Who is EIT Health?

EIT Health is one of nine Knowledge and Innovation Communities (KICs) of the European Institute of Innovation and Technology (EIT), an EU body. EIT Health is an Institutionalised Partnership under Horizon Europe's Pillar III – Innovative Europe. Established in 2015 to tackle the societal challenges of 'health, demographic change and well-being' within the EU, its mission is to help overcome the well-known EU paradox whereby state-of-the-art education, excellent research and a dynamic industry are challenged to turn breakthrough ideas into new transformative products and services.

Within the EIT Health network, over 130 partner organisations and institutions from academia, business, research and health care delivery collaborate across disciplines, borders and sectors to reinforce excellence, create knowledge and innovation and encourage greater investment in innovation that delivers the outcomes that matter to citizens and patients. As a result, EIT Health represents a unique match between a sustainable innovation ecosystem model gathering and leveraging different partners and funding sources, and a change agent with extensive capacity to generate real-world data for evidence-based policymaking and the transformation of health care (Figure 1).

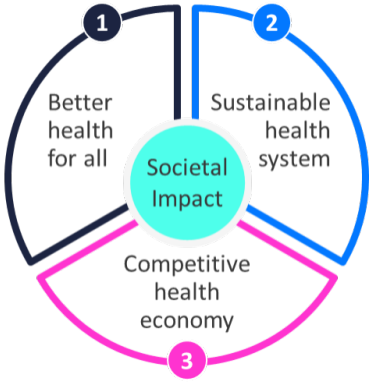

Figure 1: EIT Health main goals.

The EIT Health Think Tank

The EIT Health Think Tank is EIT Health's thought leadership forum. It brings health care leaders together to prepare the ground for life-changing innovation and to identify the next opportunity for a step-change in how health care is delivered. Research participants collaborate across disciplines and borders to explore and assess the most pressing topics impacting health and the uptake and adoption of innovation. This allows for continual assessments of the environmental needs of EIT Health's portfolio of projects and programmes. To facilitate this dialogue and its findings, EIT Health drives a range of activities to generate knowledge and insight, including research, expert Round Tables and interviews, publications, and dissemination of key information.

Previous EIT Health Think Tank projects have focused on determining how to overcome the barriers to, and capitalise on the opportunities of, the adoption of innovation and new technologies in health care, including the harmonisation of digital medical devices, use of Big Data, future-proofing Europe's digital health innovation pathway, the role artificial intelligence (AI) can play in health care workforce and organisational transformation, and the impact of the new Medical Device Regulation (MDR). In 2021, the EIT Health Think Tank produced a report entitled "Learning from health data use cases: Real-world challenges and enablers to the creation of the EHDS" that served as an initial step towards EIT Health's focus on the EHDS regulation, producing an overview of challenges in roles, regulations, and policies and practices. The latest EIT Health Think Tank report focuses on digital medical devices and explores pathways to regulatory harmonisation across Europe.

Introduction: How implementable is the EHDS?

EIT Health assesses countries' readiness for the legislation

To assess the feasibility of implementing the European Health Data Space (EHDS) in different EU regions and Member States, EIT Health is conducting a pan-European stakeholder consultation initiative. This initiative aims to gather experiences and real-world insights of EIT Health's partners and other relevant agents of the EU healthcare innovation ecosystem to shed light on what the realities and needs are in the individual countries in relation to adopting the EHDS, but also to distil lessons learnt and best practices from previous experiences of health data sharing for secondary use.

A series of 10 national or regional roundtable discussions is being held throughout Europe in 2023 to compare and contrast the ability across sectors and borders to put the regulation as it currently stands into practice. A European steering committee made up of experts from different countries and chaired by Dr. Andrzej Rys, Director of Health Systems, Medical Products and Innovation at the European Commission's Directorate-General for Health and Food Safety, is overseeing the initiative.

A roundtable was held on October 10th, 2023, in Munich to discuss Germany's readiness to implement the planned EU legislation for a European Health Data Space (EHDS) and gather insights from Switzerland about its challenges and progress made with respect to establishing a digital health data space aligned with the EHDS. It brought together 9 experts representing the fields of public health, healthcare, academia, and industry/start-ups to discuss six key dimensions of implementation: Capacity and Skills, Resources and Funding, Governance, Data Quality, the relationship between Primary and Secondary Use, and Awareness, Education and Communication. Additional written evidence was collected from Dr. Georg Münzenrieder representing the Bavarian State Ministry of Health and Care.

Roundtable Participants

Public Sector	
Adrian Costea	Swiss Federal Office of Public Health
Dr. Georg Münzenrieder*	Bavarian State Ministry of Health and Care
University/University Hospitals	
Dr. med. Lars Riedemann	University Hospital Heidelberg
René Raab	FAU Erlangen-Nürnberg
Prof. Dr. Oya Beyan	University of Cologne
Harald Wagener	Berlin Institute of Health, Charité
Industry	
Jared Sebhatu	digital health transformation eG
Jakob Defèr	Amgen
Dr. Lena Fanter	Takeda
Start-ups	
Christian Hieronimi	myoncare

* Due to unexpected drop-out, input was collected after the meeting in writing.

The six dimensions of implementation

1. Governance

Readiness for implementation

Germany and Switzerland are taking steps to provide a legal framework for health data

Acknowledging that Germany's healthcare system is far behind in digitalisation, the Federal Ministry of Health has made some initial steps in order to prepare for the implementation of the EHDS and proposed several draft legislations to support the digitalisation of health data. These legislative proposals include the Digital Act (*DigiG*) as part of Germany's larger digitalisation strategy seeking to progressively digitalise health records and introduce e-prescriptions; the Health Data Use Act (*Gesundheitsdatennutzungsgesetz, GDNG*) aims to create a decentralised health data infrastructure to coordinate and facilitate the use of data; finally, the Hospital Transparency Act promotes the publication of structural and performance data of hospitals in Germany. All three legislations are supposed to come into effect in 2024. However, as Georg Münzenrieder from the Bavarian State Ministry of Health and Care pointed out, the GDNG and DigiG proposals are just a first step which should be maintained in a future initiative, but a second step will have to follow to implement the EHDS especially regarding interoperability of EHR systems between member states.

Since the EHDS regulation and therefore the definition of the data holder in the EHDS regulation is still under discussion and has not been finalised, it is not yet clear which data holders will come under the scope of the EHDS. The Health Data Use Act foresees the Health Data Lab (*Forschungsdatenzentrum Gesundheit*) at the Federal Institute for Drugs and Medical Devices to make pseudonymised billing data from people insured in the statutory health system as well as all the data from the German EHR system and the national and federal cancer registries available for research purposes in the near future. The Health Data Act foresees that other data holders shall fall under its scope in the future, but these data holders have not yet been specified.

Switzerland is facing similar challenges like Germany when it comes to establishing a coordinated health data space. It currently ranks at the lower range of digitalisation of healthcare compared to other European countries. Recognising this, the Federal Council mandated the Federal Department of Home Affairs, in collaboration and coordination with other agencies of the Federal Administration, to draw up a program to promote digital transformation in the healthcare sector: the *DigiSanté* program. The aim of *DigiSanté* is to allow for seamless data flows free of media discontinuity in treatment, billing, research and public authority services and the guarantee of data protection, informational self-determination and cyber security. Furthermore, the secondary use of the resulting health data for planning, control and research is to be facilitated within the framework of the legal requirements. With this, Switzerland

aims to define and implement a Swiss Health Data Space be compatible with the EHDS without formally being part of it.

The federal structures of Germany and Switzerland pose challenges to implementation

Germany currently does not have a unified approach to data collection, protection and use. While the Federal Data Protection Authority is in charge of overseeing Federal public entities, each of Germany's 16 Federal States has their own data protection authority (or even two as in the case of Bavaria) in charge of data processing activities of public and private-sector entities within each Federal State.

Switzerland as a federal country with a federal health care structure, distributed among 26 cantons is facing similar challenges when it comes to establishing a seamless data sharing and major steps are needed to streamline and unify data collection and use. In both countries, major efforts have to be undertaken in order to ensure that the EHDS can be implemented.

No agreement yet as to who should take the main responsibility for health data access

The panel discussed the question of who should take the main responsibility for the implementation of the health data framework. The responsibilities of a health data access body could be a state agency (the Federal Ministry of Health is thinking in this direction) initially be affiliated with the Federal Institute for Drugs and Medical Devices (*Bundesinstitut für Arzneimittel und Medizinprodukte, BfArM*), but it could also be an independent body or even serval bodies on regional level. No decision has yet been taken.

Some argued that responsibility should be clearly assigned to one entity responsible to take decisions and next steps. We need to be able to describe who is doing what, otherwise we will not get to the solution. "If responsibility is not identified, everyone can shift the responsibility to the other" Lena Fanter from Takeda said.

Conversely, Harald Wagener of the Berlin Institute of Health at Charité underlined that experts and institutions already more advanced in the digitalisation of data should take on some of the responsibility as well and think how to enable the decision makers in taking the right steps to move forward with the implementation of the EHDS. "It should not primarily be a question of who is responsible but rather a question of what can everyone do with the resources available to support the process".

Implementation is supported if stakeholders offer their expertise

Different observations and experiences were presented by the panellists as to how open decision makers currently are to accept support and expertise from outside stakeholders in the formulation of political decisions. Some observed a clear political will to make things work in practice and argued that the Ministry of Health is willing to work with stakeholders to find the best solutions: What outwardly appears as the Ministry's own proposal, tightly linked to broader European developments and the EHDS is actually based on a lot of direct consultations with the relevant stakeholders at an operational level. The way to go in future implementation stages, it was argued, will be to approach the law maker with kernels of functionality to support the legislative process pro-actively. Other panellists by contrast pointed out that it is difficult to get support from the highest Ministerial level but that this will be necessary to ensure that decisions taken are in the best interest of people working on the ground.

Priorities for implementation

Make sure risks and responsibilities are adequately shared

The question of who should be responsible does not end at the highest level of public authorities. Other stakeholders down the line of implementation also have to be considered. In order to properly prepare the implementation of the EHDS, some thought has to go into the question of how risks and responsibilities, especially in the realm of data protection, can be adequately shared. A data protection officer, for example, has no incentive to share the data if they are liable for the consequences should data leakages or data misuse occur. Therefore, the option of signing an insurance comparable to a business liability insurance for them has to be considered, to avoid that they get punished if something goes wrong.

Increasing the trust in the system in order to encourage sharing of the data might require an increased awareness of the shared responsibility for their quality and use. Data protection is like referring a patient to a colleague: each one is responsible for their own data protection. There was some discussion around whether decentralised data protection reduces the risk.

Implementation should not burden or impair the care processes

At the same time, it will be important to ensure that the implementation of the EHDS regulation regarding the primary use of electronic health data in medical practice does not result in the impairment of the healthcare processes. Obligations of data collection should be sensitive to the constraints and needs of practitioners and informed by the realities of people working on the ground.

Key recommendations

- *Decision makers and experts in the field of health data should work together to ensure that the implementation of the EHDS is running smoothly and not negatively affecting the work of practitioners*
- *Risks and responsibilities have to be considered at all levels of implementation to assure that different stakeholders buy into it*
- *Enough attention should be paid to the needs and constraints of health professionals to avoid that their work is impaired or overly burdened*

2. Capacity and skills

Readiness for implementation

Capacity for health data gathering and use is currently missing

In addition to the gaps in the current legislative framework, Germany and Switzerland are also facing major challenges with respect to the capacity and skills of stakeholders involved in the health data space to collect, store, adequately protect, and share the electronic health data for secondary use.

In order to comply with the requirements of the new EHDS legislation, capacity building will be necessary in all sectors of the health system, from the public administration and official data holders to the users of the system, physicians and patients, but also the various bodies and private companies involved in secondary use of the data.

Tools are not in place for primary and secondary use of health data

While some frameworks for health data already exist in Germany, for example for oncology data (*Krebsregister*) panellists broadly agreed that currently the necessary infrastructure is not in place to allow for a seamless collection and sharing of the health data for primary and secondary use. The federal structure of the German (and likewise the Swiss) state is an additional level of complication and the EHDS is not contributing to the solution of countries' internal challenges. Harald Wagener from the Berlin Institute of Health cautioned that while the EHDS governs the cross—border use of electronic health, it does not give any guidelines on the question of how data is shared nationally.

As Oya Beyan from Cologne University pointed out "We don't have tools to enable people to use the data". Different people have different roles, this needs to be streamlined and we need a good definition of those roles, not only the technicians who set up the systems but also the different users. We also need educational tools and materials to support the implementation.

If you want to change the system, you have to know the system

One of the essential foundations for the successful implementation of the EHDS is to establish a common language and a common understanding of the use of health data. There needs to be a lot of work to understand the different stakeholders' perspective and design a system that incorporates all of them. Practitioners need to be open to show their work to other stakeholders involved. As one panellist mentioned, there are technicians and health economists who have never been to a hospital and the same

holds for government officials who are too far away from what actually happens inside health providers on a daily basis. Consequently, decision makers and technicians design systems for realities that they have never seen from the inside. People need to be immersed into the system, including in clinics that struggle, not only in university hospitals, not only 9-5 but also night shifts, weekend shifts, show them why doctors cannot spare 10 minutes of their time to fill in a data sheet, be a shadow, to understand the complexity. This should also be financed as part of system development initiatives.

Panellists reported that this concerns not only those who generate and collect the data in primary use but also those concerned with the secondary use of the data. Even many start-ups that want to design solutions for the health sector do not know enough about the reality on the ground. They sometimes cannot explain what exactly they need the patient data for and create solutions for problems that have already been solved.

Adequately dealing with health data requires a major shift of mindset

Germany excels in an engineering and planning approach with very clear processes. However, the implementation of the EHDS will require more of an iterative approach in small steps, learning from failures and through constant experimentation. As Harald Wagener from the Berlin Institute of Health at Charité pointed out, this represents a big cultural shift in ways of working and approaching the task. The agile mindset, an iterative approach to development, learning from errors, keeping what is working and shedding what is not is not currently established in the health system as a whole. “If we wait for someone to come with a grand unified solution, it will never happen.”

Priorities for implementation

A strong skill set needs to be established at all levels of the system

In the short and mid-term, capacities need to be built at all levels of the system. Based on a common language and a clear understanding of the purpose of health data actors involved both in primary and secondary use of the data need to be able to navigate the system to take an active part in it. Healthcare professionals need to be able to explain to the patients why and how their data can and should be shared. Similarly, actors concerned with the secondary use of the data need to have a clear picture as to how best to use this data while respecting restrictions to maintain a high level of trust. Decision makers need to be knowledgeable and aware from direct experience how infrastructure needs to be established so that it will support everyone involved. Citizens and patients also need to be educated on topics like data literacy to be able to make informed decisions about their personal health data.

To ensure that decisions taken at the legislative level are reasonable and well informed by the reality on the ground and the actual needs and constraints practitioners are facing, those taking decisions should be confronted with the reality on the ground. As Lars Riedemann from Heidelberg University suggested “We need a living lab where we try to create a learning system.”

Education institutions need to introduce digital literacy in their curricula

In the longer term, digital literacy, including an understanding of the functioning of the EHDS and its implications for the practical work of physicians and other stakeholders working in the health system, needs to be introduced systematically not only in medical schools but also in engineering schools and other education sectors. This does not only apply to data users and medical professionals but also to the citizens themselves. Data literacy should be a much bigger topic in all school curricula. Education material needs to be made available for everyone outside of school as well.

To spread digital literacy in the current healthcare system and bring practitioners up to speed, lifelong training, upskilling and reskilling initiatives need to be undertaken in various sectors, following the example of countries like France.

Key recommendations

- *Infrastructure needs a major upgrade to support data collection and use*
- *Capacities need to be developed at all levels of the system*
- *Citizens/patients need to be educated on data literacy and enabled to make informed decisions about their health data*
- *Digital literacy, including a solid understanding of the EHDS, needs to be introduced not only in medical schools but also other faculties concerned by the changes*