removed, apart from the speakers as named in the agendas. In addition, no country is identified in the minutes of the Policy Forum, as was agreed with participants in the forums. The Policy Forum was following Chatham House rules to stimulate a genuine and interactive exchange.

Table 2: Dates of each Project and Policy Forum during TEHDAS

Forum	Date	Month
Project Forum #1	18-19/05/2021	M4
Policy Forum #1	28/06/2021	M5
Project Forum #2	29/10/2021	M9
Policy Forum #2	29/11/2021	M10
Project Forum #3	22/06/2022	M17
Policy Forum #3	29/06/2022	M17
Project Forum #4	15/12/2022	M23
Policy Forum #4	30/12/2022	M23

Project Forum #1

The aim of the first Project Forum (18-19 May 2021) was to hear from projects working and sharing health data across borders, to initiate collaborations between TEHDAS and other projects. The Forum was organised around the main topics covered by the TEHDAS JA, with different projects/initiatives pitching in each session:

- Topic 1: Sharing data for health – Frameworks and governance principles
- Topic 2: Semantic interoperability, data quality assurance
- Topic 3: Service and architectural technical interoperability
- Topic 4: Citizen engagement

Within each topic, the WPL of the corresponding TEHDAS Work Package presented their planned work and activities. This was followed by project pitches related to that topic area. Each project/initiative was asked to address the following key questions in their pitch presentation:

1. What do you do with regards to this specific topic that could be of interest to TEHDAS?
2. What can we learn from your experience? What should we build on?
3. How would you like to get involved with the EHDS? How do you see your collaboration with the EHDS?

50 projects and initiatives attended the first Project Forum, 13 of which gave pitch presentations, including: Beyond 1 Million Genomes (B1MG), SNOMED, DARWIN, EHDEN, RD-CODE, PHIRI, IN-4-AHA, InteropEHRate, MyData, H2O Observatories, Personal Health Train, and Gravitate Health. In addition, there was a presentation on the study 'Assessment of the EU member states' rules on health data in light of the GDPR', which showed many differences between countries in the interpretation of the GDPR.

Potential areas for collaboration with TEHDAS that were identified by the projects included: data harmonisation and interoperability, GDPR interpretation, sharing concrete findings on data quality and metadata, sharing learnings on how citizens want their heath data to be used, and leveraging initiatives' previous experience and difficulties encountered (e.g., implementation of interoperability standards).

Participants were separated into smaller breakout sessions, all of which covered the topics of technical interoperability and citizens' engagement. There were in-depth discussions on the technical infrastructure, for instance on lack of interoperability and system integration. In terms of the technical infrastructure for the EHDS, at the beginning of TEHDAS all possible options were considered (from centralisation to a distributed model). Several participants in the first Project Forum expressed a preference for federated or hybrid models.

Project Forum #2

The second Project Forum took place five months later (29 October 2021) and brought together 130 participants from 23 countries. It took a step further in diving into the different TEHDAS WPs and their initial findings. The Forum started with a presentation from the TEHDAS WPLs, presenting the progress in their work, as well as future planned activities.

WP5 on governance focused on the work done to achieve milestone 5.3 'GDPR interpretations in the secondary use of health data in different Member States and other participating countries'. WP6 on data quality presented its first published milestone, which provides recommendations on elements that should be legally bound within the data quality assessment framework. WP7 on the technical infrastructure presented the main initial findings from the Work Package Advisory Group (WPAG), which included the first outline of the overall architecture and the user journey of the EHDS for secondary use. WP8 on citizens' engagement presented the work planned for a consultation to understand citizens' perceptions, preferences, and expectations on secondary use of their health data.

Based on feedback from participants from the first Project Forum, breakout sessions then took place, in line with the different TEHDAS topics. The four breakout sessions were:

1. Harmonisation of GDPR interpretation
2. Governance elements of data quality
3. Individual data linkage cross-domain at regional/national/European level
4. Citizen's engagement

Each TEHDAS WPL proposed specific questions to be addressed in the breakout session corresponding to their area of work. The questions are presented in table 3.

Table 3: Preparatory survey questions for each of the four Policy Forums

Breakout session	Questions
Harmonisation of GDPR interpretation	TEHDAS and other projects have identified wide differences in GDPR interpretations across EU countries, hindering cross-border sharing and re-use of health data. 1. Have you faced such a challenge before in your work, and if yes how did you overcome it? 2. How, in practice, can EU achieve alignment for better GDPR interpretation across countries? 3. What do you think should be the position of the EHDS on this topic to improve this?
Governance elements of data quality	Setting up proper governance mechanisms to data quality is key, particularly in federated approaches: 1. What mechanisms should be used for data holders to become trustworthy nodes in the BBMRI federation? A way forward to increase data quality may be setting up "auditing and promotion" (A&P) procedures – auditing according to standards, and promotion according to improvements in data holders' maturity: 2. What is your experience on A&P approaches? 3. What are the 'must' items to audit data holders on data quality assurance?

	4. Any thoughts about legal enforcement on A&P mechanisms? 5. Any thoughts about incentivising data holders' maturity? 6. Any alternatives to A&P mechanisms?
Individual data linkage cross-domain at regional/national/European level	1. How can we link individual data coming from different domains (e.g., healthcare providers, research infrastructures, registries, medical societies, personal devices)? What are the technical challenges? 2. How can we process the linked data across countries? What are the architectural challenges? Can we move data between countries? And algorithms?
Citizens' engagement	3. Can consent withdrawal or modification create legal uncertainty for researchers or innovative businesses which have obtained data through recognised/registered data altruism organisations? If so, how? 4. Are there any specific security and privacy features or requirements of providing health or health-related data for research and scientific purposes, compared to other data sharing/access, e.g., travel or purchase/rent of real estate or banking? If so, which are they? 5. The different possible forms of citizens' involvement in health data secondary use and sharing systems.

Participants were able to select which breakout session they wanted to participate in via a registration form prior to the Forum. In each breakout session, a project presented about their work on that topic. The projects that pitched were: X-eHealth, BBMRI, EOSC-Life and Smart4Health. Discussions in each breakout room then centred around the questions posed per room.

On GDPR interpretation, a key discussion point was that, although when GDPR was being discussed there was pressure for national derogations, the problems of a fragmented system are now being recognised. There is now increasing pressure for harmonisation.

On data quality, there was a long discussion on incentives for quality assurance. Participants noted that there are already many incentives for data quality (e.g., in the hospital sector) but these can introduce financial bias and skew data. Certifications were discussed as an option to ensure that data holder become trustworthy nodes in a federation. However, it is important that they are accompanied by incentives as they can become costly. On auditing and promotion (A&P) mechanisms, there was general agreement that audit should focus on

procedures at institutional level rather than the substance or content of individual data sources.

On cross-domain individual data linkage, it was highlighted that technical challenges are sometimes not the most challenging. Regulatory challenges are difficult to solve. An interesting point was that technical solutions can be used to solve legal barriers (e.g., technologies that allow data analysis without moving from the original source). Personal identifiers were the final discussion point. There is no standard system for identifying patients in all countries. The question raised whether an EU recommendation is needed to harmonise patient identifier practices to facilitate data linkage within and across countries.

On citizens' engagement, different consent models were discussed (e.g., broad consent, dynamic consent). Examples were provided on how apps can provide technological solutions for dynamic consent. Importantly, citizens' involvement should not be restricted to consent. Citizens must be active participants in the operation of data sharing activities, systems and projects.

Project Forum #3

The third Project Forum took place on 22 June 2022. It brought together over 120 participants from 23 countries. The discussions centred on the European Commission's Proposal for a regulation on the European Health Data Space (EHDS), which had been recently published on 3 May 2022.

The Project Forum started with a presentation on the EHDS proposal by representatives of the European Commission. The regulation is in two parts: primary and secondary use of health data. The main objective is effective use of health data. On primary use, all member states will be required to participate in the MyHealth@EU cross-border infrastructure. On secondary use, the proposal creates a new infrastructure for secondary use, HealthData@EU. It was explained that some of the main provisions of the proposal regarding secondary use include:

- A set of minimum categories of health data
- Allowed and prohibited purposes for secondary use of health data
- Setting up a health data access body/bodies (HDABs) for secondary use of health data, building on the Data Governance Act
- Tasks and obligations of the HDABs
- Implementation of data altruism in health
- Duties of data holders
- Provisions on transparency and structure of fee calculations
- Penalties by HDABs
- Conditions and requirements for a data permit
- Development of a new decentralised EU cross-border infrastructure, HealthData@EU
- Provisions on cross-border access and mutual recognition
- Provisions on dataset description and quality, establishment of an EU Dataset Catalogue

The general design for the architecture is that data stays with data holders, data users can come from any country in Europe, and the cornerstones for the decentralised framework are the HDABs. Other authorised participants include data sharing infrastructures, and European level agencies who need access to data for their function (e.g., EMA, ECDC).

The TEHDAS WPLs then presented the progress in their work, and how their work would change considering the EHDS proposal. WP4 on outreach, engagement and sustainability presented the methodology and initial findings from the first eight country visits performed. The aim of the TEHDAS country visits was to provide the state-of-play of health data management systems, and countries' preparedness to join the EHDS. WP5 on data governance presented the progress so far, and the plan to add a milestone looking at how to make multi-country and cross-border data requests work in practice. WP6 presented the progress made in terms of defining a data quality framework, following the different steps in the data life cycle. WP7 on the technical infrastructure outlined progress made in defining the user journey and general architecture for the EHDS for secondary use. Each step in the user journey had been populated with the associated services (software components that provide functionalities). WP8 presented the initial findings of an online citizens' consultation performed, including a conceptual framework on the citizen's voice in the EHDS. The online consultation was carried out among citizens of three countries (Belgium, France and UK) to garner insights on how citizens want their health data to be used.

There were then presentations from four projects/initiatives on how their work relates to the EHDS for secondary use. The projects/initiatives that presented were: Health-RI, IN-4-AHA, Data Saves Lives, and SHAPES.

There were then four breakout sessions on specific topics from the EHDS proposal:

1. Health data access bodies (HDABs) and EHDS Board
2. HealthData@EU cross-border health data access infrastructure and secure processing environments
3. Data quality aspects
4. Citizens' engagement, link to the Data Governance Act and consent

On HDABs and the EHDS Board, there are a lot of questions regarding their roles and tasks. Participants noted that there is a long way to go to establish HDABs in many countries. The discussion on the EHDS Board focused on its role, composition, who would chair it, and how it would relate to other governance elements (e.g., ethical committees, data protection authorities).

The discussion on data quality mainly focused on the data quality and utility label proposed in Article 56 of the proposal. A lot of questions were raised, such as the depth of data covered by the label, how anonymisation and pseudonymisation would be dealt with, and who would apply the label. Many participants noted that a two-step approach for applying the label would be needed.

The breakout room on the HealthData@EU infrastructure noted the importance of secure processing environments (SPEs), and the need for a central SPE provided by the European Commission. There is a need for standardisation in SPEs to ensure trust.

The breakout room on citizens' engagement started by discussing consent and the importance of giving individuals control over their data and how it is used. It was noted that the description of HDABs in the EHDS proposal describes that these authorities should take citizens'/patients' opinions into account, but not the way in which this should be done, or the power that their recommendations or demands would have. In addition, if countries all have different consent models, this interferes with interoperability. It is important to find a common framework or baseline.

Project Forum #4

The fourth and final Project Forum took place on 15 December 2022. It brought together 165 participants from 25 countries. The discussions went more into depth on specific topics that the TEHDAS WPLs identified as being particularly relevant to their work.

The Forum started with presentations by the TEHDAS WPLs on the work completed so far. WP4 presented the overall findings from all 12 country visits carried out between December 2021 and December 2022. The ensuing discussion with participants focused on the need expressed by stakeholders for guidance regarding differing interpretations of GDPR, and how best to provide this. Another discussion point was how to increase health data literacy in both healthcare providers and citizens. WP5 on governance aspects noted that guidelines for European countries when planning national legislation on secondary use of health data, and guidelines for multi-country data access requests, were being finalised. WP7 on the technical infrastructure presented the data lifecycle, which extended the previously developed user journey to include both the user interaction and the data preparation (the data holders' journey). After the EHDS proposal, WP7 had extended its work to cover three additional areas: guidelines for national dataset catalogues, guidelines for data permit application management systems, and guidelines for secure processing environments. WP8 presented the two streams of work being undertaken: citizens' engagement and data altruism. On citizens' engagement, the final recommendations on citizen sensitisation to and engagement with health data in the future EHDS were being drafted. On data altruism, a final document was being prepared on recommendations for data altruism. The presentation from WP6 on data quality and interoperability focused on the latest achievement, providing recommendations to enhance interoperability within the HealthData@EU infrastructure. The two main elements in the data lifecycle where this work is applicable are the data preparation (harmonisation, semantic standardisation) and publication (standards that allow discoverability). The final step is to frame the final data quality framework.

The TEHDAS presentations were followed by breakout sessions covering dedicated topics:

1. Sustainability and governance concepts for the EHDS
2. Secure processing environments (SPEs): technical and organisational requirements
3. Data minimisation and purpose limitation: implementation and risks
4. Data altruism and maximising the impact of citizen input for the EHDS

On governance aspects, in particular multi-country data application requests and cross-border projects, participants suggested learning from countries with exchange systems in place and from projects that have established their own federated systems. On sustainability, participants noted the importance of considering data re-use already from the point at which

data is collected. The role of incentives and of training healthcare professionals (without overburdening them) were highlighted. On SPEs (systems that allow sensitive health data to be analysed in a trusted and remote environment), participants noted the importance of collaborating with other projects in the development of SPEs, and to have forums for discussion to find common ground. The concept of data minimisation is that only the data relevant for the research question should be provided to applicants. A detailed protocol and data management plan could suffice to cover the minimisation principle. However, participants noted that the interpretation of minimisation varies even within institutions – there is a need for a common interpretation. Participants noted the practical challenges that come into play with data minimisation, which need to be addressed. In the discussion on data altruism, it was noted that data altruism is regulated in the Data Governance Act and that the concept will be further developed. However, there is concern from citizens and the expert community that more types of voluntary data sharing are needed. The consideration of how data donated through data altruism could be used by commercial entities was also discussed.

Following the breakout sessions, five projects/initiatives presented in a plenary session on how they will interlink with the EHDS for secondary use, the HealthData@EU infrastructure. The HealthData@EU pilot will set up a first version of the European system for secondary use of health data. The two main objectives of the project are to build a network of health data platforms on European scale and develop services, and to test the network and services through use cases (cross border research projects). The Genomics Data Infrastructure (GDI) aims to provide the data infrastructure to support access to the 1+ Million Genomes (1+MG) virtual cohort of genomic and phenotypic data. The HealthData@EU pilot includes a 1+MG use case, which will address how GDI will connect to the EHDS. The aim is to find ways to make both infrastructures as interoperable and connected as possible and benefit from synergies. DARWIN EU is an initiative of the European Medicines Agency (EMA), a federated network for real-world data (RWD) that supports decision-making by generating real world healthcare data. It was noted that in a way, DARWIN EU is a pathfinder in the EHDS, the same way other projects such are paving the way for the EHDS. The knowledge will be transferred from those projects into the EHDS. The Population Health Information Research Infrastructure (PHIRI) was the fourth project to present. PHIRI aims to facilitate population health research across Europe and exchange best practices to support decision making. PHIRI has developed the Health Information Portal (HIP), which provides an overview of main public health databases and how you can access them. PHIRI has been working closely with users of the EHDS. It is key to understand their needs to make the EHDS functional. Finally, the last project to present was HealthyCloud, which is developing a strategic agenda for a Health Research and Innovation Cloud (HRIC), mapping what initiatives exist and what gaps remain in terms of services to be provided for researchers.

Policy Forum #1

The first Policy Forum brought together 70 participants, including representatives of the Ministries of Health, Research and Economy from 21 MS and associated countries. This first Forum set the scene and established a dialogue between the Ministries and TEHDAS around their needs and expectations from the future EHDS. The discussion evolved around three main questions that were shared among the participants in preparation for the Forum (see

table 1 in section 3.2), regarding expectations and perceived benefits of EHDS, and experience of successful data exchange.

A welcome was given by the Portuguese Presidency of the Council of the EU. This welcome stressed the fact that the notion of a health ecosystem is increasingly important. Digitalisation of the healthcare sector involves many organisations that are important to make the EHDS a well-balanced initiative. The EHDS will bring great value to citizens and society, it is about using new digital tools and creating a strong data economy. Furthermore, access to and use of health data are core elements to improve the outcomes and develop proper health strategies. However, access to health data remains the biggest barrier. Finally, the representative indicated the potential of the Policy Forum as an excellent platform for dialogue and creating consensus among MS and stakeholders.

Thereafter, a representative from the EC DG SANTE presented an introduction and overview of the EC's work on the EHDS, and the broader context of the common data spaces across the EU. The main objective of the EHDS is to facilitate timely and simplified exchange of and access to health data. The framework presented for the EHDS for secondary use focused on overcoming 6 main challenges:

1. Sharing health data for healthcare
2. Single market for digital health products and services: Study showing different implementation of GDPR across Member States raises important questions for the single market
3. Access to health data for research, innovation, public health policymaking
4. Artificial intelligence: developing/building new technologies on top of that

The EC representative noted that TEHDAS plays an important role for the developments of the EHDS. The preparation of a pilot project (as a proof of concept) was presented which was planned to be launched end of 2021.

Thereafter, TEHDAS coordination presented the Joint Action, its vision and upcoming activities. A discussion session followed on Ministries' expectations for the EHDS. Expectations included that the EHDS would: improve patient care; improve collaboration and cooperation between experts; help in profiling the population to inform policymaking; provide a harmonised framework for data exchange which may lead to further health research and innovation. Other discussion points included: the importance of a secure environment and a sound legal basis for the EHDS; implementation of the GDPR; and federated and distributed analysis of data.

An intermediate presentation was given by the European Observatory on Health Systems and Policies. An example was provided on cross-sectoral benefits from data sharing from the perspective of exploring ageing and fiscal sustainability.

A second discussion session took place in which ministries then discussed how they believe the EHDS can benefit their Ministry. The main discussion point was improving the findability of data. Furthermore, ministries provided some examples of successful data exchange

across sectors. Examples included: a legislative proposal to establish a technical platform for data sharing where users can use data stored in different national registries; and a data exchange project that merges data across four national archives to evaluate the effects of work on health.

Policy Forum #2

The second Policy Forum brought together 59 participants, including representatives of ministries from 16 MS and associated countries. This Forum aimed to have a discussion on the national single information point and went more into depth on the user's journey within the EHDS and the services the ministry representatives expect from it.

The Forum was welcomed by a representative from the Slovenian Presidency of the Council of the EU. The presidency highlighted the importance of digitalisation in health. The creation of a common EHDS will promote better exchange and access to different types of health data. It will support healthcare delivery as well as health policy making purposes. Cross border sharing of health data has so far been project-based and there is no common legal basis for the secondary use of health data in Europe.

A first discussion round focused on the survey questions that were sent to the participants prior to the meeting (see table 1 in section 3.2). Most ministry representatives interpreted a national single information point as a gateway to information on the available health data and the accessibility procedures. This aligns with the official definition of the single information point described by the Data Governance Act. The representatives also described the single information point as a service that acts as a primary interface with regards to requests for data from other member states or other sectors.

To be feasible, participants highlighted the need for legal clarity over the secondary use of health data, the GDPR interpretation, the necessary infrastructure to be built across the EU and the development of a national health data governance framework. Some ministry representatives highlighted the need to incentivise data sharing and the establishment of a national single information point, especially in countries where the healthcare sector and health data management are privatised. Finally, the importance of citizens' engagement in the authorisation of health data sharing, through patient consent and literacy, was also mentioned.

Next, WP7 from TEHDAS presented their ongoing work on the user journey, providing a proposal of the envisioned architecture for the EHDS, comprised of a network of nodes, linking different entities. The user journey represented the steps that the data consumer will have to take to access and use health data: starting with data discovery and pre-study; permit application, contracts and training; consent collection if needed; data preparation; data access provision; data use; and results output.

Thereafter, the participants were split into breakout sessions to enable further discussion. All breakout sessions covered the same topic, MS's views on the user's journey and the services that should be offered by the EHDS. In a plenary session, a summary of each breakout session discussions was shared. It was mentioned that there is need to make a facility that would allow health data discoverability through the establishment of a public metadata catalogue and an advisory service in each node. Moreover, interoperability which would enable communication across nodes, the consent model and training to improve literacy in each step of the user's journey were discussed. It is important to highlight that some participants expressed their concerns over this proposed user's journey as it does not include the steps needed before reaching health data discoverability.

Policy Forum #3

The third Policy Forum brought together 58 participants, including ministry representatives from 21 MS and associated countries. The discussions focused on the progress made by the member states in assigning a national contact point for the secondary use of health data in the EHDS, the financial sustainability of the EHDS, potential data access fees, and mutual recognition of data access application evaluation.

The Forum was welcomed by a representative of the French Presidency of the Council of the EU, who gave an overview of different activities implemented during the presidency to move forward with the EHDS. The presidency tried to pave the way to the negotiation, first by establishing ethical prerequisites necessary for citizens to trust digital health and to be supportive of the EHDS. After paving the way with ethical principles, it was important to accelerate the journey towards European interoperability. The French Presidency compiled use cases and promoted the adoption and use of SNOMED-CT. The next step was to work on harmonisation of clinical evaluation criteria for Digital Medical Devices (DMDs). All along the presidency, a strong focus was set on making digital health visible for all stakeholders (patients, HCPs, hospitals, innovators, start-ups), by organising events and meetings, as well as participating in TEHDAS events.

A short discussion took place for countries to provide any updates on the developments of their national contact point since November 2021. Countries are at different stages, with some starting to discuss the establishment of a contact point, while others have already established institutions likely to take on the role.

A presentation by representatives from the EC's DG SANTE was provided on the legislative proposal for EHDS. The main objective presented for the EHDS is effective sharing and use of health data. Regarding secondary use of health data, the proposal has specific provisions, including:

- Minimum categories of electronic health data available for secondary use. Defined (and prohibited) purposes for secondary use (Art. 33-35)

- Setting up Health Data Access Bodies (HDABs) (Art. 36) – building on the Data Governance Act. This can be one body or several, depending on the MS
- Tasks and obligations of the health data access body, data holders and data users (Art. 37-39)
- Implementation of data altruism in health (Art. 40)
- Duties for data holders (Art. 41)

The presentation of the proposal also included its provisions on fees and on penalties. Conditions for data permits are being set, including data minimisation and access requirements, such as the requirements for secure processing environment (SPE). There are also provisions for the new decentralised EU cross border infrastructure (HealthData@EU); provisions for fostering cross-border access and mutual recognition; and provisions for data description and quality with the establishment of an EU metadata catalogue. Furthermore, a proposal for the technical infrastructure was presented as a federated network of health data access bodies, data sharing infrastructures and other EU institutions like EMA/ECDC. Core services are considered and are foreseen to be provided by the EC to support the infrastructure. Finally, next steps were presented regarding the negotiations and discussions at the European Parliament and the Council of the EU.

Next, a presentation from the Finnish Social and Health Data Permit Authority, Findata, explained their experience in setting up the authority and the development of the Act for Secondary Use. The aim of setting up the authority and the legislation was to better facilitate access to datasets from data controllers in a timely manner. Lessons learned were also shared. Mainly, these include involving all relevant stakeholders from the start and ensuring a continuous flow of communication through the legislative process and beyond. The importance of stakeholder engagement for the EHDS was also noted.

The model for centralised data requests through Findata was presented, as well as the different services provided by Findata. Challenges were also shared. It was noted that the process needed a systemic change within the research and development environment. New duties were given to data controllers, concerning standardisation, and providing descriptions. Another aspect was the need to increase data security, for instance through audited SPEs. It takes time and the transition is still ongoing. The Act on Secondary Use took effect in 2019 and Findata started operating in 2020. Other challenges include the fees for health data access, and ambitious timetable to develop the services. It was advised to be agile, and the importance of sustained cooperation from the beginning was highlighted. It is crucial that the authority granting permits for the secondary use of health data has a solid legal mandate to operate, as well as sufficient resources, both financial and other (e.g., qualified staff). The EHDS will likely create a legal mandate, but authorities set up before the EHDS takes effect would need to develop such a mandate in national legislation.

In this Forum, breakout sessions for discussions were held. The breakout sessions focused on two topics:

1. Financial sustainability of the EHDS. Principles and rules for the fee policies in the secondary use of health data.

2. Multi-country data application requests and mutual recognition.

Most participants were in favour of a mixed funding model which includes both EU and national funds for preparing the MS for the EHDS and its implementation and scale up. EU funding will be required at the start for the implementation of the EHDS in member states, after which national funding will be needed to ensure long-term sustainability. Furthermore, on national funding, there was a discussion on public-private models, including examples from some countries' successes in combining different sources of financing. It was stressed that it is important to balance funding with public trust in how people's data is used.

The participants also discussed whether data users should pay to access health data. Different views were presented. Some participants were in favour of fees as long as pricing policies are transparent. Others voiced concerns that fees could become a barrier to research in some member states and said that data access should be free if it is in the public interest. It was mentioned that fees should be considered for the work required to prepare data and make it available for research, rather than paying for the actual data. The importance of aligning price policies across member states to avoid discrepancies was highlighted.

Finally, with regards to mutual recognition, most participants were in favour of the concept that a data permit issued by one health data access body in one MS would be recognised by an access body in another MS. This was important as to avoid duplicating work and reduce the time required to access data.

Policy Forum #4

The fourth and final Policy Forum brought together 59 participants, including ministry representatives from 19 MS and associated countries. The meeting focused on discussing the countries' needs from the EHDS for the secondary use and how each country plans to make use of EU funding to support the development of data management and preparedness for the EHDS.

Representatives of the EC's DG SANTE provided an update on the developments since publishing the proposal for a regulation on the EHDS in May 2021. A brief explanation on the ongoing negotiations in both the European Parliament and the Council of the EU. It was presented that the final adoption depends on the conclusion of the ongoing negotiations. In the meantime, TEHDAS is doing an important preparatory work, mobilising stakeholders and preparing solutions and guidelines. On the technical side, the HealthData@EU Pilot was mentioned as an important project to prepare the countries for scale up. Other upcoming actions were presented, from the EU4Health Work Programme for 2023 and Horizon Europe Work Programme for 2023. The EC also presented the upcoming direct grants as part of EU4Health, to support MS in setting up the Health Data Access Bodies.

Next, a representative from Czech Presidency of the Council of the EU provided an update on the work done and the ongoing discussions related to the EHDS proposal. It was noted that in general there is support in the Council, but more time will be required to finalise the agreement on the EHDS proposal. It was explained that currently the discussions were ongoing with regards to the first three chapters of the proposal, and challenges and amendments were proposed. However, there are many challenges in the remaining chapters

that were not covered in the compromise proposal, such as: tasks of HDABs, setting the right balance of fees for getting access to data, the question of sharing data with third countries, and the length of the transition period for implementation in MS. These will continue to be discussed in the coming months.

The coordinator of the HealthData@EU Pilot project presented the project and how it builds on outcomes of TEHDAS. The objective of the pilot is to build a first version of a European network of data platforms and propose a first number of services to be provided at European level (e.g., common metadata catalogue, common data application form). The second objective is to test the network and show the feasibility and added value of running such an infrastructure, through a number of cross-border use cases. The pilot aims to cover important pieces of the user journey that a researcher will go through in the EHDS infrastructure for secondary use:

- Data discovery: working on a metadata catalogue and a Health extension to the DCAT-AP metadata standard (led by Sciensano and Norwegian Directorate of eHealth). The possibility of federated queries is being investigated.
- Data permit requests: developing single access application form and conditions of use, starting by looking at application forms currently in place across different countries.
- Data preparation: working on interoperability standards, building on work done in TEHDAS.
- Data use and finalisation: also looking at how to inform citizens, ensure compliance with GDPR rights and ensure that study results are published.

It was also indicated that there will be many opportunities to engage with the pilot: for example, call for external advisory board will be launched shortly; stakeholder meetings and roundtable discussions; interactions with HDAB community. Importantly, the attendees were asked whether they had any objections in having their contact information provided to the HealthData@EU Pilot project coordinators.

Furthermore, the results of mapping exercise which took place as one of TEHDAS' activities was presented by the WP leads of WP4. The mapping exercise aimed to provide an overview of the health data management systems in 12 MS, and their readiness to join the EHDS for secondary use, as well as reflect on MS needs and expectations. The mapping exercise took place in the form of country visits and semi structure interview with relevant national stakeholders.

Key findings were presented on the readiness levels of the visited countries. This was assessed regarding the state of existence of a digitalised health data, a common metadata catalogue, and a unique personal identifier for health. Additionally, the existence of secure processing environments was mapped in the different countries, the wide use of internationally recognised standards and the state of semantic interoperability. Finally, access procedures were identified, and the status and will to join EHDS. Main technical, organisational and legal challenges and needs were identified, as well as horizontal needs for training and resources. The presentation concluded that there are positive views on the impact and the added value for the EHDS for secondary use and willingness to join across MS. However, some important aspects to consider still remain, as indicated by the MS:

- Consider the diversity and local sensitivities in MS
- Ensure equal benefit for all countries and stakeholders
- Focus on data security and citizens' trust
- Improve transparency in access processes and decisions
- Communicate with all stakeholders and citizens
- Demonstrate clear and tangible benefits for citizens, researchers, healthcare providers and policymakers.

The participants were then divided into breakout sessions for discussion on the topics of the preparatory questions sent to participants prior to the meeting (see Table 1 above).

The breakout sessions were summarised in a plenary session. With regards to the needs that countries have to start implementing the EHDS for secondary use, many of the participants identified with the needs and concerns which were found and presented by the TEHDAS country visits. Several participants expressed concerns that current funding will be insufficient, especially in terms of long-term sustainability and potential costs for data users, such as researchers and healthcare providers. Furthermore, most ministries in the countries were aware of the direct grants, and plan to make use of them for the preparation and implementation of EHDS.

On discussions with different stakeholders at national level, all countries recognise the importance of engaging with stakeholders to facilitate the secondary use of health data through the EHDS. Some countries have already started such discussions across different ministries and with the wider stakeholder community. Ministry representatives noted that some key topics that have come up in these national-level stakeholder discussions included the importance of ensuring transparency to citizens. The research community also highlighted the importance of harmonising data and of improving its findability. It was reported that, in contrast, some countries feel that it is too early to start such discussions, given that EHDS legislation has yet to be finalised.

At the end of this final Forum, participants were asked whether they would like to see such a Forum continued. There was a large and positive response on keeping such a Forum active to inform ministries of the progress of EHDS.

4 Next steps

In general, at the end of each Policy and Project Forum, participants were asked to evaluate the meeting via an online tool (Mentimeter). The evaluations included the questions on whether the Forum was well organised, there was enough time for interaction, the participants found the Forum useful, and if there was enough preparatory information. Most participants were satisfied with the organisation, the usefulness and the preparation of the Project and Policy Forums. However, the Mentimeter results showed that, although there were breakout sessions of at least 40 minutes in each Forum, time allocated for interaction with the participants may be improved. Therefore, this may be considered for future projects that want to conduct Project or Policy Forums. Further analysis of the evaluation results revealed that ending the meetings with breakout sessions was preferable to ensure the participants sense of interaction during the Forum. Finally, all the Forums that were organised

in TEHDAS took place virtually. Therefore, a suggestion that may also improve the interaction with the participants is to organise future Forums face-to-face to enable further networking and informal chats among the participants.

Taking into consideration the next steps, when the last Policy Forum was concluded, participants were also asked whether they would like these forums to be continued. All participants who answered responded positively, demonstrating the added value of the Forums. One comment from a ministry representative demonstrated the added value of selecting the three ministries to attend the policy forum. The following quote by a representative from a Ministry of Education explains the importance of participating in files dealt by other ministries and the fact that the Policy Forum enabled that: “Thanks to TEHDAS Policy Forums I have started communicating with the other ministries and getting informed about the EHDS. I appreciate this push to bring together these three ministries”.

Therefore, in collaboration with the HealthData@EU Pilot project it was decided to organise one more Policy Forum at the end of 2023, to bridge the gap with the potential follow-up Joint Action TEHDAS 2. Moreover, the HealthData@EU Pilot project indicated that it is also planning on organising stakeholder engagement forums to inform stakeholders about the progress of the Pilot project and the different business capabilities that are being designed and tested.

5 Conclusion

In conclusion, this document presents the outcomes of the TEHDAS Policy and Project Forums, which took place between May 2021 and December 2022. The aim of the Forums was to ensure engagement with different groups of stakeholders. The results section of this document presents in more detail the discussions that took place. The topics of both the Project and Policy Forums were decided in collaboration with TEHDAS WPLs and the European Commission, to ensure the relevance and utility of the discussions. The topics followed a clear progression, reflecting updates in the work done in TEHDAS as well as in external developments.

The Forums were well-received by participants, with high levels of engagement. The Project Forums brought together many different projects and initiatives with the aim of creating networks and making sure that TEHDAS built on existing work and knowledge. The Project Forums were valued by participants.

The Policy Forums directly initiated cross-ministerial discussions. In addition, country representatives reported that the Policy Forums also indirectly supported several member states in the national processes and discussions around the EHDS regulation. They also increased awareness and facilitated a deeper understanding of TEHDAS and the EHDS within member states. Each Policy Forum started with a welcome statement from a representative of each Presidency of the Council of the EU at that time (Portugal, Slovenia, France, Czech Republic), demonstrating the political value of the Policy Forum. In future iterations of the Policy Forum, it would be important to evaluate if other ministries should also be invited to ensure the Policy Forums benefit as many relevant policymakers as possible.

Based on positive feedback from participants, the value of continuing such Forums is clear, considering the learnings from the TEHDAS Project and Policy Forums. Building stakeholder networks, increasing awareness and facilitating dialogue between different stakeholder is key to building a sustainable EHDS.

Annex 1 – Policy Forum invitation and one pager

Joint Action Towards the European Health Data Space (TEHDAS)
Project Number 1989

10/10/2022

Petronille Bogaert, Sciensano

To Ministries responsible for
Research & Innovation, Economy
and Health

Subject: Invitation to designate representatives for the Health Data Policy Forum

In February 2021, the Member States and the European Commission launched a Joint Action Towards the European Health Data Space (**TEHDAS**), which develops and promotes elements of the cross-border sharing of health data in secondary use (e.g., research and policymaking). The major expected outcome of TEHDAS is a **sustainable roadmap for the EHDS implementation**, built on the needs and expectations of national and international stakeholders, citizens' engagement and existing infrastructure.

Since its inception, TEHDAS has organised three Policy Forums through 2021-2022 with the aim of **integrating the views, needs and expectations of Ministries of Research, Ministries of Economy and Ministries of Health of the European Health Data Space**. The TEHDAS Policy Forums provide a platform to bring together views from the sectors of research, economy and health.

The news articles for each of the previous Policy Forums are available here: first Policy Forum - 28 June 2021, second Policy Forum - 29 November 2021, Third Policy forum - 29 June 2022.

In preparation of the final Policy Forum planned for end of 2022, and in light of possible governmental changes since last year, we kindly invite you to re-designate one **representative and one alternate from your ministry**. This is to ensure the largest representation of Member States and ministries in these important discussions on the set up of the European Health Data Space (EHDS). The representatives will receive an official invitation to the meeting.

Please provide the contact information of the representatives by email to TEHDAS.sciensano@sciensano.be by **Friday 28 October.**

Looking forward to your reply,
Sincerely,

Petronille Bogaert
Project Coordinator and Researcher
Head of EU health information system unit
SD Epidemiology and Public Health, Sciensano, Belgium

TEHDAS **Policy Forums**

The EU's Heads of State called in October 2020 to set up a **European Health Data Space** (EHDS):*"The European Council welcomes the creation of common European data spaces in strategic sectors, and in particular invites the Commission to give priority to the health data space, which should be set up by the end of 2021."*[1]

As a response, the Member States and the European Commission launched the Joint Action Towards the European Health Data Space (TEHDAS) in February 2021. The major expected outcome of TEHDAS is a sustainable roadmap towards the EHDS implementation to promote the cross-border sharing of health data for secondary use. It **built on the needs and expectations** of national and international stakeholders, citizens' engagement and existing infrastructure.

What

Within WP4 outreach engagement and sustainability, **four Policy Forums** are organised. The Policy Forums aim:

→ to reflect on the **needs and expectations** of the EHDS from the perspective of **policy makers**
→ to explore views on the economic sustainability of the EHDS, and
→ to suggest concrete ways to integrate the results into the future EHDS.

When

4 Policy Forums are planned:

1. 28th June 2021 from 15:00-17:00
2. 29th November 2021 from 09:00-11:15
3. May 2022
4. March 2023

Who

Representatives of Member States and Associated Countries

→ Ministry of Health
→ Ministry of Economy
→ Ministry of Research
→ European Commission representatives

Why

To invite Ministries to be part of the discussion in shaping the EHDS and have a direct influence on its upcoming legislative proposals.

Annex 2 – Project Forum minutes

TEHDAS – 1st Project Forum Meeting Minutes

Tuesday 18th – Wednesday 19th May 2021, 09:00-12:00, via WebEx (online)

Contents

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1 Attendees

Over 100 European health data specialists representing over 50 projects and initiatives.

2 Welcome session

2.1 Welcome and aim of the Project Forum

The first TEHDAS Project Forum began with a welcome from **Petronille Bogaert (Sciensano)**. Permission to record was gained.

Aim of the meeting

Exchanging knowledge, methods and tools and identifying synergies with other European initiatives and projects working in the field of secondary use of health data is essential to build TEHDAS on what exists and to avoid duplication. Therefore, the first Project Forum aims to:

1. Present TEHDAS's objectives and activities to the different European projects and initiatives in four themes: Sharing data for health: Frameworks and Governance principles, Semantic interoperability, data quality assurance, Service and architectural technical interoperability and Citizen's engagement.

2. Host pitches from relevant projects working in one of the four themes to identify synergies and areas of collaboration.

3. Connect European projects with relevant TEHDAS partners.

To learn about the different projects in Europe and more broadly that work on the secondary use of health data. To collect material on these different projects so that the work package leaders of TEHDAS can build on what has already been achieved, use the knowledge and expertise that projects have already developed.

Structure of the meeting

This first Project Forum is split it up into four topics mirroring the different topics of the JA TEHDAS:

1. Sharing data for health: Frameworks and Governance principles

    a. Options for transparent and FAIR operational framework and governance models for the exchange and secondary use of health data, based on trust, citizen empowerment and a common good.

2. Semantic interoperability, data quality assurance

    a. Providing guidance on data quality assurance and solutions for semantic interoperability.

3. Service and architectural technical interoperability

   a. Technical architecture and interoperability, that we will propose to the European Commission for the building of the EHDS.

4. Citizen's engagement

   a. Information on the relation between citizens and health data to better inform and sensitise citizens regarding health data, data altruism practices.

In a nutshell, TEHDAS aims to provide options on how the EHDS can be built in these four different areas.

Interactive sessions: Mentimeter and MIRO software tool.

2.2 Introduction to TEHDAS

Markus Kalliola (Sitra), the coordinator of the TEHDAS Joint Action, gave an introduction to TEHDAS.

TEHDAS overview

TEHDAS stands for Towards the European Health Data Space. It is a project co-financed under the 3rd and 4th EU Health Programme. It is divided in 8 work packages and is driven by the work of 26 partners from 25 European countries, 21 member states and 4 associated countries. TEHDAS JA started on the 1st of February 2021 for a duration of 30 months but most of the deliverables will be ready by the 24th month.

Under the eHealth Network there have been many projects on health. Markus Kalliola presented the EU data strategy that was published last year in February. Health is only one of these sectors. We need to think of what is horizontal in health data. How health data can affect different sectors.

TEHDAS focuses on the secondary use of health data and more specifically, the legal governance, quality of data and infrastructure.

Vision and mission

To help member states and the European Commission in developing and promoting concepts for sharing of health data for secondary use purposes. The key is that TEHDAS is there to help the Commission and not act as a separate project with standalone outcomes.

TEHDAS is not defining what the EHDS will be, it is not a legislative body and it does not build working IT solutions. It creates concepts for the secondary use of health data in Europe, it is a preparatory body and it has a clear scope with deliverables and a timeline.

Overall themes covered by TEHDAS

Governance, Data quality, Infrastructure, Citizen engagement, Data altruism and Sustainability.

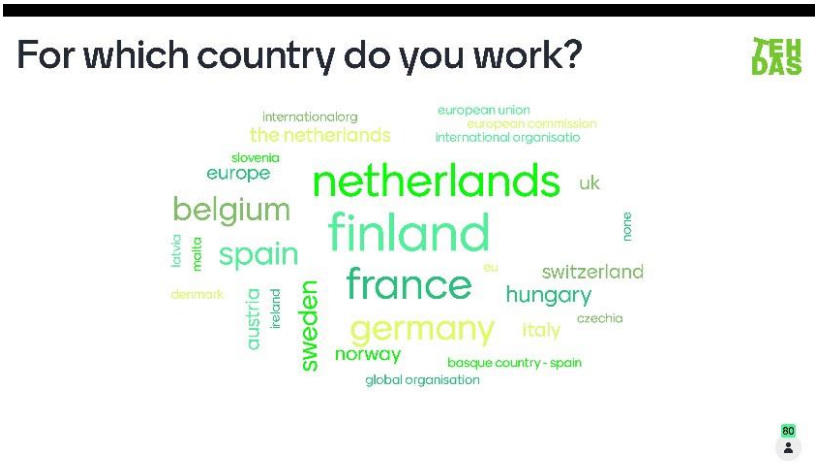
The first results of the joint action will be on Governance (WP5) and will be ready in June.

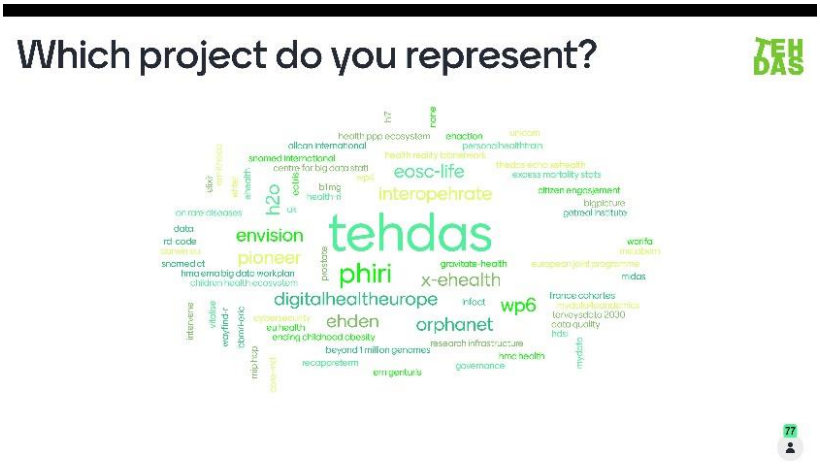
EHDS consultation is open from the 3/05/2021 to the 26/07/2021.

TEHDAS Stakeholder Forum in October in Helsinki.

Mentimeter survey

1. For which country do you work?
2. Which project do you represent?
3. What kind of institution/organisation do you represent?





3 Topic 1: Sharing data for health – Frameworks and governance principles

Every pitch will have a maximum of 10 minutes to present and all speakers have been given three questions to prepare and guide their pitch:

1. What do you do with regards to this specific topic that could be of interest to TEHDAS?
2. What can we learn from your experience? What should we build on?
3. How would you like to get involved with the EHDS? Or how do you see your collaboration with the EHDS?

3.1 Presentation of TEHDAS WP5: Sharing data for health – Frameworks and governance principles

Michel Silverstri (Swedish eHealth Agency) presented TEHDAS WP5, co-led by Coen Van Gool from the National Institute of Public Health (RIVM) in the Netherlands.

Overview of WP5 activities

T5.1 User perspectives: researchers and innovators and policy maker perspective on the secondary use of health data. European case studies.

T5.2 Data permit authority perspective, interpretation of the GDPR, business models, financial sustainability. Enabling the secondary use of data by aligning the interpretation of the GDPR.

T5.3 Best practices for EU-cross border sharing of personal health data, bilateral cross border projects, aim to have a Memorandum of Understanding as an outcome.

T5.4 Synthesis of all the other tasks, resulting in final governance models for the secondary use of health data. Options for governance models for the EHDS.

Q&A

- How are the use cases organised? Is there any interaction and what kind of researchers does it include?
    - Task 5.1 has performed an extensive literature review, involving a search of different types of barriers and enablers experienced across Europe with regards to the secondary use of health data. Based on that, a survey has been developed for countries to give specific examples.

3.2 'Assessment of the EU Member States' rules on health data in light of GDPR'

Evert-Ben van Veen presented the study conducted by Johan Hansen, Petra Wilson, Eline Verhoeven, Madelon Kroneman, Mary Kirwan, Robert Verheij and Evert-Ben van Veen with the title: 'Assessment of the EU Member States' rules on health data in the light of GDPR'.

Examination of the interpretation of the GDPR in the EU member states and the UK by doing country visits, workshops and panel discussions. Many differences were identified between countries in the GDPR interpretation for the secondary use of health data.

Results showed that there is no fully harmonised approach in Europe. Patients do not feel fully empowered to exercise their right to access of health data.

The EHDS is seen as a good opportunity to address this, to provide centrally governed infrastructure and develop a code of conduct.

Connection with TEHDAS

Our consortium has been resolved but we are still here and we are willing to help you if you need support for interpretation.

3.3 Beyond 1 Million Genomes

Katja Kivinen (Finnish Institute of Molecular Medicine) presented Beyond 1 Million Genomes. There are two related organisations: The initiative 1+Million Genomes which aims to provide pan-European access to at least 1 million human genomes and the related healthcare data by 2022. Beyond 1 Million Genomes (B1MG) was created to support and coordinate this mission.

Federated ELSI-compliant infrastructure for: data discoverability, data reception, storage and interfaces, data access management tools and processing.

Each participating country will provide a node. They are using the Global Alliance for Genomics and Health (GA4GH) standards.

Focus areas: rare diseases, cancer, common and complex diseases, infectious diseases. Having both host data and pathogen data and being able to link these. Work on tracking the virus genome and link it with health data.

Connection with TEHDAS

- There are a lot of barriers in the legal systems. A federated solution is what we are aiming for. We would like to collaborate with TEHDAS on the issues of data harmonisation and GDPR interpretations. We can produce case studies for you.

- Specifically, with T5.2 there could be some interactions.

The lack of linkage between existing data is something complex where GDPR plays an important role. Missing data is also a big barrier.

3.4 Data Analytics and Real-World Interrogation Network (DARWIN)

Stefan Blixen (EMA) presented the DARWIN project. The mission of the EMA is to foster scientific excellence in the evaluation and supervision of medicines. To support the work of the EMA, scientific committees provided a set of recommendations on the sharing of health data. Heads of Medicines Agency EMA Big Data Steering group was established to implement these recommendations. One of these recommendations has been the DARWIN EU initiative.

Top 10 recommendations and the Big Data steering group report on the EMA website. Here are some examples of the recommendations useful to TEHDAS:

- DARWIN to deliver a sustainable platform to access and analyse health data in Europe.
- To determine the level of quality of health data.
- Identify a key set of metadata needed to support regulatory decisions.

DARWIN EU: coordination centre with scientific expertise that will connect queries with different nodes, the network. Principles: data stays local, queried remotely, common data model. Aim to establish connectivity with the EHDS pilot node in 2021.

Connection with TEHDAS

- Sharing knowledge and TEHDAS participating in consultations and workshops.
- Aligning big data task force activities.
- Share tangible deliverables, such as the discoverability work stream, we defined the metadata that would be necessary to identify data sources for use in the regulatory context. Would be interesting for TEHDAS WP6 for example.
- Participation in the EHDS pilot. On the DARWIN EU advisory board will include both TEHDAS partners and EHDS representatives.

3.5 Q&A session

- Will TEHDAS work include any interaction with external projects or programmes?
    - This Project Forum is one way of interacting with the users of health data, e.g. researchers and policy makers. We also have an advisory group with +30 representatives from research, authorities, industry, patients/citizens and other stakeholders
    - Deliverables are going to be available but not all milestones.
- How can one define guidelines on secondary use for the MS without making normative choices?
    - That is a good question, and would probably need a full debate on its own. The ambition here is to identify a set of general guidelines that could be applicable for most MS, however the level of detail - and perhaps relevance for individual MS - may differ.
- In EMA presentation, DARWIN planning mentions links to EHDS pilot; TEHDAS is not working on pilots based on the presentation from Sitra. Who will be working on the EHDS pilots? What is their scope?
    - European Commission is working on the pilot of the EHDS 2, about the secondary use of health data. A large number of stakeholders will be involved and the idea is to develop the concept of the European nodes (ECDC, EMA) and the National nodes, to promote the secondary use of health data.

4 MIRO interactive activity

Participants went into breakout rooms for interactive activity. Material was collected, analysed and shared with the TEHDAS Work Package Leads.

5 Topic 2: Semantic interoperability, data quality assurance

5.1 Presentation of WP6: Data quality and semantic interoperability

Enrique Bernal Delgado (IACS) presented WP6, which is co-led by IACS and Central Region Denmark.

The overarching question to debate in this work package is how to get excellence in data quality. Providing solutions and insights for a trustworthy secondary use of health data. Digital transformation of the health system. We are looking at different levels of analysis of health data. Looking at data quality we might want to go to the variable level, the data source level and the institution level.

Data sources: EHRs, population registries, disease-specific patient registries, observational data etc.

Expected outcomes: Develop a data quality assessment framework and make recommendations on the semantic interoperability issues.

5.2 SNOMED

Ian Green (SNOMED International) presented from SNOMED. SNOMED is a non-for-profit organisation. Member owned organisation, offering SNOMED CT, completely virtual organisation, complete remote working. 40 member countries, 18 EU countries and 3 European non-EU countries. SNOMED CT implemented in 80 countries.

Ontological basis, 480.000 concepts, collaboration with global standards.

Connection with TEHDAS

- Understanding of terminology, interoperability
- Share collaborations that we have already established
- Tooling development
- Leveraging SNOMED experience on implementation and the difficulties that lie under the banner
- Advising and provide support towards secondary use, data analytics capabilities

- European members are mandating SNOMED for data collection, a lot of the data going into the EHDS will be in SNOMED format

Q&A

- What role is seen for IHE standards within TEHDAS?
    - All elements that have to do with semantic and syntactic interoperability are relevant. We are browsing through different initiatives at the moment.

5.3 EHDEN

Peter Rijnbeek (Janssen), EFPIA lead of the IMI2 EHDEN project presented the EHDEN project.

EHDEN aims to build a large federated network of databases in Europe to perform observational studies in Europe. This is done by standardising data to a common data model at a large scale. The project is not only about standardising data but also about using it. Evidence is important as we can run studies on the network.

This is a large IMI project, private-public collaboration. A large part of the budget is dedicated to standardise data, to support partners in this task. It is important that the process from the data source to the research query is fully transparent, to generate reliable evidence.

How can we do this on large scale? From many databases in Europe and for many types of research questions. We have to build adaptors of the tool, to improve the syntactic interoperability to unlock the data for observational research. Building also standardised analytics. Sustainability is also a key part.

It is built on the common data model: OMOP

Two different types of calls to apply for funding dedicated to data standardization. 26 SMEs have been trained to standardise data to the same data structure. E-Learning environment: academy.ehden.eu.

Collaboration with the OHDSI community.

Q&A

- What kind of data do you deal with? Clinical data, survey data? The types of data sources that we are looking are diverse. Are there all applicable to the OMOP standards? And if not what could be the work in that area?
    - It is broad the use of OMOP. What has not been looked enough is the genetic data but there is ongoing work and TEHDAS could help with shaping that.
    - The core layers are covered and all different standards are also covered.
- Are imaging data included?
    - This is a data type that has not been included in the data model. But the data that you extract from the images can be placed in the data model. There are no limitations I think, it is something that can be worked.

5.4 RD-CODE ORPHANET

Ana Rath (French Institute of Health and Medical Research, Inserm) presented ORPHACODE.

Rare diseases are underestimated and not visible in the health information systems. Development of a codification for the rare diseases. To identify patients in a consistent and standardized way.

Adoption of the ORPHACODE in the member states. There is a need not only to have a nomenclature but also guidance and tools to implement this nomenclature. This is the role of the RD-CODE project.

Objectives: to promote the use of the Orphanet nomenclature but also to achieve transnational interoperability and use of health data for secondary use.

Connection with TEHDAS: We can provide a useful real-world experience. Implementation in 4 countries, developing tool-kits and support, enhance the use of the Orphacode and develop guidelines for coding undiagnosed RD patients.

6 Topic 3: Service and architectural technical interoperability

6.1 Presentation of WP7: Technical infrastructure

Carlos Telleria (IACS) presented WP7.

WP7 is about connecting the dots, providing options for the technical interoperability framework that would connect the different participating nodes in a federated network.

We need:

- A common health data access infrastructures for the secondary use of data.
- A federation of data providers
- Fully compliant GDPR regulations
- To ensure accountability and transparence

Q&A

- Have you already thought of the approaches of this technical architecture? Peer to peer, orchestrator, federated? Also, in terms of services what key services should be there?
    - At this stage of the project, we are thinking of all options. A centralised architecture may be useful but it depends on the feasibility of the free flow of data in different countries. A federated architecture may be the solution but it has its limitations. The services we can provide in the EHDS, we are talking for example about discoverability based on harmonised data catalogues and metadata catalogues. Maybe distributed catalogues or centralised catalogues. We are talking about data permit, how nodes that would like to join the network would be able to.

6.2 IN-4-AHA

Hille Hinsberg (Proud Engineers) presented the IN-4-AHA project. The specific objective of this project is to develop a practical validated innovation scale-up model to facilitate the scale-up of innovative solutions across EU in active and healthy ageing. Elaborate and improve the model for innovation scale up.

This project will be addressing the problems identified by stakeholders in the scaling up of innovations. Main barriers are the lack of interoperability and system integration due to the limitations by the state, the legal framework but also technical barriers.

This project aims to offer support to service providers, produce guidelines on the topics of how can they do better in managing the data, service design and innovation, impact evaluation. How this could better support scale up to the market. Guidelines on information security.

Q&A

- You are talking a lot about different networks and service providers. What about capability discoveries, what capacities are in countries already? Are you planning or have you done some similar exercise as the one that Carlos mentioned they would like to do in WP7?
    - We have not thought about it yet. This is why I would very much like to be kept in the loop and not duplicate activities.
- Lack of interoperability and system integration is a problem we are facing. Have you thought about how to address this?
    - Coming from the private sector in digital transformation including regulatory aspects and technical architecture, I would advise to look into the standards agreements. Try to find ways to come across the barriers by definite and acceptable standards in a decentralised manner. Try to comply with the main standards. Have common agreements that would protect the data in a secure and privacy agreed environment.
- How can a technical architecture overcome these issues?
    - You must consider that there are many layers in talking the same language to each other. Communication exchange, messaging standards, to connect the different systems to each other. Semantic syntactic interoperability is really intertwined with the technical elements.
    - How we construct the semantic layer, so that the nodes can interact with each other.
- Interoperability is based on standards. CEN/TC251 delivers standards in health informatics in Europe. The member countries have a lot to improve in participating in this work by active participation, proposing standard topics AND nominating competent national experts to draft these standards.
- We don't need more standards; we need to enforce the ones we have already. If we draft new ones, we'll be working on this for years.
- One form of standards is a so-called Reference Standards Portfolio (RSP). It is a quite short standard which states that use these existing standards to solve interoperability problems in each area. ISO/TC215 has a RSP for medical imaging, for example.
- We need a system that allows for MS differences at a local level, and harmonisation on top, i.e., federated. Centralisation is impracticable across EU scale, and hence this is a sociotechnical construct that requires the technical aspects, and the governance/protection aspects focused on to allow analysis of data locally, and to avoid the need to move any data.
    - I tend to agree with your view. Do you think it is worthless to debate on the possibility of centralisation within TEHDAS WP7, for a number of research questions and for the exchange of, for example, aggregated data?
    - Perhaps for some data centralisation is feasible, but it's always the data and the permissions, likely meaning a challenge to ensure consistency of

permissions, let alone interoperability, from each institution and each MS. Furthermore, though we have the EHRXF for cross-border, this is summary data, and we need the rich kaleidoscope of data for all uses. Also, and importantly, if we don't need to move the data, but can move scripts, algorithms and derived information, this is less complex and challenging from a permissions perspective, let alone technically. I think the idea of harmonising to the level we would need across the EU is not feasible and will take considerable time. Moreover, and what doesn't seem to be ever mentioned - all 27 MSs are not the same! There is considerable heterogeneity in digitalization, political intent, and maturity of health systems!

- Quite apart from the technical challenges are some organisational and administrative ones - particularly in terms of data quality and harmonisation, this is really important for data comparability purposes. It's a wide-open area that does not seem to be attracting much attention.

6.3 InteroperEHRate

Luc Nicolas (EHTEL) presented the InteropEHRate project, a 45-month project with 16 partners, SMEs and large-scale companies with Academia partners and some clinicians. Project is completely centred on the patient.

InteropEHRate tries to use the citizen and its mobile device to collect data and decentralise the exchange. The citizen can move around with their own data and it is able to interact directly with the different clinicians and researchers, for EHDS 1 and 2. They can share data with healthcare organisations through different technical services, Bluetooth, secure cloud storage of data. Ability to connect citizens with nodes.

- What we deliver is based on HL7 FHIR standards, CEN IPS and eIDAS.
- Develop tools for semantic and syntactic interoperability.
- Research query – Patient's device – participation of the citizen in the research study. Not everything is in scope but what is critical is that we define the building blocks and this is where we can interact with TEHDAS.
- Challenges addressed
- After COVID-19 60% of citizens believe that their data can be useful.

Through the EHDS we should give the citizen a concrete capacity to experience trust.

Q&A

- How do you manage identity management and consent permission management in InteropEHRate?
    - We rely on ID, secure environment.
- Who pays for cloud storage?
    - The idea is to have a framework where the citizen decides where to store the data.

- Coming back to your RD example, EJP RD (ejpraredisеases.org) has developed semantic patient-centered RD common data elements models for RD, as well as a common informed consent form using DUO and ICO that can be machine readable. Happy to have further conversations on synergizing our efforts. Very interested in your approach for re-using health data for research with the patient in control.
    - It is secondary use of data (at least partially) as the data are first all collected for continuity of care and then reused to initiate a data workflow for research.
- IntEHRoperate is patient centered, with patient control of the process, patient mostly identified. I think this is very useful in clinical trials, small studies, or even pharma Post Authorization Studies. But this is not secondary use of health data, and EHDS is directed to secondary use. Should we contemplate in EHDS/TEHDAS research question that are not strictly secondary use, but can take benefit of a federated Europe-wide infrastructure? (multicentric clinical trials, rare diseases research…) even if they are primary use studies?

6.4 Population Health Information Research Infrastructure (PHIRI)

Ronan Lyons (Health Data Research UK) presented the PHIRI project, which focuses on the COVID-19 pandemic. The creation of a rapid response system for policy makers. PHIRI is a demonstration of a working model of how to do this. We have research questions and we need to answer them. Creating a common data model.

The PHIRI architecture recognizes the existence of several sovereign data hubs in Europe. There is a kind of central technical hub, support to create re-usable scripts and instructions which are fed to the data hubs. The data hubs then implement those. None of the data actually moves. Transfer of scripts and enabling the analysis to take place in data hubs and only results move back to the central zone.

Presentation of the use cases that are examined in PHIRI.

Requests to data hubs to discover what sort of questions can we ask and what sort of data, data hubs have access to.

Q&A

- For this specific use case you are looking at one example, how can this be scaled up?
    - If you show with practical examples something working well, then you can bring capacity building and automatisation work. Consent fatigue on citizens.
- Totally agree on the lack of practicality for citizen consent. Totally impracticable for research, and data needs to be closed enough for protection, but open enough for research, based on broader permissions and reliance on relevant governance systems and processes.
- Agreed - but not a reason to do it. This is where we differentiate with consent management (one off - not practical) and permission management (generic under certain circumstances). There is quite a lot of work around this ongoing.

7 MIRO Interactive activity – Breakout rooms

Participants were separated into two breakout rooms to discuss the two topics presented on the second day of the Project Forum: Technical interoperability and Citizen's engagement

7.1 Technical interoperability

Discussion points raised:

- In rare disease we create our own standards because they do not exist. We work with those that have the developed the main ones to align and increase acceptance.

- https://www.ehealth-standards.eu/ Interoperability is based on standards. CEN/TC251 delivers standards in health informatics in Europe. Member countries have a lot to improve in participating in this work by active participation, proposing standard topics AND nominating competent national experts to draft these standards. Useful resource for researchers: https://www.physionet.org/about/database/

- EU initiative GaiaX: lots of action and resources to establish infrastructure that should be used as basis for the EHDS. Formulating what should be the principles of the health cloud. I would suggest contacting Gaia X to present their work. The National Health Enterprise has put a proposal e-health. mandatory application s for e-health. European application frames as a use case. These standards should allow exchange data across border and to develop the product and get it certified.

- We will end up with a hybrid: centralisation of certain types of data and federated systems. The vast majority of the health data is generated about us. Not by us. That is also another question; the integration of this data in the clinical workflow. There are also challenges on HOW this info is used. Then we get to the secondary use of this data. Lots of heterogeneity. There are a lot of technical issues, but the social issues and governance issues might be more of a challenge. The idea of Nodes at MS level can help coordinate at national and local level this harmonization layer on top of data. Actually, data should not be moved.

- In H2O, we will use a hybrid approach, centralized PROMs and decentralized clinical data.

- In PIONEER we use a hybrid too

- We need to think about national nodes - to be federated at the European level - at WP7 we yesterday afternoon had already a structure image showing this

- BBMRI has a hybrid approach too with more focus on federated / centralised exception

- I think it is not the right assumption to say it is secondary use of data: it is the continuation of clinical care! We will be using what is existing. The data would be transmitted in a way that they are of 'citizen quality' and of such quality that it can be reused. There is a whole spectrum to explore. We should start with what we have and try to advance.

- Agreed. The idea: if we should open the scope of TEHDAS, at least technical and semantic solutions that could include these kinds of studies.

- If opt in is a fundamental concept then how do we deal with lack of representativeness?

- There are data that will never be captured by "normal" channels and that are in patient's hand and needed for secondary use. There is need for a bridge there

- Also think it is important to keep bridging with healthcare practitioners and researchers who feel confident- and trained enough to use these data. Something we have been working on in PIONEER with support of the EHDEN academy

7.2 Citizen's engagement breakout session

- From ESC biomedical alliance on cardiology, we have created COREND on medical devices where data is collected on the safety of medical devices. Single consent vs multiple consent. We still have conflicting legal requirements that should be clarified by the European Commission. It is bothersome that the consent needs to be asked every time a medical device is used.

- Health data needs to be treated with a lot of care and respect. We need to give citizens reassurance that this is how it is going to work. Governance about legal clarity is needed.

- EC has acknowledged that the GDPR needs to be revised, especially the legal and regulatory aspects.

- The main point still missing is the value back to the consent giver, give back to the citizens information on how their information and data was used, for which purpose.

- How does InteropEHRate communicate with the patients that have given consent to use their data for secondary use, research on clinical studies for example, do they inform them afterwards on the outcome of the study? Another question is whether they share patients' data only for clinical research or also for fundamental research?

    - About the scope of InteropEHRate it is indeed important to make those data available for fundamental research. For the time being we believe that we need to make the connection available for the citizens. We need to inform what value citizens have provided by sharing their data, we need to engage citizens as they are lost and afraid. A more decentralised and point-to-point communication is important.

    - Regarding patient consent, we try to have usability, to try to reinvent the way that consent is given. The idea is that citizens would give consent to the idea of having their data shared for secondary use.

    - To answer a question and discussion from the chat, I am talking about re-using data for secondary use not primary use indeed. It is important to create a relationship with the citizens and have a workflow established where the citizens that have given consent receive feedback. …. he was then taken out of the breakout room

- What exactly would you like to receive as a citizen that has shared their data?

    - I want to know what was done with my data and my money; the research behind. In a general way not specifically my individual data.

- This is a very good point we need to clarify to the policy makers what the ethical point is exactly.

- It is extremely important for citizens to be in control of their data.

- Medical devices data is pseudonymised. I do not find the idea to go back to the citizen each time such a good idea, but on a general level we could. TEHDAS could do more on the data privacy issue.

- Data privacy is very important. For example, now with the COVID19 pandemic we have shared a lot of personal data, addresses, names, age, vaccination history, phone numbers, and this is fine as long as we live in democracy but in non-democratic countries it can create a lot of problems. We need to find a system that would preserve our personal data in case of a political change. Data altruism organisation. Permission and consent management. The EU has to take this into consideration when creating the legislative proposal.

8 Topic 4: Citizen's engagement

8.1 Presentation of WP8: Citizen's engagement

Zoé Perrin (French Health Data Hub) presented WP8, which focuses on the role of citizens in the future EHDS. Citizen's acceptance of the governance framework is very important for the success in the sharing of health data for secondary use. Therefore, it is key for TEHDAS to understand their views on the governance framework and have the opportunity to play the role they would like to play within the future EHDS.

TEHDAS will focus on the following two objectives:

1. Improving citizens' understanding and trust in health data sharing and its secondary use

    a. Citizen engagement: e-consultation, assess perception, experience and expectations of citizens on the EHDS. Workshops with national and European stakeholders. Final recommendations.

2. Empowerment of citizens around health data

    a. Data altruism: construction of a catalogue on best practices linked with current data altruism practices. Stakeholder workshops. Recommendations on fostering GDPR compliant data altruism practices within the GDPR.

We used the data altruism definition provided by the GDPR act. Possibility of citizens to voluntarily share their health data for common good purposes.

Q&A

- What role do you expect for citizens in the future EHDS?

    - It depends on the feedback that we will receive from the e-consultation. Whether it is in regards to consent or to engagement in the governance.

- Mobile digital Health Apps would be a good use case since it's a new dynamic developing care segments in all MS and providers need studies (secondary use) to fulfil the requirements of MRD and national reimbursement - but also their users (patients) need to transfer self-recorded data via secure Infrastructure to their physicians in- and outpatient care (option to collect primary data)

- Does the citizen engagement work in TEHDAS extend beyond data altruism? There should be other mechanisms and models too, in my opinion.

    - Yes, it could. With regards to citizen sensitization and engagement we are also investigating methods of engaging citizens with other means, such as data cooperatives.

8.2 My Data

Isabelle De Zegher (founder of b!loba) presented My Data Global, the mission of which is to empower individuals by improving their right to self-determination regarding their personal data. Human-centric paradigm is key. Balanced and fair relationship between people and organisations.

TEHDAS and the EHDS could not be sustainable without taking into account the citizen centric view.

Thematic groups that can collaborate with TEHDAS: MyData operators, MyData 4 pandemics, making sure that we are ready for the next pandemic.

We need to re-use data collectively. MyData Operators give governance support to data using services and data sources. 27 organisations certified as MyData Operators. Value is very important to incentivize participants and citizens.

Connection with TEHDAS

- The EHDS should be organisation centric, assuming we can overcome the legal disparities that exist. Management of identity and permission by the EHDS. How could we manage cross-sector sharing of data.

- It is important that citizens are active stakeholders of the EHDS.

Q&A

- Considering the EU population of 447 million, how scalable are all the citizen-centric programs, ensuring diversity, representativeness and re-use of health data? There needs actually be a balance between citizen needs and societal needs, and perhaps the pendulum is swinging too far to the former. For a large majority of research individual data is of little use on its own, we need rich, large cohorts (perhaps different for rare diseases). We don't need identifiable data for a lot of research, and indeed it's a complication. There needs to be an emphasis on data not being identifiable as part of the discussions in citizen protection, vs. control, consent, etc.

- Data are assets, I think it is possible to make the parallels with the banking system. There is a big learning curve in computer literacy and data literacy. We should be careful at inequalities but we should still try to start working with the data and computing literate individuals.

- Will the need for active participation not introduce a bias towards patients/citizens who are more likely to share data than others?

    - Yes but if you take the example of clinical trials, currently 4% of people participate in clinical trials. There is a bias but it could not be worse than now.

8.3 Health Outcome Observatory (H2O)

Melponemi Styliadou (Takeda) presented the H2O initiative. Why value-based healthcare hasn't happened yet in Europe. Why digital health hasn't happened in Europe yet. The approach we took is to think about people and their incentives.

Objective: to empower patients with digitals tools that would allow to measure their outcomes in a standardize way. What would we like to see measured?

Immediate value to citizens through feedback and benchmarking.

Connection with TEHDAS

- We intend to create a pan-European H2O/Observatory, an orchestrator, the gateway of research that can happen. This will be working with leading hospitals in different countries. Data from these hospitals, using digital tools that would have been provided to the patients, will be stored in an independent storage.

- Aiming to also achieve a common patient identifier.

- National observatories will be individual legal entities.

Q&A

- One of your main outputs is to provide clarity to citizens. What will be a methodology to do that and which the EHDS can consider?

    - Create clarity about how the health data is going to be used and who is going to be using them. Patients or citizens don't expect to get something in return.

    - We need to think about other ways to engage other than data altruism.

- I have noticed that the model on which you are relying is hospitals and I wonder how would you incorporate the perspective from the fragmented access and re-use of this data from national nodes, regional nodes and domain nodes. How will you clarify this to the patients?

    - This is why we insist on creating independent observatories. The patients would go to different hospitals and ask to use these digital tools. The patients could start this revolution. The whole concept is that we will give something very practical to the patient. It is a tool to record the health data and communicate with their doctors.

8.4 Personal Health Train

Lianne Ippel (Statistics Netherlands) presented the Personal Health Train. The Personal Health Train is more of a paradigm that can be implemented by various organisations. A privacy-preserving infrastructure.

There is a data station, either an individual data station or a hospital where many patients have their data stored. The data is FAIR data. The train tracks are the governance models, whether the analysis, the train, is what has been agreed upon. If the consent is available and if the analysis is valid then the train tracks allow the train to enter the station so the analysis can be conducted. Then the train tracks again check whether the train, so the analysis, has the results it should have and can leave the station.

This infrastructure facilitates remote access. No copies of the data, guaranteed GDPR "right to be forgotten" compliance. If patients or an individual wants to withdraw their consent this is fine it works, their data are no longer there.

Connection with TEHDAS

Regarding TEHDAS, we are eager to develop techniques and facilitate our high-quality statistics in a timely manner.

- Data virtualisation project, a federated infrastructure that may be interesting to TEHDAS.
- CARRIER project

8.5 Gravitate Health

Anne Moen presented Gravitate Health, which aims to equip the underpowered citizens as users of digital tools to make them confident and active in the use of health data and improve the safety of medication use.

The big question is how can we apply an open-access digital platform to transform the way citizens access and understand health information and apply this in personal health for adherence to treatment, risk minimization and quality of life. The health information sources: electronic product information, electronic health records, health education materials.

We will do piloting and evaluation of our approach across the EU and the US. Technology development, G-Lens services and development of a White Paper.

Connection with TEHDAS

Regarding the involvement with the EHDS, in Gravitate Health we will do research and development activities to understand how citizens capabilities to access, understand, curate and use their relevant health data and how we can improve that.

- We will create a digital health platform. There the standards from the EHDS come in handy.
- We can offer important learning and experiences through case studies.

Q&A

- According to you what would be needed from the EU governance level to facilitate your work on data altruism and citizen engagement?
    - Allowing and creating an infrastructure where citizens can actually use their data for their own health.
    - It would be very helpful in focusing on what we CAN do with health data instead of what we CAN'T do with health data.

9 Concluding remarks

Petronille Bogaert (Sciensano) thanked all participants for the participation in both days of the Project Forum.

There are a lot of initiatives in Europe that have a lot of expertise in sharing health data for secondary use. We are happy to see that there were over 100 participants, 13 projects pitching with one interactive whiteboard to collect material. Finally, it was very important the knowledge that was shared through the discussions, presentations and the chat. We had 20 countries participating and many international organisations.

There will be three more Project Forums organised in the lifetime of TEHDAS. This first Project Forum was mainly aiming to receive as much information as possible. The next one might focus more on some of the results that have already been delivered in different WPs of TEHDAS.

Mentimeter feedback

- More interaction and more time for discussion between participants, Q&A.

Next steps

4 follow-up questions to WPLs:

1. Think about possible connections with the projects and initiatives that pitched during the Forum
2. Contact the stakeholders to discuss further possible collaborations
3. Inform us of two key actions you have taken to follow up on the meeting
4. For the next Project Forum, what would be a specific theme that you would like to propose?

TEHDAS Project Forum n° 1		
No	**Day 1: 18th of May (9:00 - 12:00)**	Time
1	**Welcome:** Aim of the Project Forum and brief introduction of TEHDAS Mentimeter survey Moderator: Petronille Bogaert Speaker: Markus Kalliola	9:00 – 9:15
2	**Topic 1. Sharing data for health: Frameworks and Governance principles** Providing options for a transparent and FAIR operational framework and governance models for the exchange and secondary use of health data, based on trust, citizen empowerment and a common good.	9:15 – 10:10
	TEHDAS WP5 Michel Silvestri	9:15 – 9:25
	"Assessment of the EU Member States' rules on health data in the light of GDPR" Evert-Ben van Veen	9:25 – 9:35
	Beyond 1 Million Genomes Katja Kivinen	9:35 – 9:45
	Data Analytics and Real World Interrogation Network (DARWIN) Arlett Peter and Stefan Blixen	9:45 – 9:55
	Q&A	9:55 – 10:10
BREAK		10:10 – 10:30
3	**MIRO Interactive activity**	10:30 – 11:00
4	**Topic 2: Semantic interoperability, data quality assurance** Providing guidance on data quality assurance, and solutions for semantic interoperability	11:00 – 12:00
	TEHDAS WP6 Enrique Bernal Delgado	11:00 – 11:10
	SNOMED Ian Green	11:10 – 11:20
	EHDEN Peter Rijnbeek	11:20 – 11:30
	RD-CODE ORPHANET Ana Rath	11:30 – 11:40
	Q&A and Mentimeter	11:40 – 12:00

TEHDAS Project Forum n° 1		
No	**Day 2: 19th of May (9:00 - 12:00)**	Time
	Welcome **Petronille Bogaert** **Mentimeter survey**	9:00 – 9:05
1	**Topic 3: Service and architectural technical interoperability** Providing options for the technical interoperability elements of the EHDS, according to the European Interoperability Framework.	9:05 – 10:00
	WP7 presentation Carlos Telleria	9:05 – 9:15
	Proud Engineers Hille Hinsberg	9:15 – 9:25
	Interopehrate.eu EHTEL Luc Nicolas	9:25 – 9:35
	PHIRI Ronan Lyons	9:35 – 9:45
	Q&A	9:45 – 10:00
2	**MIRO Interactive activity**	10:00 – 10:20
BREAK		10:20 – 10:40
3	**Topic 4: Citizen's engagement** Aiming to obtain a better understanding of citizens' relationship with health data in the EU, to better inform and sensitize citizens regarding health data and recommends data altruism practices for the EHDS.	10:40 – 11:45
	TEHDAS WP8 Louisa Stuwe	10:40 – 10:50
	My Data Isabelle de Zegher	10:50 – 11:00
	H2O Observatories Melpomeni Styliadou	11:00 – 11:10
	Personal Health Train Lianne Ippel	11:10 – 11:20
	Gravitate-Health Anne Moen	11:20 – 11:30
	Q&A and Mentimeter	11:30 – 11:45
4	**Concluding remarks** Petronille Bogaert	11:45 – 12:00

TEHDAS – 2nd Project Forum Meeting Minutes

Friday 29th October, 09:00-12:00, via WebEx (online)

Contents

1 Attendees

Number of participants: 130. Number of countries: 23 EU Member States and associated countries.

2 Welcome session

2.1 Welcome and aim of the Project Forum

The second TEHDAS Project Forum began with a welcome from **Petronille Bogaert (Sciensano)**.

Previously, the first Project Forum took place on 18-19 May 2021. There were over 100 participants from 20 countries, including public health institutes, research institutes, ministries, universities, international organisations, and private companies. Discussions centred around 4 thematics aligned with the Work Packages (WPs) of TEHDAS:

1. Sharing data for health: Frameworks and Governance Principles
2. Semantic interoperability, data quality assurance
3. Service and architectural technical interoperability
4. Citizens' engagement

The aim of the forum was to hear from other projects. Of 50 projects present, 13 projects pitched, including: Beyond 1 Million Genomes, SNOMED, DARWIN, EHDEN, RD-CODE, PHIRI, Proud Engineers, EHTEL, MyData, H2O Observatories, Personal Health Train, and Gravitate Health. The session was organised around key questions:

1. What do you do with regards to this specific topic that could be of interest to TEHDAS?
2. What can we learn from your experience? What should we build on?
3. How would you like to get involved with the EHDS? How do you see your collaboration with the EHDS?

Today we are taking a step further and dive into the different WPs. A request last time was to have more discussion so there will be breakout sessions. The breakout sessions will begin with a short pitch from a project about that topic. If any project is interested in pitching during the next Project Forum do not hesitate to let us know.

Permission to record for minutes purposes.

2.2 Introductory words

Markus Kalliola (Sitra) gave introductory words to the TEHDAS project and its outcomes to date.

We all know that the EHDS legal proposal is being prepared. You might argue that we already have the Data Governance Act so why do we need the EHDS legal proposal? The first

TEHDAS document entitled 'Why health is a special case for data governance' explains the specificities of health data and answers that question.

The next argument you might have is that we already have the EMA, ECDC, big projects (e.g., 1 Million Genomes) so why do we need more? In September, we published a document called 'Potential health data governance mechanisms for the European Health Data Space', which concludes that the existing EU structures in place do not solve the existing problems.

The third question is what problems do we have? In July, we published a document called 'Case studies on barriers to cross-border sharing of health data for secondary use'. We highlight that these unmet needs must be solved. They need specific legislation, and current structures are not giving the answers.

How do we build the EHDS? The most heard sentence in health policy is "do not reinvent the wheel". To grasp the understanding that we already have, we analysed 14 European data initiatives and published a document entitled 'Technical and operational analysis report of existing data sharing and/or secondary use initiatives in health and biomedical sciences'. We also have the Advisory Group where we gather experts, and WP4 gathers EU initiatives, projects and policy makers together to share knowledge.

We have progressed on the guidance we can provide to the European Commission. We have worked on the concept of data altruism, introduced by the Data Governance Act. We have published a review entitled 'Presentation of a first set of data altruism definitions, use cases and findings', on what it means in the health sector, showing the diversity in definitions and understanding of the topic. Work continues to provide concrete proposals.

We have also defined the user journey for the EHDS in the 'Report on EHDS services users' expectations'. This means the steps to access the data in the EHDS. We need a common language of how we access the data. We have also defined important terminology that could also be used in a legal act.

In terms of data quality, we have concrete proposals for the legal proposal. You will hear about them today. Some of the unfinished work is about citizens' engagement. One of the most difficult things is about financing, how to make the EHDS sustainable. We will have to wait a few months for that.

I am looking forward to the Project Forum, and to share the knowledge that you have gathered from your projects. We cannot solve all the problems alone.

3 TEHDAS Work Package updates

3.1 WP5: Sharing data for health – Frameworks and governance principles

Co-leads of WP5 are **Coen Van Gool (RIVM)** and **Michel Silvestri (Swedish eHealth Agency)**.

4 tasks of WP5 (Sharing data for health):

T5.1: User perspectives
T5.2: Data permit authority perspectives – this is the one that the presentation will focus on
T5.3: Best practice for bilateral cross-border exchange of health data for secondary use
T5.4 aims to boil down all this work into proposed governance models

This presentation focuses on milestone 5.3 'GDPR interpretations in the secondary use of health data in different Member States and other participating countries'. The methodology for this work was:

1. Literature study on public information about guidance and legislative frameworks on how to approach secondary use of, and sharing, health data
2. Analysis of the 'Assessment of the EU Member States' rules on health data in light of the GDPR' and potential gaps within that study
3. Use cases from the survey in task 5.1 on GDPR and other barriers when it comes to the sharing of health data for secondary purposes
4. A survey in the TEHDAS partner countries mapping organisation for granting access to health data for secondary purposes

1. Literature study

The literature study identified three meta-levels: legal frameworks, guiding frameworks, and frameworks for preparing health data to be shared and used by other parts. From these, 9 thematic blocks were identified.

The general conclusion was an overall uncertainty about how secondary use of health data can be conducted in accordance with data protection rules. The recurring theme in publications is how to practically enable secondary use of health data from a legal, technical and ethical perspective.

2. Analysis of the NIVEL study (Assessment of EU Member States' rules on health data in the light of the GDPR)

This is an important and complex study, especially the Annex, which looks at different interpretations of GDPR and elements that affect cross-border exchange of health data in the EU. Mentioned throughout the study is that Member States had different understanding of the survey questions. The team identified gaps in the NIVEL study: interpretation of GDPR; possibilities under GDPR (for Member States to have additional regulation or structures on top of GDPR); national complementary laws (on top of GDPR); organisational differences (different healthcare system organisation between Member States).

3. Case studies

The third part of the milestone was to look at priority barriers. The main barriers are:

A. There are differences in governance and health data systems in Europe
B. There is no common European interpretation of what constitutes 'sufficient anonymisation' to transform personal data to non-personal data
C. There is no common European interpretation of what constitutes 'pseudonymisation'
D. There is no common European interpretation of what is, and what is not, 'secondary use' of data
E. European countries have national laws/rules on health and research data in addition to the GDPR.
F. European countries have the ability to set their own derogations under the GDPR
G. European countries have different preferences as to the choice of legal basis for processing under the GDPR
H. Health data is considered sensitive data e.g., special category data under GDPR and is treated differently from other types of data when it comes to health data ethics, management and use
I. No standardised data sharing agreements exist for products developed by private sector providers using public sector health data to (a) facilitate safe data sharing and (b) protect taxpayers' investment
J. Across Europe, different taxonomy and ontology codes are used to label the same health condition, making comparison between datasets challenging
K. Poor data management practices reduce the ability to reuse data

Barriers B, C, D, F, G, H are caused by differing interpretations and implementation of the GDPR in relation to the secondary use of health data across Europe.

Two key conclusions from the case studies:

1. It is vital to consider the user perspective when developing guidance and recommendations on planning national legislation on secondary use of health data.
2. Barriers to data sharing under the GDPR are experienced by researchers and policymakers alike.

It is also important that while the simplification and harmonisation of EU interpretations of GDPR are the ultimate goal, there are also cases where ambiguity can be helpful or necessary. The right for Member States to set their own derogations must be respected and treated sensitively.

4. Survey for mapping organisation for granting access to health data for secondary purposes

The fourth part of the methodology was a survey to identify data permit authorities in participating countries and map their organisation. Extract:

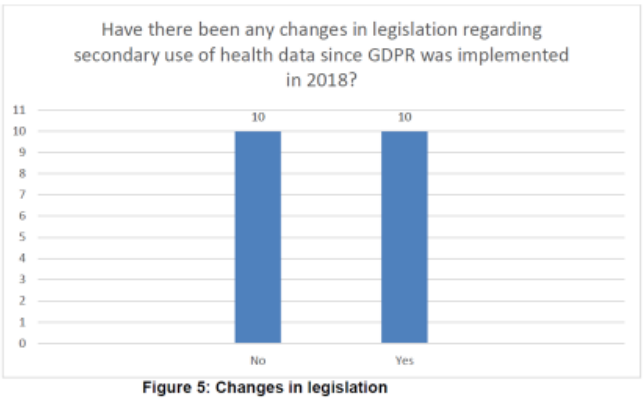


Figure 5: Changes in legislation

Final remarks

There were disparities in interpretation of survey questions and responses, and in the level of detail provided. It is important that the guidance for European countries (planned outcome of this WP) must be compatible with the Data Governance Act, and sensitive to national legislation and GDPR derogations.

Next steps for T5.2:

- Policy development (Q2 2021 – Q2 2022): conduct further analysis to fill the gaps as identified in this report
- Drafting (Q2 2022): develop draft recommendations and guidance for European countries
- Consultation (Q3-Q4 2022): test draft recommendations and guidance with European country representatives and key stakeholders
- Submission (Q4 2022): present final report to TEHDAS and European Commission

Questions for breakout session

TEHDAS and other projects have identified wide differences in GDPR interpretations across EU countries, hindering cross-border sharing and re-use of health data.

1. Have you faced such a challenge before in your work, and if yes how did you overcome it?
2. How, in practice, can EU achieve alignment for better GDPR interpretation across countries?
3. What do you think should be the position of the EHDS on this topic to improve this?

Q&A:

- Have you looked at what is done on GDPR interpretations OUTSIDE of health, in other sectors? There are other types of personal data apart from health data, we should not have a sector specific interpretation.
    - TEHDAS attempts to clarify why we should take specific considerations when it comes to health data in comparison to other data, and perhaps also other personal data. Part of the project is to clarify if there are important differences that motivate these distinctions between different categories of personal data.

3.2 WP6: Semantic interoperability, data quality assurance

Enrique Bernal Delgado (IACS) presented WP6, which is co-led by IACS and the Midt Region of Denmark.

The overarching aim is to provide solutions for trustworthy secondary use of health data with a view to fostering the digital transformation of European health systems. It particularly focuses on secondary use for 3 purposes: policymaking, regulation and research.

This overarching aim is split into objectives, which ultimately aim to provide a data quality assessment framework (DQAF) for the EHDS. The expected outcomes of this data quality assessment framework include:

- Recommendations on what elements should be assessed, and what methodology
- Specific hints on what specific elements should be brought into legislation. We will take some time on this
- Semantic and syntactic interoperability

What have we done so far?

We have summoned thematic working groups to get a consensus building process between the 10 institutions involved in WP6. The first milestone was published a few weeks ago, and approved this week by the Steering Committee. It provides recommendations on elements that should be legally bound within the data quality assessment framework.

This is a table included in the milestone:

Data quality framework: governance and regulation in the EHDS2

EHDS2 journey	Matters of regulation	Who is liable / accountable	Legal enforcement		
			No	R	M
Data collection	Regular audits	Competent bodies | DPA | Data hold's | Data coll's			X
	Rating system and promotion	Competent bodies | DPA | Data hold's | Data coll's		X	
Data publication	Meta-data catalogues - DCAT	DPA | Data holders | Data collectors			X
	Meta-data catalogues – machine readable	DPA | Data holders | Data collectors		X	
Eligibility to the EHDS	Bases for the development of the network of EHDS trusting institutions	EU DPA | Competent bodies | DPA			X
	Communication protocols with/across DPAs	EU & Nat'l DPAs			X
	Communication with data collectors	Competent bodies |DPA | Data holders			X
Data discovery	Standard query language in place (ie. API)	Competent bodies |DPA | Data hold's | Data coll's		X	
	Building synthetic data sets mirroring data collections | publishing visual analyses of quality at variable level	Data holders | Data collectors		X	
Data access	Clear access procedures (guidelines published)	DPA | Data holders | Data collectors			X
	Safe access to individual level data	Competent bodies | DPA | Data hold's			X
	Guidelines to comply with Ethical Principles	DPA | Data holders | Data coll's			X
	Data management plan	Users			X
Data delivery	Clear processing procedures (guidelines published)	DPA | Data holders			X
	Not hampering meaningful reuse – pseudonyms as preferred system	DPA | Data holders		X	
	Communication system for data delivery	DPA | Data holders		X	
Data processing & analyses	Access through Secure Computing Environment	Competent bodies | DPA | Data hold's | Data coll's		X	
	Auditable software	Data user		X	
Finalization & Devolution	Destruction of the datasets obtained	Data user			X
	Open-source outputs	Data user	X		

5

We are starting from the journey/steps that any actor in the EHDS would be exposed to. The identification of steps was based also on discussions on the EHDS pilot process started by the Commission this year. We identified elements/matter454785s of regulation that deserve analysis in terms of data quality, under the technological, semantic, legal, or organisational perspective. We then identified areas within the European interoperability framework that are particular areas of interest (red in the table). Conclusions on what is needed:

- For data collectors/controllers: regular audits
- For data publication: good metadata catalogues (discoverable, compliant with standards, machine readable)
- Data discovery: datasets that allow discovery and visual analysis so you can understand the quality of data when you discover it
- Data delivery: transparent processing procedures so users can know what is there, and provide recommendations on pseudonyms

For all these elements, we discussed potential topics of regulation. The last three columns show the strength of legal enforcement (no legal enforcement, recommendation, or mandatory). Finally, there were just three elements affecting data quality in the realm of WP6 that should be legally bound:

- Data holders should be audited on procedures of quality assurance, and a national authority should audit the data holder institutions and their data sets in accordance with the EHDS Data Quality Assurance Framework
- Data holders should be obliged to publish their data preparation procedures and ensure highest degree of transparency
- Data holders should be obliged to publish metadata about their data collections

Next steps

The legal apparatus is just a small element of the discussion about data quality assurance framework.

We are working with WP5 on data quality governance. We need to establish what should be assessed and the benchmarking methods to compare institutions in this auditing process.

We will convene a number of working groups within WP6 and have advice of external experts. The DQAF drafting group will build upon what we have learnt.

The second part of this work is semantic and syntactic interoperability. We are now framing the work and will then reach out to stakeholders of interest for consensus building process rounds.

Questions for the breakout session

Setting up proper governance mechanisms to data quality is key, particularly in federated approaches:

- What mechanisms should be used for data holders to become trustworthy nodes in the BBMRI federation?

A way forward to increase data quality may be setting up "auditing and promotion" (A&P) procedures – auditing according to standards, and promotion according to improvements in data holders' maturity:

- What is your experience on A&P approaches?
- What are the 'must' items to audit data holders on data quality assurance?
- Any thoughts about legal enforcement on A&P mechanisms?
- Any thoughts about incentivising data holders' maturity?
- Any alternatives to A&P mechanisms?

3.3 WP7: Service and architectural technical interoperability

Juan González García (IACS) presented WP7, on technical interoperability.

Technical interoperability can be difficult to understand. Simply put, the EHDS will be supported by computers. WP7 aims to define how the computers should interact, and what services they should provide.

WP7 uses a co-design process, aiming to foster interaction between multiple actors that will use the EHDS and aid in its deployment.

4 overarching objectives:

- O7.1: Study existing initiatives on secondary use of health data focusing on the requirements for their deployment
- O7.2: Foster the participation of future users of the EHDS and EHDS implementers on MSs, institutions or industry, to participate in the co-design of

the services for secondary use of health data as well as to provide architecture and infrastructure options. This is catalyes by the Work Package Advisory Group (WPAG)

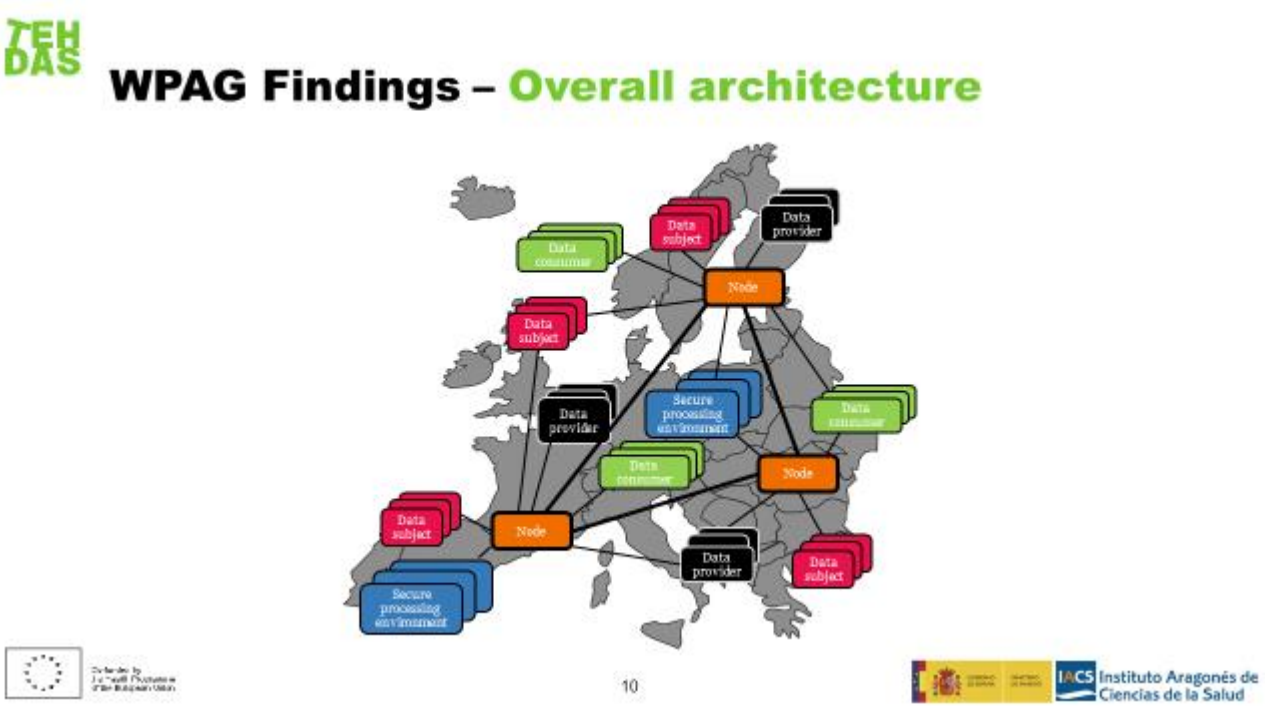
- O7.3: Define the options for the EHDS services for secondary use of health data
- O7.4: Detail the architecture and infrastructure options of the EHDS services for secondary use of health data, fully compliant with legal frameworks and with total guarantee of privacy and security.

The end products of WP7 (service catalogue and architecture and infrastructure proposals) will start by understanding existing initiatives and gathering knowledge from Work Package Advisory Group (WPAG).

Where are we now? We have finished the first task (survey of 14 organisations sharing data for secondary use). Results are available on the website.

The second outcome so far is the findings from the WPAG. The WPAG comprises stakeholders from big research infrastructures, pharma and biotech industry, research centres etc. There have been three thematic workshops so far. Two main outcomes of the WPAG:

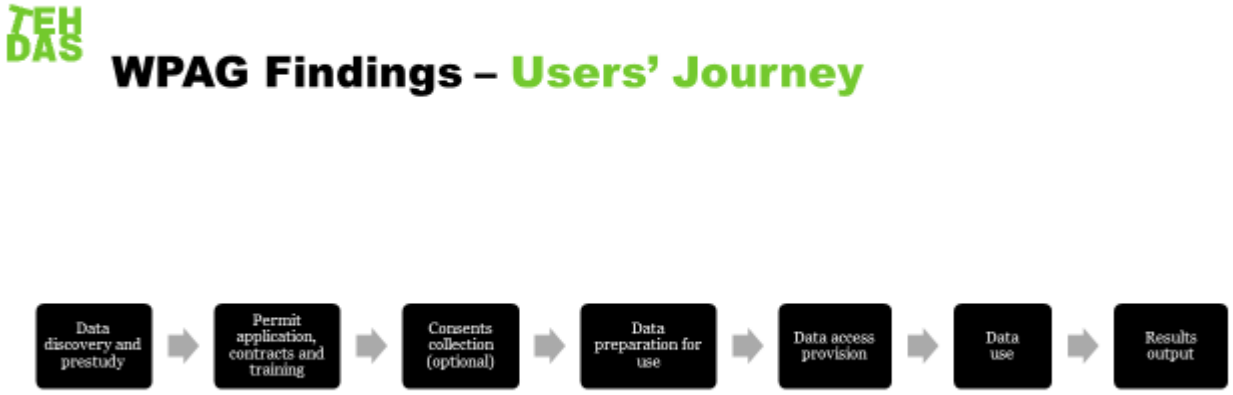
1. **Overall architecture:**



   - The main elements are **nodes** that interact amongst each other (peer to peer architecture).

- Three actors: Within these nodes, **data providers** are connected to **data consumers**. The nodes also provide features for **data subjects** (the citizens whose data is gathered) to have some control of how this data is shared.
- **Secure processing environment:** avoids that the data moves outside the premises of the data provider. This reduces possible risk for data breach. The secure processing environment is regulated in the DGA so it should something that should be fostered through the deployment of the EHDS.

2. **User journey:**



The user journey comes from the WPAG and from discussions in different forums. It defines the steps that a data consumer should follow within the EHDS, from the first step until they have results. In some of the steps, there is actual interaction between user and the EHDS, while others happen in the background.

Questions for the breakout session

1. How can we link individual data coming from different domains (e.g., healthcare providers, research infrastructures, registries, medical societies, personal devices)? What are the technical challenges?
2. How can we process the linked data across countries? What are the architectural challenges? Can we move data between countries? And algorithms?

3.4 WP8: Citizens' engagement

WP8 is co-led by the French Health Data Hub and the National Directorate General for Hospitals of Hungary (OKFO).

2 main objectives:

1. How to improve citizens understanding and trust in health data sharing and its secondary use
2. Empowering citizens so that they can become true actors of innovation as part of the future EHDS, including through enhanced data altruism practices

The WP8 work has been articulated around 2 main sets of recommendations:

- D8.1: How to better ensure citizen sensitisation and engagement with their health data and the future EHDS
- D8.2: How to foster data altruism practices – this is the deliverable on which we will focus today

Citizen's engagement – what has been done? (Zoé Perrin, French Health Data Hub)

The activities are organised into 3 main steps:

- T8.1 preliminary work (February – November 2021):
  - Literature review on citizens' perceptions of and role in health data secondary use and sharing in Europe
  - Qualitative study with 60 stakeholders from the health data ecosystem to assess their perception, experience and expectation of citizen involvement in the future EHDS
- T8.2 e-consultation (November 2021 – June 2022):
  - E-consultation dedicated to citizens in French, Dutch and English to better understand their perceptions, preferences and expectations towards health data secondary use and sharing
  - Publication of the results of the e-consultation
- T8.3 preparing recommendations (June 2022 – January 2023):
  - Workshops with national and EU stakeholders to discuss the results of the e-consultation and develop recommendations on citizen sensitisation to and engagement with health data
- Final deliverable: recommendations on citizens sensitisation to and engagement with health data in the future EHDS

The e-consultation (in French, Dutch and English) will start in late November or early December, and end March or April 2022. Results will be published in June 2022. The consultation will be only in 3 languages but it will be open to any EU citizen.

The results from the e-consultation and preliminary work will feed into the final recommendations, which will be drafted after workshops with national and EU stakeholders to discuss the results from the 2 first phases. We are now at the end of preliminary work, about to deliver the literature review to TEHDAS and launch the e-consultation.

Data altruism – what has been done? (István Csizmadia, OKFO)

The work is divided into 3 main steps:

- T8.4 preliminary work (February – September 2021):
  - Literature review providing state of play of data altruism definitions, use cases, issues and good practices

- T8.5 (1) Preparing primary recommendations (September 2021 – May 2022):
    - Workshops with national and EU stakeholders, including WPAG, to discuss and identify new definitions, good practices of data altruism, with a focus on use cases
    - Publication of results of the workshops
- T8.5 (2) Writing primary recommendations (May 2022 – January 2023):
    - Primary recommendations to foster GDPR-compliant data altruism mechanisms for the EHDS
- Final deliverable: Recommendations on lessons learned and recommendations for data altruism practices in national and European health data spaces

The preliminary work involved a literature review collecting definitions on data altruism and altruism practices. The first draft was discussed with WPAG members. There is no solid definition of data altruism. It is interesting to see whether we are talking about how and why people provide access to their health data, or about how intermediary/broker organisations collect, use and provide this data for further processing.

It is important to emphasise that we found different views on the question of whether data can be owned or not, not only in legal terms (possession, provision, donation etc.). We also spent time on whether there is an ethical obligation to allow health information to be used for research for other secondary purposes. This should be further assessed.

The next two milestones include workshops with trusted stakeholders to discuss specific questions.

We may also make a type of SWOT analysis of data sharing through different models. This is important because if we want to provide recommendations in the final deliverable on how to promote data altruism practices, we should understand the advantages, opportunities and barriers. We will finalise our recommendations in the second half of next year.

Questions for the breakout session

1. Can consent withdrawal or modification create legal uncertainty for researchers or innovative businesses which have obtained data through recognised/registered data altruism organisations? If so, how?
2. Are there any specific security and privacy features or requirements of providing health or health-related data for research and scientific purposes, compared to other data sharing/access, e.g. travel or purchase/rent of real estate or banking? If so, which are they?
3. The different possible forms of citizens' involvement in health data secondary use and sharing systems.

4. Breakout sessions

Each session started with a short pitch from a project on the specific questions that have been put forward by our WPLs, followed by interactive discussion.

4.1 Breakout room 1: Harmonisation of GDPR interpretation (WP5)

Project pitch: X-eHealth (Vanja Pajic)

The focus of X-eHealth is on primary use of data. Deliverables:

- Information paper on the current legal challenges of cross-border exchange of personal data
- Recommendation paper on legislative enablers for cross-border personal data interoperability

Like TEHDAS, X-eHealth aims to identify challenges to cross-border data sharing and to develop recommendations. X-eHealth approaches this question from the primary data perspective while TEHDAS is focused on secondary use of data.

“Together, we can consider how we bridge the gap between primary and secondary use of data in cross border legal domain” - Vanja Pajic, X-eHealth Legal Domain Task Lead, eHMSEG Legal Work Group Chair

Next steps for discussion:

- How to bridge the gap between primary and secondary use of data in the cross-border legal domain?
- How to more efficiently connect XeHealth and TEHDAS on legal matters?

Discussion

A key discussion point was that, ironically, although when GDPR was being discussed there was pressure for national derogations, people now recognise the problems of a fragmented system. There is now increasing pressure for harmonisation.

It was highlighted that in Germany, for example, there are Data Protection Authorities (DPAs) in each region as well as at a national ministerial level. Sometimes the DPAs have a narrow definition of secondary use of health data. One colleague suggested that there should be a mandate at the European level to make DPAs agree politically on priorities and systems.

Participants were asked if they were aware of any real problems from data not being protected adequately or from patients being concerned about the use of their data. It was interesting that no examples were shared.

As a final comment, the group discussed ways in which data could be shared and analysed. It was discussed that the federated analysis method would fit many types of secondary use of data but not all.

A question on the need for consent with anonymised data was also raised from a participant working in industry, given that anonymised data is untraceable to the patient. If the data is not untraceable then other conditions should apply. From a clinical perspective, there was a discussion about whether patients could provide a single permission for all secondary use of their data. Most participants found the opt-out model the most reasonable.

4.2 Breakout room 2: Governance elements of data quality (WP6)

Project pitch: BBMRI (Petr Holub)

What is data quality?

- Compliance of data with set of requirements ISO 8000
- Aspects of data quality:
    - Technology has advanced: is the data up to date?
    - Consistency in the data set
    - Traceability: think about data fraud

Data quality in EHDS context.

Discussion

The WP6 discussion was on governance elements of data quality. Governance of the EHDS is a focus point of WP5; we are doing our best to make sure that WP5 and 6 make a coordinated effort to present governance elements. WP6 discussions about governance are exclusively about health data quality assurance.

The discussions were supposed to focus on auditing mechanisms but the group discussed incentives for quality assurance at length. The first question was what mechanisms should be used for data holders to become trustworthy nodes in the federation. Certifications were discussed as an option. However, it is important that they are accompanied by incentives as they can become costly.

The next question was about having an auditing and promotion (A&P) mechanism that affects data holders. There was general agreement that audit should focus on procedures at institutional level rather than the substance or content of individual data sources. The group discussed whether legal enforcement should be based on providing proof of regular audits or go beyond and build on actual results. The general agreement was that we should focus on accountability.

The main discussion focussed on incentives and how to incentivise data quality improvements irrespective of having an auditing system in place. 5 key points:

- There are already strong incentives to ensure data quality (e.g., in the hospital sector because of reimbursement). However, that can introduce financial bias and skew data. It is important to note that we are not only talking about patient records as a source of data. It was also discussed that the focus is on the whole data value chain (from collection to sharing). Considering the great variation in data sources, the solution should take a broad perspective.
- Data monetisation can introduce ethical dilemmas.
- The last example was to look at clinicians coding skills. It will be difficult to make clear incentives that clinicians should focus on coding skills for research purposes, but these incentives should exist.
- The last question was potential alternative mechanisms to A&P approach to make data holders trustworthy institutions. Some time was spent on data altruism or individually owned data. The challenge is that coverage might be limited. For example, in relation to registries, it may not be realistic to gain specific consent from large samples of the population in order to make policies.
- Metadata was suggested as one of the most to promote trust and transparency.

4.3 Breakout room 3: Individual data linkage cross-domain at regional/national/European level (WP7)

Project pitch: ELIXIR (Niklas Blomberg)

Breakout room 3 started with an introduction by Niklas Blomberg from ELIXIR about activities relating to research, using genomics data combined with clinical data. The conclusion was that we should build on existing experiences and international standards. The discussion noted that genomics is an easier type of data for standardisation than others (e.g., clinical data) because it is quite stable and not as variable/heterogeneous.

Discussion

Healthcare information systems are quite isolated. They use different clinical coding systems, making interoperability difficult.

On the clinical side, there should be big driver projects for gathering standards and common practices (e.g., as currently happens in rare disease and genomic activities).

It was highlighted that technical challenges are sometimes not the most challenging. Regulatory challenges are difficult to solve. Regulations should be seen as an enabler not just as a restriction.

An interesting point was that technical solutions should be used to solve legal barriers. For example, fear of reliability can be tackled by technologies that allow data analysis without moving from the original source.

Another non-technical issue mentioned was incentives. Researchers have to be motivated to share and collect data, which does not always happen (e.g., due to competition). Challenges should be solved by all actors. Cost, resources, and competence needs are barriers.

Technology is moving fast and healthcare lags behind. Some countries are better developed than others. There have been problems in developing Europe as a whole for cross border data sharing. More investment is needed in this domain. We need to explain to decision makers the benefits of data sharing e.g., with simple use cases with high benefits (drugs, images or personalised data).

The group discussed the problematics of processing data in its original location or moving data to form big cohorts for research. The discussion noted that it may not be feasible to collect data in permanent European collection systems. We need project based cohorts that can be collected in one place, which can then be protected and secured for the lifetime of a project.

Personal identifiers were the final discussion point. We do not have a standard system for identifying patients in all countries and question was asked whether we need an EU recommendation. National ID is in sufficient in many cases because the data of one person is normally in one country, however there is a need to harmonise patient identifier practices.

4.4 Breakout room 4: Citizens' engagement (WP8)

Project pitch: Smart4Health (Attila Wohlbrandt)

Consent withdrawal and modification – Smart4Health approach

Even with anonymous data, Smart4Health follows the highest security measures. Only the citizen can link himself or herself to the pseudonym. There are regular manual data quality checks.

If there are any breaches, we come back to citizen and in the worst case delete the data.

Legal uncertainty must be prevented by the right formulation of consent. In Smart4Health, data is pseudonymised form to allow re-contacting, and adding to longitudinal data sets.

Types of citizen's involvement in Smart4Health

Citizen's involvement through type of consent. Smart4Health uses broad consent with dynamic options:

- No selection for kind of research or research fields
- Restriction to health, medical and biomedical research
- Health data may be used for research questions that we cannot foresee today
- Dynamic consent modifications

Smart4Health has worked on dynamic consent but considers that it would give citizens too much choice and overwhelm them. Instead the project opted for broad consent with dynamic options.

Citizen's involvement through transparency and choice:

- Informed consent process

- See what kind of research is being carried out
- Select which data to provide
- Modify consent

Citizen's involvement through contacting: Another form of citizen involvement is through contacting citizens.

The important thing to point out is that the ultimate aim is personalised health services:

- Citizen-facing apps powered by longitudinal health data
- Sources: EHR, clinical data, wearables, and genomics
- Actionable insights for behavioural change

Enabling multi-modal risk scores would provide most benefit to citizens and society.

Discussion

The group discussed that an important starting point is to decide whether a system will have a centralised or distributed form. Smart4Health decided for centralised secure cloud system. The project is currently discussing end-to-end encryption with citizens. If the citizen loses their key they lose their data, so the project is looking for solutions for citizens who don't want that responsibility. The conclusion was that the responsibility for the safety operation should be on the system operator rather than the patient.

It was emphasised that controlled access of users to the system must be assured. In Smart4Health researchers use their own code.

Pseudonymisation and anonymisation are key aspects for data sharing systems. In Smart4Health, data are pseudonymised in order to reconnect citizens. Once consent is withdrawn all data are anonymised.

There is a challenge with anonymisation in that it is difficult to guarantee that the data remains anonymous in the future. It is important to reassess anonymisation regularly. Anonymisation can make the data less useful, so striking a balance is key.

The second question was about consent. The important point was made that the legal uncertainty can be avoided by the right formulation of consent. Several types of consent exist (also a conclusion of WP8 literature review). For each system it is important to define the type of consent used.

The broad consent with dynamic options system used in Smart4Health answers the potential uncertainty of citizens to opt out. In this system, data are not selected for specific research fields and health data can be used for research questions which are not foreseen at the time. However, due to the dynamic feature, citizens can always modify or withdraw their consent. In case of withdrawal, data should either be deleted (right to be forgotten) or anonymised (which is from a legal point of view equal to deleting personal data).

Re-consent is always demanding when citizens or patients participating in a system have to give consent for future activities. Broad consent is a good solution because the right to be forgotten is always guaranteed.

In terms of citizen involvement, there were interesting examples from other projects like the Sensotrend diabetes diary project from Finland on how apps can provide technological solutions. Importantly, citizens' involvement should not be restricted to consent. Citizens have to be active participants in the operation of data sharing activities, systems and projects.

It was concluded (in line with literature review from WP8) that public interest is important for citizens and it is important to share the benefits created by the activities and data sharing. Participants need to be informed of how the secondary use can create value and how the value will be shared. Primary use of data is key, and it can serve as a good basis for secondary use. A validated app can increase trust to consent for further research.

5. Plenary

5.1 Presentation of breakout room discussions

See above for the summary of the discussions in the breakout sessions presented from the rapporteur from each room in the plenary session.

Irene Kesisoglou asked all WPLs and co-leads whether these conversation were helpful for your upcoming work and if they have already found some connections or potential collaborations with a project to continue your work?

- WP5: It has been very interesting to listen to all the participants and experts. We may not have got clear answers to our questions but we could not expect that, because these are complex matters. For instance, in the chat we are discussing anonymisation, how to define it, and how to interpret legislation. This is one example of where we still have more important steps to make. I look forward to continuing this work.
- WP6: The discussion about anonymisation and pseudonymisation is something that we will also look at in WP6. Our breakout session discussed the dilemma with anonymising health data as you can lose a lot of the value. I agree that if a patient retracts their consent, you cannot just anonymise the data and thereby over-rule the retraction. This is something we will discuss in TEHDAS over the next few months and years.
- WP7: There are two important points for WP7. We need to raise awareness that technical solutions can overcome some legal challenges, so we will need to focus some of our work on teaching this to policymakers. Regarding collaboration, we have good ties with good projects so it is a matter of keeping on working with them.
- WP8: With regards to potential synergies, the Sensotrend project would be interesting to follow up with. We also had the opportunity to discuss other forms

of citizens' engagement beyond applications, such as involvement in research projects, decision-making and deliberation processes. This could be further investigated in our future work.

5.2 Concluding remarks (Linda Abboud, Sciensano)

Linda Abboud (Sciensano) gave concluding remarks. Thank you everybody. It was very interesting to learn from each other about what TEHDAS is doing and from other projects who are really dealing with these topics. To quote Markus: "we cannot solve everything alone", and we need these collaborations that we are creating in this Project Forum.

For the pitches and projects, please share slides and include contact in case people want to contact you and collaborate.

Our next project forum will be in 6 months, in May or June 2022. We also have additional activities in WP4. The upcoming Policy Forum focuses on engaging with ministries. It brings together Ministries of Health, Research and Economy. It is a closed door meeting but we will keep everyone updated on the TEHDAS website through a news article.

WP4 is also doing country visits. These are mapping exercises where we engage with different stakeholders and conduct interviews to map the data management developments in different countries. These activities are very complementary with the Project and Policy Forums to create a good overview and provide recommendations to the European Commission when they create the EHDS.

Do not hesitate to reach out to the different WPLs and have a look at the different outputs that were mentioned at the start of the meeting on the website.

We look forward to seeing you again in the upcoming meetings.

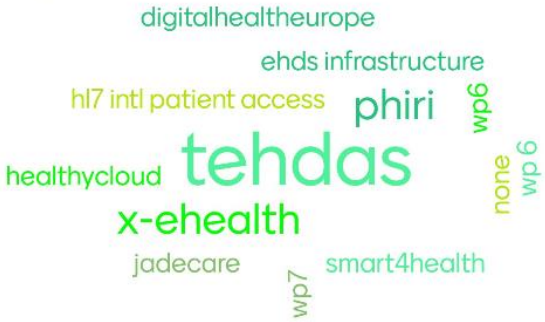
Mentimeter feedback for next Project Forum

- More time in the breakout sessions
- Using menti or other tools during the event to collect views
- When the country visits start, get some feedback and understanding/results from the first country visits
- More background information prior to the meeting

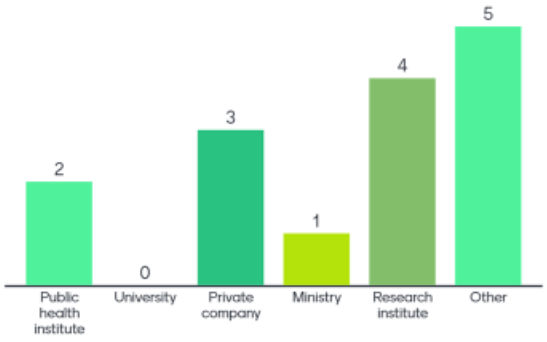
Mentimeter result

For which country do you work?

Which project do you represent?



What kind of institution/ organization do you represent?



TEHDAS Project Forum n° 2			
29th October 2021 (9:00 – 12:00)			Time
1	**Welcome and Aim**	*Petronille Bogaert Sciensano* *Markus Kalliola Sitra*	9:00 – 9:15
TEHDAS WPs updates			
2	**Sharing data for health- Frameworks and Governance principles** *TEHDAS WP5 update of achievements*	*Michel Silvestri The Swedish eHealth Agency*	9:15 – 9:25
	Semantic interoperability, data quality assurance *TEHDAS WP6 update of achievements*	*Enrique Bernal Delgado Institute for Health Sciences (IACS)*	9:25 – 9:35
	Service and architectural technical interoperability *TEHDAS WP7 update of achievements*	*Juan González Institute for Health Sciences (IACS)*	9:35 – 9:45
	Citizen's engagement *TEHDAS WP8 update of achievements*	*Zoé Perrin French Health Data Hub* *István Csizmadia OKFO*	9:45 – 9:55
	Q&A		9:55 – 10:05
Breakout sessions			
3	**Introduction to breakout rooms**	*Petronille Bogaert Sciensano*	10:05 – 10:10
4	**Breakout room 1: Harmonisation of GDPR interpretation (WP5)** **Project pitch**	*Project pitch: Vanja Pajić, Kraj Vysočina*	10:10 – 11:00

	X-eHealth **Discussion** 1. TEHDAS and other projects have identified wide differences in GDPR interpretations across EU countries hindering cross-border sharing and reuse of health data ○ Have you faced such a challenge before in your work and if yes how did you overcome it? ○ How, in practice, can EU achieve alignment for better GDPR interpretation across countries? ○ What do you think should be the position of the EHDS on this topic to improve this?	*Moderator: Michel Silvestri, The Swedish eHealth Agency*	
	Breakout room 2: Governance elements of data quality (WP6) **Project pitch** BBMRI **Discussion** 1. The importance of liability and accountability in federated approaches. ○ What mechanisms should be used for data holders to become trustworthy nodes in the federation? 2. An "auditing and promotion" system applicable to data holders – auditing according to standards, and promotion according to improvements in data holders' maturity: ○ what is your opinion about having an auditing and promotion mechanism that affect data holders? And what data quality issues should be deemed "must" in an audit and promotion mechanism? ○ Should legal enforcement lay on providing proof of regular audits, or should it go beyond and build on the actual results? ○ How to incentivize data quality improvements irrespective of having an "auditing and promotion" system in place? ○ What could be an alternative mechanism to our "audit and promotion" approach, to get data holders as trustworthy institutions?	*Project pitch: Petr Holub, BBMRI* *Moderator: Enrique Bernal Delgado, Institute for Health Sciences (IACS)*	
	Breakout room 3: Individual data linkage cross-domain at regional/national/European level (WP7)	*Project pitch: Niklas Bloomberg, ELIXIR*	

	Project pitch EOSC life **Discussion** 1. How can we link individual level data coming from different domains? (Health Services, Research Infrastructures, Registries, Medical Societies, etc.) ○ What are the technical challenges? 2. How can we process the linked data across countries? ○ What are the architectural challenges? ○ Can we move data between countries? And algorithms?	*Moderator: Juan González, Institute for Health Sciences (IACS)*	
	Breakout room 4: Citizen's engagement (WP8) **Project pitch** Smart4Health **Discussion** 1. Can consent withdrawal or modification create legal uncertainty for researchers or innovative businesses which have obtained data through recognised/registered data altruism organisations? - If so, how? 2. Are there any specific security and privacy features or requirements of providing health or health-related data (system-captured or self-generated from apps and wearables or collected in work place context, after one completes a separate consent) for research and scientific purposes, compared to other data sharing/access, e.g. travel or purchase/rent of real estate or banking? - If so, which are they? 3. The different possible forms of citizens' involvement in health data secondary use and sharing systems	*Project pitch: Attila Wohlbrandt, Hasso-Plattner-Institute* *Moderator: Zoé Perrin French Health Data Hub*	
BREAK			11:00-11:15
5	**Plenary** Presentation of the solutions discussed in each breakout room by a designated rapporteur	*Designated rapporteurs* *Moderator: Irene Kesisoglou*	11:15 – 11:45

		Sciensano	
6	**Concluding remarks**	*Linda Abboud* *Sciensano* *Petronille Bogaert* *Sciensano*	11:45 – 12:00

For more information visit:
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For questions contact:
TEHDAS.sciensano@sciensano.be
Twitter:
#TEHDASforum
@tehdas
@EU_Health

TEHDAS – 3rd Project Forum Meeting Minutes

Wednesday 22nd June 14:00-17:00, via WebEx (online)

Contents

1 Attendees

Number of participants: 121. Number of countries: 23 EU member states and associated countries.

2 Welcome session

2.1 Welcome and aim of the Project Forum

Shona Cosgrove (Sciensano) welcomed participants to the third TEHDAS Project Forum. Permission to record was gained.

Recap of the 2nd Project Forum

The 2nd Project Forum took place on 29th October 2021. There were 130 participants from 23 countries, representing a variety of institutions (e.g., public health institutes, ministries, private companies). The 2nd Project Forum started with an update from the TEHDAS Work Packages (WPs). There were four parallel breakout sessions, covering the topics:

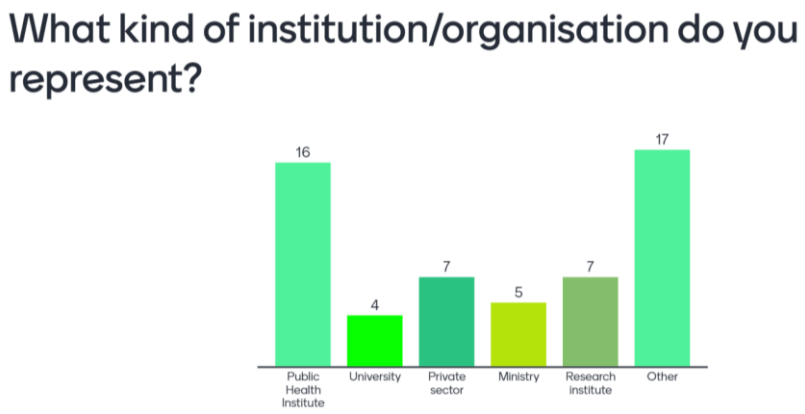
1. Harmonisation of GDPR interpretation
2. Governance elements of data quality
3. Individual data linkage cross-domain at regional/national/European level
4. Citizen's engagement

In each breakout, a project presented about their work on that particular topic. The projects that pitched were: X-eHealth, BBMRI, EOSC-Life and Smart4Health. Each breakout then had interesting discussions.

3rd Project Forum: Icebreaker mentimeter

1. What country do you work in?

2. What kind of institution/organisation do you represent?



3. What project do you represent?

Responses included: TEHDAS, SHAPES, HealthyCloud, PHIRI, BY COVID, 1+MG, MetabERN, RWE4Decisions, DH-Convener, AHEAD, In-4-AHA, Helmholtz Metadata Collaboration, Gravitate-Health IMI, Open DEI, EHTEL, Medical Informatics Platform – Human Brain Project, Nordic Commons, EU telemed projects, IMI PIONEER, OPTIMA, ERN, ENVISION.

Linda Abboud (Sciensano) was the moderator for the 3rd Project Forum.

2.2 Presentation of the Proposal for a Regulation on the EHDS

Karina Zalite and **Licinio Kustra Mano (DG SANTE, European Commission)** presented the Proposal for a Regulation on the European Health Data Space (EHDS), published 9 May 2022.

The EHDS emerges from the European Strategy of Data, and is a key pillar of EU Health Union. There is no better time to act than now, when COVID has shown the importance of digital health services and of health data. Across several studies, the EC has identified challenges in member states that make health data sharing and access difficult.

3 major challenges in harnessing the power of health data:

1. Individuals' access to health services is hampered by difficulties accessing and controlling their health data (both across and within Member States).
2. Different standards and limited interoperability mean manufacturers of digital health services/products face barriers and costs when entering markets of different member states.
3. Fragmented legal rules and frameworks, standards, and infrastructure for re-using health data restrict researchers' access to health data. A wide variety of GDPR legal bases are applied by different data holders in different member states, making cross country studies very difficult.

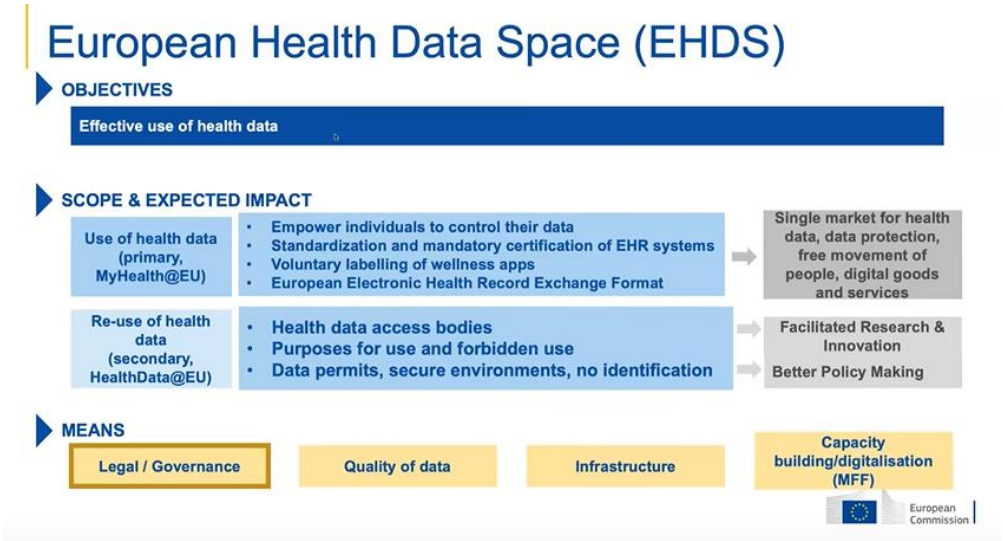
Voluntary measures mean that the current regulatory framework has shown limited effectives. The EHDS is the EU's response to these needs. It is the first common EU data space in a specific sector.

What does the EHDS mean? The EHDS is the health specific ecosystem comprising of rules, common standards, infrastructure and governance framework that aims at: empowering individuals to access and control their personal health data; fostering a single market; and providing an EU framework for use of health data for research, innovation, policymaking and regulatory activities.

The EHDS builds and complements on other legal proposals and initiatives:

- GDPR: EHDS builds upon GDPR rights and further develops some of them
- European Health Union: EHDS will boost the work of EU Cancer Plan, HERA, Pharmaceutical Strategy for Europe
- Data Governance Act, Data Act: EHDS complements and provides more tailor-made rules for the health sector
- EU cybersecurity framework (NIS directive): EHDS complements and provides more tailor-made rules for the health sector
- Artificial Intelligence Act: EHDS supports and complements training of AI, interoperability of AI and EHR systems and data quality
- Medical Devices Regulation: if manufacturers notify interoperability of devices with EHR systems, EHDS requirements apply

The regulation is in two parts: primary and secondary use of health data. The main objective is effective use of health data.

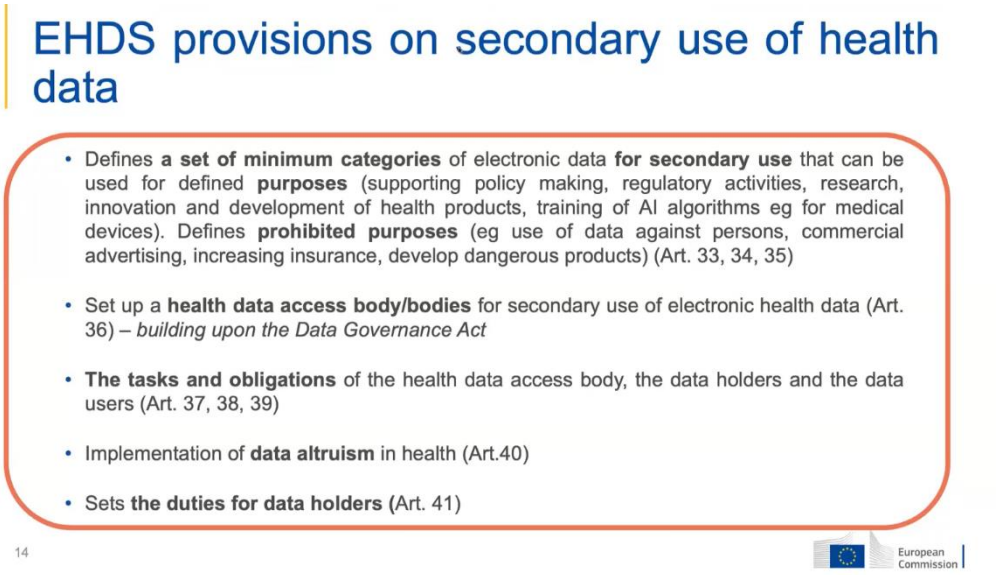


All member states will be required to participate in the MyHealth@EU cross-border infrastructure for primary use, and the proposal creates a new infrastructure for secondary use, HealthData@EU.

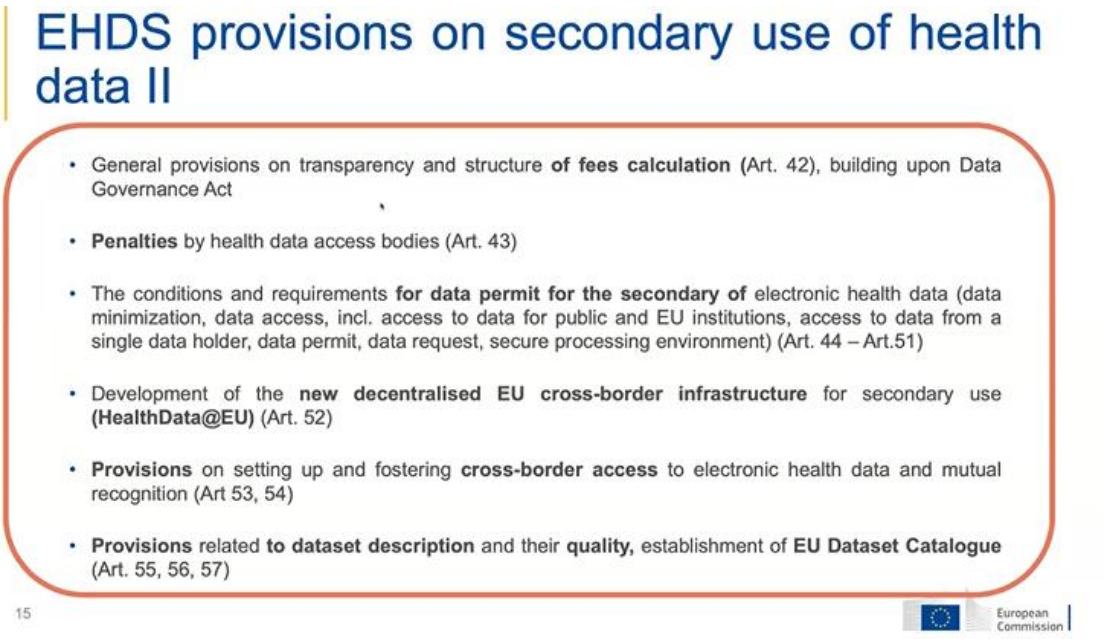
Benefits of the EHDS:

- For individuals: more control over their data, more efficient healthcare, improved helath outcomes.
- For industry: same interoperability standards and specifications will open new markets. Greater availability of health data will facilitate research and innovation for development of new products.
- For researchers: access to large amounts of data and the ability to know what data is available, where, and with what quality. Access to data in a more effective way through health data access bodies, whilst maintaining privacy.
- For regulators and policymakers: easy eacces to health data for the benefit of public health and functioning of health system will improve health outcomes for patiens and broader public.

Provisions of the EHDS Proposal for secondary use



Regarding fees, the spirit is about creating fair compensation for the costs of making data available.

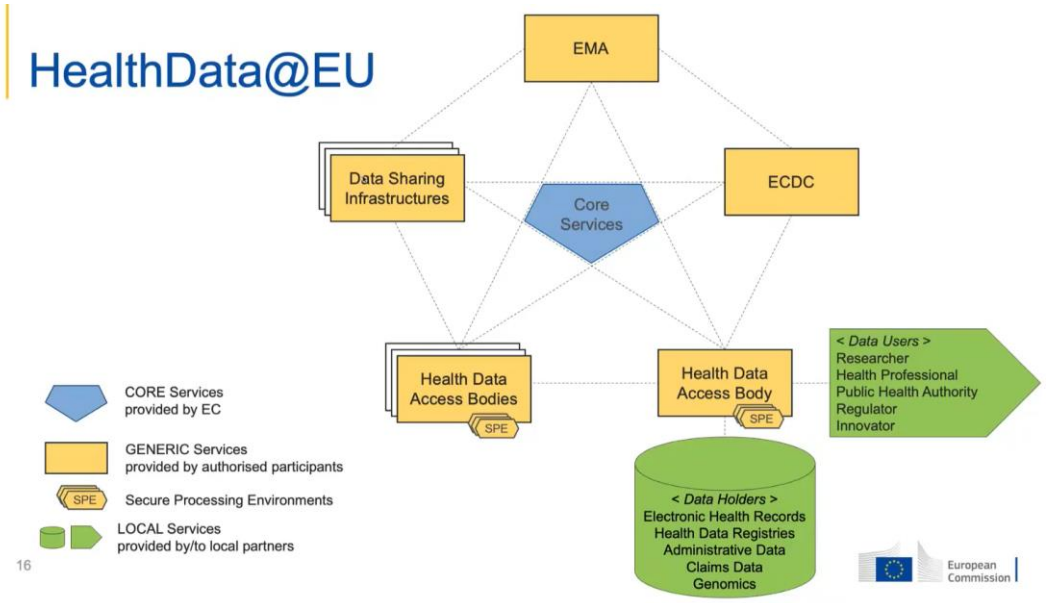


The data permit is the central instrument to facilitate streamlined access to health data for secondary use. The EC wants to make these one stop shops in Europe in the same way.

For that we need a new infrastructure for secondary use and we are learning from TEHDAS which are the building blocks for this.

On data quality, the proposal outlines a short dataset description that all data holders need to make publicly available. Describing quality characteristics of the data is on a voluntary basis. The purpose is to create transparency for those seeking data. The second part of the data quality label is the maturity model for data holders. It sets out the requirements for data holders to improve the quality of their data. This dataset catalogue that can have different technical forms, and the EC counts on TEHDAS for that.

General design for the architecture: data stays with data holders, data users can come from any country in Europe, and the cornerstones for the decentralised framework are the health data access bodies. Other authorised participants include data sharing infrastructures, and European level agencies who need access to data for their function (e.g., EMA).



Trust from the data subjects is extremely important. Trust means different things in primary use and secondary use. The EC sees a very important role to be provided by the secure processing environments with common rules and security requirements, and that no personal data can be downloaded.

Next steps

- Negotiations with the Council and European Parliament
- EHDS2 pilot (starting in September)
- Shift of TEHDAS towards implementation. Proposed areas: benchmarking, fees, HDABs work on cross-border level (permits, multi-country requests etc), minimum dataset description, data quality and utility label, secure processing environment, broad consent)

3 TEHDAS Work Package updates

TEHDAS results are available on the TEHDAS website.

3.1 Introduction from TEHDAS Coordination

Minna Hendolin (Sitra) introduced TEHDAS. TEHDAS aims to help the European Commission and member states in building the guidelines and dialogue related to the EHDS. We have now reached mid-term of the project, almost 1.5 years.

Since the publication of the EHDS Proposal, we are looking at potential changes to be made to the project. There will be very open dialogue within the teams, and with the European Commission.

Overall, the project is going very well and we have reached the objectives originally set at the start of the project. Last week we had the TEHDAS Stakeholder Forum. There were 1000

people registered to the stakeholder forum and of those 700 participated, with 250 people were in the room. Very proud of the visibility achieved by TEHDAS.

The Project Forum today is a springboard for future collaboration between different project and stakeholders.

3.2 WP4: Outreach, engagement and sustainability

Irene Kesisoglou (Sciensano) presented Work Package 4, which focuses on outreach, engagement and sustainability. The aim is to engage in dialogue with stakeholders and incorporate the views into the project, including needs and expectations for the EHDS.

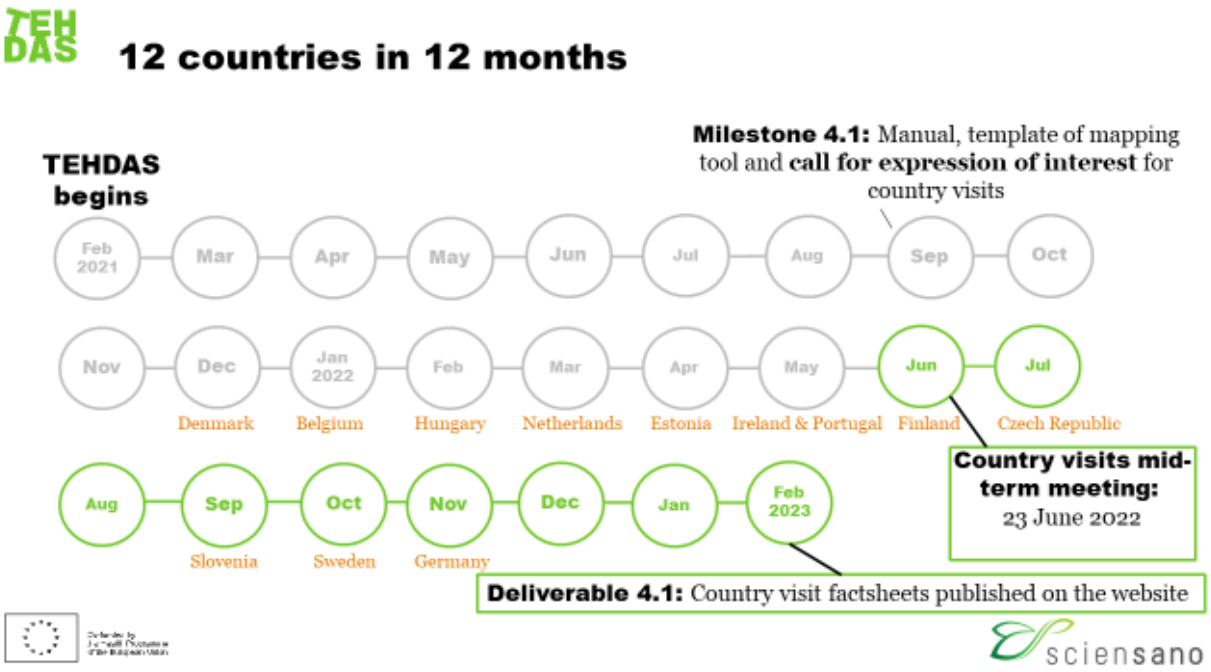
WP4 does this in 3 ways:

- Country visits
- Project Forums and Policy Forums
- Sustainability plan for the EHDS

WP4 wants to ensure that the project's results are integrated and influence the drafting but also the implementation of the EHDS.

Country visits (Task 4.1)

The aim of the country visits is to map the state of play of the health data management system of member states and their preparedness to join the EHDS. We aim to identify capacity building needs and opportunities in preparation for the EHDS.



A final meeting will be held in January presenting results. Fact sheets will be published in February 2023.

The tool for the country visits is based on the WHO health information system assessment tool, adapted in order to add questions regarding the preparedness of the countries to join the EHDS. Topics covered:

- Data collections and sources (e.g., EHRs, health insurance data, registers, quality registers)
- Data quality aspects
- Data infrastructure: storage, access, interoperability and standards in use
- Data governance (legislative framework for secondary use)
- Resources (human, technical, financial)
- Readiness to join the EHDS (political will, cross-border collaborations, needs and expectations to join the EHDS) and training opportunities and needs

Methodology:

1. Preparatory desk review
2. Country visit: semi-structured interviews using assessment tool, virtual or in-person, stakeholders from different sectors
3. Debriefing meetings: multi-stakeholder meeting at the end of the visit
4. Reporting: one-pager (publicly available) and detailed report (internal, shared only with EC, TEHDAS partners and stakeholders interviewed)

Overarching findings from the first 8 countries visited (preparedness to join the EHDS):

1. Political will to join the EHDS (8/8 countries visited)
2. National contact point established (3/8)
3. Common metadata catalogue (1 existing + 3 ongoing/8)
4. Remote secure processing environments (4/8)
5. Digitalisation (7/8)
6. Semantic interoperability (3/8)
7. Usage of personal unique identifier for health (7/8)
8. Equal access for national and foreign researchers (7/8)

Proposed changes to the work of WP4 in TEHDAS

- Refine mapping tool in order to provide guidelines for a future benchmarking tool. It is a qualitative tool, we are not adding values to the benchmarking tool yet.
- The EHDS proposal includes the concept of fee policies, which will be considered within D4.3 on the sustainability plan for the EHDS.

Next steps

- 23 June 10:00-12:00 – Country visits mid-term meeting and publication of first one-pagers (joint with PHIRI project)
- 29 June 14:00-16:00 – Policy Forum #3

3.3 WP5: Sharing data for health – Frameworks and governance principles

Mario Jendrossek (French Health Data Hub) presented WP5 on data governance.

WP5 has 4 sub-tasks.

- Task 5.1: Aimed to collect user perspectives and needs on the secondary use of health data. This task has provided recommendations to address barriers to secondary use of health data.
- Task 5.2: Looks at the perspective of data permit authorities, in terms of national legislation on secondary use of health data, basing itself on experiences of countries having already established national legislation.
- Task 5.3: Looks at best practices for cross border collaborations. A memorandum of understanding has been signed between French Health Data Hub and Findata on the secondary use of health data. There is also a compilation of practice procedures to access data for both national and EU researchers in those different settings.
- Task 5.4: Bringing together the outcomes of these different tasks, and putting forward options for governance models for the EHDS.

Proposed changes to the work of WP5 in TEHDAS

M5.6 'Compilation of best practices for EU cross-border exchange including data access and data permit processes in different national settings' will be changed to 'Compilation of perspectives on multi-country data application requests, mutual recognition and cross-border requests through a workshop approach'.

Milestone 5.6 will look at how to make multi-country and cross-border data requests work in practice. It will not define the final version of how those will work. One additional piece is the role that mutual recognition could play, which is referenced in the EHDS proposal.

D5.3 'Recommendations for best practices for EU cross-border exchange including data access and data permit processes in different national settings' will be change to 'Guidelines document for multi-country data application requests, including mutual recognition and cross-border requests'.

Next steps

- August 2022: D5.4 presenting the best options for governance models for the EHDS
- November 2022: D5.2 presenting recommendations intended to facilitate the planning (and implementation) of national legislation on secondary use of health data
- January 2023: new M5.6 presenting perspectives on multi-country data application requests, mutual recognition and cross-border requests through a workshop approach
- May 2023: new D5.3 presenting guidelines for multi-country data application requests, mutual recognition and crosso-border requests
- Work Package Advisory Group meeting (tbc)

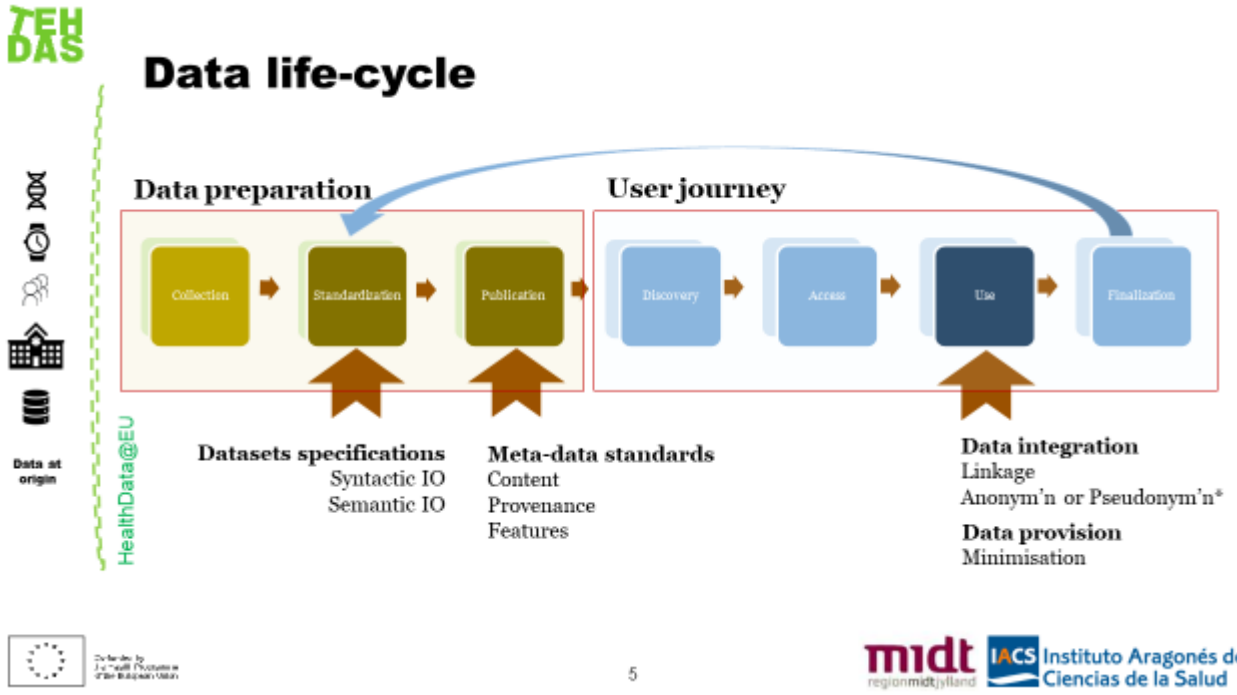
3.4 WP6: Semantic interoperability, data quality assurance

Enrique Bernal Delgado (IACS) presented WP6 on data quality and semantic interoperability.

WP6 is co-led by IACS and the Central Region of Denmark. It is expected to provide guidance on a data quality framework for the re-use of data. The recommendations look at: 'what' and 'what for' (the concept), 'where' (what institutions it should apply to), 'when' (in the data life cycle), 'how' it should be implemented and 'by whom'.

Presentation will focus on the data life cycle part because it is touched upon in the legislative proposal.

Data life cycle:



In data preparation, there are two steps where a data quality framework may play an important role:

1. Specifications for datasets to syntactically and semantically interoperable in the EHDS.
2. If you want this data to be re-used then you need to publish it in a standardised way. Users need metadata standards to be applied with information on the features, content, and provenance of the data, understandable by the user.

After data preparation, the user journey begins (user contact with health data access body). Elements to consider in the user journey for application of the data quality framework:

- Data integration and data provision, e.g. whether linkage is robust, secure, if there is bias in data.
- Anonymisation and pseudonymisation.
- How the minimisation principle is applied.

In the upcoming work (planned for publication in April 2023), WP6 will provide guidelines on elements that affect the data life cycle and the user journey:

- Data resources description
- Minimum set of data categories
- Data quality and utility labelling
- Data minimisation and de-identification
- Data sources linkage

Would like to learn more from different projects about the maturity model for the EHDS.

3.5 WP7: Service and architectural technical interoperability

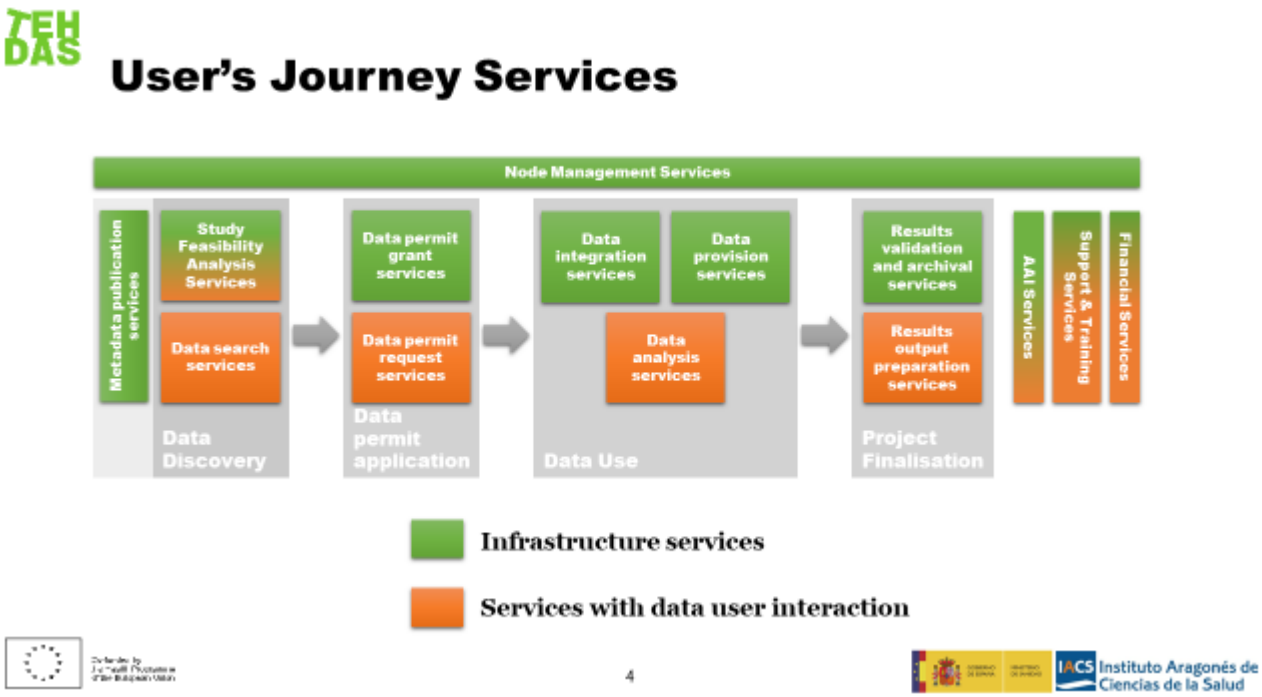
Juan González García (IACS) presented WP7 on the technical infrastructure.

The first Deliverable 7.1 is about the user journey, the services to support it, and the architecture where that user journey will be deployed.

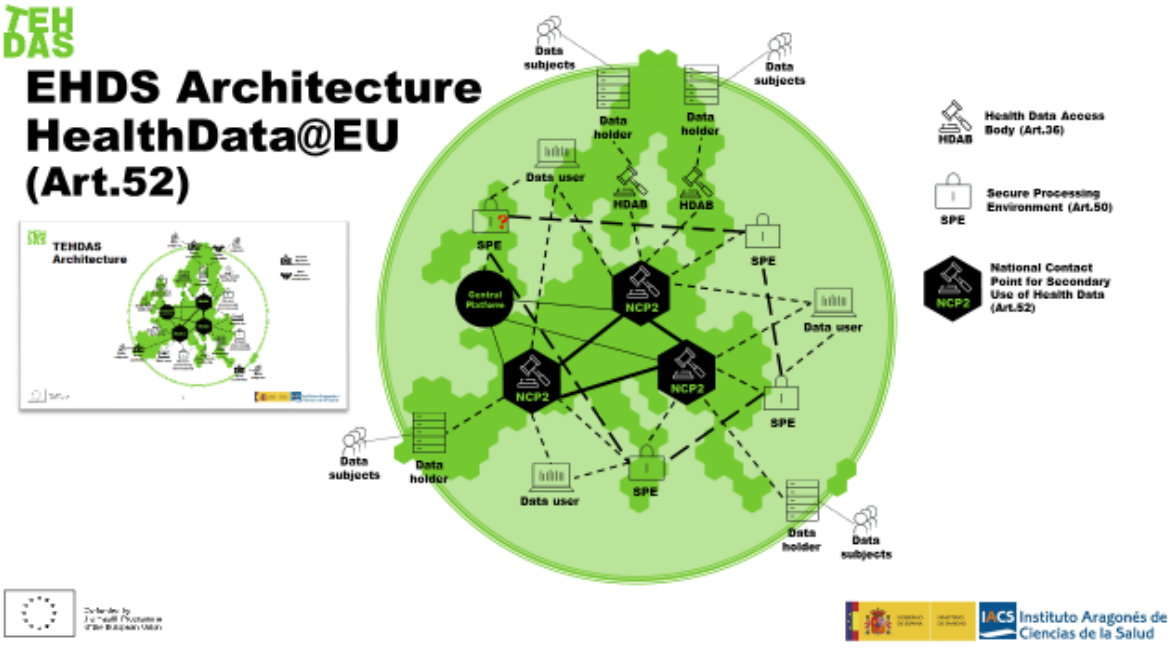
The user journey is the last step in the data life cycle, describing the process that a user of the EHDS2 needs to follow to access data and start analysing it. There are 4 steps:

- Data discovery
- Data permit application
- Data use
- Project finalisation

Services (software components that provide functionalities) for every step in the user journey are foreseen as:



Architecture:



The architecture we have foreseen in TEHDAS is the small figure above, while the big figure is as defined in the EHDS Proposal. They are mostly the same. It is built as a peer to peer network, where member states are represented by their national contact points (NCPs) for secondary use. The NCPs have the same responsibilities in the different member states and they communicate to each other as peers.

There is a central platform defined in the EHDS proposal. This is a special node operated by the EC, which will aid NCPs in some of the services. NCPs are the ones providing services to data users: they contact health data access bodies (HDABs) and are in charge of providing data in the secure processing environments (SPEs) for analysis.

NCPs will have an active role in each step of the user journey, coordinating the actors in the data life cycle.

Next steps

WP7 has been asked to focus on guidelines for secure processing environments.

There are two interesting inputs for the work:

- Regulation by Findata for secure processing environments (SPEs)
- Health Data Research UK (HDR UK) document defining trusted research environments

HDR UK are also thinking about a federated model (SPEs that communicate amongst each other), as opposed to Findata, which thinks of them as isolated SPEs. The federated model means that you can provide much more complex features, e.g. federated learning. WP7 will also check other documents from the French Health Data Hub and other frontrunners in SPEs.

3.6 WP8: Citizens' engagement

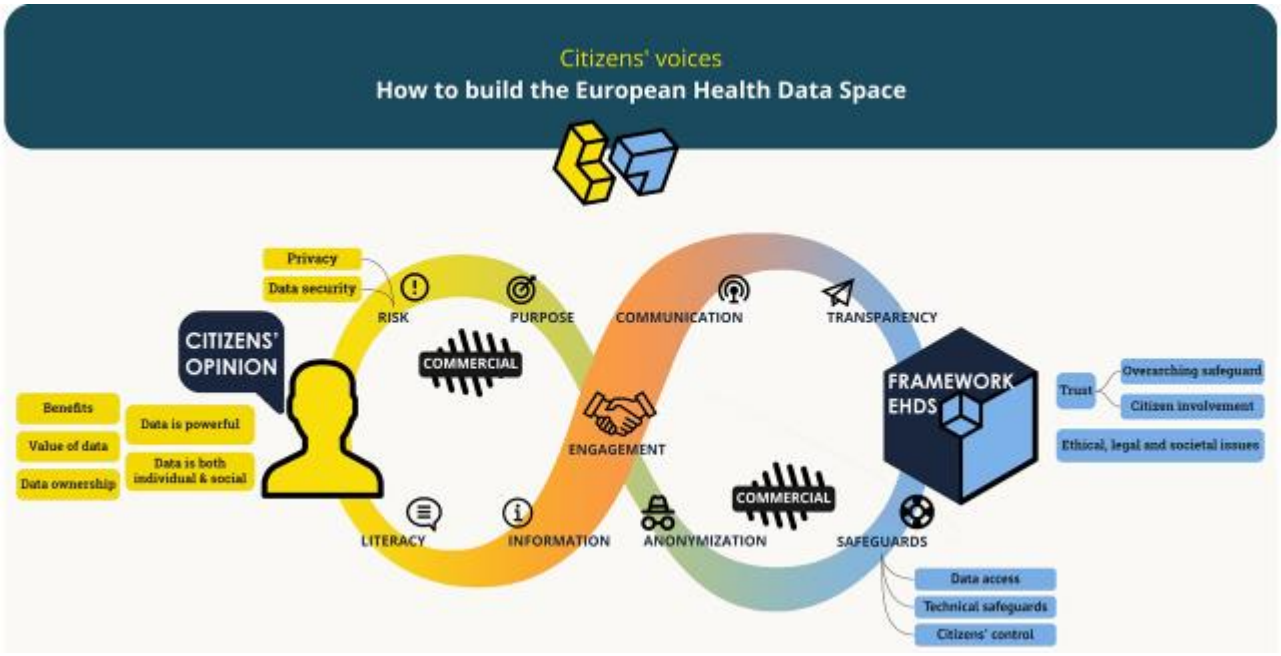
Louise Mathieu (Sciensano) presented WP8, which is focused on citizens.

Within its work, a citizen consultation is conducted in order to inform citizens and gather their perceptions on secondary use of data and how they wish to be engaged.

How was the consultation created?

- Preparation:
  - Preliminary work: literature review and stakeholder interviews
  - Neutrality
  - Inclusion of other projects (UPD)
- Dissemination:
  - Layered approach
  - Different formats
  - Different communication strategies
- Results:
  - 5,932 contributions
  - 24,573 visitors
  - 4,244 interactive tests

WP8 then carried out a semantic analysis. Visual scheme showing how you can read this semantic analysis:



On the left you have citizens' opinions and core values, and on the right you have what the EHDS should look like according to citizens. They are connected by two flows, across these flows you can see the main themes highlighted in citizens contributions. The flow should be read in both directions. The link http://ourhealthydata.eu includes the raw pedagogical material.

The green flow highlights how citizens' core values can translate into a framework for the EHDS, and from right to left how this framework can respect those core values from citizens. The orange flow is about how citizens can be involved within this framework, and from right to left how a framework can foster trust and listen to the citizens' voice. The report will be available on the TEHDAS website.

Next steps

The main goal of this deliverable is to present recommendations to the European Commission on how to engage citizens with the EHDS. Next steps to get from contributions to recommendations:

- September 2022: 3 National workshops
- October 2022: 1 European workshop
- February 2023: final report with recommendations

4 Project presentations

Four initiatives presented on how their work relates to the EHDS and the secondary use of health data.

a. Health-RI

Jan-Willem Boiten presented about Health-RI and the EHDS in the Netherlands. Health-RI is a coalition of organisations working on secondary use of health data for research and innovation.

EHDS in the Netherlands:

- Still early days:
  - Fragmented landscape
  - Ministry of Health is taking the lead consulting a broad network of partners
  - No concrete plans yet for a Health Data Access Body or Health Data Authority
  - Health-RI is a key player for data (re)use in research and innovation
- June 3rd letter sent to parliament about the Dutch position:
  - Dutch government perceives EHDS as a positive development
  - However, many questions remain
  - First step: impact scan
  - Clear role for personal health data environments

The EHDS in the Netherlands is still at the drawing board. The first step that was taken was a government letter to Parliament. The tone was very positive, and EHDS is very welcome but there are many questions.

Health-RI and how they fit in

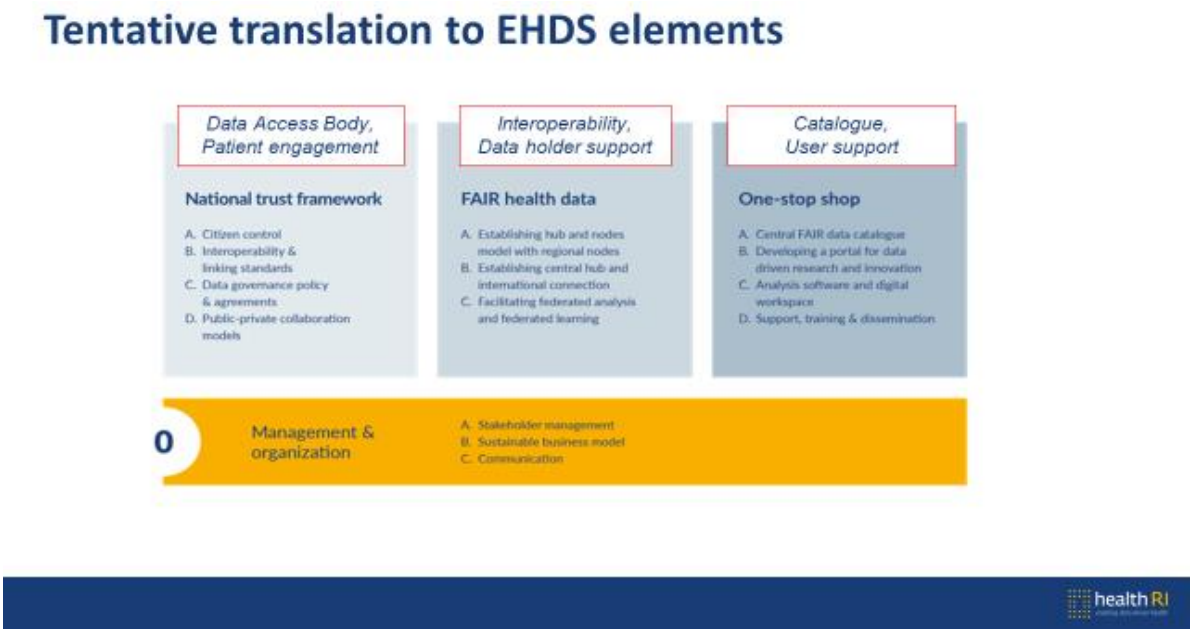
The goal of Health-RI is to support a learning healthcare system, and make sure the real world data (RWD) is available for research. It also aims speed up the feedback loop between clinical care and research. Today's patient informs the treatment of tomorrow's patients, but that loop is currently too slowly. We should pick up the momentum from the COVID experience.

The EHDS has a great promise of dealing with this, but there is a distinction between processes, technology and governance in primary and secondary use. One of the main reasons this loop is going slowly is that these are seen as completely different worlds. Health-RI considers it as a missed opportunity that the EHDS consists of the two EHDS' separately. We hope to use this opportunity to bring those two worlds together.

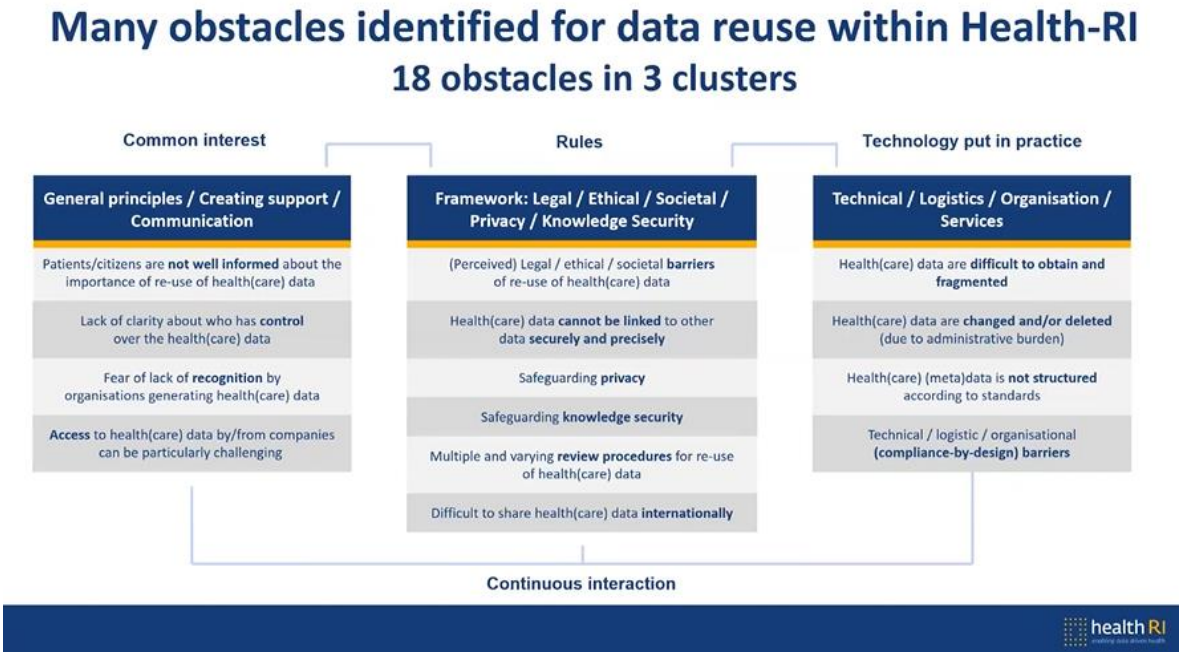
3 areas in which Health-RI is active:

1. National action to set up a trust framework
2. Making data interoperable, implementing standards, trusted environment
3. A one-stop-shop for researchers to make use of the data

Health-RI works in a federated manner, similar to what is proposed in the EHDS. There is no central database in the Netherlands, it runs from regional nodes. Many activities done by Health-RI currently could be re-used in the local implementation of the EHDS in the Netherlands.



Health-RI has identified obstacles to re-use of data, under three clusters:



It is important to learn from this experience and make use of it when implementing the EHDS.

Contact details: servicedesk@health-ri.nl and www.health-ri.nl.

b. **In-4-AHA**

Hille Hinsberg presented In-4-AHA, which has developed data governance guidelines for technology providers in the active healthy ageing domain. It qualitatively collected views of service providers to identify what impedes proper data management practices. With proper control over data, you can make it available for secondary purposes.

The guidelines will be available next month in a pre-final draft (not approved by EC) on the website. They highlight the data management and governance cycle in the organisation in terms of people, processes and technology. They also go into tooling, risks, data protection, privacy, security, and the legal context, including the EHDS Proposal.

The TEHDAS WP6 work on a data quality framework will be useful based on what we have learnt. The problem when there are many data controllers: stakeholders need guidelines to be sure of the data quality. The FAIR principles are good but service providers need help on how to make them happen in practice. There is a need for communication and capacity building to bring a common methodology to stakeholders.

These service providers say it is difficult to balance the EHDS aspects in their internal data policies. How can they enable more control, more user access and decision making on their own data?

Lastly, industry recommends leaning on responsible data sharing initiatives that exist and are driven by industry. Going into further use on open technologies and taking aboard the community initiatives as the base to build on something. Smaller service providers are

struggling with security standards, the technical how for encryption, anonymisation, pseudonymisation etc.

Contact details: hille.hinsberg@proudengineers.com and https://innovation4ageing.tehnopol.ee.

c. Data Saves Lives

Gözde Susuzlu Briggs (European Patients Forum) presented DataSavesLives. This is a multi-stakeholders initiative (secretariat hosted by EPF), which tries to raise wider patient and public awareness of health data, improve understanding of how it is used and establish a trusted environment for dialogue in this issue.

EPF welcomes the timely initiative of the EHDS. To achieve a trustworthy environment, we need to involve patients in the design and development from the beginning.

Patients first need to understand the concepts. People who do not understand the topics (e.g., secondary use, anonymisation, pseudonymisation) have trust issues. We need to lift that curtain above the whole concept of health data. We also need to show the benefits and value propositions around health data, but also the pitfalls/risks. It is important to stay transparent.

Data Saves Lives has built a toolkit. It is dynamic and will grow. Initially we aim to reach our members to show them general communication guidelines around health data topics: how to do risk assessments when getting engaged with health data projects, what questions to ask, what answers they should expect.

A toolkit is not enough, so now we are helping them with a boot camp for our ambassadors. They will discuss secondary use concepts, GDPR, EHDS, with one-on-one sessions to explain to them what is happening, what is expected from patient communities, what benefits they will get, how to get engaged.

For these ambassadors we will put a call out to members but will also ask for other partners (e.g., industry, academia) to bring those views to the table and have the space to discuss openly.

Contact details:

- www.datasaveslives.eu
- dsl-info@eu-patient.eu

d. SHAPES (Sari Sarlio-Siintola)

Sari Sarlio-Siintola presented the SHAPES (Smart and Healthy Ageing through People Engaging in Supportive Systems) project. SHAPES started 2.5 years ago and will continue until October next year. It aims to provide recommendations for a pan-European platform and digital solutions across Europe, a key component of the project.

The SHAPES digital solutions cover a wide range of assisted technologies. The SHAPES architecture is based on a federated data model:

- Data will be stored in digital solutions
- Big data platform allows the digital solutions to send their data to the data lakehouse for advanced processing using AI based analytics engine. It enables bringing questions to the data instead of moving data, because the analysis tools are included in the big data platform.

SHAPES and the EHDS proposal

SHAPES will be considered a platform of digital solutions that generates health-related data. The current version of SHAPES has several types of data included in the minimum categories in the EHDS proposal.

Some topics that need refinement from the point of view of SHAPES:

- Challenges regarding the definition of 'data holders': the EHDS proposal and the Data Governance Act are not strictly consistent. Can SHAPES digital solutions be considered data holders despite not being entities of health or care sectors? Will the EHDS obligations for data holders apply to providers of wellness applications, or are they optional for wellness applications?
- Regarding the SHAPES architecture, can this type of pan-European solution be connected directly to national nodes, so that SHAPES data could be seen in search results? There are also single applicants looking for SHAPES data, so we need to ensure that our data processing environment is compliant with new requirements.
- The legal basis for processing health data in SHAPES is mostly explicit consent. How can we formulate consent so that it considers future use in accordance with EHDS proposal? Can the data subject control his consent for the secondary use in their country's citizen interface?
- We should speak about 'wellbeing' applications rather than 'wellness' applications.

SHAPES is developing use cases for secondary use of data and defining the SHAPES governance and data management. We are willing to open collaboration with TEHDAS and other projects.

5 Breakout sessions

There were 4 breakout rooms covering different topics from the EHDS Proposal. The discussions were reported back to the plenary by designated rapporteurs.

5.1 Breakout room 1: Health data access bodies and the EHDS Board (WP5)

On health data access bodies (HDABs), there are a lot of questions regarding their roles and tasks. Many participants reported that their country is in the process of building those but there is a long way for many. There are quite a lot of questions on the role of the HDABs to make sure that data flows in from clinical practice into data lakes where it can then be used. There were two opinions:

1. It is a huge task and will take a long time.

2. It is a huge task but if we start now, we can do it little by little. Based on the Finnish experience, it is better to start it now, using a growth model, step by step.

On the EHDS board, there was discussion about the role, the composition, who is chairing it. Another important discussion was what will be the relation of the board with many other governance elements e.g., data protection authorities, ethics committees, and member states.

5.2 Breakout room 2: Data quality aspects and metadata catalogues (WP6)

Breakout room 2 on data quality focused mainly on Article 56 of the EHDS Proposal, on the data quality and utility label. A lot of questions remain: what is the depth of data that will be covered by the label, what about anonymisation and pseudonymisation regarding data quality. This is an important issue because anonymised datasets are difficult to deal with.

There was also a discussion about who will apply the labels: data providers themselves or a third party? There was no group consensus but most of the group supported a two-step process: data holders label their own data and then a third party provides a review and possible adjustments.

5.3 Breakout room 3: HealthData@EU cross-border infrastructure and secure processing environments (WP7)

Breakout room 3 discussed the HealthData@EU infrastructure and secure processing environments (SPEs). Regarding SPEs, everyone was in favour. It can relieve researcher pain as it moves responsibility to authorities. There was support for a centralised SPE from the European Commission, as not all countries will be able to set up these and they can use centralised services.

One use case demonstrated a problem in that SPEs have different ways of working, so it is important to standardise them. Trust between health data access bodies will also be very important.

Another discussion was that healthcare institutions that collect data may not be willing to share their data. They should be involved in discussions, so they see the benefits of solutions being proposed. If they do not see the benefits, it does not matter if patients give consent. TEHDAS tries to align that and connect the primary and secondary use.

There was a short discussion on the architecture and a question if people have experience accessing health data across borders and what challenges they face. An example was presented about 60 projects trying to access health data. There are many technical aspects: data management agreements, tools for researchers, procedures to communicate how to manage sensitive data. It is important to take all of these into account.

5.4 Breakout room 4: Citizens' engagement (WP8)

Breakout room 4 on citizen's engagement started by discussing consent and the importance of giving individuals control over their data and the way their data is being used.

The description of digital health authorities and health data access bodies (Articles 10 and 37) describes that these authorities should take citizens'/patients' opinions into account, but not the way in which this should be done, or the power that their recommendations or demands would have. It is important to implement mechanisms that allow individuals to control what happens with their data (e.g., through consent or electronic portals).

Regarding consent, if countries all have different consent models, this would interfere with interoperability. It is important to find a common framework or baseline from which we can start.

On data altruism, it was discussed that this is a very broadly defined term that is put very central. It might not mean the same thing to citizens as it does to data users or processors. It is important to define it and think about what it means to citizens on an individual level rather than an institutional level.

6 Plenary

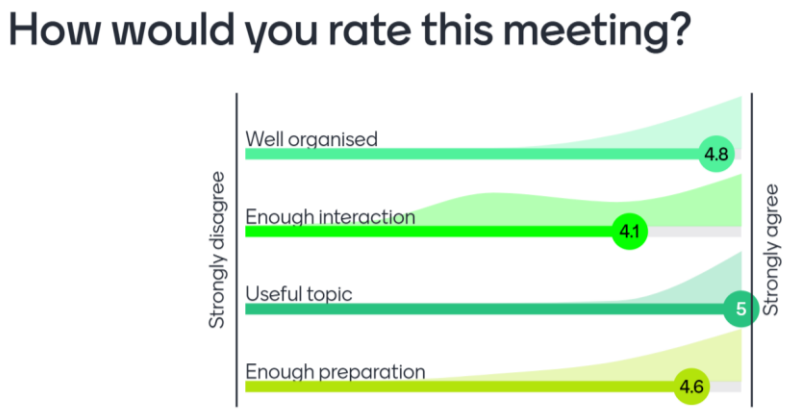
6.1 Concluding remarks (Linda Abboud, Sciensano)

Thank you to everyone for joining. It is encouraging to see interaction between different initiatives. We need to work together to make the EHDS a success. It will be helpful to learn from each other's experiences and work done to be able to go forward with the EHDS.

The slides and minutes will be shared on Teams and via email. The fourth and last Project Forum will take place in November this year.

Mentimeter feedback on the meeting

1. How would you rate this meeting?



2. What do you like about the Project Forum? Some responses included:
    - Seeing developments in other projects

- Learning about EHDS from different angles
- Seeing connections between projects and the bigger picture
- Possibility to explore links between projects and the future EHDS
- Interaction
- Getting information on a wide spectrum of initiatives, networking, discussing very pertinent topics and getting new ideas
- Interesting and important topics, informative
- Good content, well thought through, timely information

3. What could be improved? Some responses included:
    - More time for specific discussions and more regular interactions
    - Focus on less, perhaps one or two topics to allow more in-depth discussion. Arrange follow up topic-specific meetings
    - Preparatory reading on some material, longer breakout sessions
    - Topic suggestion: cross-border data sharing/federated analysis network
    - Face to face

TEHDAS Project Forum n° 3 – AGENDA

	22nd June 2022 (14:00-17:00)		Time
1	**Welcome and aim**	*Welcome: Shona Cosgrove (Sciensano)* *Moderator: Linda Abboud (Sciensano)*	14:00-14:05
2	**Presentation of EHDS Proposal**	*Karina Zalite & Licinio Kustra Mano (European Commission)*	14:05-14:20
3	**How will TEHDAS adapt and support the EHDS?**	*Minna Hendolin (Sitra)*	14:20-15:05
	TEHDAS results and future plans WP4 – Country visits: benchmarking tool and recommendations on capacity building needs WP5 – Data governance: guidelines for multi-country data application requests and mutual recognition WP6 – Data quality assessment framework: latest deliverable and how will it support the EHDS2 WP7 – Technical infrastructure: guidelines for Secure Processing Environments WP8 – Citizen's engagement: presentation of the initial results from TEHDAS citizen consultation	- *WP4: Irene Kesisoglou (Sciensano)* - *WP5: Mario Jendrossek (French Health Data Hub)* - *WP6: Enrique Bernal Delgado (IACS)* - *WP7: Juan González-García (IACS)* - *WP8: Louise Mathieu (Sciensano)*	
	BREAK		15:05-15:15
4	**Project presentations** 4 projects present how the EHDS relates to their (future) work, and how their work may adapt - Health RI - In4AHA - Data Saves Lives - SHAPES Project	*Project representatives:* - *Jan-Willem Boiten* - *Hille Hinsberg* - *Gözde Susuzlu Briggs* - *Sari Sarlio-Siintola*	15:15-15:55

BREAKOUT SESSIONS			
5	**Breakout sessions** 4 breakout rooms on different sections of the EHDS proposal relevant to the secondary use of health data 1. Health data access bodies, EHDS Board (Articles 36-43, 64-65) 2. HealthData@EU cross-border health data access infrastructure, Secure Processing Environments (Articles 50, 52-53) 3. Quality aspects (Articles 55-58) 4. Citizen's engagement (Article 40, link to Data Governance Act, consent) Data access will be discussed in all 4 breakout sessions		15:55-16:35
6	**Plenary session** Reporting back from breakout sessions and plenary discussion		16:35-16:55
7	**Closing remarks**		16:55-17:00

For more information visit:
https://tehdas.eu/
For questions contact:
TEHDAS.sciensano@sciensano.be
Twitter:
#TEHDASforum
@tehdas
@EU_Health

TEHDAS – 4th Project Forum Meeting Minutes

Thursday 15 December 2022, 14:00-17:00, via WebEx (online)

Contents

1 Attendees

Number of participants: 165. Number of countries: 25 EU member states and associated countries.

2 Welcome session

Petronille Bogaert (Sciensano) welcomed attendees to the last TEHDAS Project Forum and provided a recap of the previous Project Forum, which took place on 22 June 2022 bringing together over 120 participants from 23 different countries. The discussions centred on the EHDS proposal, published on 9 May 2022. There were four breakout sessions on:

- Health data access bodies and EHDS Board
- HealthData@EU cross-border health data access infrastructure and secure processing environments
- Data quality aspects
- Citizens' engagement, link to the Data Governance Act and consent

Irene Kesisoglou (Sciensano) was the moderator for the final TEHDAS Project Forum.

3 TEHDAS results

TEHDAS results are available on the TEHDAS website.

3.1 WP4: Outreach, engagement and sustainability

Linda Abboud (Sciensano) presented WP4, which is responsible for outreach, engagement and sustainability.

WP4 has three streams of work:

1. Country visits: mapping the health data management system in 12 European countries through interviews. The first results are available on the country visits page of the TEHDAS website.
2. Project and Policy Forums: engaging with European projects, stakeholders and national authorities to reflect on their concerns and expectations with regards to EHDS.
3. Sustainability plan: exploring sustainability options for the EHDS for secondary use (EHDS2). A milestone was finalised in early 2023 looking at preliminary funding sources for the costs for secondary use of health data. The sustainability plan will be finalised in May 2023.

Country visits

The aim of the TEHDAS country visits is to engage with national stakeholders, explore health data management systems and preparedness for EHDS2, and reflect on needs and expectations for the EHDS. The scope of the country visits covered: data sources, data quality, data infrastructure, data governance and legal framework, needs (resources and capacity building), and preparedness for the EHDS.

12 countries were visited over 12 months (December 2021-December 2022): Denmark, Belgium, Hungary, Netherlands, Slovenia, Czech Republic, Finland, Sweden, Ireland, Portugal, Estonia and Germany.

Key results with regards to preparedness for the EHDS:

- Digitalised health data (9/12)
- Common metadata catalogue in place or work ongoing (5/12)
- Universal usage of personal unique identifier for health (10/12)
- Remote secure processing environments (8/12)
- Wide use of internationally recognised standards (4/12)
- Semantic interoperability (10/12)
- Similar access for national and foreign researchers (10/12)
- Political will to join the EHDS (12/12)
- Potential national contact point for the EHDS2 already existing (3/8)

Overarching *needs* were identified across countries.

Organisational needs:

- Incentives to achieve full digitalisation
- Manual providing overview of national data management systems in EU countries
- Transparency in access processes and decisions
- Guidance and specifications for the EHDS implementation including timeframes
- Unique personal identifier implemented across the health sector

Technical needs:

- Standards for collecting and storing and structuring data
- Data interoperability and harmonisation
- Requirements for secure processing environments

Legal needs:

- Clear legislative framework around secondary use of data and linking data
- Guidelines to interpret GDPR
- Harmonised rules on how to anonymise and pseudonymise
- Ensure adequate privacy protection practices

The country visits also looked into *capacity building*. General capacity building needs include:

- Support to researchers throughout access request procedures, including ethical submission
- Programming and data analysis courses
- Knowledge and training on cyber-security and data protection
- Strengthen AI capacity in health sector

There are some capacity building expectations that stakeholders specifically expect from the EU level:

- EU training on semantic interoperability and structured datasets
- EU workshops to discuss legal interpretations
- Shared trainings and best practices at EU level
- Academic incentives at EU level for training of data analysts e.g., through a *Health Data Academy:*
    - Education of data scientists
    - Improve health data literacy to healthcare providers
    - Demonstrate value of good quality data input for research - training for proper coding at the source

Finally, the country visits explored *resource needs* for the EHDS2 on three different levels – human, technical and financial resources:

- Human resources: overall there is a large need for IT expertise in the public sector.
- Technical resources: need to improve technical capabilities of data holders, not only through training but having the correct hard and software to enable sharing of health data.
- Financial resources: financial incentives to healthcare providers (HCPs) to digitalise and to share their data. The possibility to use citation and publication as an incentive was raised.

In general, there are positive views on the added value of the EHDS2, and willingness to join. However, several challenges must be considered when finalising the regulation. Some key points include ensuring data security, maintaining citizens' trust, and demonstrating equal benefits for all.

Thank you to everyone who supported and collaborated the country visits, including the local contacts who organised the visits, and WHO for allowing us to adapt their assessment tool. We collaborated with the PHIRI project (on training, events and conferences) who carried out similar assessments on COVID-19.

Q&A:

- Who expressed views regarding the need for guidance on GDPR?
    - These points were mentioned across the variety of stakeholders interviewed: ministries, researchers, data protection authorities, hospitals, research institutes, industry.
    - Researchers face challenges knowing what is needed when applying to different data holders, both within and between countries.
    - There is a need for a place that to see the different legal interpretations / legal bases across countries, bringing together existing publications on this topic in an accessible manner.
- On capacity building, can you provide more information about the Health Data Academy?
    - Health Data Academy was mentioned by stakeholders in Belgium, to increase health data literacy in HCPs (e.g., training on collecting data in a structured way, increasing awareness on data management).
    - Academy could provide a place to share capacity building activities: make trainings provided in one MS open to other MS.
- How can we address capacity building in citizens?
    - Stakeholders highlighted the importance of maintaining citizen trust that has been built.
    - It is important to inform citizens where and how their data will be used e.g., portal on a website showing studies that are being conducted thanks to secondary use of data.

3.2 WP5: Data governance

Michel Silvestri (Swedish eHealth Agency) presented from WP5 'Sharing data for health', devoted to data governance.

The main objectives of WP5 are to develop options for governance models for the exchange and secondary use of health data between European countries, based on transparency, trust, citizen empowerment and the common good. It also provides recommendations for European countries on planning national legislation to enable cross-border exchange and secondary use of health data.

The WP5 results are published on TEHDAS website:

- Task 5.1 worked on the barriers and enablers for secondary use of health data from the perspective of users. Technology is not a major barrier but rather legal obstacles.
- Task 5.2 brought forward this work and also explored data permit authority perspectives (interpretation of GDPR, recommendations to MS).
- Task 5.3 has worked on best practice experiences. It includes bilateral or multi-country collaboration between MS with a centralised model (Finland, France) in addition to more decentralised models (Spain, Netherlands). A Memorandum of Understanding was achieved between France and Finland on how to collaborate.
- Task 5.4 produced reports on governance mechanisms, leading up to the upcoming deliverable on governance models and options for those in the EHDS.

Next steps and upcoming deliverables:

- D5.4: Options for governance models for the EHDS – being finalised
- D5.2 (January 2023): Guidelines/recommendations for European countries when planning national legislation on secondary use of health data
- M5.6 (March/April 2023): Compilation of perspectives on multi-country data application requests, mutual recognition and cross-border requests through a workshop approach
- D5.3 (May 2023): Guidelines for multi-country data application requests, including mutual recognition and cross-border requests
- Work Package Advisory Group meeting (May 2023)

A new deliverable (D5.3) was added after the publication of EHDS proposal in May 2022. We have tried to adapt the scope and outcome of this to better fit in the ambitions of the EHDS proposal.

Regarding the value of this work to the EHDS, we have provided valuable perspectives from key stakeholders. It is of great value to present best practices e.g., from the collaboration between Finland, France, Spain and the Netherlands. We are defining elements and recommendations regarding governance, both at the European and national level (e.g., when planning future national legislation).

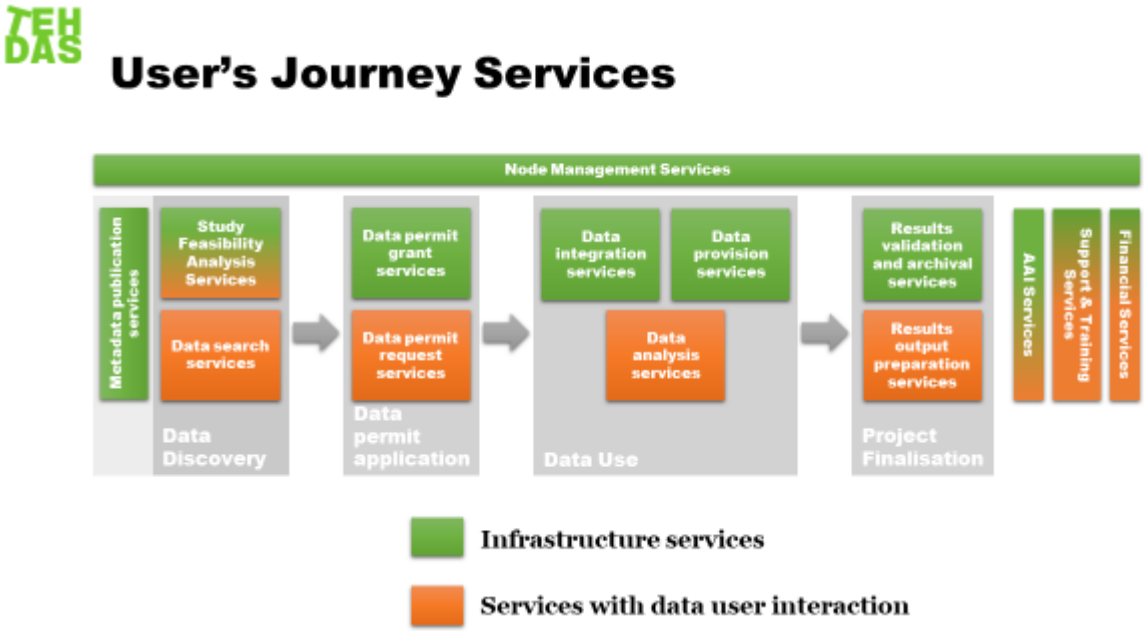
Some challenges still remain on different levels:

- Political: heterogenous conditions, knowledge/awareness, high/low on the agenda
- Legal:
    - Different interpretations of GDPR
    - Different regulatory frameworks
    - Different interests (e.g., individual vs common good?)
    - Sense of urgency/slow process
- Economic:
    - Lack of resources / uneven distribution
    - Complicated business models
    - Return of investment lies far ahead
- Social:
    - Inequalities (national and pan-European)
    - History/tradition/culture

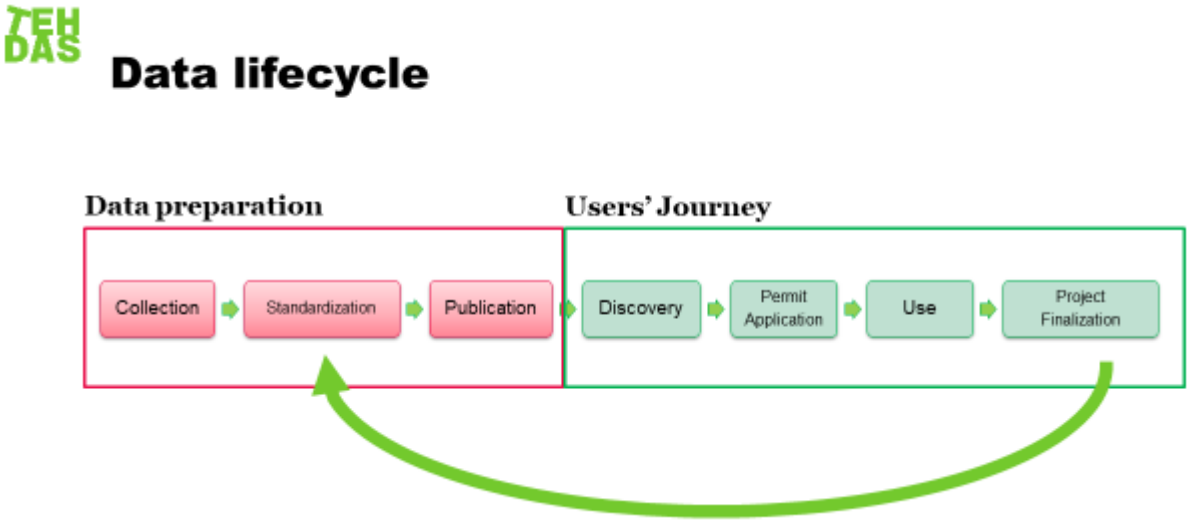
3.3 WP7: Technical infrastructure

Juan González-Garcia (IACS) presented the advances of WP7, devoted to the technical infrastructure.

The TEHDAS *user journey* shows the steps a user of the EHDS2 should follow. We have populated the steps with services (i.e., specific elements that MS or service providers should put in place):



The *data life cycle* is a holistic view, including both the user interaction and data preparation (data holders' journey). It considers the steps that a data holder should do to make data findable to start the user journey. The extension of the user journey with these steps is more comprehensive:



Apart from the regular WP7 work to develop the infrastructure, we are working on three specific requests after the publication of the EHDS proposal, on guidelines for three points in the data life cycle:

1. *Guidelines for national datasets catalogues to register and facilitate the discovery of health datasets available for secondary use (Art. 37(1)(Q)(i))*

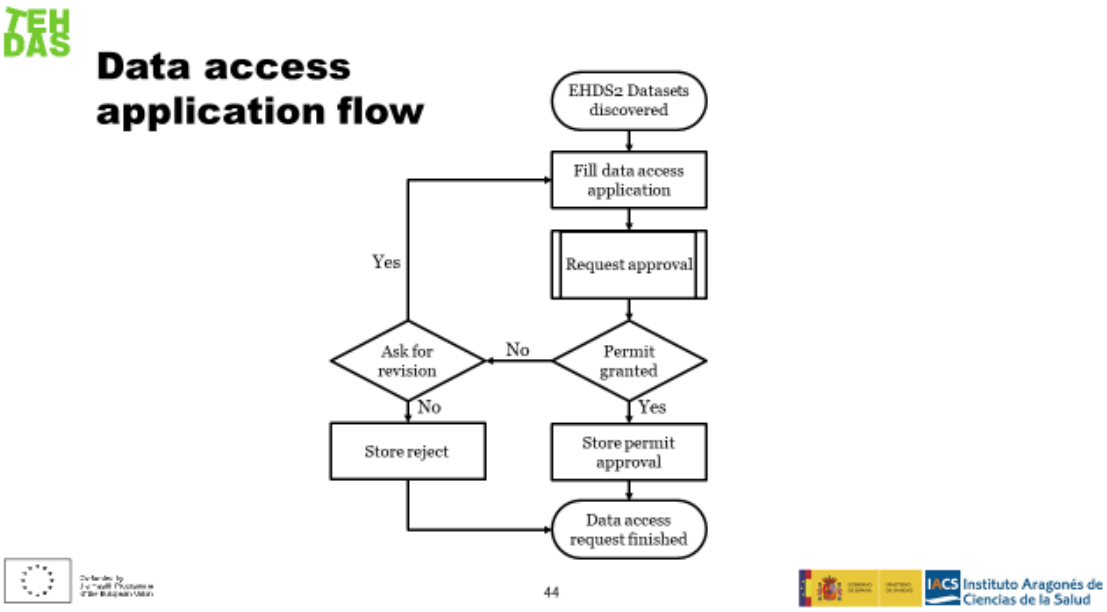
These are guidelines to support the development of metadata catalogues, putting information in national catalogues in the HDABs and an EU dataset catalogue.

There are multiple actors: HDABs, research infrastructures, EU agencies. The relationships between the different players must be put in place technically. Some specific questions may arise e.g.,:

- How should MS organise themselves to publish the national metadata catalogue?
- What is the relationship between HDAB and other participants and the EU-level dataset catalogue?
- How can data users interact with these catalogues e.g., can searching the national catalogue get results from EU catalogue?

2. *Guidelines for management systems to record and process data access applications, data requests and data permits issued, and data requests answered (Art. 37(1)(K))*

Once data has been discovered, the user needs permission to access it:



This process could be simple or more complex (e.g., if more than one country involved). The approval process has to be clearly defined to guarantee coordination among different actors and MS. That requires specific softwares. We have studied existing possibilities that could be adapted for HealthData@EU.

3. *Guidelines for secure processing environments (technical, information security and interoperability requirements) (Art. 50(4))*

Secure processing environments (SPEs) are the systems for using sensitive data. Data will be deposited in a pseudonymised or anonymised way in a SPE where users perform the analysis.

SPEs are mediated by the HDABs and communicate with data holders. We have discussed different possible ways of operating:

- Traditional: all data transferred into one SPE for processing
- Federated: if there are multiple data holders in multiple countries, the data stays in different SPEs (minimising movement) and a mechanism is provided to perform federated analysis

To study SPEs, we have been gathering information from existing initiatives with the help of the HealthyCloud project. This work will be reflected in our final deliverable by May 2023.

Q&A:

- What is the difference between SPEs and TREs for TEHDAS?
    - For TEHDAS they are synonyms

3.4 WP8: Citizens' engagement and data altruism

WP8 is divided into two parts:

- Assessing citizens' views of secondary use and how they wish to be engaged in a future EHDS: final deliverable will translate these views into concrete recommendations (February 2023)
- Data altruism: final deliverable will provide recommendations to foster data altruism practices in the implementation of national and European health data spaces (May 2023)

Citizen's engagement

Louise Mathieu (Sciensano) presented the work done on citizens' engagement:

- Background work: literature review of citizens' perception of secondary use of health data and interviews with stakeholders from the health data ecosystem in different countries.
- E-consultation: online consultation to gather views on secondary use and preferences in terms of engagement. Intermediary report published in June 2022 with descriptive results.
- Stakeholder workshops (three national and one European): to present results to other stakeholders and get their feedback to shape the deliverable.
- Final deliverable with recommendations on citizens' engagement in future EHDS: currently being drafted.

The following slide shows the structure and main points that will be raised in the final document:

- Data relationship: The focus is on how citizens perceive and are attached to health data. Each time we use health data, citizens feel that we use a piece of them. No matter what you do when you use health data, you are entering a relationship with them directly. We

will highlight the main topics citizens raised on how to take care of the different elements that constitute this relationship.
- Power balance: Citizens perceive a power in health data (to generate huge societal benefit but also a power that must be kept under control to avoid harm). The consultation results showed that it is very important to find a balance between maximising benefits and minimising risks. We will develop the idea of safeguards that were important to citizens.
- Citizen powered framework: Based on these first two parts, we will develop a citizen-powered framework for secondary use, based on ethics values that take into account the values from citizens.

Data altruism

Zsófia Bulla (OKFO) presented the second part of WP8 focusing on data altruism, which has delivered several milestones. The final deliverable is due in May 2023. The process for the work has been:

- Literature review for data altruism definitions and use cases
- Presentation of first set of data altruism definitions, use cases and findings about consent and accessibility issues
- Multi-stakeholder workshop to discuss these issues in a wider audience
- Published overview of the workshop
- Primary recommendations to foster GDPR compliant data altruism mechanisms
- Planning of final deliverable has been kicked off. It will include a summary of what we have found and final recommendations on data altruism practices

Focus topics of the final deliverable:

- Data altruism definition
- Importance of data altruism and coordinated mechanisms to foster altruism
- Data altruism organisations
- Citizen science
- Broad consent in EHDS and types of consent to be considered
- GDPR compliance
- Ethics

3.5 WP6: Data quality and interoperability

Enrique Bernal Delgado (IACS) presented WP6.

WP6 focuses on data quality and interoperability with the overarching objective of building a data quality framework for EHDS2 (by April 2023). The results published so far are available on the TEHDAS website.

The presentation focused on the latest achievement: deliverable on 'Recommendations to enhance interoperability within HealthData@EU'. The data quality framework will contain this piece and others.

There are two big elements in the data life cycle where this deliverable is applied:

- Data preparation: harmonisation, standardisation (especially semantic standardisation)
- Publication: standards that allow discoverability

This deliverable also applies to the 'use' part of the data life cycle. When sensitive data is prepared in SPEs or when non-sensitive data is delivered after processing, there will be interaction between nodes and semantic standards for communication are needed.

Over the last 12 months, we have:

- Identified standards for three utilities: data discoverability, semantic interoperability, and interoperable communication across nodes at semantic level
- Assessed the standards using the CAMMS tool (from the EC)
- Surveyed the countries in WP6 (around 13 countries). There is uneven use of these standards and they are generally not widely adopted. This is quite consistent with the WP4 country visits.
- Developed nine recommendations that were voted on.

Exchange with other initiatives

Several interactions have helped us to frame the DQF or provided insights:

- Collaboration with EMA in development of the Big Data Steering Group and DARWIN EU project: common views and concepts have been built of a data quality framework for regulatory purposes; we are providing insights to their new metadata standards and mapping to DCAT (as it ranks the highest in discoverability); currently opening a new work stream on real world evidence
- Interviews with the people responsible for the standards assessed: part of this is in research infrastructures (RIs) (e.g., ELIXIR, BBMRI, CESSDA, ECRIN, EUROBIOIMAGING, PHIRI)
- HealthyCloud Strategic Agenda
- European Institute for Innovation through Health Data: key actor in quality and utility labelling
- Gaia-X

Next steps

We have 3-4 months to frame the final data quality framework. We are going into more depth on the elements included in Chapter 4 of the EHDS legislative proposal, in particular the section on health data quality and utility (Art. 55-58).

4 Breakout sessions

There were four breakout rooms covering dedicated topics.

4.1 Breakout room 1: Sustainability and governance concepts for the EHDS

Regarding multi-country data application requests and cross-border projects, participants suggested learning from countries with exchange systems in place and from projects that have established their own federated systems. The model of having research infrastructures as facilitators could be considered for the EHDS.

TEHDAS is currently drafting a sustainability plan for the EHDS, considering sustainability from a broad perspective, for instance considering capacity needed in each member state for the EHDS infrastructure and citizen trust. Participants noted that it is important to consider that data will be re-used when it is being collected in the context of primary use. The role of incentives for managing health data and the importance of training healthcare professionals and not over-burdening them were highlighted.

4.2 Breakout room 2: Secure processing environments: technical and organisational requirements

SPEs are systems that allow highly sensitive data to be analysed and processed in a trusted and secure remote environment, facilitating privacy-by-design. There was a discussion about synthetic data, but participants agreed that there is no need for SPEs in that case.

Participants noted the importance of collaborating with other projects (e.g., B1MG, GDI) in the development of SPEs, and to have forums for discussion to find common ground. Participants also raised the idea of having use cases to test SPEs.

4.3 Breakout room 3: Data minimisation and purpose limitation: implementation and risks

The concept of data minimisation is that only the data that is relevant for the research question should be provided to applicants. A detailed protocol and data management plan could suffice to cover the minimisation principle. However, participants noted that the interpretation of minimisation varies even within institutions. There is a need for a common interpretation of minimisation.

The low utility of anonymisation as the default mechanism for data protection leads to thinking of pseudonymisation as a compromise solution. However, delivering data out of data holders' premises risks data protection. Pseudonymisation should be accompanied by processing within SPEs/TREs.

Member States are genuinely interested in a solution that balances individuals' data protection and data utility. Participants noted the practical challenges that come into play with data minimisation, which need to be addressed.

4.4 Breakout room 4: Data altruism, and maximising the impact of citizen input for the EHDS

In the discussion on data altruism, it was noted that data altruism is regulated in the Data Governance Act and that the concept will be further developed now. However, there is

concern from citizens and the expert community that more types of voluntary data sharing are needed. The consideration of how data donated through data altruism could be used by commercial entities was also discussed.

5 Project presentations

Five projects presented on how they will interlink with the EHDS2.

5.1 HealthData@EU Pilot

Mario Jendrossek (French Health Data Hub) presented the HealthData@EU Pilot.

Health data sharing has become a major priority for the European health policy. There are several issues: fragmentation, multiple conditions for use, different access processes (at national and European level). Solutions are being put in place through legislative processes (e.g., Data Governance Act, Data Act, AI Act and EHDS legislation) and project-based action (e.g., TEHDAS, HealthData@EU Pilot). The HealthData@EU Pilot will set up a first version of the European system for secondary use of health data.

It is a large consortium of 17 partners, bringing together different types of actors: national health data platforms, EU agencies (EMA, ECDC), European RIs (BBRMI, ELIXIR). The diversity of actors will contribute to the project's success. Many partners are also involved in multiple other projects (e.g., ELIXIR and the Genomics Data Infrastructure, EMA and DARWIN, many TEHDAS partners).

The two main objectives of the project:

1. Build a network of health data platforms on European scale and develop services
2. Test the network and services through use cases (cross border research projects)

The project tries to cover important pieces of the overall HealthData@EU user journey:

- Data discovery: Sciensano is leading the WP on metadata standards. They will develop an extension to the DCAT metadata standard, Health DCAT AP, to build an interoperable metadata catalogue.
- Data permit requests: See what the current processes and forms are in use in the different platforms and identify common and different elements to come up with a single application form.
- Data preparation: interoperability standards, quality control and data preparation
- Use of data: We are also interested in learning how we can inform citizens and make sure that GDPR compliance is ensured.
- Finalisation: publication of the study and valorisation

All the services rely on a common IT structure and EU central services to allow exchange between actors. This information exchange will use European building blocks and open-source standards (e.g., eDelivery).

Five concrete cross-border use cases will show the feasibility and added value of the HealthData@EU infrastructure. The use cases mobilise data from several European countries and are different study types.

There are multiple engagement opportunities throughout the project to get involved (24 months):

- Open call for External advisory board (December 2022-January 2023)
- Stakeholder meetings to present and discuss project activities and outcomes
- Stakeholder roundtable discussions
- Interactions with the community of HDABs (working on direct grants for HDABs)
- Multiple presentations, roundtable discussions and forums

Contact details:

- Twitter: @ehds2pilot
- Website: https://www.ehds2pilot.eu/
- Email: ehds2pilot@health-data-hub.fr

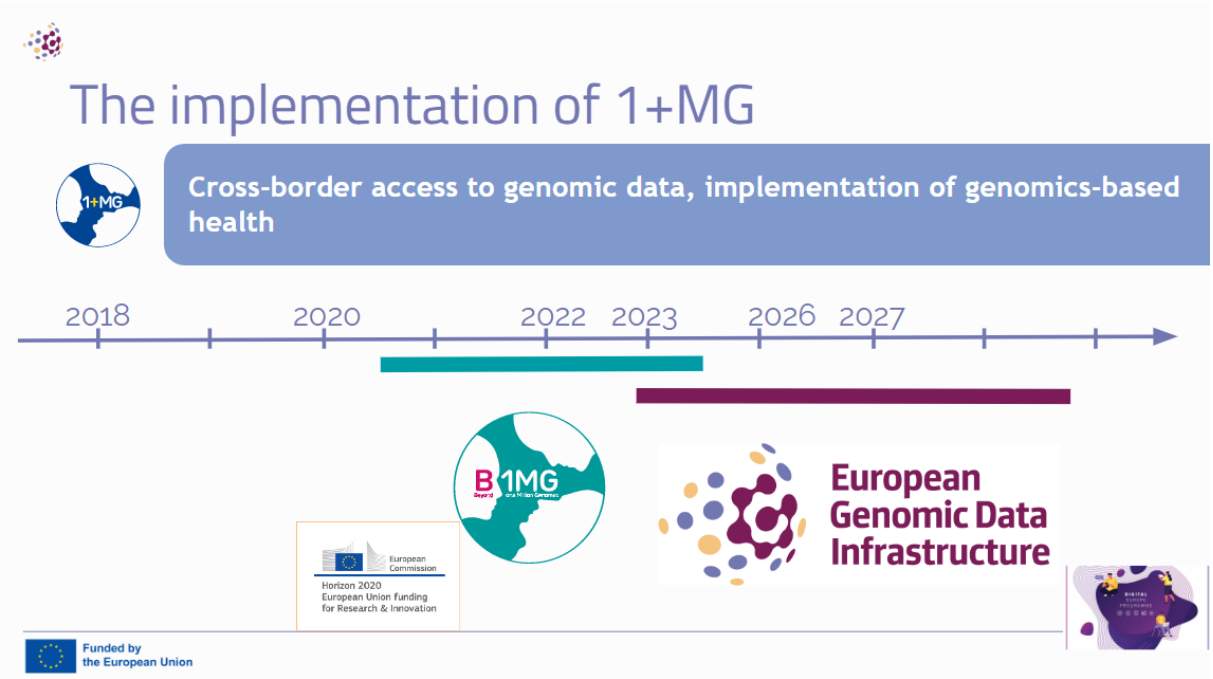
5.2 Genomic Data Infrastructure (GDI)

Juan Arenas (ELIXIR) presented the Genomic Data Infrastructure (GDI).

ELIXIR is coordinating the Beyond 1 Million Genomes (B1MG) and the Genomic Data Infrastructure (GDI). The main goal is to provide a data infrastructure required to accomplish the 1+ Million Genomes (1+MG) ambition, through two projects:

- B1MG: working on recommendations and guidelines (working closely with MS).
- GDI: deployment of the infrastructure.

Timeline of implementation of 1+MG:



1+MG and EHDS share the same broad ambition. The role of 1+MG and GDI is mainly to ensure that we can get access for researchers to data coming from health and to be able to generate new knowledge to benefits citizens and patients.

What will GDI deliver?

The infrastructure must be operational in a couple of years with at least six countries where we will show how the infrastructure will work with synthetic data. We expect to also use the infrastructure to show what could be possible if there is change in the regulatory landscape to improve the situation in this area.

How will GDI connect to EHDS? There is a 1+MG use case in the HealthData@EU Pilot. We will find ways to make both infrastructures as interoperable and connected as possible and benefit from synergies. The first output of GDI will be a starter kit bringing together all standards and reference implementations tailored for GDI. ELIXIR's ambition in the HealthData@EU pilot is to ensure wide interoperability of the starter kit.

What GDI will not deliver (at least initially) is the solution for deployment in each country. But the standards and reference implementation will be there for anyone who has to process genomic data. The EHDS could see what parts of those standards and implementation they could re-use if they are aligned.

We truly believe that this is a unique opportunity. We have an obligation to connect this infrastructure and maximise benefit for patients.

Contact details:

- Twitter: @GDI_EUproject

- LinkedIn: /company/gdi-euproject
- Website: https://gdi.onemilliongenomes.eu/

5.3 DARWIN EU

Denise Umuhire (EMA) presented DARWIN EU and how it will collaborate and integrate with the EHDS.

There are three main areas where we need real world data (RWD):

- When designing and planning studies from the applicant: Evaluation committees need RWD to put things into context and to validate representativeness of the study submitted during the application
- To define disease epidemiology, understand current standard of care (clinical management) and drug utilisation
- To support in measuring the impact of different measures put in place (e.g., evaluating safety or effectiveness of drugs in real life, measuring impact of regulatory actions)

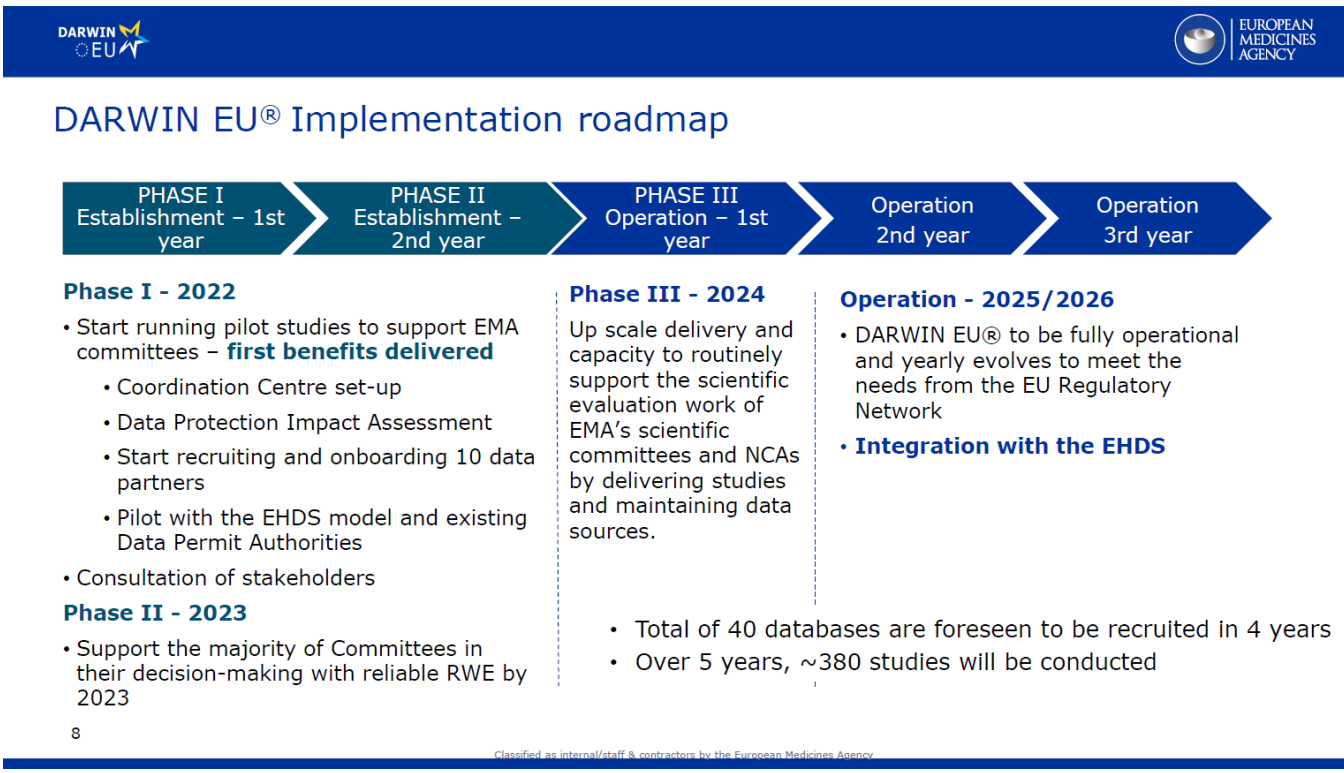
Until 2022, EMA had two main ways of generating real world evidence to support evaluation committees:

1. EMA studies using in-house databases
2. Studies procured through EMA framework contracts
3. DARWIN EU – now provides a third pathway

DARWIN EU is a federated network approach. Federated network principles: data stays local, use of Common Data Model (OMOP) to perform studies in a timely manner and increase consistency of results. When committees have questions, the team within EMA collaborate with committees to structure the research question and work with DARWIN EU coordination centre (Erasmus MC) to design a study outline and generate the evidence across different databases in the network in a rapid way to provide evidence to committees.

DARWIN EU is one of the initiatives of HMA-EMA Joint Big Data Steering Group work plan. It is a flagship project that comes together with other initiatives to drive the agenda of big data.

Implementation roadmap:



- We are coming to the end of the first phase. First database was on-boarded this year, concluding with eight databases now. This year there is also a plan to test the network with a number of studies and test the collaboration with the EHDS.

When selecting data sources to be part of DARWIN EU, there are a number of criteria to have as much representativeness as possible:

- Routine healthcare data
- Large geographic scope
- Patient level data
- Data which contain medicines with identifiable quantities (dose and packages)
- Data have enough information on clinical events (analyse outcomes, indications, and diseases)

There are four categories of studies that will be performed, to standardise the information generated and make it robust, but also to speed up the approach:

- Routine repeated analyses – generic protocol
- Off the shelf studies – generic protocol but adapted to a research question but in a very short period (e.g., evaluation of prevalence or incidence)
- Complex studies
- Very complex studies

The first studies are ongoing (three off the shelf studies) and one is being drafted (complex study).

In terms of the link with EHDS, EMA is leading one of the use cases in the HealthData@EU Pilot where the connection of DARWIN EU in the EHDS will be tested. DARWIN EU is a network in itself. The purpose is to see how this network integrates into the larger EHDS network. DARWIN EU has many databases already integrated in OMOP common data model. The aim is to see how we can work together to bring the same protocol to different data nodes that do not have necessarily the same data model.

In a way, DARWIN EU is a pathfinder in the EHDS, the same way other projects such are paving the way for the EHDS. The knowledge will be transferred from those projects into the EHDS.

5.4 Population Health Information Research Infrastructure (PHIRI)

Petronille Bogaert (Sciensano) presented the Population Health Information Research Infrastructure (PHIRI).

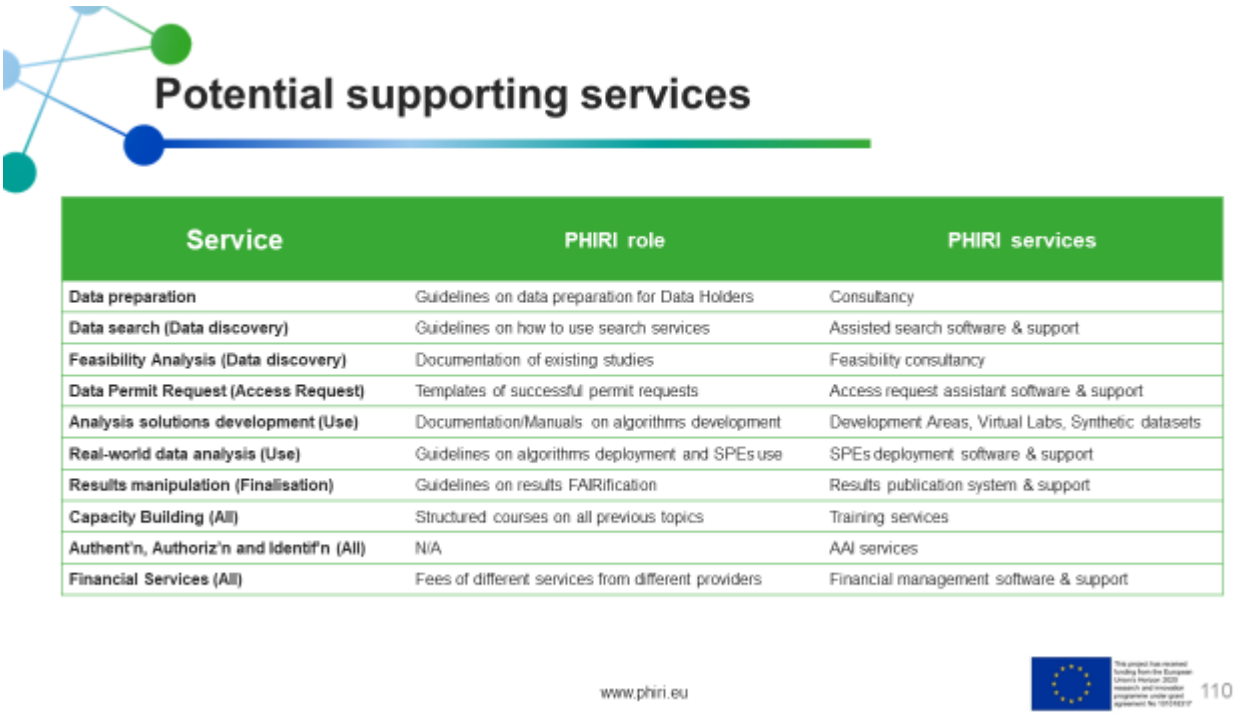
PHIRI aims to facilitate population health research across Europe and exchange best practices to support decision making.

PHIRI activities in a nutshell:
- Health Information Portal (HIP): Provides an overview of main public health databases and how you can access them. They can be findable through FAIRdata point and schema.org. It also includes reports, guidelines and training resources.
- Federated research: Four use cases measuring the public health impact of COVID-19. Federated platform for queries.
- Health information support: Rapid Exchange Forum (REF) comes together once/twice per month to respond to specific COVID or other population health questions. COVID-19 Health Information System assessments use the same design as taken forward in TEHDAS.
- Training: European school on health information.

PHIRI goes beyond pure data handling. It creates a community around population health, which can then function as data stewards or provide supporting activities.

The use cases provide a proof of concept of doing federated data analysis in a rapid but transferable way. We have built up expertise in countries and shown that it is feasible. For instance, the Europeristat use case significantly decreased the time to be able to investigate a research question and broadcast this all around Europe. We are using the same methodology in the use case in HealthData@EU pilot, which Sciensano and IACS and other colleagues are working on.

There are also supporting services that could be further rolled out in alignment with the EHDS:



PHIRI has been working closely with users of the EHDS. It is key to understand their needs to make the EHDS functional.

Contact information:

- Twitter: @PHIRI4EU
- LinkedIn: /company/phiri
- Email: phiri.coordination@sciensano.be

5.5 HealthyCloud

Maria Panagiotopoulou (ECRIN) presented the HealthyCloud project.

The idea for HealthyCloud and the Health Research and Innovation Cloud (HRIC) started in 2018. DG RTD organised a workshop with representatives from health research projects to discuss opportunities and challenges to establish a pan-European HRIC. The workshop outcomes are reported in a publication.

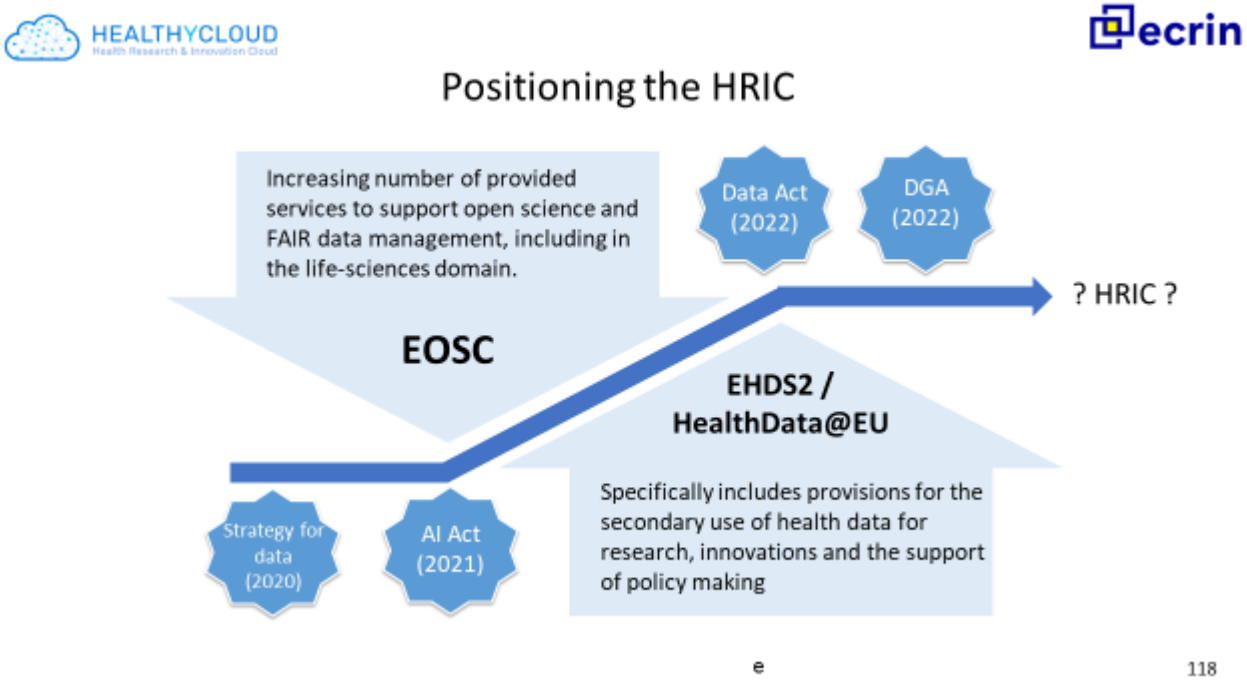
The representatives gave five recommendations to funders and policymakers to build the HRIC:

1. Provide and foster standards, good practices and guidelines necessary to establish the European HRIC
2. Develop and certify the infrastructure and services required for operation of the HRIC
3. Enable the HRIC to operate within an ethical and legal framework adequate for health systems

4. Establish a proper environment for the training of a new generation of data and medical scientists
5. Fund public and private initiatives for the development of the HRIC through EU Framework Programmes (Horizon 2020 and Horizon Europe)

The HealthyCloud project was funded as a direct follow up. The project is coordinated by IACS and BSC and brings together a consortium with wide expertise across the health and the cloud aspects. It is a coordination and support action (CSA) running from March 2021 to August 2023. The overall aim of the project is to produce a Strategic Agenda to help advance the establishment of the HRIC.

The first challenge we faced when putting together the strategic agenda was the European landscape itself. The situation has changed a lot since 2018:



There have also been developments in national data infrastructures and initiatives, all operating at different speeds and in different ways. How can we position a HRIC in an ever moving landscape?

HealthyCloud decided to take a step back and discuss within the community to map the current situation, gaps, and uncertainties linked to the development of these initiatives:

- Better coordination between developments, over extended time periods
- Specific support for sensitive data management
- Better legal and regulatory guidance
- Good support for multinational research, especially using RWD
- Greater data interoperability – amidst huge data diversity

- Improved data findability, especially across traditional domains, and RWD
- Clarifying roles of EOSC and EHDS2, and their interaction
- Provision of Secure Processing Environments
- Retaining public involvement and trust
- Good links to and interactions with existing RIs
- Adequate training

The first draft of the Strategic Agenda has been published. 10 services are proposed, which are being discussed with stakeholders to identify priorities:

1. A monitoring service for health related research
2. An EOSC sensitive data users service
3. A legal / regulatory guidance service
4. A training service for researchers
5. A metadata standards service
6. A data interoperability service
7. An EOSC Health catalogue service
8. An EOSC Health resource service
9. A research community interface service, with HealthData@EU
10. A research community interface service, with the general public

The final Strategic Agenda is expected in August 2023.

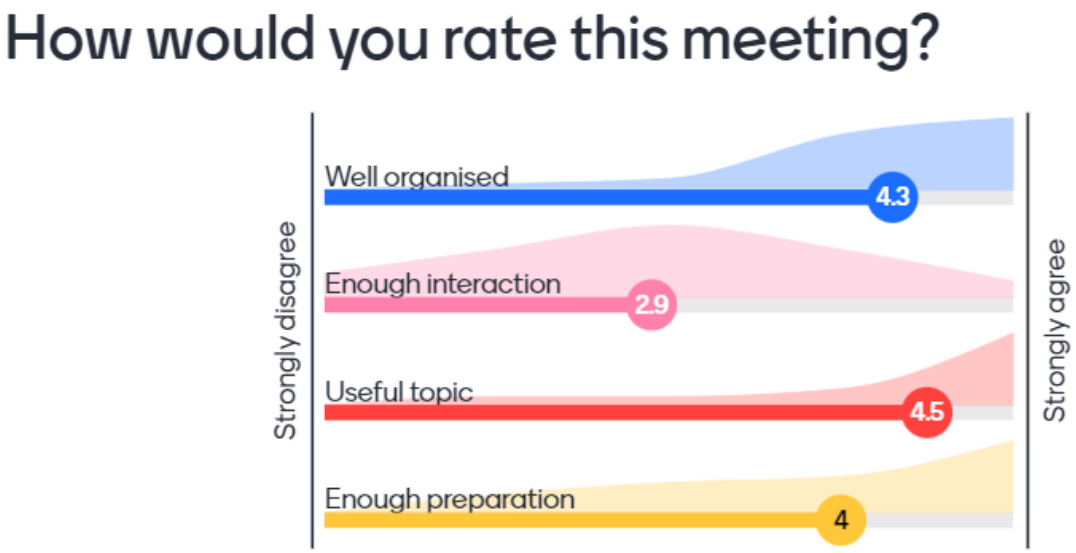
Contact details:

- Website: https://healthycloud.eu/
- Twitter: @HealthyCloudEU
- LinkedIn: /company/healthycloudeu/
- Email: info@healthycloud.eu

6 Meeting evaluation

Mentimeter feedback on the meeting

How would you rate this meeting?



Did you find the Project Forums useful? What did you like/dislike?

- Yes, they were useful
- May be better to have shorter meetings
- More around actual synergies
- Presentations were useful but too rushed, no time for discussion remained
- Very useful. I would like to have the presentations before the meetings to be better prepared
- Presentations and status update and connections with other projects good
- Very informative
- More time needed for discussions and exchange

7 Closing remarks

Shona Cosgrove (Sciensano) thanked participants for joining.

It was good to see a lot of activity in the chat. Whilst this was the last Project Forum of TEHDAS, the project itself is not ending just yet. We encourage you to keep those collaborations going. There are more deliverables coming up in the next six months so keep an eye on the website and the social media channels of TEHDAS. The final Stakeholder Forum will take place in June 2023, and all are invited.

Thank you to all the projects who presented and to the TEHDAS Work Package Leads.

AGENDA - TEHDAS Project Forum n° 4

	15th December 2022 14:00-17:00		Time
1	**Welcome and aim**	- *Petronille Bogaert (Sciensano)*	14:00-14:05
2	**TEHDAS results** WP5 – Data governance WP4 – Country visits WP7 – Technical infrastructure WP8 – Citizens' engagement and data altruism WP6 – Data quality and interoperability	- *WP5: Michel Silvestri (Swedish eHealth Agency), Coen Van Gool (RIVM)* - *WP4: Linda Abboud (Sciensano)* - *WP7: Juan González-García (IACS)* - *WP8: Zsofia Bulla (OKFO), Louise Mathieu (Sciensano)* - *WP6: Enrique Bernal Delgado (IACS)*	14:05-15:00
	BREAKOUT SESSIONS		
3	**Breakout sessions** 1. Sustainability and Governance concepts for EHDS 2. Secure Processing Environments: technical and organisational requirements 3. Data minimisation and purpose limitation: implementation and risks 4. How to maximise the impact of citizen input for the framework of the EHDS and Data altruism: definition, ethics and data altruism organisation	- *All* - *Moderated by TEHDAS WPLs*	15:00-15:45
	BREAK		15:45-15:55

4	**Project presentations** 1. EHDS2 Pilot – Developing the technical infrastructure for EHDS 2. Genomic Data Infrastructure (GDI) – How will Genomics data link with the EHDS 3. Darwin – Using RWD to make real-world decisions and linking to EHDS 4. PHIRI – Potential PHIRI services for the EHDS 5. HealthyCloud – Strategic Agenda for a Health Research Innovation Cloud (HRIC)	- *Mario Jendrossek (French Health Data Hub)* - *Juan Arenas (ELIXIR)* - *Denise Umuhire (EMA)* - *Petronille Bogaert (Sciensano)* - *Maria Panagiotopoulou (ECRIN)*	15:55-16:50
5	**Evaluation** Evaluation of Project Forums	- *Irene Kesisoglou (Sciensano)*	16:50-16:55
6	**Closing remarks**	- *Shona Cosgrove (Sciensano)*	16:55-17:00

For more information visit:
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Twitter:
#TEHDASforum
@tehdas
@EU_Health

Annex 3 – Policy Forum minutes

TEHDAS – 1st Policy Forum Meeting Minutes

Monday 28th June 2021, 15:00-17:00, via WebEx (online)

Contents

1 Attendees

Number of participants: 70. Number of countries: 21 EU member states (MS) and associated countries.

Countries:

1. Austria
2. Belgium
3. Croatia
4. Cyprus
5. Czech Republic
6. Denmark
7. Estonia
8. Finland
9. France
10. Germany
11. Greece
12. Italy
13. Latvia
14. Lithuania
15. Malta
16. Netherlands
17. Norway
18. Poland
19. Portugal
20. Slovenia
21. Spain

2 Welcome session

2.1 Aim of the meeting

The aim of this Policy Forum is to engage with the Ministries of Health, Economy and Research in the shaping of the European Health Data Space (EHDS). It is a platform where opinions can be shared and the discussion can have a direct influence on the EHDS and its upcoming legislative proposal.

Ministry representatives had the opportunity to prepare the following questions for discussion prior to the meeting:

1. What are your expectations of the European Health Data Space (EHDS)?
2. How do you think the EHDS can benefit your ministry?
3. Please give us an example of successful data exchange and use across sectors in your country. Why has it been successful?

2.2 Welcome and insights from first Policy Forum

Petronille Bogaert (Sciensano) welcomed participants. This first policy forum is about setting the scene and getting your initial views on the EHDS.

2.3 Welcome from moderator

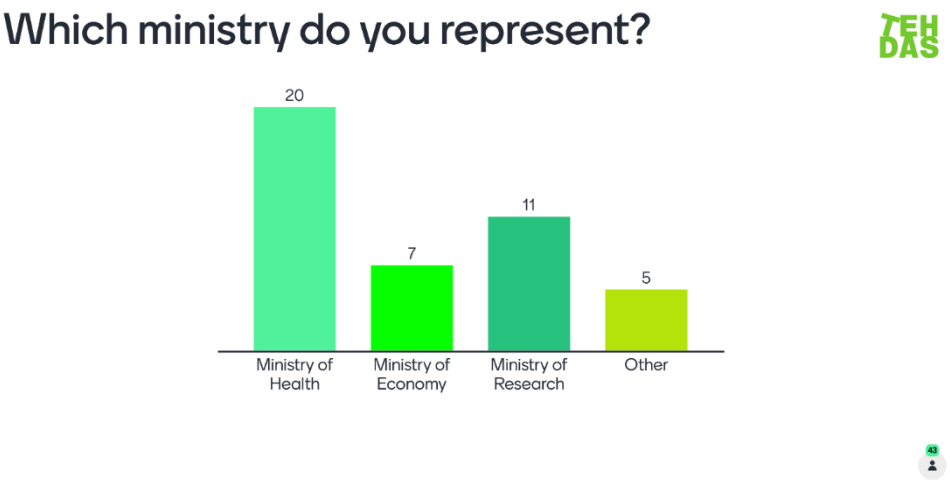
Neville Calleja (Ministry of Health, Malta) welcomed participants. The idea of the Policy Forums is to convey Member States' (MS) wishes to the European Commission (EC) on what they want the EHDS to deliver. We will focus on the secondary use of health data.

Permission to record, no country will be identified in external materials.

Structure of the meeting

1. Introduction from the Portuguese Presidency
2. Mentimeter questions
3. Introduction to European Health Data Space
4. Introduction to TEHDAS
5. Discussion
6. Short presentation on cross-sectoral data sharing
7. Discussion and concluding remarks

Mentimeter survey



3 Welcome from the Portuguese Presidency

Diogo Martins represented the entity carrying out digital health initiatives of the Portuguese Presidency of the Council of the EU. He is a Public Health doctor with experience in global health and development, including with the United Nations (UN) and the World Health Organization (WHO).

The TEHDAS Policy Forum is a valuable initiative to the broader discussion on the EHDS.

The notion of a health ecosystem is increasingly important. The COVID-19 pandemic showed that all sectors play a role in the sustainability of the national health systems. Digitalisation of the healthcare sector involves many organisations that are important to make the EHDS a well-balanced initiative.

The EHDS is about health as a citizen and a society, about using the new tools provided by digital revolution. It is about how can we create a strong data economy. Access to and use of health data are core elements to improve the outcomes and develop proper health strategies. Access to health data remains the biggest barrier.

6 main ambitions:

1. Broaden the EHDS discussion with more stakeholders
2. Every single actor plays a role
3. Data is the new world; data is also the main barrier, lack of interoperability, we need to start thinking of how we make data safe
4. Better evidence based policy making
5. Quality of data is very important
6. It is also about the citizens and how we can connect the dots.

This is an excellent platform to have a dialogue between policymakers and researchers, and create consensus among MS and stakeholders. It is important to create a well-balanced EHDS which involves many actors.

4 Introduction to the European Health Data Space (EHDS)

Ander Elustondo Jauregui (DG SANTE, European Commission) gave an overview of the EC's work on the EHDS. It is important to contextualise the EHDS in the common data spaces across the EU. The horizontal framework of Data Governance Act sets a common approach for data sharing. There are 9 sectors identified as key common data spaces, including health.

The EHDS is the framework for the sector-specific ecosystem. EHDS1 focuses on the primary use of health data for healthcare. EHDS2 focuses on the secondary use, re-use of health data for secondary purposes, such as research, innovation, policymaking, regulatory decision-making.

The main challenges to tackle are distributed across 4 main pillars:

1. Sharing health data for healthcare
2. Single market for digital health products and services: Study showing different implementation of GDPR across Member States raises important questions for the single market
3. Access to health data for research, innovation, public health policymaking

4. Artificial intelligence: developing/building new technologies on top of that

The main objective of the EHDS is to timely and simplified exchange of and access to health data.

Scope and expected impact:

1. Use of health data (primary): Access and control of patients over their data and exchange of health data for healthcare provision. Digital health services and products. Expected impact: high quality and safe healthcare provision.
2. Re-use of health data (secondary): Research and innovation, policy and regulatory decisions. Expected impact: facilitate research and innovation and data-enabled policy making.

The means to achieve the above are:

- Legal/governance
- Quality of data
- Infrastructure
- Capacity building

Regarding the articulation of the EHDS with the existing regulatory framework it is important to mention the Cross Border Healthcare Directive (MyHealth@EU for the exchange of patient summaries and e-prescriptions), the Data Governance Act, and the AI regulation for aspects where there is an interface with health data.

Preparation of the legal proposal:

1. Inception impact assessment released in December, open for feedback until February
2. Public consultation: currently open for all citizens to contribute until July 2021
3. EC is conducting the impact assessment, regulatory gaps, infrastructure requirements
4. Consultation of the European Data Protection Supervisor (EDPS)
5. Final adoption of the legal proposal expected for Q1 of 2022

There are a number of users of the EHDS (e.g., researchers, policymakers, healthcare professionals, industry). In this context we are preparing a pilot project (as a proof of concept) which will be launched either end 2021/start 2022. It will be financed by the EU4Health Programme.

TEHDAS plays an important role for the EHDS. A lot of work in the Commission is happening in parallel. EU4Health Programme and the EHDS have as a main objective to strengthen the digital transformation.

Q&A

- Could you elaborate on the legislative proposal? Which areas would it cover?
    - It covers both primary and secondary use of health data. It aims to build on what already exists, focusing on the four pillars presented earlier.
- Can you elaborate on the pilot of the EHDS2 and on the link with EU4Health?
    - We are working on what should be included in the pilot. The pilot will be funded through the EU4Health programme.
- Regarding governance, how do you see the link between the Cross Border Healthcare Directive (2011) and EHDS? Will the governance structure stay the same or will it be renewed for the secondary use?
    - Impact assessment is ongoing so cannot know the result already. We are evaluating the current framework, the directive and the work on the governance between the stakeholders of EHDS2.
- Will EHDS have only data held by public institutions?
    - One of the elements of the impact assessment is the scope of the data that will be included in the EHDS and the links with private stakeholders. Linked with the access requirements and access conditions. At the moment there is no clear answer.
- I had understood previously that it was only going to focus on structured data, Clinical Document Architecture (CDA) level 3 data. MS struggle with that CDA level because of the standards that are not supported by the master value catalogue. We need to have master mapping catalogue.
    - The idea is to broaden the scope of categories of data currently shared by MyHealth@EU. There is no decision on the standards and data models currently. The legal text and the proposal might not have details on standards.

- In the EU Beating Cancer Plan the EHDS is mentioned as the place where cancer patients can access their integral health record, and share it with anyone to increase the quality of cancer care in Europe. That goes beyond 'secondary use'. How is that being taken into account in TEHDAS?
    - Access to personal health data is considered primary use and not in scope of TEHDAS, but very much in scope of the EHDS.

5 Introduction to TEHDAS

Markus Kalliola (Sitra) presented the TEHDAS Joint Action.

He thanked the Portuguese presidency for the good collaboration, and hoping that would continue with future presidencies.

It is rare to have events bringing together representatives from different ministries. Health is a much wider policy. We need the other ministries to discuss these important topics. TEHDAS also discusses the sustainability aspect and hence it is very useful to have these policy forums.

TEHDAS Joint Action (JA) covers the secondary use of health data under the three first pillars: legal governance, quality of data, and infrastructure. It does not cover primary use.

TEHDAS in a nutshell:

- Project coordinator: The Finnish Innovation Fund Sitra
- Project acronym: TEHDAS
- Start date: 1 Feburary 2021
- Duration: 30 months
- Participants: 25 European countries
- Co-funding: €4.16 M (EU €2.5 + MS €1.66)
- Work packages: 8
- Website: www.tehdas.eu
- Contact: tehdascoordination@sitra.fi

TEHDAS vision: to help MS and the EC in developing and promoting the concept for sharing of data in secondary use for purposes in Europe.

The first results will be published in June and August, such as the results from WP5 on data governance and a guide on potential health data governance mechanisms for the EHDS.

EHDS consultation is open and TEHDAS stakeholder forum will be happening in October, registrations will start after the summer holidays.

6 Discussion

6.1 What are your expectations of the European Health Data Space?

- Ministry of Research: Improving the development of diagnostic methods or personalised medicine. Supporting collaboration between experts in the medical care field.
- Ministry of Health: Linking data sources to improve profiling of the population for efficient implementation of interventions.
- Ministry of Health: Collaboration and cooperation with a broad spectrum of stakeholders and partners.
- Ministry of Health: The EHDS needs pre-requisites to ensure a safe and secure working environment. The legal background is extremely important, with a harmonised framework, compliance to GDPR and a secure platform for data exchange. Health data becomes more valuable when it is linked with other sectors.
- Ministry of Health: A harmonised framework with strong legal basis. Allowing data analysis where the data is and not moving data sets to different places. Distributed analysis. Staged access to the data. Ensure data protection and compliance to GDPR.
- European Commission: We envisage queries being exchanged but not that data will move around. The need for anonymised, aggregated, or more granular data depends on the use case.
- TEHDAS representative: TEHDAS is looking at different options (e.g., peer to peer system, or a system with a central orchestrator). We are looking at technical options for federated analysis.
- Ministry of Health: It is important to create common rules for the implementation of the GDPR and data management. It is important to adapt common rules and methodologies for the EHDS.

- Ministry of Health: The discussion on federated and distributed analysis is important for countries with decentralised healthcare systems. It is important to consider the role of private healthcare providers. If EHDS focuses only on public organisations then for some countries this would not make sense.

- TEHDAS representative: We need to acknowledge the difficulty. Regarding a harmonised framework for privacy and compliance with GDPR, looking at the subsidiarity principle, it is important to adapt the system to the existing systems in different countries. We have to adapt to the fact that different countries will act differently.

- Ministry of Health: The idea to have everything the same in every country is an illusion. With federated analysis you avoid sharing and export of personal data.

- TEHDAS representative: On the use of private and public data, it could cover both private and public sector data. Regarding the question of federated learning vs access to data, we should not think of it as either or, we need both. If in your analysis you need access to different data repositories and link individual data, this is not possible with federated analysis. TEHDAS is not building IT systems or testing use cases with real world data but to create a concept and to provide options for the legislative proposal of the EHDS.

- Ministry of Health: It is important that the starting point is a federated model, where we exchange analysis rather than actual data. We should make concrete use cases and examples to test a federated model. It is important to have a framework that respects local regulations.

7 Presentation on 'Cross-sectoral benefits from data sharing: exploring ageing and fiscal sustainability'

Jon Cylus (European Observatory on Health Systems and Policies) presented experience on the benefits of cross-sectoral data sharing.

Population ageing affects all sectors of the economy and government. It is important to have access to health data to know how people are ageing, whether they are ageing in good health.

How much would healthcare cost and how healthy people are to work at an older age are important questions that have an effect in policies and the economy.

To have a lot of this essential information, we need data from different countries. There is a lack of health data sharing across countries. The European Observatory on Health Systems and Policies has

developed a model called the Population Ageing financial Sustainability gap for Health systems (PASH), a simulator tool to look at how health financing will change due to changes in health demographics. The tool is limited because of lack of available data.

A country example (Belgium) was provided. Because of lack of availability of health spending by age data, these are hypothetical lines. It would be much better if we had the actual data. Using the simulator, we can come up with financial sustainability gap. Spending and revenue are diverging as the population ages. The exciting part of the simulator is the ability to explore the effect of different policy options.

This simulator tool would benefit ministries of finance and ministries of labour, having better linkages from health policy options to spending patterns. It would be useful to also have a better understanding the work capacity at older ages.

This is a clear example of secondary use of health data and the impact it can have across sectors.

Q&A

- It is surprising because Belgium has a rich data landscape, those data gaps could be filled.
    - It is more that the ability to share across borders and that this data is not publicly available across borders. The data exists in EU countries but it is difficult to access it across borders.
- This is a good example of the added value of the European data spaces.

8 Discussion (continued)

8.1 How do you think the EHDS can benefit your ministry?

- Ministry of Health: To what extent is improving findability of data in scope of the EHDS? Finding the institution that has the data available is not always easy.
- TEHDAS representative: Findability of data is definitely in scope of the EHDS and TEHDAS.
- Petronille Bogaert: It is very important to find data sources available in different countries. We have been working on a project, the Population Health Information Research Infrastructure (PHIRI). It helps identify the landscape of available data in each country. In PHIRI we are also looking at implementation of a federated analysis approach. We have 4 themes and areas where we have explored how we this federated data architecture can be set

up. We are also identifying hurdles that we are experiencing with this federated data approach. Capacity and expertise in the country is the major challenge.

- Ministry of Health: Smaller Member States often lack capacity.

8.2 Please give us an example of successful data exchange and use across sectors. Why have those been successful?

- Ministry of Health: Since 2018, there is a national effort on this in my country. There is a proposal for legislation to establish a technical platform for data sharing, where users are invited into analytical rooms where they can use data stored in different national registries, and they can also bring their own data to compare. They also get access to different analytical tools. We have also established a Data Permit Authority that will be responsible for this platform. This legislation will be debated in the Parliament in autumn 2021. We now start to connect through the EHDS with other countries and EU agencies on data sharing.

- Ministry of Health: My country has a data exchange project across sectors since 2007. Its aim is to evaluate the outcome of work related effects on health (e.g., accidents at work) and the effects of health changes on work. It uses existing data flows. We merged data from 4 national archives, such as data from statistics, insurance companies and the ministries.

- Ministry of Health: In my country we collect data in a centralised infrastructure, from socioeconomic data, health, employment data etc. For many years this data has been accessible in a secure environment. You can apply as a researcher and you can go to a secure data processing environment to analyse the data you applied for. This has been a valuable infrastructure and it would be great to do it at a European level.

9 Concluding remarks

This first Policy Forum aimed to set the scene on the EHDS. These areas will be further explored in more depth in the next Policy Forums. We discussed sharing of data, federated arrangements and we have also seen several benefits highlighted by many participants.

Some of the other themes we would like to discuss in the next Policy Forums are the economic value of the secondary use of health data, how to work within countries, the EHDS nodes functions and responsibilities, and discussions on the barriers and enablers in the sharing of health data for secondary use.

The next Policy Forum will take place in November 2021.

Mentimeter survey

1. Is there a specific topic that you would like to discuss in the next policy forum?
2. How would you rate this meeting?
3. What could we improve?

TEHDAS Policy Forum

The Joint Action Towards the European Health Data Space (TEHDAS) is organizing a series of four Policy Forums over the course of two years. The Aim of the TEHDAS Policy Forum is to engage the Ministries of Health, the Ministries of Economy and the Ministries of Research in the shaping of the European Health Data Space (EHDS). The Forum will provide a platform where opinions can be shared. The discussion can have a direct influence on the EHDS and its upcoming legislative proposals.

No	**Date : 28 June 15:00-17:00**		Time
1	**Welcome**	**Moderator:** **Neville Calleja** Director of Health Information and Research, Ministry for Health, Malta	15:00 – 15:05
2	**Welcome from the Portuguese presidency**	**Diogo Martins** Representing the Portuguese presidency Shared services for the Ministry of Health, Portugal	15:05 – 15:15
3	**Introduction to the EHDS**: Sharing health data for secondary use.	**Ioana Gligor** DG SANTE European Commission	15 :15 – 15 :30
4	**Introduction to TEHDAS** TEHDAS – Towards the European Health Data Space	**Markus Kalliola** Sitra Finland	15 :30 – 15 :40
5	**Discussion:** 1. What are your expectations of the European Health Data Space (EHDS)? 2. How do you think the EHDS can benefit your ministry?	**Open floor**	15:40 – 16:20
Intermezzo Cross-sectoral benefits from data sharing: exploring ageing and fiscal sustainability		**Jon Cylus** European Health Observatory, LSE Health	16:20 – 16:35
	3. Please give us an example of successful data exchange and use across sectors in your country. Why has it been successful?	**Open floor**	16:35 – 16:50
6	**Closing remarks**	**Neville Calleja** Director of Health Information and Research, Ministry for Health, Malta	16:50 – 17:00

TEHDAS – 2nd Policy Forum Meeting Minutes

Monday 29th November 2021, 09:00-11:30, via WebEx (online)

Contents

1 Attendees

Number of participants: 59. Number of countries: 21 EU member states (MS) and associated countries.

Countries:

1. Austria
2. Belgium
3. Croatia
4. Czech Republic
5. Denmark
6. Finland
7. France
8. Germany
9. Hungary
10. Ireland
11. Italy
12. Latvia
13. Lithuania
14. Malta
15. Netherlands
16. Norway
17. Poland
18. Portugal
19. Slovenia
20. Spain
21. Sweden

2 Welcome session

2.1 Aim of the meeting

The aim of the Policy Forum is to engage with the Ministries of Health, Economy and Research in the shaping of the European Health Data Space (EHDS). It is a platform where opinions can be shared and the discussion can have a direct influence on the EHDS and its upcoming legislative proposal.

The second Policy Forum included in depth discussions of the user journey for the EHDS. Ministry representatives discussed the following questions:

1. What do you think a national single information point is or should be?
2. How would you estimate the feasibility of having a single information point in your country?
3. Do you have a similar structure already existing in your country? Or are you in the process of developing this?
4. As a user, what services would you expect the European Health Data Space (EHDS) to provide (data discoverability, data accessibility and/or data analysis)?

2.2 Welcome and insights from first Policy Forum

Petronille Bogaert (Sciensano) welcomed participants.

The first Policy Forum (June 2021) was about setting the scene of the EHDS and reflecting on the needs and expectations. We also discussed the value of cross-sectoral sharing of health data.

Some key takeaways from the discussion in the first Policy Forum and from your responses to the preparatory survey were:

1. **What are your expectations of the EHDS?**
   - EHDS will provide a framework for exchange of health data. It will be an important step to address data shortages.
   - Strong focus on safety: key words secure and trusted
   - EHDS will ensure same standards or basic rules for data exchange, and will promote quality of data

2. **How do you think the EHDS can benefit your Ministry? Benefits that you expect from the EHDS include**:
   - Enabling the use of data from across European countries
   - Providing legal clarity on cross-border sharing and access to data
   - Better monitoring and response to infectious diseases and rare diseases
   - Cross-border collaboration will add value to your own data
   - Data-driven healthcare systems and informed decision-making
   - It will stimulate innovation in healthcare
   - EHDS will provide benefits at national level:
     - Strengthening cooperation between actors (eg data permit authorities) in the system
     - Help upscale national health information systems

3. **An example of successful data exchange and use across sectors in your country:**
   - Legislative proposal for a technical platform for data sharing, where users can access data stored in different national registries and institutes
   - Cross-sectoral project which combines health and occupational data to monitor the work-related effects on health

- Centralised infrastructure collecting data across sectors, accessible in a secure environment.

TEHDAS Work Package 4 (WP4) is also carrying out other outreach activities, including country visits. The country visits aim to engage with national stakeholders and provide an overview of the state-of-play of the national health data management systems in relation to the EHDS. There will be 12 countries mapped in one year, starting in December 2021.

2.3 Welcome from moderator

Consent for recording for minutes purposes, no country will be identified in external materials.

Agenda for the meeting

- Introduction from the Slovenian Presidency
- Mentimeter questions
- Discussion
- Juan Gonzalez Garcia – Presentation of the user's journey for the EHDS, TEHDAS WP7
- Discussion in breakout sessions
- Concluding remarks

Mentimeter survey

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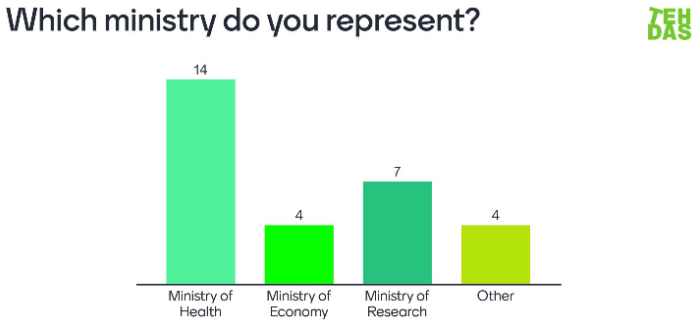


3 Welcome from the Slovenian Presidency

Mag. Franc Vindišar, State Secretary for Health, Slovenia welcomed participants to the second TEHDAS Policy Forum on behalf of the the Slovenian presidency of the Council of the EU.

The creation of the EHDS is one of the priorities of the European Commission (EC). A common EHDS will promote better exchange and access to different types of health data. It will support healthcare delivery as well as health policy making purposes. Cross border sharing of health data has so far been project-based and there is no common legal basis for the secondary use of health data in Europe. Differing interpretations of the GDPR means that health data is being poorly used in decision making and research. The COVID-19 pandemic has revealed pressing needs for digitalisation.

The Presidency trio, Germany, Portugal and Slovenia, have highlighted the importance of digitalisation in health. TEHDAS will support the EC in building the EHDS. TEHDAS and other joint actions are great examples of EU cooperation, exchanging ideas, sharing good practices and promoting research. It is important to ensure that health data is accessible, compatible and reusable.

4 Discussion

A survey was sent to participants prior to the meeting with the preparatory questions.

4.1 What do you think a single national information point is/should be?

Answers on the national single information point included: the concept of a gateway to regional data spaces, a source of information regarding data accessibility, a point to capture information from other MS or from other sectors.

There is a definition for the single information point in the Data Governance Act. The single national information point is expected to be a focal point receiving requests for re-use of categories of data and transmitting them to the competent public sector bodies in the MS. Someone from outside of the MS may not be familiar with the available data, such an information point is needed to make a register of available data resources available electronically.

4.2 How would you estimate the feasibility of developing such a single national information point?

Some answers to the survey were positive and the basis is already in place in some countries. Other countries mentioned that the necessary infrastructure still needs to be put in place.

Some countries noted that it could be implemented if:

- The legal basis for the secondary use of health data (incl. GDPR) is established.
- The necessary organisational and technical measures for consistent, coordinated health data usage are prepared.
- Authorisation to one national institution responsible for exchange, and secondary use of health data is given.
- National Health Data Governance Framework is established.

Are there any other concerns if the Commission asked you to implement this by 2022?

- Ministry of Health: Drawing from experience when building the national contact point for eHealth in the context of primary use of health data, it will be difficult. The national healthcare landscape means it is complicated to build something central. It might not be impossible but it will require a lot of effort. If you have a central information point, all actors in the field have to connect to this information point.

They need to see a benefit for them to connect as well. The EHDS may be an accelerator but it will not be an easy task.

- Moderator: We can think about incentives for countries to create the single information point and health data sharing rather than forcing it through legislation.
- Ministry of Health: It will be difficult in my country to have one single institution responsible for all data exchange. Is it envisioned that the single information point is the way to input your demand or is it envisioned to be the authority to approve data exchange? Especially for personal data this will not be possible in my country.
- Moderator: We are expected to deliver an entry point. It is not going to be a single central authority responsible to authorise access to all data itself.
- Ministry of Economy: It is important to consider the individual whose data it is. Citizens themselves should authorise what happens to their data not private companies.
- Moderator: We must consider to what degree anonymisation techniques have to be built in the data governance framework.

4.3 Do you have a similar structure already existing in your country? Or are you in the process of developing this?

Two particular examples were received:

- Ministry of Education: The institute of health, information and statistics is established in my country. It collects all data provided by medical providers and creates statistics. It will collect all data, also from the research environment. Medical data are highly structured and anonymised. Research data are less structured and they need citizens' or patients' consent.
- Ministry of Health: My country is highly decentralised. We are planning a national health data space. Governance and data protection are the most important elements to consider. We propose a scheme of federated data lakes with a national contact point. The data will remain in the institutes that store them. We will guarantee interoperability, data quality and security. Our national data lake will communicate with the EHDS.

- Ministry of Health: My country has a data permit authority for health and social care data. It has not been decided yet whether it will be the national single information point for the future EHDS. The only data missing in the scope is genomic data. There is a draft legislation regarding a genome centre and other centres of excellence. It currently allows access to many types of data (not just health data), including: social healthcare data, socioeconomic data, data from national and local registers, benefit data. There are many benefits regarding single points of information but also barriers. Resources and technical capability must be invested to make the centralised system work. A decentralised system would be preferable.

Comments in chat

- Ministry of Health: My country is establishing a similar system but not establishing a new institution. The role of a one stop shop for secondary use of health data is being delegated to the Statistics Department. Furthermore, for the cross border services, the National Contact Point is another institution.

- TEHDAS representative: In the Data Governance Act (DGA) the article 8 single information point is not health specific. It is a single information point for all data regardless of the policy area. In my understanding a health data permit authority could be Article 7 body according to DGA. They can be sector specific. The EHDS legal proposal will most likely have "nodes" or single point of contacts for each Member State regarding health data. How these two legal acts will work together could be that all EHDS nodes would be sector specific article 7 bodies in DGA.

5 Presentation of WP7 user journey for the EHDS

Juan González García (IACS) presented the work of WP7. WP7 entitled 'Connecting the dots' is devoted to providing options for the technical interoperability of the EHDS, i.e. how the computers that will support the EHDS will work together.

It is carried out by 12 MS in TEHDAS, as well as the Work Package Advisory Group (WPAG). The WPAG brings together nearly 40 European institutions and companies related to health data sharing, reinforcing the value of the work.

WP7 includes the definition of:

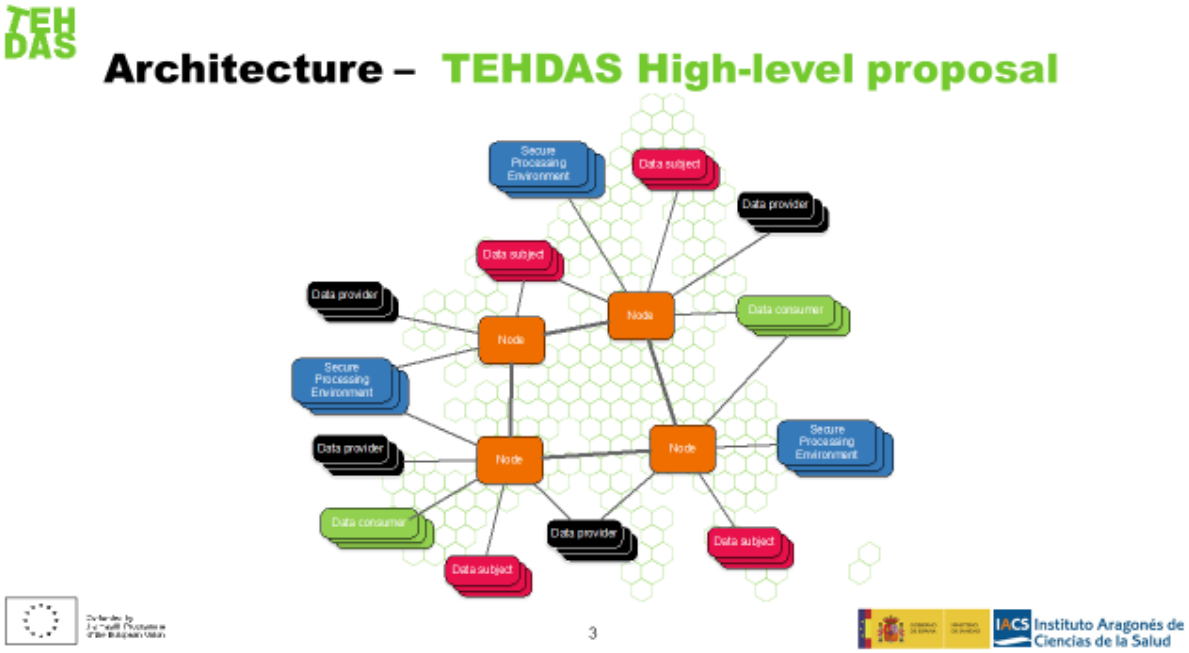
- Services: the technical solutions (software tools) that the EHDS offers.

- Architecture: the organisation of these services and its relation with EHDS entities or actors.
- Infrastructure: the physical elements of the EHDS (types of computers, networks etc).

This presentation will focus on the services and the architecture. All the elements in this presentation are options proposed within the scope of the TEHDAS JA and not in the final version of the EHDS.

Architecture

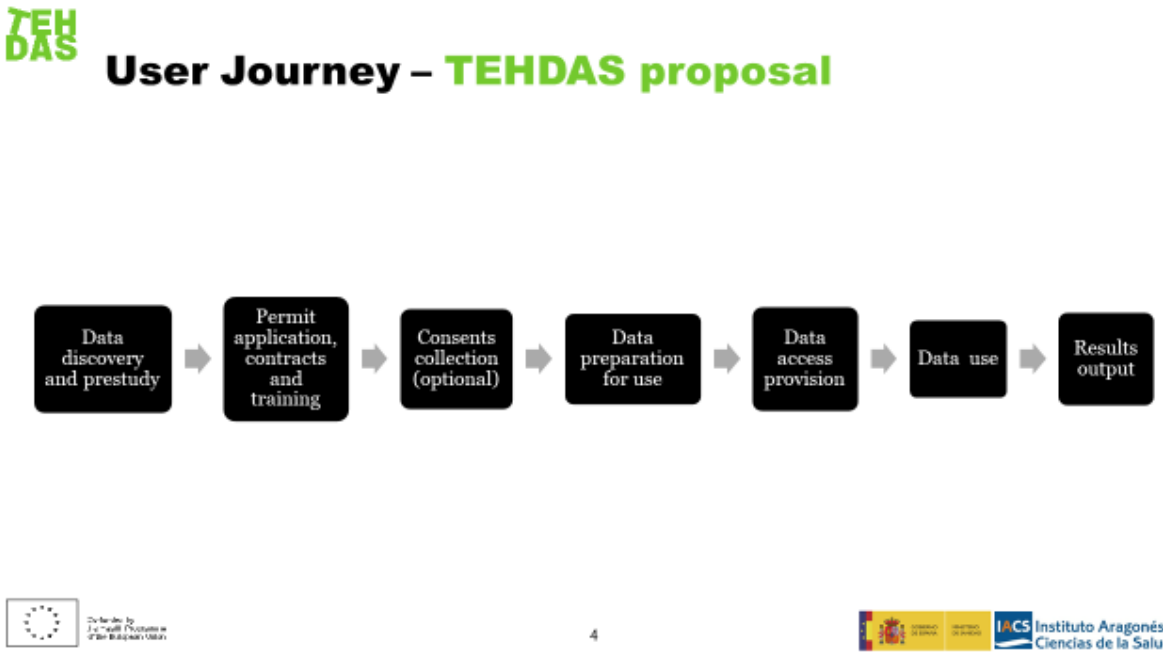
The current envisioned architecture is a network of nodes, linking different entities:



- Nodes (orange): main entry points to the EHDS, where users interact with the system.
- Data providers (black): institutions with the mandate for holding and managing data for secondary use. Data providers communicate with the nodes to provide access to the data.
- Data consumers (green): those that will use the data (policy-makers, regulators and researchers). They interact with nodes to access data and analyse it.
- Data subjects (pink): the citizens who's data can be shared. They interact with the system giving their consent for using their data or monitoring the use of it.
- Secure processing environments (SPEs) (blue): special entities where data is placed to give data consumers a safe place to perform their analysis, avoiding security breaches or "hacks" and in compliance with existing regulations, e.g. the GDPR or Data Governance Act.

User journey

The TEHDAS proposal for the 'user journey' represents the steps that the data consumer will have to take to access and use the data. It implies the involvement of multiple entities.



1. **Data discovery and pre-study:**
    a. Concept: Find the required data in the EHDS (e.g., to answer a research question).
    b. Services: search, which also implies a way to distribute the search among multiple nodes.

2. **Permit application, contracts and training:**
    a. Concept: Once a data consumer has found data, they must request permission to use it.
    b. Services devoted to formalise the data request application:
        i. Digital data request forms.
        ii. Tools for permit acceptance and management, which puts in contact the different entities required (ethical boards, permit authorities, etc.).
        iii. Contract signing programme.
        iv. A training platform on how to proceed with the rest of the steps.

3. **Consent collection (optional step):**
    a. Concept: How data subjects intervene, can be seen as a special permit given by the citizens in the form of consent.
    b. Services: this step may involve two kind of interactions:
        i. For a single project that requires specific consent, citizens may be actively contacted to provide it (consent acceptance notification).
        ii. In a broader scenario, the data sharing control (permanent available service) will offer the possibility to citizens to opt-in or to opt-out of the sharing of their data for all purposes or specific purposes.

4. **Data preparation:**
    a. Concept: extract and transform data for its further use.
    b. Services:
        i. Data retrieval: Gathering the data from where it is
        ii. Data integration: Linking data sets that refer to same individuals, harmonise the encodings (e.g., using ICD-10) and transform to common data models, data bases or data tables that have a well-known structure that facilitate the further analysis.
        iii. Data anonymisation/pseudonymisation: When using individual level data it will be required to fully anonymise it or pseudonymise it. Anonymisation (more common): removing all elements that may allow re-identification of the individuals. Pseudonymisation is less intrusive: giving a number to the dataset of a patient for example, a secure third party holds the method to re-identify the ID of the individual.

5. **Data access provision:**
    a. Concept: Before the data can be used, it should be placed in a safe space, where it can be appropriately manipulated
    b. Services:
        i. SPE (ideally): a remote desktop where data consumers access through a VPN
        ii. An API to access it through a machine (alternatively): Processing APIs are also secure places, but the access is done through an application written by the data consumer performed in a machine-to-machine way. The processing APIs are much more complex, but open the door to much richer analyses of Big Data.
        iii. Data download: finally, there is also a less desirable option for the data provider which is making it available for download to the data consumers (the

traditional way of providing data in the old days). This option should only be provided with aggregated data, because it is risky for individual level data in terms of security and puts a lot of responsibility on data consumers.

6. **Data use:**
    a. Concept: the step where the actual analysis of the data takes place.
    b. Services:
        i. Statistical tools, for example SPSS, Stata or SAS, that can be used interactively in the secure processing environments.
        ii. Analysis runtimes: When using API access, analysis runtimes are the libraries that help data consumers to build complex applications

7. **Results output:**
    a. Concept: Key step to maximise impact in terms of disseminating results of the analyses (if possible).
    b. Services:
        i. Result storage and cataloguing: for consultation and possible re-use.
        ii. Document repository: may help store other data than results (e.g., pre-prints).
        iii. Results communication: announce findings (e.g., messages in social networks).
        iv. Notification of clinically relevant findings: wherever possible, there should be channels to notify health services (or even individuals) on clinically relevant findings.

There are also a set of transversal services to support the overall journey:

- Authentication/authorisation/identification
- Node management
- Financial management
- Data donation
- EHDS communication

Q&A

- Ministry of Health: Regarding anonymisation, you mentioned that you will anonymise information that will be in the European data lake, but we are going to send the information in an anonymised manner. Could you elaborate on how you will manage that?

- This is an interesting question on how data is manipulated before its provision. The idea is that when you request data, the first step is to gather it from where it actually resides. In this place it is not anonymised, it has all the identifiers. When you then process and link individual level data, then you have to do the anonymisation step after it has been linked. After this point, it is hard to re-identify the data.

- Ministry of Health: Will countries need standardisation in the methods of doing anonymisation in the EHDS?

  - It is about defining standards to ensure that all entities in the EHDS follow the same processes, to build trust between parties involved. We are only proposing options here, not the final solution. For anonymisation, we have not defined the possible algorithm.

Comments in the chat

- Ministry of Research: Could you please elaborate on the consent collection? Why will it be optional? In some cases, consent might have an effect on the possible use in later analysis.

- Ministry of Health: Do citizens give consent one time for all use cases or the consents are gathered for each data demand?

  - Our idea is to provide both options: broad consent (opt-in/opt-out) approach.

- Ministry of Health: Consent is a great challenge for secondary use across EU. In my country we notice that actors in the healthcare sector are implementing consent heterogeneously.

6 Breakout session – Discussion on the user journey and services provided by the EHDS

All breakouts covered the same topic: *What services would you expect the EHDS to provide (data discoverability, data accessibility and/or data analysis and/or results dissemination)?*

6.1 Breakout room 1

Tour de table: Thoughts on the user's journey and the national single information point

- Ministry of Health: The issue of consent and its notification is difficult (e.g., is this done by email?).
- Ministry of Health: We do not have consent with regards to secondary use in my country. The user journey was not totally clear to me. It is crucial to look into federated models. A very important standpoint of my country is that individual level data does not leave the country.
- Breakout room moderator (TEHDAS): There are different approaches that can be taken (e.g., downloading data or one where you do not move data). It is important to incorporate opinions from different countries.
- Ministry of Health: I am not convinced about the name 'user journey'. It is missing the most important step: collection and storage. All those processes need to be represented in the workflow.
- Breakout room moderator (TEHDAS): The idea in WP7 is that we think that the data resources are somewhere already. We do not mind how they are collected, the EHDS is just facilitating access to data resources that are there already. It is an important comment but we do not cover that part in the user journey.
- TEHDAS representative: In my country we are in the process of establishing the national node and contact point. We are going to provide data discoverability and accessibility, but not analysis. In my country data collection is quite centralised. Data collection is defined by law, which says that you do not need consent for secondary use of health data.
- Ministry of Health: Data analysis is not foreseen in the single contact point. My country has several levels of government, a single point of access across all the levels may not be easy. Federated model will be the best.
- Ministry of Health: In my country we do not need consent for analysing data for policymaking within the country. However, with the EHDS we are talking about Europe.
- Ministry of Health: We must do the analysis in each country and share the results.

6.2 Breakout room 2

The discussion started around the need for an advisory service within each data source to improve data accessibility. Participants discussed that GDPR is interpreted differently in every member state and especially the consent collection. The EHDS can be an accelerator for interoperability, a harmonised interpretation of the GDPR and the development of a common consent collection model.

- Breakout room moderator (TEHDAS): It is important to note that the nodes mentioned in the architecture are not only national nodes but it can be European agencies (e.g., EMA, ECDC) or Research Infrastructures (ERICs).

- Ministry of Research: It is important for single information points to offer training (e.g., explain the consent procedure). Literacy can be transversal.

- Breakout room moderator (TEHDAS): In my country there is a national primary care database. If you do not follow the training you cannot have access to this database. The opt-in and opt-out approach for citizens happens via a communication platform.

- Ministry of Health: This might not be feasible in all countries in Europe. Consent is important, more in some countries than others. We need a harmonised consent model. Patients and citizens in general need clarity on how their data are being used.

- Ministry of Health: It would be nice to have an explicit consent for secondary use, but this might be difficult. Using an SPE and distributed analysis could improve citizens' trust, as data does not cross borders.

6.3 Breakout room 3

Tour de table: The national single information point

- Ministry of Health: The EHDS should provide the search mechanisms based on metadata. It should also perform provision of data. It is not clear whether the EHDS should also provide results.

- Ministry of Health: Financing models are an important issue: should it be user paid or basic funding? It is important to consider how to balance commercial rights with the interest of the common good.
- Ministry of Health: We have issues with consent for secondary use of health data. We are not sure if the EC will lay down recommendations for consent or if we will have to create our own national regulations.
- Ministry of Health: Within the public space in my country it would be possible to have a data permit authority. The consent issue is secondary when it comes to use of health data for public health reasons. We have a lot of private providers and we are going to require those providers to make data accessible. This is doable within the GDPR.
- Ministry of Health: My country has a new law for access to public data. It is quite clear with regards to primary use how the issue of consent is arranged according to the GDPR, there is a quite slight uncertainty for the secondary use. The Data Governance Act and the EHDS will hopefully help with this.

Tour de table: Expectations for the EHDS services

- Ministry of Health: Discoverability as the bare minimum and information on data access. Analysis will be too much.
- Ministry of Health: I agree, but it is not an easy issue. For instance, the PHIRI (Population Health Information Research Infrastructure) project is trying to do mapping and it is already an issue to find the data. We need a stepwise approach. Giving permit authorities and allowing access will be further in the future.
- Ministry of Research: A great first step would be to have information on where the health data in other countries is and how potential users can get access.
- Ministry of Health: Discoverability based on metadata, then the service to have processing environment (data analysis).
- Ministry of Health: Consent issues are important. How can data subjects manage consent themselves along the life cycle of the data.
- Ministry of Research: Data discoverability on proper metadata.

- Ministry of Health: Any help is very important, for instance on how to collect data from different countries with different regulations, and provide a safe environment for use.

7 Plenary session

7.1 Reporting from breakout rooms

Breakout room 1

The discussion started with a tour de table where countries gave their opinion on the user journey. Some participants expressed concern about the term 'user journey', including that it appears incomplete as it does not consider the previous steps of data collection, storage, mapping etc.

Consent models were discussed. Some countries do not require consent for the secondary use of health data.

There was also a general consensus that a federated model for the EHDS is best.

There was an important discussion about data transfer in the EHDS. The EHDS is not envisaged as a central European health data repository. It aims to make health data that is already there jointly accessible and analytically available for exploitation at European level. It is about accessibility, harmonisation, standardisation, and flows of work.

Some participants expressed concerns about data quality – TEHDAS WP6 has produced a report, searching for data quality standards and common data models.

Breakout room 2

Expectations of the EHDS include to create a facility to discover data through a proper data catalogue. The concept of an advisor service was mentioned. Achieving interoperability is important; making data available throughout Europe does not mean it can be used.

Consent was an important topic of discussion. There was a regional example of data lakes where there is an active opt out system. The biggest challenge is that in Europe there is heterogeneous implementation of consent. Asking for consent is laborious, especially for researchers. Privacy is also linked: how do you create a system that is privacy-sound and compliant with data protection regulations by design? Examples included distributed analysis.

On anonymisation, with current or future technologies, anonymisation is not perfect as technologies can re-identify a person.

Training and literacy is an important topic. It is relevant to all the steps of the user journey.

Breakout room 3

The concept of consent was discussed and that this should be more clear. There may be a need for recommendations at national or EU level.

The financial model is an important topic to be discussed.

In terms of expectations from different services, most countries think that discoverability with a proper metadata set is the minimum. Some mentioned the expectation for a safe environment for analysis.

7.2 Concluding remarks

We plan to have two more Policy Forums, in June and November 2022. Potential topics for the next Policy Forums:

- Costs and benefits for the different governance options of the EHDS
- Discussion on the barriers and enablers in sharing health data for secondary use

7.3 Mentimeter results

Is there a specific topic that you would like to discuss in the next Policy Forum?

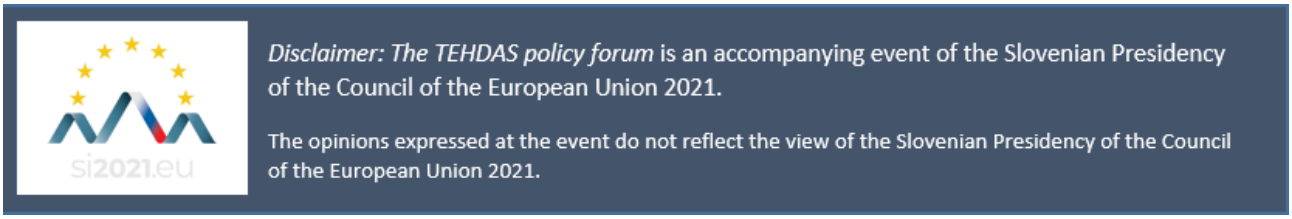
- Integration of genomic data
- GDPR interpretation cross-border
- Determine what the key principles are of the EHDS according to the Member States and whether the EC is actually taking up the input from TEHDAS
- Impact of GDPR on the development of the EHDS
- Training and digital health literacy for the EHDS
- GDPR and its implications for health data sharing, including definitions and distinctions between pseudonymised and anonymised data

TEHDAS Policy Forum n°2

The Joint Action Towards the European Health Data Space (TEHDAS) is organizing a series of four Policy Forums over the course of two years. The Aim of the TEHDAS Policy Forum is to engage the Ministries of Health, the Ministries of Economy and the Ministries of Research in the shaping of the European Health Data Space (EHDS). The Forum will provide a platform where opinions can be shared. The discussion can have a direct influence on the EHDS and its upcoming legislative proposals.

No	**Date : 29 November 09:00-11:15**		Time
1	**Welcome from WP4 lead and chair**	**Petronille Bogaert** Sciensano, Belgium **Moderator:** **Neville Calleja** Director of Health Information and Research, Ministry for Health, Malta	9:00-9:15
2	**Welcome from the Slovenian presidency**	**Mag. Franc Vindišar** State Secretary, Ministry of Health, Slovenia	9:15-9:25
3	**Discussion** **1)** What do you think a national single information point is or should be? **2)** How would you estimate the feasibility of having a single information point in your country? **3)** Do you have a similar structure already existing in your country? Or are you in the process of developing this?	**Open floor** To start the discussion, we will present a few of the answers we received prior to the meeting through the survey	9:25-9:45
4	**Presentation of WP7 user's journey for the EHDS**	**WP7 Juan González-García** IACS, Spain	9:45-10:00
6	**Breakout sessions:** -Divide into breakout sessions -Mix of MoH, MoE and MoR per session. **Discussion** As a user what services would you expect the EHDS to provide (data discoverability, data accessibility and/or data analysis)? Discussion on the users journey presented previously.	Representatives of the MoH, MoE and MoR from EU Member States and Associated Countries	10:00-10:30

	Break		10:30-10:40
7	**Plenary session** Reporting back on the outcomes of the breakout sessions and discussion	**Open floor**	10:40-11:00
8	**Closing remarks**	**Neville Calleja** Director of Health Information and Research, Ministry for Health, Malta	11:00-11:15



TEHDAS – 3rd Policy Forum Meeting Minutes

Wednesday 29th June 2022, 14:00-16:00, via WebEx (online)

Contents

1 Attendees

Number of participants: 58. Number of countries: 21 EU member states and associated countries.

Countries:

1. Austria
2. Belgium
3. Cyprus
4. Czech Republic
5. Denmark
6. Estonia
7. Finland
8. France
9. Germany
10. Hungary
11. Ireland
12. Italy
13. Latvia
14. Lithuania
15. Luxembourg
16. Malta
17. Poland
18. Portugal
19. Romania
20. Slovakia
21. Spain

2 Opening session

Irene Kesisoglou (Sciensano) opened the meeting with the aim and agenda of the meeting, and provided a brief summary of the previous two Policy Forums.

Consent for recording for minutes purposes was given, no country will be identified in external materials.

Aim of the meeting and summary of previous meetings

The aim of the Policy Forum is to engage with the Ministries of Health, Economy and Research in the shaping of the European Health Data Space (EHDS). This is the 3rd meeting in a series of 4 Policy Forum meetings.

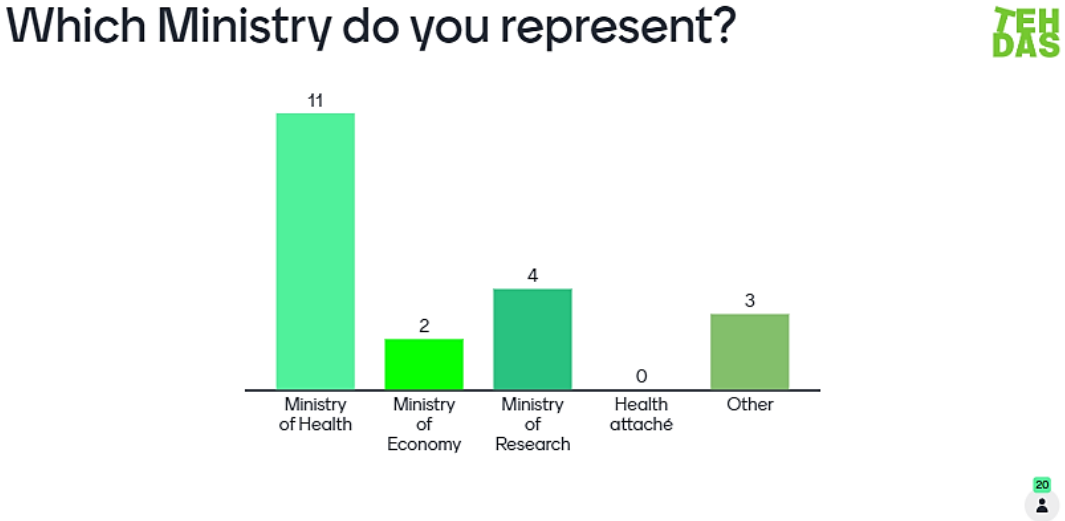
Previously, in the first Policy Forum, the EHDS and TEHDAS were introduced. In the second Policy Forum, discussions focused on the national single information point for the EHDS (including its role and feasibility in the different member states), and on the user journey and expected services.

In this meeting, the aim is to have a discussion on the national contact point of the EHDS for secondary use,and go in depth into selected topics from of the EHDS legislative proposal that was recently published in May 2022.

Agenda

1. Welcome from the French Presidency
2. Open floor for updates from Member States on the establishment of a national contact point
3. Presentation of the EHDS legislative proposal
4. Presentation of the Finnish model
5. Discussion in breakout sessions
6. Plenary
7. Closing remarks

Mentimeter survey



Neville Calleja, Director for Health Information in the Ministry of Health of Malta moderated the meeting.

3 Welcome from the French Presidency of the Council of the EU

Mélodie Bernaux (French Ministry of Health), representing the French Presidency of the Council of the EU, gave an overview of different activities implemented during the presidency to move forward with the EHDS.

The presidency tried to pave the way to this negotiation, first by establishing ethical prerequisites necessary for citizens to trust digital health and to be supportive of the EHDS. Secondly, harmonising technical standards and market access, which is very important both for healthcare providers (HCPs) and for innovation and researchers.

The EHDS aims to harness the power of health data for people, patients and innovation. It is important that people are engaged and at the centre of the proposal development.

To reflect on this, 16 principles were organised in 4 dimensions and proposed to MS in the eHealth Network at the end of December 2021. The principles were finalised and adopted on January 26, 2022.

The principles set the scene for the right direction/negotiation of an EHDS.

After paving the way with ethical principles, it was important to accelerate the journey towards European interoperability. The French Presidency compiled use cases and promoted the adoption and use of SNOMED-CT. The next step was to work on harmonisation of clinical evaluation criteria for Digital Medical Devices (DMDs).

Innovation was promoted by supporting digital health entrepreneurs and ecosystem through a platform that can help to decrypt national digital health regulation, identify players in digital health ecosystems, discover trends and identify eHealth events all over the world. It was set up for innovators and start-ups to get acquainted with the environment. All along the presidency, a strong focus was set on making digital health visible for all stakeholders (patients, HCPs, hospitals, innovators, start-ups), by organising events and meetings, as well as participating in TEHDAS events. The eHealth Network meeting in Paris in June was a major event in which the EHDS regulation was discussed.

4 Updates from Member States on the national contact point

A short discussion took place regarding the single national contact point and the questions that were sent to the designated representatives prior to the meeting:

- *What progress has been made in the last 6 months regarding the national contact point for the EHDS for secondary use in your country?*

- *Is there an already established national contact point for the EHDS for secondary use in your country?*

Discussion

- Ministry of Education: Thanks to the TEHDAS Policy Forums I have started communicating with the other ministries and being informed of what is happening with the EHDS. I appreciate the push to bring together these three ministries. The national contact point has not been established yet. However, there is a working group set up.

- Ministry of Health: In my country we are working on a draft law on reuse of personal data, which will serve as the legal basis for secondary use of health data. It will also set up the national authority responsible for issuing data permits and facilitate the secure access and processing of data. This authority will probably be the national contact point for the EHDS for secondary use.

- Ministry of Health: We have not made a formal decision on the national contact point but it will likely be the central health data authority.

- Ministry of Health: In my country, we are building a health data authority, as a new independent organisation. We have written the legal proposal. The specific work packages include one working on the legal aspects, which is setting up the governance for the data streams, and a code of conduct. Then there are additional work packages focusing on ontological aspects, ethical aspects and data science aspects. In July/August we are going to start building the open source metadata portal framework. Hopefully in September we can have a first view and a data request portal. We aim to have one unique point in Belgium to ask questions about secondary use of health data.
- Furthermore we strongly believe in setting up a data academy. There is a significant need for health data literacy. This also includes topics like who owns the data and who controls the data? And what is the difference.

- It would be great if we Europeans also align on technical aspects and definitions and use the same nomenclatures. This will make it easier for people to understand it.
- Another important aspect is the return on investment and business models. We want to see what the investment needs are to facilitate access to health data for secondary use. What will the outcome be? How do we help citizens/ healthcare professionals, the government, researchers, and industry? We are looking into making a sustainable business model.

5 Presentation of the EHDS legislative proposal

Karina Zalite and **Licinio Kustra Mano (DG SANTE, European Commission)** presented the EC proposal for the EHDS regulation. The main objective is effective sharing and use of health data. The proposal consists of two parts: primary and secondary use of health data. The focus today is on the second part.

Regarding secondary use of health data, the proposal has specific provisions, including:

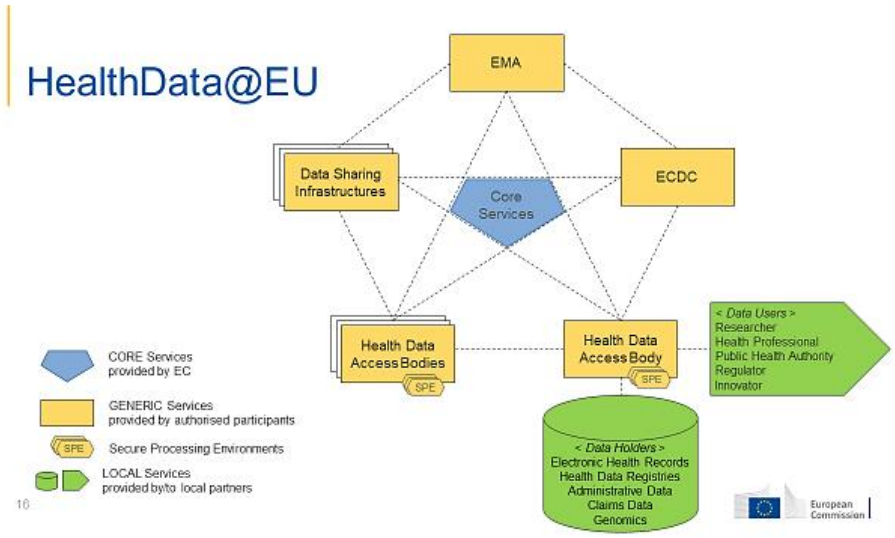
- Minimum categories of electronic health data available for secondary use. Defined (and prohibited) purposes for secondary use (Art. 33-35)
- Setting up Health Data Access Bodies (HDABs) (Art. 36) – building on the Data Governance Act. This can be one body or several, depending on the MS
- Tasks and obligations of the health data access body, data holders and data users (Art. 37-39)
- Implementation of data altruism in health (Art. 40)
- Duties for data holders (Art. 41)

The proposal also includes provisions on fees and on penalties. Conditions for data permits are being set, including data minimisation and access requirements, such as the requirements for secure processing environment (SPE).

There are also provisions for the new decentralised EU cross border infrastructure (HealthData@EU); provisions for fostering cross-border access and mutual recognition; and provisions for data description and quality with the establishment of an EU metadata catalogue.

Licinio Kustra Mano introduced the vision for the HealthData@EU infrastructure. An important step is establishing the Health Data Access Bodies. A synonym “national contact point for secondary use” is also used. These are the interphases with the data users, data holders and with the citizen. The EHDS infrastructure will allow them to communicate with each other by communicating data

permits/data requests/data authorisation (not communicating data). This infrastructure is a federated network of health data access bodies, data sharing infrastructures and other institutions like the EMA/ECDC. The core and central services mean that when needed the EC can provide services to support the infrastructure.



These core services can be very IT oriented, but can also be about providing a data portal that federates data catalogues for all countries, allowing researchers to find in one place all data existing across Europe. Another example is that the EC could provide an SPE for multi-country data requests, which is especially helpful for those countries who do not have an existing SPE yet.

An important aspect is the trust of citizens. Permits should be issued in a common format. The conditions for the SPE should be similar.

Next steps:

- Negotiations in the Council of the EU and in the European parliament
- Upcoming EHDS2 pilot will be starting in September.
- EC is planning to launch direct grants for member states. This means each Member State should apply individually. It is a big package of €30 million for the support of setting up the health data access bodies in the countries that apply. Call will be open from 15 September 2022 to January 2023.

Q&A

- Ministry of Health: Are there efforts to harmonise the interface of the different secure processing environments, or to bring them together in one place?

- The principle is that data stays in the country, it stays with the health data access body secure processing environment. But if we elaborate we may have situations like the following: a researcher needing data from 27 member states and he would need to pay for 27 SPEs, which will lead to unsustainable research projects. So is there a way this data can be processed together in one place to avoid all these costs? There are arguments against and in favour. This is still under discussion; at this point the regulation does not offer an answer for that. I would like to keep this open for the work of TEHDAS and the EHDS2 pilot to explore the possibilities.

- Ministry of Research & Ministry of Health: Are the applications for setting up the Health Data Access Bodies all individual applications or could countries also collaborate on that to align on the development of national services?
  - The applications are for mono beneficiaries. For this 30M you need to apply as one organisation i.e., one application per country.

- Ministry of Health: There is sometimes a lot of resistance. Hospitals think they own the data, but in reality it is also said that the citizen has control over their data. We need to be clear on this at EU level.
  - The concept of data ownership is not reflected in the EHDS. There is the concept of data subject, data holder, data user. We try to avoid the data ownership question. We focus on data holder: if you collect data this regulation applies to you and you need to obey by these obligations except if you are a microenterprise.

6 Presentation of the Finnish model

Joni Kumulainen (Ministry of Health and Social Welfare, Finland) and **Johanna Seppanen (Findata)** presented the Finnish experience.

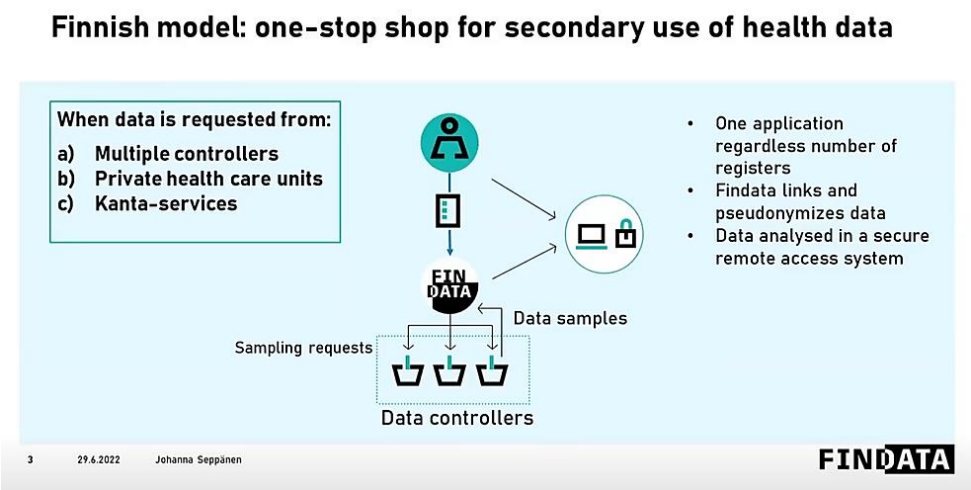
Johanna Seppanen explained that Findata is the social and health data permit authority in Finland. It started to operate in 2020. Findata operates and has been instituted on the basis of the Act on Secondary Use of Health and Social Data, which took effect in 2019 in Finland. It institutes Findata, and describes its services and steering supervision system. It also gives us the mandate to grant permits to practically all health data collected in Finland in all data health and social care services.

Joni Komulainen explained the development of the Act: the background of legislation was first of all that we had secondary use legislation in Finland before. It was on a decree level. For constitutional

reasons, we had to have it legislated on an Act level. The second reason for legislation was that the GDPR was coming and that the then legislation that we had was not compliant with the GDPR. The third reason was that when you try to get datasets from data controllers, it used to take a long time to get a data permit, and even more time to get the actual data especially when you wanted data from various controllers. Different timelines depending on the authorities and different fees. That was the main reason for the Act on Secondary Use.

Joni continued to elaborate that the lessons learned were to get all the stakeholders involved from day 1 (all data controllers, different authorities, researchers) and keep having conversations with them throughout the legislative process and even once it is passed. It is the same for the EHDS legislation: when it is adopted by the European Parliament, it is important to maintain those conversations with all those stakeholders. That is the key to success.

Johanna Seppanen presented the Finnish model for data requests through Findata. The Finnish model when data is requested from multiple controllers, private health care units or Kanta services (which are the electronic health records) is the following:



Prior to setting up Findata, one had to apply to each data controller separately but now it is narrowed down to a single application. This is regardless of the number of datasets that are needed. The application is sent to Findata, who then gets in touch with the relevant data controllers to negotiate and collect the data, link it, pseudonymise or anonymise it, and finally provide it to researcher to use in a secure processing environment.

It is important to note that the model is centralised for the request application only, not for the data itself. It is not considered federated either, because the data is collected and sampled case by case

from the data controllers. In the case that data is needed just from one registry, it is possible for the data controller to provide permit themselves.

Johanna went on to describe Findata services: Findata grants permits for secondary use of social and healthcare data. They also collect the data and process it (compatible with necessary data safety and security actions). Findata is also able to produce aggregated data on statistical level if requested.

Findata maintains a secure IT environment for applying, transferring, managing and analysing the data. Through this environment they provide the most common tools (SAS, SPSS etc), and a help-desk for users, which has been very popular. As such, Findata is considered as a national contact point where it is possible to ask about data availability, quality, price, etc.

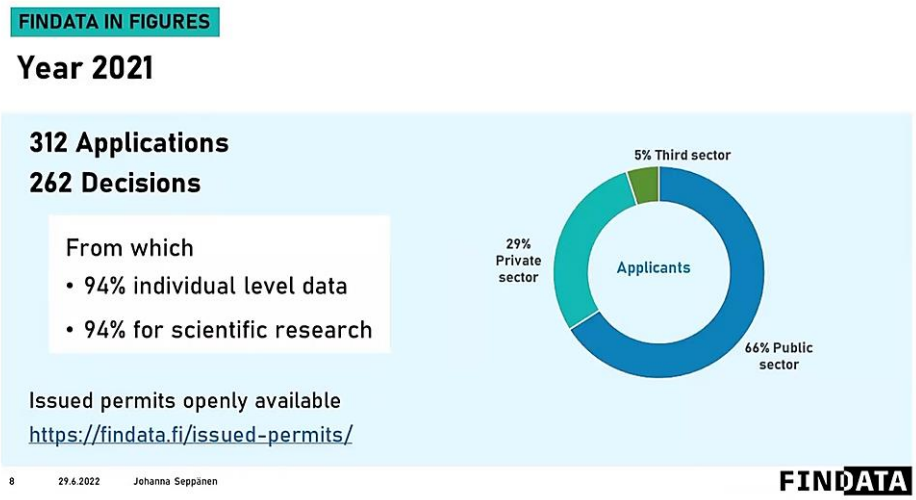
Data accessed via Findata:

- Social and health care operating units, public and private sector:
    - Patient records in primary and special health care
    - e-prescriptions
    - Social services
- National registers:
    - Finnish Institute for Health and Welfare
    - Digital and Population Data Services Agency
    - Social Insurance Institution
    - Statistics Finland
    - Finnish Centre for Pensions
    - Finnish Institute of Occupational Health
    - Finnish Medicines Agency Fimea
    - National Supervisory Authority for Welfare and Health Valvira
- Biobanks 2023? Genome data?

Finland has a long history in storing high quality health data, over a long time series, and covering the whole Finnish population. These registries are used a lot, and have a long history of secondary use even before the creation of the Act on Secondary Use. Reflecting on the EHDS Proposal, its mentioned that the scope is much wider compared to the Finnish Act on Secondary Use, as it currently does not include biobanks and genome data.

Findata has a steering group that is located within the National Health and Welfare Institute but is chaired by the Ministry of Social Affairs and Health. The steering group is set for a 3 year period. The steering group is complemented by multiple subgroups and a high-level expert group that provides guidelines on data privacy and security. Joni added the lessons learnt that other Member states can learn from is that before setting up Findata, there was a temporary steering group working on different aspects before having the actual authority.

Johanna briefly presented a figure for the first full year of operation of Findata (2021):



It was noted that applicants are mainly from the public sector. However, the division between public and private is not clear because many projects are a combination between public and private (e.g., university projects that are joined by a pharma company). Furthermore, all permits are published on the Findata website.

Challenges:

- A systemic change in the whole R&D environment: not just a new player on the field, the rules have changed for all
- An ambitious timetable for setting up the data permit authority and its services: agile process
- Legal frame still developing: compatibility with other regulation
- Data controllers' resources and capabilities: data availability and interoperability
- Need for public discussion about the price and costs of data

With regards to some of the challenges experienced, it was noted that it has been a systemic change for the whole research and development environment. New duties were given to data controllers, concerning standardisation, and providing descriptions.

Data security has been levelled up and data is not allowed to be analysed on laptops anymore, it has to be put in the audited SPEs. It takes time and the transition is still ongoing. The Act on Secondary Use took effect in 2019, Findata started operating in 2020 and are still adjusting.

Another challenge is finances. There is no common understanding as a society in Finland what should be the cost of health data and who should pay for that (including whether it should be covered by tax money, fee for researchers, should it be higher for private sector? etc). There is a lot of criticism about the fee for health data.

A tight and ambitious timetable is also challenging. Services had to be up while people were still being recruited. Therefore it is important to plan, but not too much because this is a new kind of operation. In any case not all the issues will be foreseen ahead when the operation starts. It was advised to be agile, and the importance of sustained cooperation from the beginning was highlighted. Additionally, it has been crucial in Finland that the authority has a legal basis, including a legal mandate and budget. Working with a network or temporary projects is not a long term solution. The authority should be permanent and well instituted.

Joni elaborated on the lessons learnt:

- It is important to plan, but not too much. A new mode of opertion, prepare for agility. Data availability issues will always surface.
- Actively maintain strong cooperation between data authority, data controllers and other stakeholders.
- The data permit authority should be a permanent actor with sufficient budget and legal mandates for its operation.

Q&A

- Ministry of Health: It is interesting to think about business models and if requests could be paid. Are stakeholders willing to pay?
    - Some stakeholders were willing to pay, some were not. There is a fee, which covers some costs for Findata management, in addition to the data controller's fee. The costs vary a lot depending on the sampling challenges etc. For example, doctors working in hospitals that have no funding often report that the prices are too high. However, for pharmaceutical industries the fee is considered low. Thus, willingness varies a lot and projects with funding usually dedicate a specific part of the budget for the fee for accessing the data.

7 Breakout sessions

The breakout sessions were focused on the following discussion topics:

1) *Financial sustainability of the EHDS. Principles and rules for the fee policies in the secondary use of health data.*

2) *Multi-country data application requests and mutual recognition.*

8 Plenary: reporting back from the breakout sessions

8.1 Breakout room 1

Regarding whether people would be in favour of mutual recognition of data access requests, most participants were in favour. The cost elements would be important to consider. There are also issues around privacy (e.g., with rare diseases). That can be balanced by inviting people with rare diseases for consent for data sharing.

Aligning metadata standards was mentioned. The issue of subsidiarity also came up in terms of whether policymakers will be in favour of allowing this data to go into a centralised research process, not having control over the outputs/results.

On the funding side, how health data authorities can be self-sustainable was discussed. There is general willingness to pay when the processes are transparent. However, it is difficult to measure this in euros. Real world use cases are useful. We should have solid assumptions on funding models and fine tune them.

There was also a discussion on accelerated fees. This is not desirable but is a possible option. The issue of who has the mandate to set fees was discussed (Health Data Access Bodies or Ministry of Health).

8.2 Breakout room 2

On the principles and rules for fee policies, there were three types of responses: the group that agrees that fees must be implemented if justified and transparent; a second group agreeing but with 2 principles that should be taken into account that are that general access should be free and the issue of harmonisation at EU level; the third group said that it should be discussed and debated further .

Is a researcher capable of paying fees? In all countries it is a pertinent issue. Should there be differential fees for public sector/academia vs private sector? It is not only about transparency but also visibility (what costs are going to be paid and why).

The topic of ownership of the data was touched upon, that there is value of data. Ownership is not a given.

Furthermore, there was a discussion on the fact that the better the processing is, the lower the cost is. The costs depend on some obstacles that we have, the fluidity of the processes.

Should there be a common approach at EU level or at national level? It was very clear, in all countries the discussion is only starting now. Some countries noted that pricing should be aligned at EU level. The EC noted that data governance principles are the ones that will govern fees. The EC appreciated hearing these discussions. Collaborative data is a strong need for small countries, but they may not be able to pay as much as other countries. Therefore, the fees cannot be totally European.

8.3 Breakout room 3

Regarding financial models, most countries have selected the idea of a hybrid model, indicating that there is need for EU funding. When it comes to national level funding, there were discussions about whether there is need for public-private partnerships. There needs to be a balance with trust of the citizens and usage of data, and it should be an open process.

With regards to the fees, some countries reported that currently there are no fees, while in others there are fees that are mainly not for accessing the data but to finance the manual work behind the data management and preparation of the datasets for the researchers.

Another discussion point was the harmonisation of the price for accessing data between different countries, to avoid creating discrepancies. It was agreed that this is something that needs to be clarified in the current proposal.

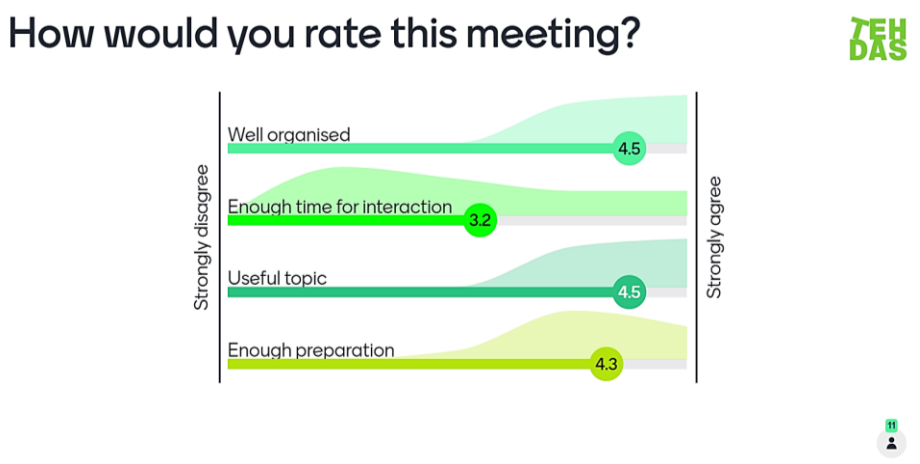
Finally, regarding the concept of mutual recognition, the discussion focused on the different processes in countries that rely on consent, and whether it would be accepted that EHDS would over-rule such a consent requirement.

9 Closing remarks

Neville Calleja, Ministry of Health, Malta: A reminder about the open calls mentioned by the EC, do keep an eye on them. The next and last Policy Forum will be planned for November 2022 and will hopefully be a joint event with the upcoming EHDS2 pilot project.

Meeting evaluation Mentimeter

1. Is there a specific topic that you would like to discuss in the next Policy Forum? Responses included:
    - Data quality
    - EHDS pilot
    - Public trust
    - Help for the policy process that TEHDAS can give
    - Share more lessons learned (very useful) to reuse what is being done
    - Data interpretation
    - Funding issues e.g., part of data collection cost that could be covered by fees
    - How EHDS links to research networks
2. How would you rate this meeting?



3. What could be improved about the Policy Forum?

- Time keeping
- Slides shared beforehand

TEHDAS Policy Forum n°3

The Joint Action Towards the European Health Data Space (TEHDAS) is organizing a series of four Policy Forums over the course of two years. The Aim of the TEHDAS Policy Forum is to engage the Ministries of Health, the Ministries of Economy and the Ministries of Research in the shaping of the European Health Data Space (EHDS). The Forum will provide a platform where opinions can be shared.

No	**Date : 29 June 14:00-16:00**		Time
1	**Welcome from WP4 lead and chair**	**Irène Kesisoglou** Sciensano, Belgium **Moderator:** **Neville Calleja** Director of Health Information and Research, Ministry for Health, Malta	14:00-14:05
2	**Welcome from the French presidency**	**Mélodie Bernaux** Project Director eHealth Delegation Ministry for Health, France	14:05-14:15
3	**Icebreaker** Recap of the previous Policy Forum answers on the national contact point. 1. Update from the past 6 months regarding the national contact point and health data access bodies.	**Open floor** To start the discussion, we will present a few of the answers we received prior to the meeting through the survey	14:15-14:25
4	**Presentation of the EHDS legislative proposal** focusing on the articles relevant for the secondary use of health data	**Karina Zalite & Licinio Kustra Mano** DG SANTE, European Commission	14:25-14:40
5	**Presentation of the Finnish model** Best practices to build a national data space	**Joni Komulainen** Senior Ministerial Adviser, Legal Affairs, Ministry of Social Affairs and Health **Johanna Seppänen** Director at Findata	14:40 – 15:00
6	**Breakout sessions:** -Divide into breakout sessions -Mix of MoH, MoE and MoR per session. **Discussion**	Health attachés and Representatives of the MoH, MoE and MoR	15:00-15:40

	1) Financial sustainability of the EHDS. Principles and rules for the fee policies in the secondary use of health data. 2) Multi-country data application requests and mutual recognition.	from EU Member States and Associated Countries	
7	**Plenary**		15:40-15:55
8	**Closing remarks**	**Neville Calleja** Director of Health Information and Research, Ministry for Health, Malta	15:55-16:00

TEHDAS – 4th Policy Forum Meeting Minutes

Wednesday 30th November 2022, 10:00-12:30, via Webex (online)

Contents

1 Attendees

Number of participants: 59. Number of countries: 19 EU member states (MS) and associated countries.

2 Welcome session

Petronille Bogaert (Sciensano, Belgium) opened the meeting, the fourth and last Policy Forum.

Markus Kalliola (Sitra, Finland), coordinator of TEHDAS, welcomed the participants to the meeting. TEHDAS has been running since February 2021 and will conclude in August 2023. 17 deliverables have been published and more will be finalised in the coming months. The outputs can be seen on the results page of the TEHDAS website. The final Stakeholder Forum of TEHDAS will take place in June 2023 and all are invited to participate.

Neville Calleja (Ministry of Health, Malta) was the moderator of the session.

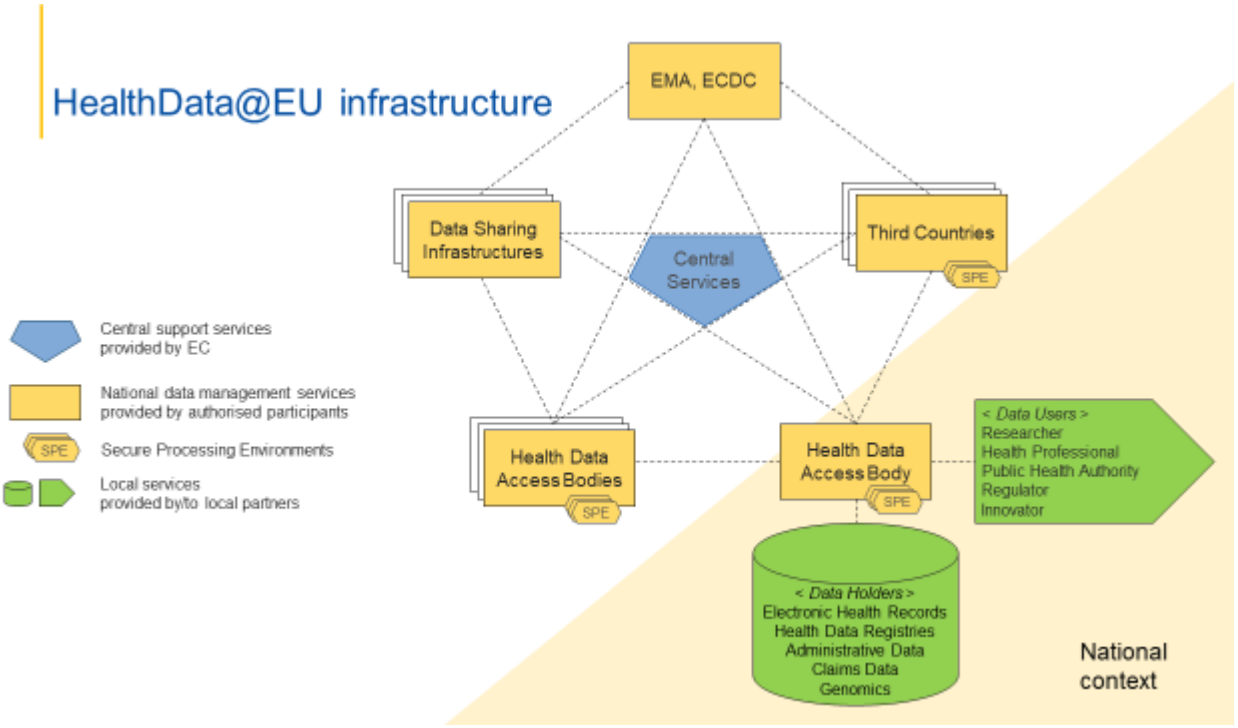
3 DG SANTE, European Commission

The European Commission provided an update on the EHDS legislative process.

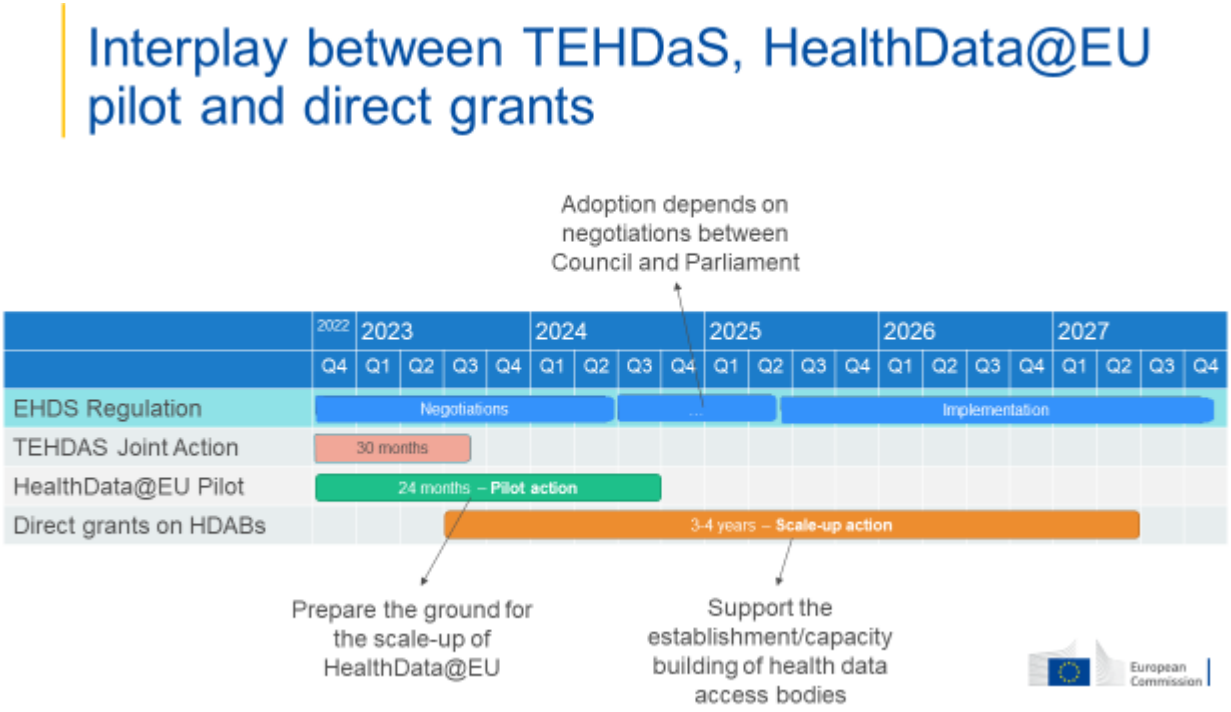
Fulvia Raffaelli (Head of Unit 'Digital Health', DG SANTE, European Commission) explained that negotiations are ongoing in both the European Parliament and the Council of the EU. The European Commission (EC) is happy with the advancement of the file and hopeful that the file will be concluded under this Commission remit, by June 2024. In the European Parliament, the ENVI and LIBE committees will be jointly in the lead, and a draft report is expected at the beginning of February. The rapporteurs and shadow-rapporteurs are known: ENVI committee – MEP Tomislav Sokol (EPP Group). LIBE committee – MEP Annalisa Tardino (Identity and Democracy Group). IMCO and ITRE committees will be involved as opinion-givers.

Ander Elustondo Jauregui (DG SANTE, European Commission) explained the HealthData@EU infrastructure, which is presented in the legal proposal and is guiding the implementation and actions being taken forward by the EC. The vison of HealthData@EU is in line with that of MyHealth@EU, which is already live for primary use of health data. In the case of HealthData@EU, the main cornerstones are health data access bodies (HDABs), which act at national level as honest brokers between data users and data holders. A network of HDABs will participate in the network (with their own secure processing environments, SPEs) as well as other

data sharing infrastructures and EU bodies (e.g., EMA, ECDC), facilitating the use of health data across borders in the EU.



The final adoption depends on the conclusion of the ongoing negotiations. In the meantime, it is important to prepare the ground. TEHDAS is doing an important job for this, mobilising stakeholders and preparing solutions and guidelines. On the technical side, the HealthData@EU Pilot is an important project to prepare the ground for scale up. There are also direct grants to support MS in setting up the HDABs.

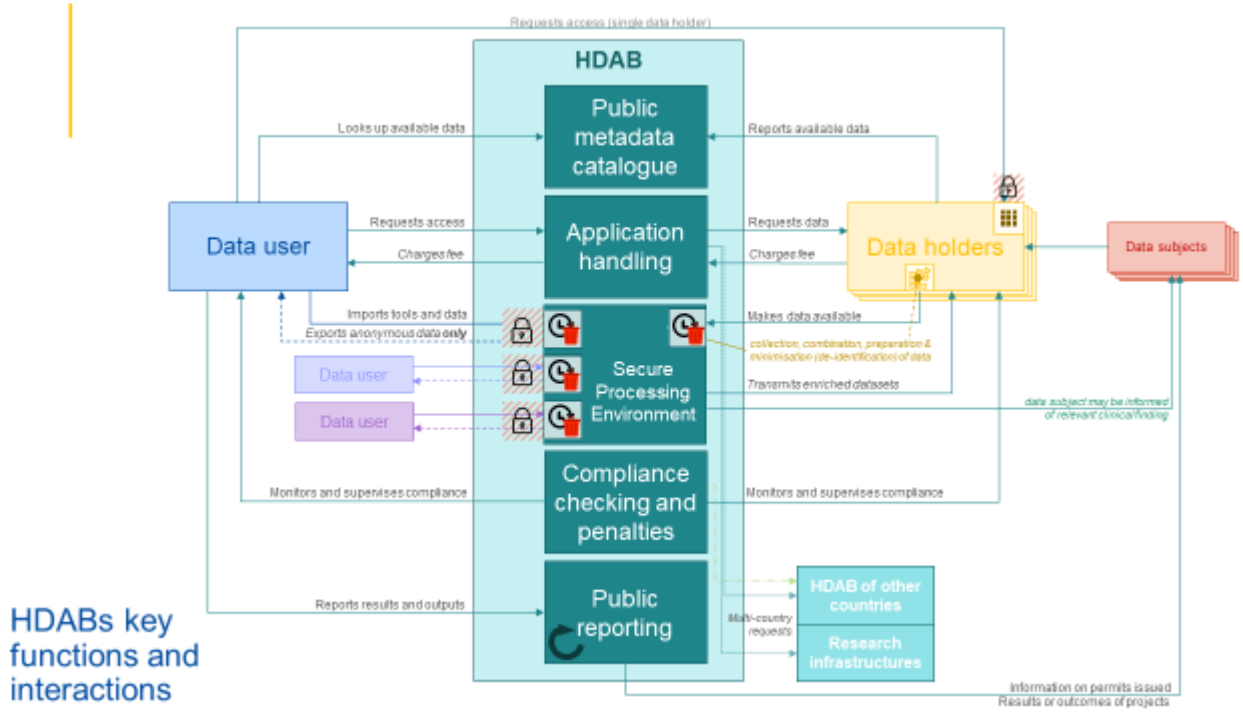


There are a number of actions planned for upcoming months and years. The EU4Health Work Programme for 2023 includes a follow up action on TEHDAS, and an action on capacity building for secondary use of health data. In parallel, in the Horizon Europe Work Programme for 2023 there is also a coordination and support action (CSA) on a data quality and utility label. These actions are important to bear in mind when planning for next steps.

Licinio Kustra Mano (DG SANTE, European Commission) explained that the scale-up is the final element of phase 1 (which started with TEHDAS). In TEHDAS we learned about the user journey and the four fundamental digital business capabilities (DBCs) i.e., what is necessary in each country for this process to work:

- Data access application management system
- National dataset catalogue
- Secure processing environments (SPEs)
- Gateways for cross-border access

What we are now doing with the HDABs is working to deploy some of these digital business capabilities (DBCs). This slide explains the four DBCs in action and how they come together to fulfil the EHDS:



The final element of phase 1 will be that HDABs will implement this at national level. We will then move on to the next phase and the follow up action to TEHDAS, looking at implementation ahead.

4 Czech Presidency

Petr Cermak (Health attaché, Czech Permanent Representation to the EU) provided an update on the work done on the EHDS under the Czech presidency. Cooperation with the EC was key in being able to progress with the file. The EHDS was the priority legislative file in health for the Czech presidency, which was mirrored in the number of Working Parties devoted to it (17).

A progress report will be presented on Friday 9 December 2022 at the meeting of Health Ministers, summarising the work done until 18 November.

The first reading showed that this is a complex file that will significantly change the landscape for digital health because it introduces a mandatory framework for both primary and secondary use. In general, there is support from MS, but more time will be required to finalise the agreement.

The first compromise proposal, focusing on chapters 2 and 3 of the proposal (regarding primary use), was tabled in October 2022. The rest of the working parties in November focused on examination of the compromise proposal.

Regarding chapters 2 and 3, some of the amendments proposed in the compromise proposal related to:

- Alignment of relevant provisions with GDPR
- Some changes in implementing and delegated acts in those two chapters
- Several amendments related to the possibility of persons to insert data in their EHR systems and to strengthen the person's right to obtain access to their personal data
- Tasks of the digital health authorities
- Connection of third countries, to strengthen safeguards when connecting to their systems

It is important to say that this is only the first compromise proposal. It will be developed and amended in ongoing discussions.

Challenges identified in Council discussions include:

- Financial resources and administrative capacity required by MS to implement this file
- Interplay with other EU legislation: GDPR, AI Act, Data Governance Act, Data Act. The Czech presidency organised several events to better understand and present these interlinkages
- Legal basis of the proposal and possible interference with organisation of healthcare in MS
- Governance and implementation structure, with several new bodies to be created in MS (e.g., HDABs)

There are many challenges in the remaining chapters that were not covered in the compromise proposal, such as: tasks of HDABs, setting the right balance of fees for getting access to data, the question of sharing data with third countries, and the length of the transition period for implementation in MS.

5 Icebreaker

Neville Calleja (Ministry of Health, Malta) presented the results of the progress made in the last 6 months regarding the national contact point (NCP) for EHDS for secondary use, based on a survey sent to ministries prior to the meeting.

For example, Malta has appointed an NCP but are also seeking more information, especially on what is expected for the direct grant and getting up to scratch on what is required for secondary use. There is more clarity than there was a few months ago.

6 HealthData@EU Pilot

Mario Jendrossek (French Health Data Hub, France), presented the HealthData@EU Pilot project, which the French Health Data Hub is coordinating.

The HealthData@EU Pilot project fits into a larger context where health data sharing has been identified as a priority for European health policy. A number of actions have been put in place, both on the legislative side (horizontal framework including DGA and Data Act, as well as sector-specific EHDS proposal), and in project-based actions (TEHDAS, HealthData@EU pilot). The HealthData@EU Pilot builds on the outcomes of TEHDAS. The idea is for these actions to take place in parallel to the legislative process, to test certain items and contribute indirectly to the outcome of the negotiation process.

The HealthData@EU Pilot consortium brings together 17 partners, representing 9 countries. It includes national data platforms, European agencies (EMA, ECDC), European research infrastructures (e.g., BBMRI, ELIXIR, EBRAINS), and other expert organisations (e.g., IACS).

The objective of the pilot is to build a first version of a European network of data platforms and propose a first number of services to be provided at European level (e.g., common metadata catalogue, common data application form). The second objective is to test the network and show the feasibility and added value of running such an infrastructure, through a number of cross-border use cases.

The pilot aims to cover important pieces of the user journey that a researcher will go through in the EHDS2:

- *Data discovery*: working on a metadata catalogue and a DCAT Health extension (led by Sciensano and Norwegian Directorate of eHealth). The possibility of federated queries is being investigated.
- *Data permit requests*: developing single access application form and conditions of use, starting by looking at application forms currently in place across different countries.
- *Data preparation*: working on interoperability standards, building on work done in TEHDAS.
- *Data use and finalisation:* also looking at how to inform citizens, ensure compliance with GDPR rights and ensure that study results are published.

The pilot will build a common IT infrastructure to allow information exchange between the different nodes and support services throughout the user journey. The idea is to connect the nodes and allow them to exchange by using European building blocks (e.g., delivery standards).

The project includes a normative laboratory. It will work on common forms and common contractual framework. It will also work on specifications for a central request portal and on the follow up process once a request has been made (especially if the request concerns several countries or data platforms). It aims to address legal or compliance questions from the use cases or technical work. We expect that there will be challenges, and we try to find solutions that can be applied later on.

Five cross-border uses cases will show the added value of building this infrastructure. They cover different topics, different types of data (e.g., economic data, clinical data) and different domains (e.g., public health surveillance, pharmacovigilance, regulatory). They will ensure linkage with other major initiatives e.g., DARWIN EU and the Genomic Data Infrastructure (GDI). It is very important not to build things in silos.

The timeline is quite short at only 24 months. The project will face challenges but that is the objective of a pilot project: to face challenges and overcome them.

There will be many opportunities to engage with the pilot: call for external advisory board will be launched shortly; stakeholder meetings and roundtable discussions; interactions with HDAB community etc.

Whilst this is the final Policy Forum under TEHDAS, the HealthData@EU Pilot would be interested in pursuing certain discussions with this group of stakeholders. If you would prefer that your email is not used for that purpose, please contact TEHDAS.sciensano@sciensano.be.

Contact details:

- Twitter: @ehds2pilot
- Website: https://www.ehds2pilot.eu/
- Email: ehds2pilot@health-data-hub.fr

7 TEHDAS Country visit findings

Irene Kesisoglou (Sciensano, Belgium) shared the findings from the TEHDAS country visits.

The aim of the country visits is to engage with national stakeholders and map the state of play of national health data management systems and their readiness to join the EHDS for secondary use (EHDS2), as well as reflect on MS needs and expectations. The scope of the country visits covers:

data sources, data quality, the data infrastructure (already in place and being built up), the legal framework (including governance and roles), resources and capacity building needs, and how prepared the country is to join the EHDS.

12 member states have been visited in one year (December 2021 to December 2022): Denmark, Belgium, Hungary, Netherlands, Slovenia, Czech Republic, Finland, Sweden, Ireland, Portugal, Estonia and Germany. The visit to Germany was ongoing at the time of the Policy Forum. The factsheets from the six first country visits are published and can be viewed on the TEHDAS website.

The country visits followed a four-step methodology:

1. Preparatory desk review
2. Country visit: semi-structured interviews using the adapted assessment tool
3. Debriefing meetings: multi-stakeholder meeting
4. Reporting: report and factsheet

Key findings on preparedness to join the EHDS2 (Germany not included as visit was ongoing):

- Digitalised health data (9/11)
- Common metadata catalogue in place or work ongoing (5/11)
- Universal usage of a unique personal identifier for health (10/11)
- Remote secure processing environments (7/11)
- Wide use of internationally recognised standards (4/11)
- Semantic interoperability (9/11)
- Similar access rights for national and foreign researchers (9/11)
- Political will to join the EHDS (11/11)
- Potential national contact point for EHDS2 already existing (3/11)

Main challenges (organisation, technical, legal)

Organisational challenges faced by countries include: the existence of paper-based records, lack of a unique identifier, data gaps (e.g., not full coverage of every citizen or from all data holders), and differing interpretations of the GDPR (both between and within MS).

Technical challenges mainly relate to interoperability, for instance due to inconsistent use of standards or existence of unstructured data.

Legal challenges include: limited access for foreign users, unclear definition of anonymisation and pseudonymisation, lack of a legal framework. Only a few MS have a legal framework for secondary use.

Needs and expectations (organisational, technical, legal)

Organisational needs:

1. Clarity on responsibility and liability in the EHDS
2. Guidance and specifications for the EHDS implementation including timeframes
3. Overview of national data management systems in EU countries: need for a reference document at EU level giving an overview of the methodologies and reporting used in different EU countries
4. Unique personal identifier used in the health sector
5. Clarity on involvement of private companies and industry in the HealthData@EU infrastructure
6. Ensure interaction with relevant research infrastructures
7. Suggestion for a HDAB per region (if coordination is moved too far from the data, then there is a risk of losing quality of the data)
8. Improving transparency in access decisions (publish evaluations)
9. Network, peer to peer support between HDABs
10. Standardised evaluation of access application form across MS is needed for concept of mutual recognition in multi-country application procedures to work

Technical needs:

1. Harmonisation of data, interoperability and setting standards for collecting and storing data in a structured way
    - Use standards compliant with the ones used in other EU bodies (e.g., Eurostat) and in other domains
2. Improve interoperability and the use of internationally recognised standards. Define clear standards that should be set and approved by the EU (e.g., openEHR)
3. Define minimum set of health data that need to be reported in a structured way
4. Reduce administrative burden on healthcare providers by creating interoperable systems that avoid duplication of reporting
5. Need for a business model that encourages digitalisation (incentives)
6. Define requirements for SPEs, and clear legislation for federated analysis

7. Allow linkage of individual level data between data sources

Legal needs:

1. Clear legislative framework for secondary use of data and legal basis for sharing and linking data
2. Guidelines to interpret the GDPR and how it complements the EHDS legislation
3. Harmonised rules on how to anonymise and pseudonymise
4. Ensure adequate privacy protection practices
5. Maintaining the public trust that has been built nationally through strong security and privacy protection processes
6. Need for a legal mandate to collect health data also from private providers

Horizontal needs for training and resources:

- Training:
    - EU to provide academic incentives for training of data analysts: Health Data Academy
        - Education of data scientists
        - Improve health data literacy of healthcare providers, demonstrate value of good quality data input for research – training for proper coding at the source
    - EU training on semantic interoperability and structured datasets
    - Programming and data analysis courses
    - Strengthen AI capacity
    - Knowledge and training on cyber-security and data protection
    - Support to researchers prior to ethical submission
    - Workshops to discuss legal interpretations
    - Share training and best practices at EU level
- Resources:
    - Human resources:
        - Overall need for skilled human resources in public sector
        - IT personnel (financial incentives to attract IT experts)
        - Data analysts and biostatisticians in hospitals
        - Data stewards

        - Lawyers
        - Experts that have both public health knowledge and an IT background
    - Technical resources: need to improve technical capabilities for registry owners
    - Financial resources:
        - Financial incentives to healthcare providers to report their health data in a digitalised and structured manner
        - Incentives for data holders to share their data for research: financial, citation

In conclusion, there are positive views on the impact and the added value for the EHDS2 and willingness to join across MS. However, it is important to:

- Consider the diversity and local sensitivities in MS
- Ensure equal benefit for all countries and stakeholders
- Focus on data security and citizens' trust
- Improve transparency in access processes and decisions
- Communicate with all stakeholders and citizens
- Demonstrate clear and tangible benefits for citizens, researchers, healthcare providers and policymakers.

8 Breakout sessions

The breakout sessions were focused on the following discussion topics:

1) *From your perspective as Ministries, what are the needs in your country to start implementing the EHDS for secondary use?*
2) *Have you applied for direct grants for capacity building to fulfil those needs? What do you plan to use them for?*
3) *Have you had discussions with different stakeholders in your country (e.g. data holders, data users, etc.) with regards to the EHDS implementation, how it will affect them, their needs and expectations?*

9 Plenary: reporting back from the breakout sessions

9.1 Breakout room 1

The group started by discussing progress made in building up an NCP or HDAB(s) for the EHDS2. It varied a great deal, with some countries already having set up a HDAB, some having a regional set-up, and others being in the preparatory phase. Those that have already built a HDAB may also face problems in changing the existing set-up to the future. Added investment and further resources may be needed.

Regarding the direct grants from the EC, many of the participants were aware of them. Some mentioned that the direct grant will be used to set up SPEs, for example.

Stakeholder engagement is happening in different ways. In some countries, it is about engagement between public entities. In other countries it is about engagement with industry. All participants noted the importance to engage the community at all different levels.

9.2 Breakout room 2

Regarding national needs, everyone identified with the challenges and needs from the TEHDAS country visits. Ministries of Research raised the question of how research infrastructures (RIs) (e.g., GDI) will be integrated into the EHDS. There is a need for clarity on how the query will happen from RIs to the EHDS.

Some countries already have data permit authorities in place. Concerns were raised on the data categories and differences with what the EHDS proposes. Standardisation will be a concern, as well as incentives needed for healthcare professionals (HCPs). There is a need for cultural change in many countries to implement the EHDS.

Regarding direct grants, most participants were aware. Those that were aware are applying and assessing what is needed for the different digital business capabilities.

Concerns were raised that we should also consider investments that will have to happen beyond the direct grants for HDABs. For instance, in hospitals HCPs will need to implement the EHDS. There is a lack of clarity on where funding will come from in different countries.

There are stakeholder discussions in all countries. Some mentioned discussions on multi-ministerial level or including the regional level to discuss implementation. Some countries mentioned industry discussions.

9.3 Breakout room 3

On what is needed, there was a discussion that to start to implement, there is a need for a finalised regulation first. It is sometimes difficult to know where to go as the legislation is not finished yet.

There is a need for harmonisation of data, and for good metadata standards. It was noted that the data categories put forward should be more limited. The current data categories suggested are very broad, and it is hard to take the first step.

On the direct grants to set up HDABs, everyone was aware of them. There were discussions on structure of HDAB. The conclusion was that there will be very different concepts. There could be virtual HDABs where the functionalities are divided across different organisations. The challenge now is to identify what we can already do before the legislation is in place. Transparency towards citizens needs to be taken up more (e.g., by setting up portals). In general, it was concluded that the funds are not sufficient.

Some countries have already involved stakeholders whilst others were more cautious to engage as the regulation is not finalised. Examples of topics that were brought up by stakeholders included metadata and standardisation (research community) and strengthening of transparency (patient community).

9.4 Breakout room 4

Regarding needs, the participants largely agreed with the points made by those who had answered the survey. Citizen trust came up as a concern, but several countries felt that they first must consider the infrastructure and what gaps need to be filled. The issue of trust should be worked on from an early stage to ensure that we do not face a lot of mistrust from the population when the regulation comes into effect.

On direct grants, not all participants were aware of whether their country is applying or not. Several participants expressed concerns about sustainability: there will be an additional burden on not just the public side (HDABs) but also on researchers to be able to work within this new environment. Some research institutes have previously invested in setting up large computer resources, which they may no longer be able to use if they have to use the HDAB's SPE, which was an interesting concern. There were some concerns about funds not being sufficient.

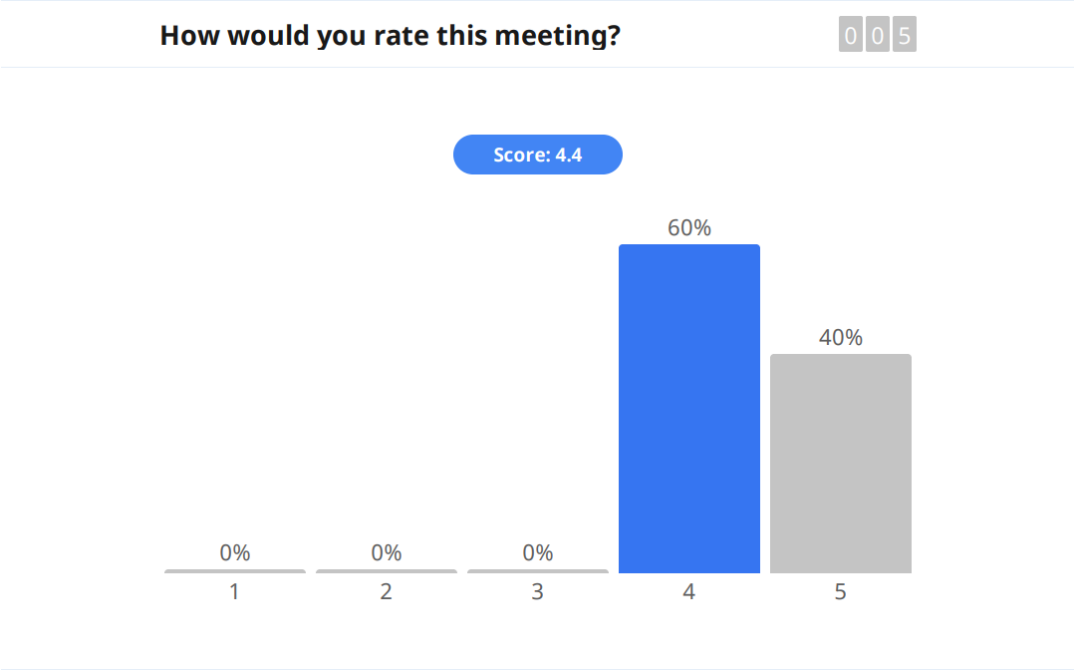
Stakeholder discussions have been taking place or are planned across all countries. It was noted that there is evolution, so expectations and concerns can change from pre- to post-implementation. It

may be necessary to consider flexible implementation that allows the policy to be shaped as we go through the first few years of implementation of the EHDS.

10 Closing remarks

Meeting evaluation

1. How would you rate this meeting?



2. Would you like to see such a forum continue? Why?

- Yes, definitely
- Definitely
- Yes, it is important to have such a place to meet the representatives of other countries
- Breakout sessions always very useful
- Yes, sharing challenges and solutions is important
- Yes, it is always very helpful to know what other countries deal with
- Valuable exchange between ministries with expertise on the ground and the EC as well
- Yes: when we get more experience from MS, it would be useful to continue sharing good and bad at not so formal discussions

- Yes
- Yes, the small group discussions are very helpful to identify common ideas and concerns
- Yes, helpful to learn from other countries

Petronille Bogaert (Sciensano, Belgium) closed the meeting and thanked participants for joining. The TEHDAS Policy Forums were the first time bringing together Ministries of Health, Research and Economy. It was important to hear the needs and expectations from all three of these ministries, as the perspective might differ with regards to the EHDS. It was very useful to hear from you what would be the biggest challenges, needs and struggles.

To stay involved with TEHDAS, on 24 June 2023 there will be a Stakeholder Forum on the outputs of TEHDAS, to which everyone can participate. There will be a follow-up action to TEHDAS, most likely beginning in 2024. Sciensano will pass on contact details to HealthData@EU Pilot, to keep participants informed of the Pilot's work.

AGENDA - TEHDAS Policy Forum n°4

The Joint Action Towards the European Health Data Space (TEHDAS) is organising a series of four Policy Forums over the course of two years. The aim of the TEHDAS Policy Forum is to engage the Ministries of Health, the Ministries of Economy and the Ministries of Research in the shaping of the European Health Data Space (EHDS). The Forum will provide a platform where opinions can be shared.

	Wednesday 30 November 10:00-12:30		Time
1	**Welcome from TEHDAS coordinator and moderator**	**Markus Kalliola** Sitra, Finland Moderator: **Neville Calleja** Director of Health Information and Research, Ministry for Health, Malta	10:00-10:05
2	**Update from DG SANTE**	**Karina Zalite, Ander Elustondo Jauregui, Licinio Kustra Mano** DG SANTE, European Commission	10:05-10:15
3	**Czech Presidency** Update on EHDS discussions in Council of the EU	**Petr Čermák** Health Attaché for the Czech Republic Representative of Czech Presidency of the Council of the EU	10:15-10:25
4	**Icebreaker** Update on progress on national contact point in past 6 months.	Presentation of survey results	10:25-10:35
5	**Presentation of EHDS2 Pilot Project**	**Mario Jendrossek**, French Health Data Hub	10:35-10:50
6	**TEHDAS Country visit findings** Presentation of overarching findings of the TEHDAS country visits Survey to Ministry representatives on the needs identified: Does this reflect your needs?	**Irene Kesisoglou** Sciensano, Belgium	10:50-11:10

7	**Breakout sessions:** Mix of MoH, MoE and MoR per session. **Discussion** 1) From your perspective as Ministries, what are the needs in your country to start implementing the EHDS for secondary use? 2) Have you applied for direct grants for capacity building to fulfil those needs? What do you plan to use them for? 3) Have you had discussions with different stakeholders in your country (e.g. data holders, data users, etc.) with regards to the EHDS implementation, how it will affect them, their needs and expectations?	Representatives of the MoH, MoE and MoR from EU Member States and Associated Countries	11:10-12:10
8	**Plenary** Reporting back from the breakout sessions	All	12:10-12:25
9	**Closing remarks** Handover to EHDS2 Pilot	**Petronille Bogaert,** Sciensano	12:25-12:30