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Implementing the European Health Data Space Across Europe

eit Health

Co-funded by the European Union

THINK TANK

Contents

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Disclaimer: This report solely represents the views of the experts involved in the EIT Health Think Tank roundtable series and consultation process. The insights and solutions included in the report stem from the 10 roundtable discussions organised in EU Member States and the interviews conducted between March and November 2023. These discussions were informed by the proposal EHDS text published by the Commission in May 2022. In March 2024, a provisional agreement on the European Health Data Space Regulation was reached by the Council and European Parliament. Therefore, certain content in this report may appear outdated in relation with the text in the EU provisional agreement. The EIT Health Think Tank report is not intended to align with the text in the provisional agreement, as it aims to reflect in an accurate and objective way the insights and information collected through the Think Tank 2023 consultation process.

Foreword

The first proposal of a European Health Data Space regulation came in May 2022, to create a health specific ecosystem which aims to empower individuals to control better their electronic personal data and support their free movement and access to treatment in all EU Member States.

At the same time, the EHDS opens increasing opportunities and use of health data for research, innovation and policy making. It will enable a genuine single market for electronic health record systems, relevant medical devices and high-risk AI systems. It will allow the EU and its Member States to make full use of the potential offered by safe and secure exchange, use and reuse of health data. The possibilities include more informed policymaking tailored to real public health needs, better identification of individuals for prevention and screening measures, more effective patient monitoring and earlier diagnosis of health incidents and diseases, improved access to clinical trials for patients treated outside of research centres, better and safer pharmaceuticals developed using real-world data and increased access to personalised medicine.

A harmonised implementation of the new regulation across the EU will be vital to avoid the pitfall of increasing complexity for research and economic actors and potentially stifling innovation.

In accordance with EIT Health's flagship, "Harnessing the full potential of health data for innovation", a pan-European, multi-stakeholder, public affairs initiative was put in place in the beginning of 2023 to identify the challenges and opportunities for EHDS implementation. This report reflects the views of key experts and relevant stakeholders and it is the result of interviews, meetings and 10 round tables held across Europe.

After a full year of research on the ground, the insights collected reflect the state of play to implementing the upcoming European Health Data Space legislation, in the context of an increasingly dense regulatory landscapes and immense diversity in the Member States' national, sometimes regional, health systems. This report reflects the challenges and opportunities, the potential solutions and captures existing practices and projects that we can build on to support the EHDS implementation.

EIT Health's role was to raise awareness on the EHDS as a legislative proposal and to enable knowledge sharing and capacity-building that will support EHDS in implementation and a fully operational EHDS. We have created a safe space for discussion and consultation on topics that were not easy to address and issues that seemed, and could still be seen by some actors in the health ecosystem, as insurmountable.

As we are concluding this consultation process, we are aware that many challenges and opportunities and much more solutions than those presented in this report remain, and need to be discovered. We have also learned the importance of the people that are behind bold actions like the EHDS. We have met health data experts, policy makers, medical professionals, pharmaceutical, Biotech and MedTech representatives, IT specialists and patients' representatives that showed continuous support, leadership skills and drive, engagement and commitment that will be key in making the EHDS a reality. EIT Health and its network of partners, its knowledge, experience and expertise working across research, and academia, industry, investors and policy making will continue to support the implementation process and contribute to bringing the EHDS and its benefits to all citizens across Europe.

Jean-Marc Bourez, CEO EIT Health

About EIT Health and the EIT Health Think Tank

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 seldom turn breakthrough ideas into new transformative products and services.

Within the EIT Health network, 120 partner organisations and institutions from academia, business, research and healthcare 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 healthcare.

The EIT Health Think Tank is EIT Health's thought leadership forum. It brings healthcare leaders together to prepare the ground for life-changing innovation and to identify the next opportunity for a step-change in how healthcare is delivered. Subject matter experts collaborate across disciplines and borders to explore and assess the most pressing topics impacting health and the 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 healthcare. These included the use of Big Data, future-proofing Europe's digital health innovation pathway, the role artificial intelligence (AI) can play in healthcare workforce and organisational transformation, the impact of the Medical Device Regulation (MDR), and leveraging innovation to make European health systems more resilient and sustainable.

Executive summary

After a full year of research on the ground, the insights collected and presented in this report reflect the complexity of implementing the upcoming European Health Data Space (EHDS) legislation, in the context of increasingly dense regulatory landscapes and immense diversity in the Member States' national, sometimes regional, health systems. The views of experts and stakeholders who were consulted in the course of this initiative reflect the challenges, opportunities and potential solutions for an efficient and sustainable development of the EHDS. The report also explores existing practices and projects that could help the relevant actors achieve this goal.

Better use of health data through the EHDS could contribute to more equitable access to high-quality healthcare as well as therapeutic and digital health innovation, thus improving health outcomes across the EU. However, this will require addressing the wide disparities detailed throughout this report and leveraging available knowledge and opportunities identified in various areas relevant to the implementation process: from existing data **governance** structures and legal provisions, through the technical capabilities and human **capacity and skills** present in different countries and regions to enable equitable access to electronic health data collection and its secondary use, to the **resources and funding** available at the national and local levels to integrate with and benefit from the EHDS. Health systems' ability to contribute to the EHDS with sufficient **data quality** to allow the generation of meaningful, unbiased insights, as well as to **close the loop between primary and secondary use** to ensure a seamless flow of data and a successful introduction of research outputs and innovation back into healthcare, will also determine whether all EU citizens can benefit equally from the system. Not to be underestimated, the cultural differences and varied perceptions surrounding health data sharing and secondary use as well as heterogeneous levels of health and digital literacy, both across and within Member States, will require differentiated and increased efforts to support **awareness, education and communication** measures that will empower key stakeholders, patients and citizens to participate competently in the EHDS.

Governance

The EHDS will introduce a common system of data governance and rules and guidelines for data exchange in the health sector, but as this roundtable series has brought to light, the adoption of this common framework will run up against diverse national realities. In some instances, overly restrictive or unclear legal provisions will need to be revised along with the data-sharing policies and practices (or lack thereof) that they have led to in different organisations over the years—an issue already highlighted in a previous EIT Health Think Tank report (EIT Health, 2021). Cross-border sharing of data for secondary use as envisioned for the EHDS will also require the 27 Member States to align more closely their national interpretations of the EU General Data Protection Regulation (GDPR), including the definitions of and requirements for anonymisation and pseudonymisation, and to ensure effective networking and collaboration between the national EHDS governance bodies.

A harmonised implementation of the new regulation across the EU will be vital to avoid the pitfall of increasing complexity for research and economic actors and potentially stifling innovation. At the same time, structural differences between centralised national health systems and those with a strong regional component to healthcare planning and provision appear to call for some flexibility in the model of governance adopted from one country to another.

These questions and others—related to how intellectual property of both private companies and academic researchers will be protected, how citizens' rights as the owners of their health data will be materialised in practice, or how actors in non-EU countries will interact with the EHDS—will require a lot more work to be effectively implemented. The perspectives of each of the relevant stakeholder groups are captured as findings together with potential solutions aiming to start this process with a clear understanding of what is at stake.

An important advantage in this regard is the fact that in most countries included in the roundtable series, there is political will and momentum to drive the digital transformation of healthcare, as well as a positive, proactive stance of national governments towards the creation of a common EHDS. Indeed, in a landscape as fragmented as Europe when it comes to secondary use of health data, harmonising the rules and practices for its secure and ethical sharing provides an opportunity to reduce inequalities in European citizens' access to healthcare. The possibilities include more informed policymaking tailored to real public health needs in different countries, better identification of individuals for prevention and screening measures, more effective patient monitoring and earlier diagnosis of health incidents and diseases, improved access to clinical trials for patients treated outside of research centres, better and safer pharmaceuticals developed using real-world data.

Capacity and skills

Establishing and maintaining infrastructure for the collection, storage, protection, sharing and secondary use of electronic health data requires specific human resources and skills that are not always readily available. The responsibility of national health data access bodies to examine requests and issue permits, to process the relevant data in more or less centralised pools and deliver access to it for users, as well as to network with their counterparts in other Member States via the core platform HealthData@EU, will require some degree of capacity-building in the public administrations of individual countries. Trusted data holders such as hospitals, research organisations and private companies will also be required to dedicate staff and resources to curating, standardising and providing access to their data.

Most EU Member States are generally in the early stages of their journey towards nationwide health data interoperability and accessibility; however, Europe's regions have in various instances benefited from their smaller scale to implement platforms for standardised collection, aggregated storage, and secondary use of their residents' health data. The technical characteristics and lived experiences of these different initiatives can, and should serve to identify best practices and solutions for implementing the EHDS at national and European level.

The picture that emerged from the discussions in this field is one of heterogeneous progress in digitalisation not just between, but also within health systems' different areas of healthcare provision. A challenge common to all countries involved in the roundtable series is that the electronic data that is available in various organisations and systems lacks the interoperability necessary to easily transfer, aggregate and process it for secondary purposes.

Healthcare institutions in particular have scarce capacity, personnel or specialised skills to standardise, extract and transfer data from often disparate information systems, and will be challenged to build these up in a context of chronic staff shortages and resource constraints.

More generally, the skills gap that Europe will have to contend with as it moves forward in the implementation process ranges from the technical qualifications of various kinds of data specialists, through legal and data protection expertise, all the way to interdisciplinary profiles capable of interfacing between the fields of medicine, nursing, IT, cybersecurity, data science, ethics and social science. Health data access bodies will have an essential advisory and supportive role to play with data holders and data users alike, and should plan their capacity-building and skills acquisition accordingly. However, significant long-term investments will equally be necessary to develop an appropriate educational offering capable of enabling competent interaction with the EHDS and creating a sustainable pipeline of talent for its operation in the future.

Various successful examples of regional, national and European data-sharing, upskilling and reskilling initiatives (e.g. partnerships under European Pact for Skills) were highlighted as possible templates or building blocks for the design of a functioning EHDS infrastructure, while the pharmaceutical, medical device and digital health industries could contribute with their expertise and financial capabilities to its implementation.

Resources and funding

As the first of nine planned Common European Data Spaces and the only project of its kind in the world to date, the EHDS is widely expected to come at a high cost of implementation. The precise amounts of the short and long-term investments needed in each country, however, are difficult to estimate. What did emerge clearly from the roundtable discussions is that many smaller Member States will be dependent on EU co-funding to be able to shoulder the financial burden. In this context, the budget so far allocated by the European Commission to the implementation effort was considered to fall short of the ambition level of the regulation proposed.

An efficient and just allocation of the resources and funding available at both EU and national level will be key to building a system that is viable for all stakeholders and which works in the interest of all EU citizens. This will require a detailed understanding of who is going to incur which costs, and to what extent the relevant organisations have a stake in and the capabilities for making the necessary investments. Health institutions, in particular, cannot be expected to bear the brunt of the financial and human effort needed to make their electronic health data available for secondary use when their main interest resides in its primary use. It will also be important to ensure that resources allocated to implementing the EHDS in the healthcare sector do not subtract from those dedicated to ensuring patient safety and quality of care. In the private sector, the costs of complying with the obligations of a data holder will be equally difficult to cover for the numerous European SMEs which tend to be the drivers of innovation in areas such as digital health. On the side of data users, the question of the fees for data access will be central to ensuring a level playing field for research actors small and large, public and private.

Templates for a cost-efficient implementation can be found in existing European projects of common interest, which have already begun developing technical building blocks and transnational data infrastructures that could be leveraged for the EHDS. Pooling available resources across different organisations and Member States also has the advantage of supporting the emergence

of standard solutions and a harmonised implementation, a critical success factor for the system's operation. In addition to the resources needed in the short term to warrant the kind of swift implementation envisioned by the European Commission, work will also be needed to identify the long-term financial mechanisms and new business models to ensure the sustainability of the EHDS over time.

Data quality

The quality of the data that flows into the EHDS will determine the value of the insights generated and health solutions developed through its secondary use. Use of incomplete or unrepresentative datasets for research, innovation and policymaking alike carries the risk of introducing bias and leading to discriminatory outcomes for EU citizens. Yet in order to aggregate data volumes on the scale made possible by the EHDS, the data needs to be interoperable not just from the technical perspective of its transferability across different systems, but also in terms of the language and coding systems used by different organisations and health systems to document patient information. While international data standards exist, their application varies drastically across the Member States and between different healthcare settings such as hospitals, community medicine or nursing care. A common data quality framework will need to be implemented consistently in each country to ensure that all Member States can participate and benefit equally from the secondary use of their data going forward. Extensive work has already been done at EU level in this area to inform the implementation process.

Still, many questions remain, starting with whether and how to approach the standardisation of vast amounts legacy electronic data held by the different health systems. While this data relates predominantly to older citizens who would stand to benefit significantly from its secondary use, the current reality is that health institutions have particularly low capacity and budgets for the data quality improvement measures this would require. In addition, indiscriminately integrating all data in the relevant categories would not necessarily be useful or desirable: many experts involved in the roundtable series highlighted the need to define much more precisely the data requirements and to tie these to concrete use purposes to ensure an efficient, goal-oriented approach to data-sharing. This applies equally to data from medical devices, the utility of which for different research applications has yet to be determined. Its inclusion in the EHDS additionally poses its own challenges as regulatory data quality requirements differ across different categories of devices and applications—an issue that is even more acute for the data that could come from wellness apps, which are not currently subject to any standard evaluation.

Considering the large cost associated with obtaining high-quality data for research, standardisation and improvement measures on the side of data holders, and potentially patients themselves, will need to be met with efforts on the side of secondary users to manage inevitable variations in data quality. Work in this area will span from educating and supporting researchers in the appropriate use of different types of datasets, to developing standard methods to scientifically validate the datasets themselves as well as the algorithms and digital health innovation they are fed into.

Closing the loop: The relation between primary and secondary use

While the focus of the roundtable series was on secondary use of health data, this could not be considered in isolation because its effectiveness will depend on the quality of data collection in the primary use setting, as HealthData@EU will provide access to data collected for primary use and processed within electronic health records (EHRs). Healthcare professionals will therefore have a key role in implementing data standards and collection practices that must not just support them in delivering patient care, but also meet the needs of the research ecosystem, in which they may not otherwise be personally involved. Ideally, primary data collection would be designed from the outset to allow reuse for secondary purposes, generating rich clinical profiles for research and reducing the need for additional processing steps to make data interoperable. The reality reported across most countries represented in the discussions, however, is that current workflows and data management in healthcare are not geared towards such structured data entry and professionals generally lack both the capacity and the incentive to record information beyond what they directly need to deliver care to patients. It is hoped that technology will resolve this conflict through new possibilities such as automated data collection and transfer, as well as integrated analytical features offering insights and decision-making support to clinicians within the data capture environment.

In this area and in many others, secondary use of data will inevitably transform its primary use. New data-driven solutions will change established clinical care processes and require new patient pathways to be defined and standardised. They could also accelerate the shift from treatment of illness to prediction and prevention in the way healthcare is delivered—a shift that will need to be accompanied by an overhaul of European health systems' current funding and reimbursement models. Healthcare professionals, patients and citizens should be included as active participants early on to keep their interests at the heart of the process and foster trust in the transformation. To ensure that the most valuable innovations reach all those who could benefit from them without delay, paths for the evaluation of data-driven innovation and its introduction into clinical pathways will need to be further developed and standardised across the EU. Here, public-private partnerships could be instrumental to ensuring that novel solutions and services are designed from the start with clearly defined unmet healthcare needs in mind.

Awareness, education and communication: Towards a data-driven culture in healthcare

Achieving the full potential and benefits of secondary use of health data through the EHDS will require buy-in across all stakeholder groups, from healthcare providers and payers, through the academic research community, pharmaceutical, medical device and digital health industries, all the way to patients and citizens at large. At present, even basic awareness of the upcoming EHDS regulation is reportedly low among key stakeholder groups, including healthcare providers, with most organisations not currently taking any measures to prepare for their future role as data holders. Providing accurate and relevant information to different groups as to what changes are coming, what the benefits are and what will be required of them to comply with the new regulation is thus, the first vital step that EU and national policymakers will need to take in the short term.

In the public engagement effort that must be sustained throughout the course of

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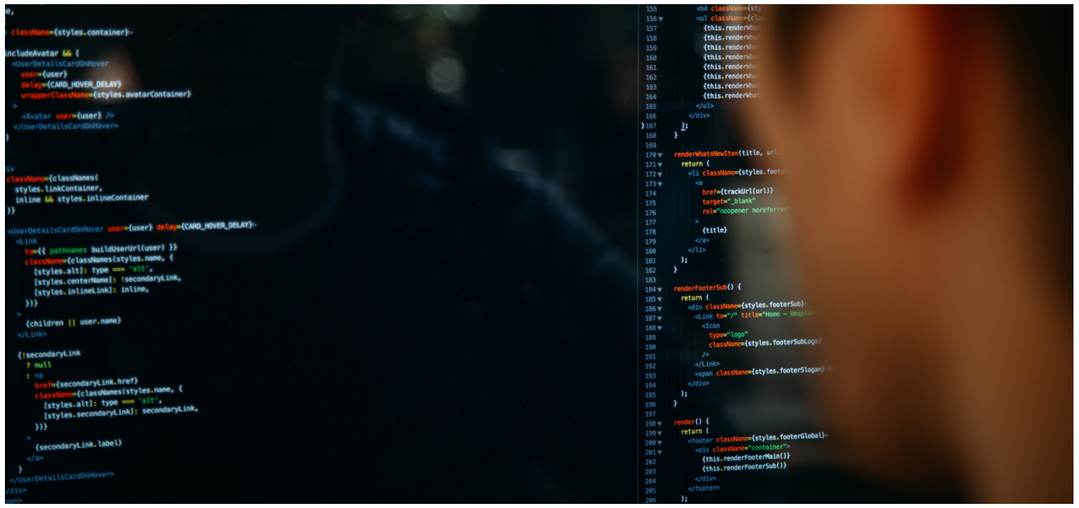


implementation and beyond, healthcare professionals will have to be won over and patients mobilised as credible voices to distil to the wider population the critical importance and life-changing benefits of data-sharing, including for secondary use. Inclusive information and educational strategies should be developed to empower citizens at all levels of digital and data literacy to exercise their rights, and support should be extended to help vulnerable groups participate in data-sharing. In the longer term, efforts should be ramped up to develop health literacy and data literacy as part of the education of all EU citizens from an early age.

Citizens' acceptance of secondary use of their health data was seen to vary between countries and to be conditioned on factors such as data privacy and security, perceptions of benefit to the community, and trust in the responsible governance bodies. In some cases, a history of risk-focused discourse around personal data or post-pandemic distrust in scientific and public health authorities will need to be overcome through open dialogue and clear answers to sensitive questions such as the security of data-sharing or ethical issues arising from the use of artificial intelligence. Direct channels of communication between data experts, especially EHDS governance bodies, and citizens will be instrumental to building and preserving public trust as more tangible examples of what can be achieved with data become available.

Introduction

On 3rd May 2022, the European Commission published its proposal for the European Health Data Space (the EHDS proposal), a new framework intended to make it easier for individuals, doctors, researchers and regulators to access and use information about the health of millions of citizens across the European Union (European Commission, 2022). The network, which will require actions at the EU and national levels, aims to create a genuine single market for electronic health record (EHR) systems—a key pillar of the European Health Union—following the EU's high data protection standards. In a statement to mark the launch of the plan, Stella Kyriakides, Commissioner for Health and Food Safety, called the European Health Data Space a fundamental game changer for the digital transformation of healthcare in the EU, placing the citizens at its centre and empowering them with full control over their data to obtain better healthcare across the EU.

"This data, accessed under strong safeguards for security and privacy, will also be a treasure trove for scientists, researchers, innovators and policymakers working on the next life-saving treatment," Kyriakides emphasised.

In accordance with EIT Health's flagship, "Harnessing the full potential of health data for innovation", a pan-European, multi-stakeholder, public affairs initiative was put in place to identify the challenges and opportunities for EHDS implementation and collect insights and views from key actors. The aim was to raise awareness on the EHDS proposal, and to enable knowledge-sharing and capacity-building for a fully operational EHDS. A series of national and regional roundtable discussions was staged throughout Europe in 2023 to shed light on the realities and needs in the individual countries in relation to the EHDS implementation, but also to distil lessons learnt and best practices from previous experiences of health data sharing for secondary use. Experiences and real-world insights of EIT Health's partners and other relevant agents of the EU healthcare innovation ecosystem were gathered to compare and contrast the ability across sectors and borders to implement the EHDS in practice.

Methodology

Objectives

This EIT Health Think Tank report aims to provide an overview of EU Member States' readiness to implement a common European Health Data Space. To aid in a harmonised and inclusive European approach, the report identifies key challenges and enablers of implementation, as well as solutions for the key actors that lead transformation at local, national and EU levels. Good practices and innovative projects are highlighted so that they may facilitate the sharing of knowledge and lessons learnt between countries and regions.

Input

This report builds upon insights generated from previous EIT Health Think Tank activities, in particular the 2021 report titled, "**Learning from health data use cases: Real-world challenges and enablers to the creation of the EHDS**".

The insights and solutions included in the report stem from 10 roundtable discussions organised in EU Member States and interviews conducted between March and November 2023. These discussions were informed by the proposal EHDS text published by the Commission in May 2022. In March 2024, a provisional agreement on the European Health Data Space Regulation was reached by the Council and European Parliament. Therefore, certain content in this report may appear outdated in relation with the text in the EU provisional agreement. The EIT Health Think Tank report is not intended to align with the text in the provisional agreement, as it aims to reflect in an accurate and objective way the insights and information collected through the Think Tank 2023 consultation process.

The EIT Health Think Tank Roundtable Series

In 2023, the 10 roundtable events were held in Austria, Belgium, France, Germany, Hungary, Ireland, Italy, Portugal, Spain, and Sweden (see Annex I)[1] . Each roundtable was held for a duration of 2–4 hours and was complemented by additional follow-up interviews. Roundtable participants were selected by the EIT Health representatives in the corresponding Co-Location Centres, in collaboration with various members of the Steering Committee. To focus the roundtable discussions, participants were provided with an ex ante survey to determine the dimensions with the highest EHDS priorities in their region. The majority of Co-Location Centres have published regional reports on the discussions that took place. Additional interviews were conducted during the roundtable series with regional experts. Insights from these discussions were published in regional whitepapers.

The Steering Committee

The EIT Health Think Tank Steering Committee was composed of experts from the EIT Health network. The Steering Committee met four times during the drafting of this report to provide a consistent dialogue and feedback on the structure, content and style of the report. The Steering Committee was selected by the EIT Health Public Affairs and Stakeholder Relations Team to cover both sectoral and geographical expertise. The Steering Committee was chaired by Dr. Andrzej Rys, Oxford University, EU Fellow and Principal Scientific Advisor at DG SANTE. Dr Rys oversaw the initiative and was consulted throughout the process.

1 A pilot roundtable on the topic of the EHDS was initially held in Poland in 2022, albeit with a different structure to the 2023 series. Its key findings are also included in this report.

The Sounding Board

In addition to the Steering Committee, complementary insights were obtained through individual interviews with the EIT Health Think Tank Sounding Board (Annex II). Pan-European stakeholders and key opinion leaders were interviewed between April and September 2023. Sounding Board interviews were conducted with European organisations, as well as regional experts in the healthcare, IT and health data sectors. These interviews served to outline key stakeholder positions on the EHDS and to validate, contradict or complement the conclusions reached during the roundtable discussions.

Analytical Approach

The roundtable discussions brought together experts and stakeholders from across the public health, healthcare and health data ecosystems. Participants discussed the context in their individual countries in relation with the EHDS under six dimensions of implementation:

1. **Governance**
2. **Capacity and skills**
3. **Resources and funding**
4. **Data quality**
5. **Closing the loop: The relation between primary and secondary use**
6. **Awareness, education and communication: Towards a data-driven culture in healthcare**

These six dimensions were chosen by the Steering Committee to structure the consultation process, and served as a basis for reflection on the enablers and changes required for the EHDS implementation. The definitions of the six dimensions were deliberately kept broad, to ensure that each region could interpret these topics within their local context.

Each of the dimensions, outlined below, offered participants the opportunity to identify: (a) their country's or sector's starting position, available resources and the changes or activities that will need to take place to ensure successful implementation, (b) the challenges that may arise in this process, and (c) the stakeholders who will need to be involved to drive and enact the changes.

1. Governance

The governance dimension includes the new common data governance rules and guidelines for data exchange in the health sector that will be required for the EHDS implementation. The governance rules and guidance will support cross-border sharing of and access to electronic health data for defined authorised use purposes, warrant data protection and privacy, and further define consent requirements for secondary use beyond current national interpretations of the GDPR, among other things.

2. Capacity and skills

The 'capacity and skills' dimension refers to the human resources and skills required for establishing and maintaining infrastructure for the collection, storage, protection and sharing of electronic health data. The EHDS will bring about significant changes and new opportunities in the way users can interact with health data that will require new skills and changes in existing European, national and regional practices.

3. Resources and funding

The 'resources and funding' dimension refers to the infrastructure and funds available and/or required to implement the EHDS at European level and across different countries and health systems, as well as between national healthcare players. This includes the various funding streams and resources available or needed by all relevant actors in the healthcare ecosystems, as well as the differences between sectoral groups, for example: small hospitals and community practices, in comparison to larger centres.

4. Data quality

The 'data quality' dimension looks into the way the collection, use and storage of healthcare data are organised differently across Member States and the ability to compare data between distinct data-sharing initiatives and between the Member States. It includes existing quality frameworks that differ in substance and in their level of enforceability across countries as well as new aspects related to the secondary use of data.

5. Closing the loop: The relation between primary and secondary use

This dimension includes all the aspects required for the secondary use of health data; it will cover the role of different actors from primary data collection towards enabling research and analysis and closing the loop towards healthcare professionals and improved healthcare service delivery and impact.

6. Awareness, education and communication: Towards a data-driven culture in healthcare

This dimension refers to how the EHDS will require the engagement and buy-in across all stakeholder groups, from healthcare providers and payers, the academic research community, pharmaceutical and health technology industries, to patients and citizens at large. It explores perceptions and preparedness to participate in the EHDS between these groups and between countries, and the varying educational and communication needs required to build a better culture around data-sharing.

CHAPTER 1

Governance

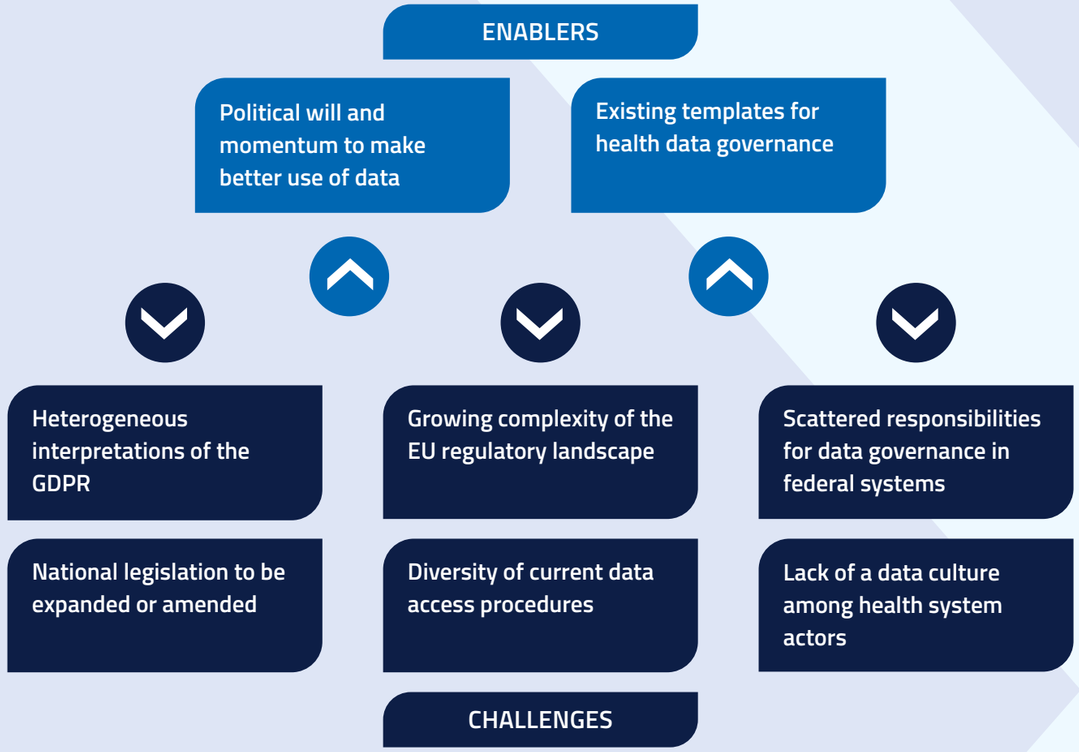
> We are very good at data protection, less so at data-sharing—we need to change that and empower patients through a rights-based approach
>
> Barbara Foley, Health Information Quality Authority, Ireland

Summary

Main findings

- Currently, the conditions and processes to access data for secondary use vary significantly between countries, with many lacking specific national legislation governing the use of health data.
- In addition to different starting positions in terms of health system digitalisation and experience with secondary use of data, there is also variation in countries' approaches in the run-up to adoption of the EHDS. Some countries have undertaken legislative changes, some have begun working on data governance structures and data infrastructures to prepare for the implementation of the new regulation, while others have not yet started their journey.
- Up to two thirds of EU Member States have a strong regional component in the distribution of competencies for public health service planning and provision, implying that a single model of centralised national EHDS governance will not fit all countries.

Challenges and enablers of implementation



Key actors, findings and solutions for implementation

Define clear policies and implementation frameworks

At European level

Minimise legal uncertainty surrounding secondary use under the EHDS by ensuring precise definitions, that are consistent with other EU regulations, especially definitions of health data for secondary use

Provide detailed guidance for fulfilling data anonymisation and pseudonymisation requirements with a focus on harmonising the rules across the EU

Minimise the risk of exploitation, intended or not, of secondary use of health data by providing a more specific definition of health data, as well as evidence-based definitions of the expected benefits for citizens and society

Foresee safeguards to avoid non-legitimate use of health data for commercial purposes through oversight and control mechanisms

Clearly identify the data categories for the data holders that will be subject to data sharing, as well as the authorised users, purposes and modalities for access to data

Clarify how data should be securely collected at primary, secondary and tertiary levels of healthcare services

Agree on an opt-out/opt-in model that balances the interests of data users with practical feasibility for data producers (for example by allowing accumulation of historical data while minimising administrative burden), which is broad enough to include both health and relevant health-related secondary use of data, and which is easy to use and understand by patients and citizens of all levels of digital health literacy

Agree at EU level on a protected interval of time during which research and other entities retain exclusive access to health data they have collected and processed, in alignment with existing rules for data protection and intellectual property (for example, as seen in the EU Clinical Trials Regulation)

At national and regional levels

Assign roles and responsibilities for data governance in line with the degree of (de)centralisation of the health system, and develop clear guidelines for the national (and regional) EHDS bodies

Clearly define how the local, regional or national health systems will connect to the health data access bodies, from a both procedural and technical perspective

Collaborate towards a harmonised implementation

At European level

Foster harmonised implementation through collaboration and mutual recognition of national health data access bodies and EU-level oversight by the EHDS Board

Support collaborative initiatives between Member States for sharing best practices and lessons learned for designing national governance frameworks

Leverage lessons learnt from existing pilot projects (like the HealthData@EU pilot) to answer practical questions surrounding data governance and use

At national and regional levels

Launch and collaborate in multi-country, multistakeholder and cross-regional collaboration projects for sharing and secondary use of health data

Mandate governance bodies to implement data quality, interoperability and cataloguing, and mitigate inequalities in a consistent way with existing EU regulations

Involve all stakeholders and support data-driven culture

At European level

Ensure meaningful patient and civil society advice and representation on EU-level data governance bodies

At national and regional levels

Ensure multistakeholder and cross-government collaboration, including involvement of regional lawmakers, hospital managers, in developing a national framework for EHDS governance, processes and systems

Engage patients and healthcare professionals at all levels including in pilot projects and local governance structures

Establish a transparent system of ethical oversight for all secondary use applications, networking in and supporting existing ethics committees as needed

Provide citizens clear communication, transparency and control (depending on the opt-out/opt-in model adopted) over who can access different categories of data within their health records, taking into account varying levels of digital and health literacy and openly addressing both the risks and benefits of the EHDS

Current national landscapes

While data collection and secondary use initiatives such as national disease registries and official health statistics exist in most countries involved in the roundtable series, few have a dedicated legal framework in place to enable the secondary use of health data either for research or for policymaking. With diverse national interpretations of the GDPR observed across the EU, current practices relating to data-sharing and secondary use also vary significantly from country to country. Similarly, the steps taken so far to prepare for the new legislation have differed between the Member States.

Legal provisions and data-sharing practices

For example, in Sweden, health data collected nationally has been made available and used for research for decades, and its integration in the EHDS is not expected to pose any difficulties (EIT Health Scandinavia, 2023). The wealth of healthcare data held in its regions, however, has so far remained largely untapped due to the fragmentation of data infrastructures and the complexity of regional data governance structures preventing its extraction and aggregation at national level. In spite of Sweden's extensive experience with national data collections and statistics, it is estimated that its legal readiness for the EHDS lags behind its technical readiness: for instance, delays in making the required legislative provisions will cause Sweden to be among the last EU Member States to connect to the MyHealth@EU platform for primary use, which has been in operation for years.

Particularly restrictive legal provisions have been identified when it comes to health data in Ireland, Italy and Spain.

The Irish landscape characterised by a highly protectionist interpretation of the GDPR and national health research legislation that sets out the governance of health data access and the rules for patient consent for research, which have been considered by researchers as a barrier to using or seeking access to patient data for secondary use (EIT Health Ireland-UK, 2023). This legal backdrop is widely seen to be the cause for considerable reluctance among health system actors to share data, even in instances when it would be deemed legitimate. The Health Information Bill published in May 2023 by the Department of Health laid the foundations for a transformation of health data capture and use, explicitly stating its alignment with the objectives of the EHDS and providing for the creation of a National Health Information Authority. However, the role of this body remains somewhat unclear and concerns have been raised that it may meet only basic requirements laid out in the EHDS for primary use of health data.

Italy has seen a similar push for the secondary use of health data in the wake of the COVID-19 pandemic, but this is made difficult by the Italian data protection agency's (*Garante italiano per la protezione dei dati personali*) requirement that consent of the data subject be collected as an essential condition for the lawfulness of the processing of personal data (EIT Health InnoStars, 2023). Although a provision exists to allow researchers to request permission from the Garante to process data without seeking consent, in cases where this would involve a disproportionate effort due to a high number of interested parties or their unavailability, or where the request for consent risks making the research purposes impossible to achieve, it has reportedly not been widely used in practice. The Garante's limited scope, which does not include a supportive function to provide guidance for structuring research projects in compliance with the GDPR, is likely a contributing factor.

In Spain, a strategic political focus on the digital transformation of the public and private sectors and wider society has been expressed through comprehensive national policies such as Digital Spain 2026, which leverages the funding provided through Europe's Next Generation EU stimulus package and includes a specific National Artificial Intelligence Strategy (EIT Health Spain, 2023). However, efforts to unlock the full potential of health data are currently limited by the country's application of the GDPR and the absence of any other legal framework regulating its use.

Another defining trait in Italy and Spain, as well as in Austria, Belgium, and Germany, is that current data governance structures and practices reflect a decentralised organisation and management of healthcare at the regional level, in line with these countries' federal political systems.

Spain, for instance, has seen several public health systems in its 17 Autonomous Regions establish infrastructure and processes enabling secondary use of their residents' health data for research and public policy, but a top-down coordination of these regional initiatives has so far been lacking.

In Austria, a unified electronic health record (ELGA) has been in place for over a decade, giving healthcare professionals and patients access to health data from different sources in the health system. While there is still room for improving the system and expanding access to and use of its data, the ELGA already constitutes an advanced implementation of the primary use facets of the EHDS. There are federal laws that allow the sharing and reuse of health data for research and, thanks to extensive digitalisation throughout the health system, a variety of electronic data collections including in every category foreseen by the EHDS. However, this so far has not translated to mature structures and processes for secondary use (EIT Health Austria, 2024). Decentralisation and the many data silos that result from it, as well as a lack among health system actors of the necessary culture, will and operational capabilities to enable data-sharing and secondary use, are contributing factors to the significant underutilisation of the country's data wealth. The Digital Austria Act presented in June 2023 could pave the way for better health data governance in the future. It provides for the expansion of the country's unified electronic health record to allow citizens to see and manage all of their health data in one digital space, defines a clear legal basis for processing health data, and aims to accelerate the implementation of digital health applications. The creation in 2022 of the Austrian Micro Data Centre at the Austrian national statistics office, Statistik Austria, has also created new possibilities to access and link data from various registries and official statistics for research purposes, although the range of datasets included currently remains limited.

Infrastructures and processes to prepare for the EHDS

Germany has taken steps to prepare for the implementation of the EHDS and proposed several draft legislations, expected to come into effect in 2024, to support the digitalisation and use of health data. These include the Digital Act (DigiG), the Hospital Transparency Act, and the Health Data Use Act aiming to develop a decentralised health data infrastructure. The latter also foresees the creation of a 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 regional cancer registries available for research purposes.

Germany's neighbour Switzerland, though not an EU Member State, is seeking with its DigiSanté programme to promote digital transformation in its healthcare sector and implement a Swiss Health Data Space intended to be compatible with the EHDS without formally being part of it. The aim of DigiSanté is to allow for seamless data flows in treatment, billing, research and public health services while guaranteeing data protection, informational self-determination and cybersecurity. It will also facilitate the secondary use of the resulting health data for legally sanctioned planning, control and research purposes. Another national initiative, the Swiss Personalized Health Network, merges data from different hospitals and focuses on making health data available for secondary use in a responsible and efficient manner following a decentralised approach.

The Belgian Health Data Agency (HDA) was created by law and funded in 2023, and officially launched in January 2024. Tasked with facilitating the collection, standardisation and secondary use of health data for the benefit of Belgian citizens and the European community (EIT Health Belgium-Netherlands, 2023), the HDA's operational framework is intentionally designed to align with the EHDS proposal. It will serve as the country's central health data access body for secondary use of electronic health data, with activities including the compilation of a national data catalogue and the development of federated analytics as an alternative to transferring datasets. However, the new agency will not itself store data and currently has no mandate to host secure processing environments.

Some of Europe's most advanced systems of health data governance can be found in France and Luxembourg. The latter has taken a major step in the run-up to adopting the EHDS by establishing the Luxembourg National Data Service (LNDS) in 2022 as a national organisation providing services for access to and value creation from various categories of public sector data, including health data. The organisation is involved in the national implementation of the EU Data Governance Act and will collaborate with the Ministry of Health on designing the health data access body for Luxembourg as part of the EHDS implementation. It is also contributing actively to the Data Spaces Support Centre, which is coordinating the development of the nine planned European data spaces and working towards common standards and interoperability between them.

France has worked consistently to enable better use of data in both the primary and secondary settings over the last few decades, starting with the structuring of its health data through the creation of coding systems for medical and hospital procedures in the late 1970s and the gradual refinement of its legal framework governing data access over the last 20 years. More recently, the Health Data Hub created in 2019 has centralised and structured the process for researchers and public bodies to obtain access to data from the French health system and in particular to its centralised claims database, the National System for Health Data (SNDS). The Health Data Hub is currently piloting the HealthData@EU secondary use infrastructure pilot project for the implementation of the EHDS. To further harmonise health data governance at the local level, a Strategic Committee for Health Data was established in 2023 and tasked with providing to health institutions a health data warehouse standardising access requests and evaluation in line with national governance rules (EIT Health France, 2024).

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Common challenges and potential solutions

Legal barriers to sharing health data

In a number of countries, legal uncertainty and fear of liability have conditioned data holders to err on the side of caution and avoid sharing health data, including in instances where this would be deemed legitimate. Restrictive regulatory landscapes at national level have also provided a basis for the development of siloed mentalities and practices preventing data-sharing even between public bodies pursuing similar goals. Experts in countries including Austria, Ireland, Spain and Sweden therefore saw a need to adapt existing laws or pass new legislation specifically to enable use of health data and potentially to create an obligation to share it for purposes of public interest.

At national and regional levels

Launch a comprehensive investigation into the legislative changes required to support secondary use of data under the EHDS

INTERPRETATION OF THE GDPR

The GDPR leaves room for interpretation and allows some particular national provisions in regulating the processing of data. As a result, difficulties navigating legal variability and heterogeneous terminology relating to health data have become common fare for cross-border research projects. Once the EHDS is introduced, these could undermine the establishment of a unified governance model and thus the user experience with the EHDS. It was also suggested that the categories defined by the GDPR to frame those who deal with data impose an obsolete mold on complex and dynamic realities, while its failure to discriminate between categories of health data is a further unjustified impediment to research. If certain protections are warranted for highly sensitive data such as a genetic profile, the same cannot be said for other types of health data which also fall under the stricter rules of the GDPR. Harmonising the data protection landscape across the EU will be an important step, but also one of the major difficulties in the implementation of the EHDS.

At national and regional levels

Collaborate at European level to harmonise the application of the GDPR

DATA ANONYMISATION AND PSEUDONYMISATION

Health data will be shared predominantly in anonymised or pseudonymised form for secondary use within the EHDS, yet similar to the heterogeneous interpretations of the wider framework provided by the GDPR, legal definitions of, and requirements for anonymisation and pseudonymisation vary significantly between countries. This runs counter not just to the way pharmaceutical, digital and health technology companies operate, especially in their research and development activities which are conceived globally, but also to the fundamental aim of the EHDS to enable the secondary use of data seamlessly across borders. More precise guidance is needed at EU level on how to fulfil GDPR requirements in this area, in a way that strikes a sensible balance between risk and benefit, to remove the legal uncertainty and resulting fear of litigation for secondary users of data.

At European level

Provide detailed guidance for fulfilling data anonymisation and pseudonymisation requirements with a focus on harmonising the rules across the EU

Regional organisation of health services and allocation of data governance roles

Up to two thirds of EU Member States have a strong regional component in the distribution of competencies for public health service planning and provision. Regions will therefore have an important part to play in operating the EHDS, which must be taken into account in the development of its governance framework and in the allocation of resources for its implementation. In Austria, Germany, Spain and Sweden, for example, attributing the responsibilities of the national health data access body was reported to pose a challenge in that the roles and tasks foreseen in the EHDS proposal are currently distributed across multiple agencies and authorities. In Sweden, data governance is decentralised even at the regional level, with different systems and data managers operating in parallel, in numbers that increase proportionally with the size of the region. A further layer of complexity can come from the presence of private healthcare providers whose data is not currently governed by public agencies. These internal challenges are not easily solved with the EHDS proposal, which governs the cross-border use of electronic health data but provides no guidelines on how it should be shared nationally.

While there are clear calls to concentrate the responsibilities foreseen by the EHDS proposal as much as possible in the hands of a single access body at national level to ensure a smooth user experience and avoid delays in data access, it is expected that in various EU Member States regional bodies will need to play a role to facilitate data retrieval. In Spain, a crossover between data holders, data users and access bodies will additionally need to be resolved in a context where the proposed regulation stipulates that the latter entities should be distinct from the other two categories.

At national and regional levels

Assign roles and responsibilities for data governance in line with the degree of (de)centralisation of the health system, and develop clear guidelines for the national (and regional) EHDS bodies

Clearly define how the local, regional or national health systems will connect to the health data access bodies, from a both procedural and technical perspective

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Enablers and opportunities

Political momentum

In most countries included in the roundtable series, there is political will and momentum to drive the digital transformation of healthcare, as well as a positive, proactive stance of national governments towards the future EHDS legislation.

In Sweden, the national governance infrastructure is already under development, and the Spanish federal government has launched a project for the implementation of the EHDS under the auspices of the Ministries of Health, Science and the Economy. In France, the regulation is seen as a vector for improving the current system and accelerating the enrolment of all relevant actors in the health sector. In Poland, meanwhile, positive previous experiences with the cross-border exchange of e-prescriptions or the creation of the COVID-19 digital certificate have raised hopes that the EHDS will further help accelerate digitalisation in the health sector and support preexisting national projects to develop the use of AI in clinical care (EIT Health InnoStars, 2022).

An exception to this was seen in Hungary, where a focus on control of information, media and data more generally constitutes a point of consensus among the country's decision-makers (EIT Health InnoStars, 2023). Healthcare data can in theory be bought from data holders, but access is very difficult in practice. Fostering the participation of willing data holders such as university hospitals in international consortia to demonstrate the results and benefits of sharing health data could be an avenue to generating political acceptance and incentive from the bottom up.

Templates for health data governance

Invaluable practical experience with data governance can be found within existing national bodies such as the Finnish Social and Health Data Permit Authority Findata, Luxembourg's LNDS or France's Health Data Hub, but also advanced regional infrastructures like those established in Spain and Sweden. Their insights could be instrumental to the development of a workable common governance framework for the EHDS and provide templates for other Member States to develop their national infrastructures and processes for secondary use. The Health Data Hub, for instance, operates as an entry point and coordinator for most requests to access health data, networking in the French scientific and ethical committee CESRES, to evaluate whether a project falls into the public interest, and the data protection committee CNIL, which is ultimately responsible for authorising or denying access. Accelerated paths to data access have been established for specific types of projects that follow so-called reference methodologies, the conditions for which are dictated by the CNIL, and for certain public bodies defined by decree to fulfil legal mandates such as public health surveillance.

On a multinational level, the HealthData@EU pilot project for secondary data use within the EHDS has undertaken to test practical approaches to data governance and cross-border sharing. This covers the auditing of national legal landscapes to inform the development of general conditions for secondary use that are appropriate for multi-country research projects, including a common data access request form, and the development of technical and network infrastructure to support request submissions and connect the national data access platforms

between them. Five use cases are serving as a basis to test the practicalities of requesting data across different countries, each involving key research and public health entities and representing areas where the EHDS could have transformative effects. The French Health Data Hub is coordinating one of these use cases and the pilot comprising a total of 17 consortium partners, including national data platforms, European platforms such as the European Medicines Agency and the European Centres of Disease Control, as well as international research networks such as ELIXIR, whose future roles within the EHDS are not yet fully understood. The experiences and templates that will emerge from this initiative will be an invaluable building block for a viable and, importantly, mutualised model of data governance in a context described above where different national interpretations of the GDPR have so far led to high variability in national procedures to access data.

At European level

Foster collaborative initiatives between Member States for sharing best practices and lessons learned for designing national governance frameworks

Leverage lessons learnt from existing pilot projects (like the HealthData@ EU pilot) to answer practical questions surrounding data governance and use

Better health and healthcare for all EU citizens

In a landscape as fragmented as Europe when it comes to secondary use of health data, harmonising the rules and practices for its secure and ethical sharing provides an opportunity to reduce inequalities in European citizens' access to healthcare. The potential solutions include more informed policymaking tailored to real public health needs in different countries, better identification of individuals for prevention and screening measures, more effective patient monitoring and earlier diagnosis of health incidents and diseases, improved access to clinical trials for patients treated outside of research centres, better and safer pharmaceuticals developed using real-world data, and the democratisation of personalised medicine. An example of how use of data for health service planning can improve outcomes is seen in Canada, where systematic data collection from various healthcare sources has allowed provincial governments to optimise allocation of available resources and equipment, target new investments, as well as implement training or financial measures to address quality and safety issues in specific institutions. However, the net effect of the EHDS in this regard will only be positive if the risks of its implementation accentuating disparities, which will be addressed throughout this report, are adequately monitored and mitigated.

At European level

Perform an evaluation study across EU's countries and regions to assess the impact of the EHDS implementation on health inequalities

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Priorities for implementation

A consistent legal framework and clear guidance

The growing complexity of the EU regulatory landscape for data, including the GDPR but also more recent legislation such as the Data Act, the Data Governance Act and the AI Act, requires EU policymakers to ensure a high level of consistency in the legal definitions and provisions of the EHDS with other regulations and avoid as much as possible ambiguity or uncertainty that would stifle research and innovation.

Additionally, medical technology sector representatives expressed concerns that adding a further layer of complexity to companies' legal obligations following well-documented difficulties in the process of transitioning towards the EU Medical Device Regulation could further slow the pace at which innovative health solutions reach patients, and thereby undercut one of the main objectives of the EHDS. As an example, it has been suggested that only a broad definition as to what constitutes an EHR system, coupled with the prospect of introducing conformity assessments for such software, risks overlooking the modular design of modern digital solutions and subjecting products not primarily intended to be an EHR to multiple assessment pathways, thus delaying their market entry.

To ensure a common understanding and consistent implementation across the Member States, the potential solutions identified require clear legal guidance and instructions on data governance for the national health data access bodies, including precise descriptions of the roles and responsibilities of the different actors involved. These should include details of when, how, and with whom various data holders will be required to share which data, and precise conditions on which users will be permitted to access that data. In particular, there were calls for a narrower definition of innovation as an authorised purpose to ensure safe and ethical use of data by commercial entities.

In addition to the fines foreseen for data holders who fail to make data in the mandatory categories available, introducing and communicating about financial penalties for data users who fall short of their data protection obligations or who misuse the data to which they are granted access would strengthen EHDS governance and trust in the system.

At the same time, attention should be paid to how the risks and responsibilities, especially those related to data protection, can be adequately shared among the stakeholders involved in implementation, for example to relieve data protection officers from ensuring compliance.

At European level

Minimise legal uncertainty surrounding secondary use under the EHDS by ensuring precise definitions, that are consistent with other EU regulations, especially definitions of health data for secondary use

Clarify how data should be securely collected at primary, secondary and tertiary levels of healthcare services

Minimise the risk of exploitation, intended or not, of secondary use of health data by providing a more specific definition of health data, as well as evidence-based definitions of the expected benefits for citizens and society

Foresee safeguards to avoid non-legitimate use of health data for commercial purposes through oversight and control mechanisms

Analogously to the fines for non-compliant data holders, consider introducing financial penalties for negligence or misconduct by data users

Protection of intellectual property

For various stakeholder groups, including the pharmaceutical and medtech industries, the academic research community, and healthcare institutions themselves, which hold assets related to the data they store and manage, the protection of intellectual property rights is a key concern. The solutions identified require specific provisions to prevent the creation of perverse incentives in the process of implementing the EHDS, and to protect the European research ecosystem from becoming vulnerable to unfair competition from extra-European or ill-intentioned actors.

Meanwhile, industry is advocating for clear definitions of which datasets will need to be shared, who will be required to do so, and who will be eligible to gain access. For example, there are calls for only data from completed clinical trials to be subject to the obligation to share, with trial sponsors retaining a right to first access to prevent the market distortions that would arise if companies were to find themselves having to disclose commercially sensitive data from their development pipeline to competitors. This is deemed legitimate by some non-industry stakeholders, who see a risk of bias being introduced into studies through hyper-selection of patients if results are required to be made public before the corresponding product is commercialised. The impact of such a mandate could be particularly stark for the medtech sector, where innovation is driven by SMEs which need to attract investors to bring their solutions to market.

At European level

Clearly identify the data categories for the data holders that will be subject to data-sharing, as well as the authorised users, purposes and modalities for access to data

Agree at EU level on a protected interval of time during which research and other entities retain exclusive access to health data they have collected and processed, in alignment with existing rules for data protection and intellectual property (for example, as seen in the EU Clinical Trials Regulation)

Plan an evaluation study to assess the impact of the regulation on the research and innovation ecosystems

A viable opt-out/ opt-in mechanism

The European Commission's original proposal for the EHDS regulation provided for data processing for secondary use purposes with no opt-in or opt-out mechanism. In the negotiations within the European Parliament and the Council of the European Union, as well as on various occasions during the course of the EIT Health roundtable series on the EHDS, different voices have advocated for additionally introducing an opt-in or opt-out mechanism for citizens to participate in—or oppose—the reuse of their data. While some have highlighted that requiring individuals to explicitly agree to sharing their data for secondary use would guarantee low participation and thus undermine the representativity and usability of the data included in the EHDS, others have also raised concerns about the practical feasibility of an opt-out variant and its potential to lead to biased data collections if certain demographic groups withdraw their data from the system *en masse*.

The consensus that emerged from the stakeholder discussions hosted by EIT Health is that, whatever opt-out/opt-in mechanism is ultimately adopted, it will have to be designed in such a way as to: a) avoid burdening citizens and healthcare professionals with repeated opt-out/opt-in forms and administrative work, b) give citizens some control over what data is shared, through mechanisms and tools that are equally usable by people with no internet access or low digital literacy, c) allow the accumulation of historical data that is essential to the development and improvement of data-driven health solutions, and d) be broad enough to permit the use of non-medical, but health-relevant data for secondary purposes.

At European level

Agree on an opt-out/opt-in model that balances the interests of data users with practical feasibility for data producers, (for example by allowing accumulation of historical data while minimising administrative burden,) which is broad enough to include both health and relevant health-related secondary use of data, and which is easy to use and understand by patients and citizens of all levels of digital health literacy

Multistakeholder and international collaboration on a harmonised implementation

In Ireland, Spain and Sweden alike, there were calls for a whole-of-government approach to implementing the national governance framework for the EHDS, including collaboration between relevant national ministries and involving other state and regional authorities as necessary to ensure that organisational, financial, but also ethical and privacy aspects are adequately addressed from the outset. In particular, some wanted to see European and national ethics committees networked in to ensure that all secondary uses of data under the EHDS are subject to the ethical oversight that exists in research. In Germany, the role of external stakeholders in supporting government actions with technical and operational expertise was also highlighted as an important means of ensuring that decisions are founded in reality and made in the best interest of people working on the ground. In particular, existing initiatives and infrastructures for health data should be mapped and brought on board from the earliest planning stages to ensure their efficient integration. Austrian and Swedish experts additionally wished to see comprehensive investigation and timely initiation of the legislative changes required to align national regulatory environments with the new European framework.

Patients were identified in various Member States as a potential driving force for implementation in that their perspectives can often help to overcome reluctance and risk-aversion within public bodies. This makes their presence on the EHDS Board and other governance bodies all the more vital. Given a seat at the table alongside healthcare, academic and industry representatives, they can help to design viable national governance frameworks that are fit for purpose and founded on the respect of human rights and human dignity.

Providing patients, and citizens at large, with digital tools to manage their health and health data and (depending on the adopted opt-out/opt-in model) dynamically grant, withdraw and trace access by third parties will also be essential to empowering them as fully-fledged participants in data governance.

From the national to the European arena, a number of tasks incumbent on the Member States in the implementation process, such as the development of data and metadata catalogues and the quality labelling of available datasets within them, would benefit significantly from concerted approaches by all countries to facilitate data discovery and ensure the practical usability of the EHDS. The same is true of the application processes for data access, which should be harmonised to a sufficient extent—for example, through the use of common electronic application forms—to support the mutual recognition of health data access bodies and the permitting decisions they make. Cross-border sharing of best practices surrounding the functioning of ethics and research committees would also be desirable to establish robust ethical oversight of secondary use within the EHDS. Common rules, principles and transparency requirements for setting the fees for data access would equally help to ensure a clear understanding of the system and avoid the negative user experiences that could arise if significant fragmentation in national approaches emerged in this area. For example, while there have been calls to establish distinct models of governance, procedures for data access, and differentiated fees for public versus private sector data users, or for policymaking versus research purposes, there is currently no consensus on these matters and different countries could well take diverging paths.

Going further still, open dialogue in the implementation process between the EU and other countries with which it has strong political and especially research ties, would ensure the EHDS does not isolate itself from the rest of the world in a context where international collaboration is becoming increasingly important in medical research and work is already ongoing to define international data standards in this area. For example, the target architecture of the planned Swiss Health Data Space will adopt, among other things, the approach of a once-only principle whereby the data generated by the primary systems no longer have to be edited manually, but can be exchanged automatically, allowing seamless system interfaces. Collaboration on a common data model, common data structures, and standardised semantics across Europe could both support such local initiatives and contribute to a broader effort towards interoperable and data-driven healthcare delivery across Europe, not just the EU.

At European level

Establish clear and well-defined governance rules for data collection and secondary use, including for policymaking, research, or commercial use, with a focus on the benefits for patients and citizens

Ensure meaningful patient and civil society advice and representation in EU-level data governance bodies

Establish EU-level mechanisms for harmonised interpretation and implementation of the EHDS at national level

Foster harmonised implementation through collaboration and mutual recognition of national health data access bodies and EU-level oversight by the EHDS Board

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Establish the model to be applied for data access and define where the actual fees can be obtained in an open and transparent manner, before requesting access to data

Ensure effective collaboration between key EU bodies and departments to be involved in the implementation process

Foster collaboration on defining common data standards also with non-EU countries interested in achieving interoperability of their national data infrastructures with the EHDS

At national and regional levels

Ensure multistakeholder and cross-government collaboration, including involvement of regional lawmakers, hospital managers, in developing a national framework for EHDS governance, processes and systems

Plan a fair distribution of resources for implementing the EDHS at the national level, considering the needs of regional actors who will incur large costs

Mandate governance bodies to implement data quality, interoperability and cataloguing, in a consistent way with existing EU regulations

Launch and collaborate in multi-country multistakeholder and cross-regional collaboration projects for sharing and secondary use of health data

Establish a transparent system of ethical oversight for all secondary use applications, networking in and supporting existing ethics committees as needed

Engage patients and healthcare professionals at all levels including in pilot projects and local governance structures

Provide citizens clear communication, transparency and control over who can access different categories of data within their health records, taking into account varying levels of digital and health literacy and openly addressing both the risks and benefits of the EHDS

Foster transparency and trust in health data access bodies

A public consultation of 6,000 EU citizens by the joint action TEHDAS about the secondary use of their medical data for research and policymaking has shown, consistent with the results of other national and international surveys, that citizens are generally open to sharing their personal data on the condition that this is done in a manner that is transparent, secure and aligned with their ethical values. Therefore, a consensus emerged around the fact that the success of the EHDS also hinges on public trust in the model of data governance it will establish and in the health data access bodies' ability to ensure appropriate secondary use. The choice in particular of entity or entities that will assume the roles and tasks of national health data access bodies, and their staffing with trustworthy, socially motivated individuals, will be key in creating a strong basis for this trust from the outset. Subsequent steps to build confidence and cultivate buy-in from all stakeholders will include developing user-friendly tools—access request portals, information portals—enabling interaction with the EHDS through its access bodies and facilitating transparent and regular communication about which datasets are used in practice, by whom, for which purposes and, ideally, with what results. The ability to issue decisions and resolve disputes arising from data requests in a timely manner will also be decisive in cementing stakeholders' trust in the ethics of data-sharing practices.

At European level

Award governance responsibilities for the EHDS to trusted institutions and people with a strong track record in public service

Prioritise the development of user-friendly tools for interacting with the EHDS and facilitating transparent communication about its use in practice

CHAPTER 2

Capacity and skills

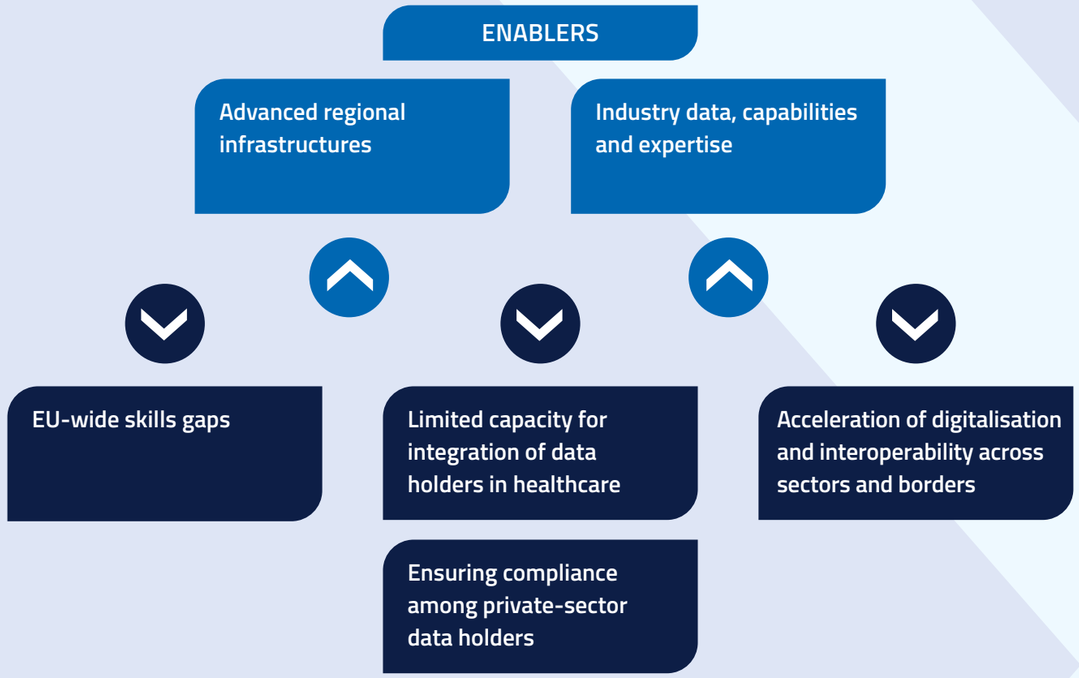
> Hardware becomes obsolete within a few years, knowledge does not
>
> Carlos Tellería, Instituto Aragonés de la Salud, Spain

Summary

Main findings

- Digitalisation in national health systems varies significantly between countries and areas of healthcare provision, with risks of bias and exclusion of certain populations from EHDS data
- Even in the most digitally mature countries, data systems in healthcare remain highly fragmented and infrastructures to connect them are scarce
- Data-sharing initiatives exist at EU, national, as well as regional levels which can serve as a basis for integration with the EHDS and inform the design of its infrastructure
- Industry will be a driving force for implementation as unprecedented access to data for innovation, especially for SMEs, and the release of new datasets into the public domain can accelerate health research across the EU

Challenges and enablers of implementation



Key findings, actors and solutions for implementation

Build a functioning EHDS infrastructure and support capacity-building

At European level

Support the development of scalable technical solutions for the EHDS based on international standards

Enable a smooth connection of EHRs with health data access bodies and Healthdata@EU infrastructure

Design an integration path for the already existing European health data sharing initiatives (DARWIN, EUCAIM, GDI, etc.)

At national and regional levels

Accelerate the rollout of interoperable EHRs where necessary, promoting the adoption of minimal EHR requirements to enable a smooth connection with national health data access bodies and aligning technical language changes in new and existing systems across the EU

Ensure modernisation of data infrastructures in healthcare to improve interoperability and connectivity between health institutions and with health data access bodies

Enable collaboration between the digital/IT industry and EHDS stakeholders to accelerate necessary upgrades to data infrastructure

Health data access bodies

Enable and support informational technology / open source providers to develop transnational IT infrastructure and tools for the EHDS including information portals and user-friendly access request interfaces

Build capacity to support data holders with data cataloguing, extraction and handling, data counselling/advice on data quality and accessibility, including good practice sharing between countries and regions

Health institutions

Build the right capacity for data gathering in healthcare workflows, automating primary data collection and improvement processes as much as possible with technological solutions

Digital health and medical devices industry

Develop health information systems around the principle of entering data only once, with more user-friendly interfaces that allow a holistic view of the patient and user-friendly access for patients

Support the creation of data storage and processing environments with strong cybersecurity

Enable data users to interact competently with the EHDS

At European, national and regional levels

Draw on the experience and expertise from fields like epidemiology, genetics and radiology regarding proper use of large datasets and design an integration path for the data already available in these specialities

Health data access bodies

Develop information material on the possibilities for secondary use, including scenario-based data access guidance for users and ethics committees, as well as supporting documentation and training for data permit applications

Build capacity to assess complex data requests and the heightened security and privacy risks they pose

Establish a support function to guide data users through the application and use process

In addition to the public health data catalogue, develop a public catalogue of secondary use projects to enable cross-border synergies and collaborations at scale

Bridge the skills gaps

At European, national and regional levels

Invest and build capacity to reduce the digital divide and related barriers that limit equitable access to digital infrastructures and participation within and between EU Member States

Support universities and leverage available training offers and reskilling initiatives at EU and national level, including existing career change and professional development pathways within health systems, to develop and source the technical skillsets needed

Develop educational materials and programmes to strengthen health data literacy among patients and citizens

Healthcare providers

Upskill current staff and develop career pathways promoting skills acquisition and development for data management and data science

Cooperate with health professional organisations, associations and medical scientific societies and form coalitions to develop capacity and skills for the EHDS and lead change in professional communities

Higher education providers

Develop micro-credential courses to train data holders in the health domain on the requirements of EHDS, the local/regional implementation choices, health data access bodies and the procedures and technical frameworks implemented in each Member State

Train researchers in the same stringent data security principles as healthcare professionals

Integrate training in digital health and digital literacy, including a solid understanding of the EHDS and health data, in medical schools and other faculties concerned by the changes: e.g. public health, engineering, pharmacy, health sciences

Develop education on new business models related to data spaces in general, and health data spaces more specifically

Develop curricula to train specialised new profiles such as health data scientists, healthcare data specialists, health data managers, etc.

Develop upskilling and reskilling offers beyond universities, for example in the form of continuous professional development courses

Implementing the European Health Data Space Across Europe
Chapter 2 | Capacity and skills

Current national landscapes

National experiences with health data collection and use vary widely across Europe.

In Ireland, paper records are still the norm as only five out of 47 public hospitals have implemented their own electronic medical records and digital maturity is similarly low among private providers. Where electronic data does exist, for example in pharmacies, labs and primary care clinics, systems are not interoperable. A notable exception is the National Integrated Medical Imaging System, which as of January 2022 connected 77 hospitals and imaging centres with almost 3,000 GP practices for the secure electronic sharing of diagnostic images. The low overall digital footprint of health system actors means that even basic public health data, such as the prevalence of chronic diseases like diabetes in the Irish population, is not currently available. Capacity-building for digital data collection and sharing has begun in recent years, with successes including the rollout to almost the entire population of an Individual Health Identifier allowing the linking of medical records from different systems, as well as electronic exchange of prescriptions and patient discharge summaries from hospitals to primary care settings. In the field of secondary use, despite the existence of almost 130 national health data collections ranging from disease registries to clinical care audits and national screening programmes, limited infrastructure exists to facilitate access by research entities and public health actors. The lack of infrastructure for clinical research also significantly limits the number of clinical trials involving Irish patients.

By contrast, healthcare systems in France, Spain and Sweden have reached a high level of digital maturity and extensive experience with the secondary use of health data has been acquired either through well-established national registries, which in Sweden are mandatory by law, or through other data-sharing initiatives like the Spanish Biobank Network linking 39 individual biobanks. In terms of technical capacity, these countries have a head start in the implementation process as much of the data infrastructure required for the EHDS is either already available or under development. In Spain, for instance, several Autonomous Regions have built data lakes making the health data of all their residents accessible for public health and research purposes, and public research infrastructure such as the Barcelona Supercomputing Centre or the University of Zaragoza's Institute for Biocomputation and Physics of Complex Systems (BIFI) provide a robust basis to support secondary use projects. In France, a unified electronic health record has been implemented since 2022 and the national SNDS database is one of a kind in Europe, linking information from France's statutory and complementary health insurance providers, hospital data, as well as medical cause of death and disability registers for secondary research and public health applications. With respect to the institutional capacity and skillsets that will be required at all levels of the system to facilitate data curation, extraction, processing, transfer and use, however, experts in all three countries cautioned that existing gaps and the difficulty of filling them should not be underestimated. Of note, France has recently taken action in this area and enshrined in law the principle of "training allowing the acquisition of basic skills in digital health" as part of the foundational training of students in the health professions from the start of the 2024 academic year. This training covers the areas of health data, health cybersecurity, health communication, digital health tools and telehealth.

In various national configurations situated between these two ends of the spectrum, health data landscapes tend to be characterised by highly fragmented digital systems in countries such as Austria, Belgium, Germany, Italy, Luxembourg, the Netherlands or Portugal. System-wide lack of interoperability creates challenges for the effective sharing and use of data, such as in the Netherlands, where collaboration between healthcare providers and academic institutions remains underdeveloped, or in Italy, where efforts such as the development of a national platform for telemedicine are undermined by heterogeneous local platforms in Italy's regions. Portugal, which has been a leader in the implementation of the primary use MyHealth@EU platform, already collects 25 types of health data through public institutions but faces challenges gaining visibility and access to data generated in its private healthcare sector. Similarly, Austria's pioneering national EHR, ELGA, has facilitated data-sharing for primary use and successfully integrated the near totality of patients, with less than 3% of people having opted out of the system. However, in its current form, its data would be difficult to use for secondary purposes, while the networking of other publicly held datasets across the country is hampered by shortcomings in cooperation between the federal provinces and the state. In Luxembourg, modern upgrades to existing health information systems are needed but the impending adoption of the EHDS has made decision-makers hesitant to commit to large investments in IT solutions that may need to be subsequently adapted. Germany is also reportedly still missing the necessary infrastructure and tools to allow data collection and sharing for both primary and secondary use.

However, various initiatives developed by healthcare, research or government actors exist across these countries and regions and at EU level, which are performing invaluable legal, technical and conceptual work that could inform national implementation approaches on a larger scale. They include the Dutch ICUdata Warehouse and the Health-RI integrated health data infrastructure in the Netherlands, the Health Big Data (HBD) project aimed at connecting data from different sources in Italy, and the Austrian Micro Data Centre, established to make data from various national registries and official statistics available for research. At EU level, the European Cancer Imaging Initiative, which aims to promote innovation and the rollout of digital technologies in the treatment of cancer, is seen as an important pillar for the future EHDS.

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Common challenges and potential solutions

Disparities in capacity and preparedness levels

The picture that emerged from the national roundtable discussions is one of great heterogeneity in the digitalisation and data connectivity achieved within Europe's individual health systems. The work and investment needed to bring all Member States to the required level for full implementation of the EHDS are massive, leading various stakeholders to predict that the process will take several years. A risk in this context is that the different conditions for accessing data that prevail across the EU, both in terms of the time required and the quality of the data available, will prompt data users to favour certain countries over others and result in competition and inequalities in the individual Member States' ability to utilise and benefit from the EHDS. Helping the countries lagging behind to accelerate the digital transformation of their healthcare systems will be essential to allow all European citizens to become active participants and beneficiaries of the EHDS.

At European and national levels

Invest and build capacity to reduce the digital divide and related barriers that limit equitable access to digital infrastructures and participation within and between Member States

Consider building transnational infrastructure to enable sharing infrastructure between countries with different levels of digital maturity

Skills shortage

The availability of skilled professionals in sufficient numbers to operate the EHDS at all levels, from governance bodies, through data holders, all the way to research and public health institutions, is expected to be a challenge in most countries. With competition for profiles like data scientists or experts in biomedicine already fierce today, the prospects for healthcare institutions and state agencies to be able to attract and retain them within their current budgetary constraints are poor. At European level, this skills shortage disproportionately affects countries such as Portugal, where uncompetitive salary offers in both the public and private sectors limit the potential to attract and keep highly specialised talent in local employment.

At European, national and regional levels

Support universities and leverage available training offers and reskilling initiatives at EU and national level, including existing career change and professional development pathways within health systems, to develop and source the technical skillsets needed

Invest in comprehensive resource training programmes with a long-term commitment, recognising the time required to yield meaningful outcomes and ensure a sustainable pipeline of skilled talent

Assuming the responsibilities of a data holder

DATA EXTRACTION IN HEALTHCARE

Although technology is constantly evolving, the possibility to automate data transfers to a secure processing environment currently still requires data experts to "flip the switch" and set up the processes for what data to make available for each request. Even though the EHDS will give health data access bodies the right to process data to make it usable for secondary purposes, data holders will nonetheless need to publicly document what data they can make available and then turn on that switch once an access request is made. While highly structured registry data stored in centralised warehouses is relatively easy to access, this is not the case for the raw data contained in EHRs and EMRs. Healthcare providers will therefore need to hire dedicated staff to satisfy access requests, especially experts capable of retrieving data from their systems. Irrespective of the degree of digital and data maturity in the represented countries, the capacity and preparedness of data holders in the healthcare sector were a cause for concern as only the largest hospitals currently tend to have dedicated data management teams and none have allocated budgets for the types of tasks that will be required of them under the EHDS. This challenge is expected to be further compounded by the fact that the skillset required is not only scarce, but also takes years to develop as it extends beyond programming alone to in-depth understanding of international, national and regional medical informatics, familiarity with the relevant organisational structures, and knowledge of how data is recorded in the different modules of an EMR system.

At national and regional levels

Support technical-legal approaches and standard-setting to enable automatic transfer of EHR data from primary to secondary use systems and smooth integration with national health data access bodies

Extend support to healthcare providers for achieving swift implementation while minimising risks to patient care and data security

Health data access bodies

Build capacity to support data holders with data cataloguing, extraction and handling, data counselling/advice on data quality and accessibility, including good practice sharing between countries and regions

Health care institutions

Recruit and train additional data management experts, pooling resources and competences where possible

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MAKING NEW CATEGORIES OF PRIVATE SECTOR DATA REUSABLE

Private sector actors who conduct health research are accustomed to the processes involved to fulfil their legal obligations under the Clinical Trials Regulation to publish clinical trial data, but many companies also collect other categories of data that fall within the scope of the EHDS proposal and which they have not routinely shared in the past. According to industry representatives, there will be practical challenges to overcome as companies assume their new role as data holders, which will include curating these additional datasets and making them reusable for third parties while maintaining the highest levels of data privacy and protection. The changes will also require a cultural shift towards data transparency and participation in a trustful system of data exchange and collaboration.

At national level, higher education providers

Develop micro-credential courses to train data holders in the health domain on the requirements of EHDS, the local/regional implementation choices, health data access bodies and the procedures and technical frameworks implemented in each Member State

Develop upskilling and reskilling offers beyond universities, for example in the form of continuous professional development courses

Enablers and opportunities

Best practices from Europe's regions

While EU Member States, with some notable exceptions like Finland or Estonia, are generally in the early stages of their journey towards nationwide health data interoperability and accessibility, Europe's regions have in various instances benefited from their smaller scale to implement platforms for standardised collection, aggregated storage and secondary use of their residents' health data. The technical characteristics and lived experiences of these different initiatives can, and should serve to identify best practices and solutions for implementing the EHDS at national and European level. In addition to the specific examples listed below, more examples can be found in dedicated collections such as the recent booklet from EUREGHA – European Regional and Local Health Authorities, gathering 13 regional practices including health data strategies, health data use and collection initiatives, and more (EUREGHA, 2023).

THE BIGAN PLATFORM

In Spain's Autonomous Region of Aragón, the regional health authority has over the last seven years been able to build a data lake with the health data of its 1.3 million residents. The development of the BIGAN platform, which is managed by the Instituto Aragonés de Ciencias de la Salud (IACS), was largely facilitated by the introduction of a single health identifier for each citizen in Aragón, as well as by a 15-year process of connecting and integrating the information systems within the public health service. Information from hospitalisations, emergency room visits, primary care, laboratory tests, radiology and medical imaging, drug prescriptions, and more, across the entire territory, can now be accessed upon application for research, public health planning and quality management purposes. The platform supports about 50 research projects each year, and its experience has been studied by the Joint Action TEHDAS (Jendrossek, Xayakhom-Dauvergne, & Zidi, 2022) and allowed the development of recommendations on how to build and manage a federated data lake for Europe.

THE STOCKHOLM CENTRE FOR HEALTH DATA

The Stockholm Centre for Health Data is a collaborative organisation within Region Stockholm designed as a hub for researchers who require access to health data, which could provide a template for managing data access through a single point of contact as foreseen by the EHDS. The department performs a service role for researchers by ensuring they do not have to refer to multiple healthcare providers to gain access to data, providing advice on data availability and quality as well as help with linking data from different sources. For healthcare providers, it offers a one-stop shop with professional, coordinated assessment of the type of data to be shared, and how this should be carried out in accordance with national confidentiality and data legislation. It conducts extensive confidentiality examinations before each release of data to ensure the recipient has the ability to guarantee the privacy and security of the data they obtain. Also included in the centre's role as intermediary is helping researchers ensure their applications are complete with a clear research assignment and ethical approval for their project from the Ethical Review Authority, sending these to the relevant data holders, and coordinating any requests for additional filings. The data available covers all healthcare provided to the region's residents, with data sources including a regional patient registry, EHRs, lab systems, radiological imaging, and others.

INTERREGIONAL COLLABORATION

In addition to driving data-sharing at the local level, Europe's regions also have a rich history of cross-border collaboration which could be learned from and utilised on the way to creating a pan-European network of health data access bodies and large-scale secondary use projects. Launched specifically to inform the implementation of the EHDS, the European Data Space in Health (EDAH) project, for example, brings together regional, national and supranational innovation networks including the Council of European Bioregions. The consortium partners are collaborating to build a coherent overview of ongoing processes and projects related to the EHDS, deepen the collective understanding of Europe's ecosystems through seven case studies, foster cross-border dialogue between important stakeholders, and develop a joint action plan to advance implementation.

Considering that these interregional collaborations also frequently include non-European partners, as is the case within EUREGHA, the reference network for European Regional and Local Health Authorities, there is also an opportunity on this level to explore the possible interactions of non-EU actors with the EHDS. In this setting, it will be important both to guarantee observance of EHDS rules in projects involving third-country members, and to ensure the introduction of the framework does not endanger existing partnerships and possibilities for future collaborations.

The medical research industry

For industry involved in health research, including the pharmaceutical, clinical research, biotech, medtech, and digital sectors, the EHDS holds the promise of unprecedented access to new types of data, as commercial entities are currently excluded from initiatives to make publicly held data available for research in many countries. The possibilities for accelerating research in the private sector will range from more effective and efficient identification of patients for enrolment in clinical trials, improved development of healthcare products and medicines through complementary trial-based and real-world research, innovation through digital technology and advanced computing methods such as artificial intelligence (AI), all the way to better data for market approval and reimbursement decisions. As future data users within the EHDS, these stakeholders were therefore identified as important potential enablers of implementation, bringing to the table expertise in health data management, technical know-how, and financial capabilities for the development of data infrastructures for secondary use.

Europe's life sciences industry, in turn, generates a wealth of digital data that could more readily be opened up to secondary use through the EHDS. The data collections here are diverse, from clinical trials for regulatory approval, genetic data from diagnostics, through device and patient-generated data from the routine use of health technologies, all the way to post-market surveillance data on adverse events. Novel types of datasets are also emerging in the medtech sector as companies move to embed sensor technology into traditional medical devices to gather clinical data such as blood pressure and optimise the management of cardiovascular disease. Other data-gathering applications already in use include fall detectors, and remote monitoring technologies such as devices for measuring blood glucose at home. The EHDS regulation will create new possibilities to measure and compare real-world outcomes from different interventions, as well as improve prediction and prevention models.

Equitable access to data for research and innovation

While some large European countries and multinational industry players with existing capabilities for secondary data use are looking to the EHDS to expand the range of research and decision-making tools already available to them, truly transformative benefits are expected by many smaller Member States and entities from having a single access point to unprecedented quantities of data. Through better means of patient identification, citizens of small countries like Ireland could see more opportunities to access clinical trials. Anticipation is equally high that novel research methods powered by real-world data could lead to breakthroughs in rare diseases, where traditional clinical trials are often not feasible. SMEs in the field of digital health, whose data needs are particularly extensive and who currently rely heavily on non-European sources, could improve healthcare, wellness and prevention for EU citizens using representative data from European patients. An EHDS that guarantees equitable access for data users could thus be a unique chance to level the playing field for all actors of the innovation ecosystem and help transformative health and healthcare solutions reach more people, faster.

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Priorities for implementation

Involve stakeholders and build on existing initiatives to develop capacity, skills and infrastructure for a functioning EHDS

The infrastructure needed to implement the EHDS is not something that can easily be bought off the shelf. Those who design the systems and processes at both European and national levels will need to have a comprehensive understanding of different stakeholders' infrastructure, capacity and skills needs, including those of the IT industry, which will be called on to deliver solutions that do not exist today, to ensure the end result is compatible with the realities on the ground. For decision-makers, technical experts, health economists, that will require communication and close collaboration to understand their complexity and the capacities of existing personnel. Designing solutions collaboratively for concrete use cases can ensure that the infrastructures developed meet the needs of their future users on the one hand, and on the other that data holders have a clear rationale for and understanding of how to implement the EHDS. This collaboration will also need to happen on an international level to allow the deployment of scalable solutions based on common standards.

At the same time, the technical implementation should build as much as possible on existing structures and initiatives, some of which have been presented in this chapter, and which have been developed in many European regions and countries, often with the support of EU funding such as the Recovery and Resilience Facility. Previous investments and existing capabilities in digital and health data, including ongoing EU initiatives, should not just be integrated, but serve to inform the design and scaling of interoperable infrastructures to maximise the efficiency of capacity-building for the future EHDS. For example, EU initiatives like the Pact for Skills and the larger partnerships established for healthcare professionals (BeWell Partnership) and for the healthcare industry workforce (The European Partnership for Healthcare industry), as well as the close collaboration established between medical industry, academia, researchers and healthcare providers, are enabling a pan-European, coordinated way for upskilling and reskilling the workforce for the EHDS implementation.

At European, national and regional levels

Draw on the experience and expertise from fields like epidemiology, genetics, and radiology regarding proper use of large datasets and design an integration path for the data already available in these specialities

Support the development of scalable technical solutions for the EHDS based on international standards

Enable a smooth connection of EHRs with health data access bodies and HealthData@EU infrastructure

Design an integration path for the already existing European health data sharing initiatives (DARWIN, EUCAIM, GDI, etc.)

Enable collaboration between the digital/IT industry and EHDS stakeholders to accelerate necessary upgrades to data infrastructure

Healthcare institutions

Support participation in data-sharing and skillsets platforms to explore tangible benefits, experiment with feasible models and workflows

Build capacity within health data access bodies

The EHDS proposed regulation foresees for health data access bodies a long list of responsibilities, from the publication and maintenance of a dataset catalogue, through the development of an infrastructure and procedures through which to channel and assess data permit applications, data processing, and delivery within secure processing environments, all the way to the creation of public tools and interfaces for guidance and information. The multitude of new data sources that will become available through the EHDS will also increase the complexity of data requests, which will accordingly need to be assessed with particular care to mitigate privacy and security risks. At scale, this will represent a significant workload for health data access bodies, which will need to resource the process with skilled staff versed in both the legal and technical dimensions of permit attribution.

Existing experiences in centralising access to health data for secondary use, such as the Stockholm Centre for Health Data in Sweden, have additionally shown that the time to access data, from the time an application is submitted to the actual delivery of the requested datasets to the user could require more than half a year. Capacities will thus need to be dedicated within health data access bodies to processing applications within a shorter time frame.

Health data access bodies

Enable and support informational technology / open source providers to develop transnational IT infrastructure and tools for the EHDS including information portals and user-friendly access request interfaces

Build capacity to assess complex data requests and the heightened security and privacy risks they pose

Leverage experiences from existing secondary use infrastructures to inform capacity-building and skills acquisition

Dedicate capacity to reducing the time to access data

Increase capacity for data collection, management and use in healthcare

As healthcare is expected to be increasingly delivered outside of hospitals in the community and home settings in the future, growing volumes of data will flow into the EHDS from primary care and nursing centres, pharmacies, as well as connected devices. Support will be needed to help the relevant data holders develop both the technical capabilities and the necessary competence in areas such as data security, privacy, ethics, and standardised collection to comply with their obligations. Flexible learning models based on micro-credential courses within academic institutions could be made available to facilitate this technical upskilling for data collection and management. Furthermore, building on existing European initiatives, like the EIT Health Education programmes, will be crucial to

strengthen the health data skills of all healthcare stakeholders. Existing programmes such as AI ProHealth and Certified Innovation Pathway in Health data could serve as a basis for further use and development.

Additionally, improving the interoperability of data systems in healthcare will be a critical task for all countries including the most digitally advanced, such as France and Spain, where numerous data silos continue to exist even within individual institutions and the multitude of different actors involved in managing data simultaneously further add to the complexity and fragmentation.

At national and regional levels

Accelerate the rollout of interoperable EHRs where necessary, promoting the adoption of minimal EHR requirements to enable a smooth connection with national health data access bodies and aligning technical language changes in new and existing systems across the EU

Ensure modernisation of data infrastructures in healthcare to improve interoperability and connectivity between health institutions and with health data access bodies

Healthcare institutions

Build the right capacity for data gathering in healthcare workflows, automating primary data collection and improvement processes as much as possible with technological solutions

Establish monitoring units for EHDS implementation to prevent new data collection and processing tasks from increasing the administrative burden on medical staff and negatively affecting healthcare provision

The digital health and medical devices industry

Develop health information tools around the principle of entering data only once, with more user-friendly interfaces that allow a holistic view of the patient and user-friendly access for patients

Support and train data users

Common gaps and errors in applications to existing organisations for data access such as the Stockholm Centre for Health Data range from a lack of clear descriptions of what health data are required, through missing information on how researchers will protect the data after they have received it, all the way to asking for data that is not available or not covered by their ethical approval. A lot of time and effort is subsequently spent by staff to follow up with applicants and make the required changes. Within the EHDS, this issue will likely be compounded by the expansion of data users to other profiles than just researchers, creating a need for targeted support and educational measures to ensure all

data users have the necessary competence to prepare valid requests, navigate the application process and handle data appropriately. Indeed, having to process data in secure environments that are completely segregated from their own data spaces, without any download possibilities, will represent a new way of working for many users. Guidance will also be essential to ensure scientifically sound use of datasets across borders, by researchers who may be unfamiliar with the characteristics of foreign databases and, importantly, with the healthcare context in which the data was collected.

Short-term training will additionally be required to enable researchers and healthcare professionals to interface competently with data specialists based on a deep scientific and ethical understanding of how to use different types of health data—including new data streams such as patient-reported outcomes measures (PROMs)—and how to interpret results obtained outside of traditional clinical trials. This will require efforts to familiarise and better integrate the distinct cultural worlds of healthcare and data analytics with one another. In particular, multimodality research using a variety of data types and leveraging machine learning technologies currently remains the purview of a select few research units, despite representing one of the most promising avenues for data-driven innovation through the EHDS. Data users must be able to evaluate and use these technologies, and to proactively address the ethical issues associated with their deployment.

Health data access bodies

Develop information material on the possibilities for secondary use, including scenario-based data access guidance for users and ethics committees, as well as supporting documentation and training for data permit applications

Establish a support function to guide data users through the application and use process

Healthcare institutions

Upskill current staff and develop career pathways promoting skills acquisition for data management and data science

Cooperate with health professional organisations, associations and medical scientific societies and form coalitions to develop capacity and skills for the EHDS and lead change in professional communities

Higher education providers

Train researchers in the same stringent data security principles as healthcare professionals

Develop data proficiency, including knowledge in the appropriate use of different types of datasets for research, and skills in advanced data analytics among academics

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A stepwise approach to implementation

Given the complexity of secondary use, stakeholders from various sectors and countries are urging for a transitional period and phased implementation, that builds on the primary use infrastructure, MyHealth@EU, to gradually build capacity for secure, compliant data collection, standardisation and reuse within HealthData@EU. More digitally mature Member States with established secondary data use infrastructures can help accelerate this process in other countries by sharing best practices, but the consensus is that, especially in the healthcare sector, connecting to the secondary use ecosystem must be done safely and correctly and therefore will take time. Indeed, exponentially adding value to the data produced within healthcare will make this data all the more desirable for ill-intentioned actors. A possible approach would therefore be to define a limited number of key datasets that data holders will need to prepare for release into the public domain in the first step of implementation. However, a phased integration of data should not be taken as a pretext to delay implementation, as there is wide recognition of the time-critical element to ensuring that global health research and innovation moves forward with EU data, rather than just that of countries with an established culture of data use, such as the US or China.

At European level

Allow a phased approach to data integration for data holders, to enable stepwise compliance over a clearly defined period before reaching full compliance

Digital health and medical devices industry

Support the creation of data storage and processing environments with strong cybersecurity

Fill skills gaps and anticipate future needs

In the medium term, modules on eHealth, digital and data literacy, the functioning of the EHDS and its practical implications for different actors within the health system will need to be introduced consistently in medical, engineering and other relevant university curricula. New qualifications will also need to be developed, especially interdisciplinary profiles capable of interfacing between disciplines such as medicine, nursing, IT, data analytics, data ethics, law, and social science. These should be complemented by investments in lifelong learning, including permanent upskilling and reskilling initiatives in various sectors from healthcare to data technology for health research. The EIT's ongoing Deep Tech Talent Initiative to skill 1 million deep tech talents in support of the New European Innovation Agenda can serve as an important enabler in this area. Since December 2023, EIT Health is the coordinator of the Skills Partnership for the European Health Industry, and in doing so, will collaborate closely with members from health and digital industry, academia and with EU and national and regional authorities to bring about positive changes and boost skills development in the in the medical devices, digital health, pharmaceutical and biomanufacturing industries. The Partnership will respond to the present and future needs and challenges faced by the health industry workforce and establish a shared strategic model for skills development in Europe.

Lastly, there are health data literacy gaps to be addressed, to enable citizens to engage with their health data and empower them to contribute actively to its collection and sharing within the EHDS.

At European level

Develop educational materials and programmes to strengthen health data literacy among patients and citizens

Health data access bodies

In addition to the public health data catalogue, develop a public catalogue of secondary use projects to enable cross-border synergies and collaborations at scale

Higher education providers

Integrate training in digital health and digital literacy, including a solid understanding of the EHDS and health data, in medical schools and other faculties concerned by the changes: e.g. public health, engineering, pharmacy, health sciences

Develop education on new business models related to data spaces in general, and health data spaces more specifically

Develop curricula to train specialised new profiles such as health data scientists and healthcare data specialists and health data managers, etc.

CHAPTER 3

Resources and funding

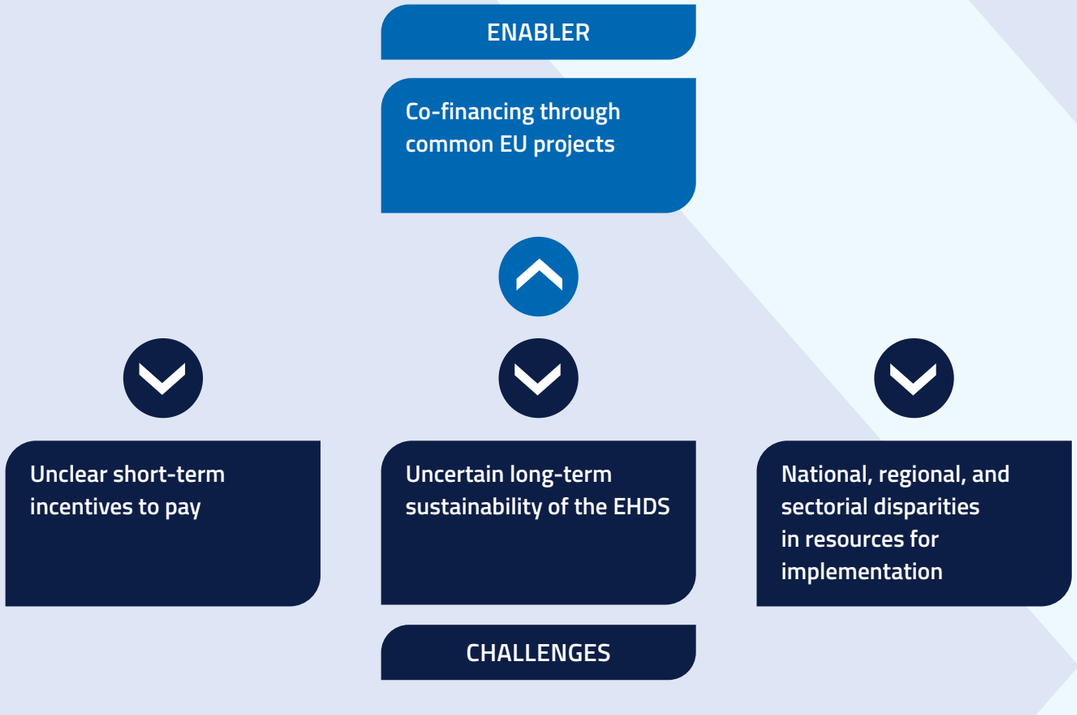
> We must provide the EHDS with a budget to match the ambitions
>
> Isabelle Zablit-Schmitz, Délégation ministérielle au Numérique en Santé (DNS), France

Summary

Main findings

- Neither the total budget nor the upfront costs of implementation could be precisely estimated for the different Member States.
- Available funding and resources for the EHDS were considered insufficient in almost every country.
- Some countries with comparatively limited national resources are also the ones where the investments required for implementation will be greatest.
- Existing and future European projects of common interest could facilitate a harmonised and cost-efficient implementation across the Member States.

Challenges and enablers of implementation



Key findings, actors, and solutions for implementation

Provide sufficient and just funding

At European level

Provide adequate EU funding and better coordination of funding allocation for projects through which healthcare providers can invest in infrastructure for the EHDS and an integrated European implementation

Leverage lessons learned from the implementation of complex EU legislation, and provide adequate financial support for countries to invest in infrastructure and resources

Dedicate funding and resources to ensuring equitable access to health data, data security and privacy and avoiding discriminatory outcomes, including through the enhancement of digital literacy and skills across the EU

Create financial incentives for Member States and regions across Europe to collaborate and pool their resources on projects of common interest (e.g. the ELIXIR, European Genomic Data Infrastructure)

In addition to EU and national public funds, healthcare payers and the life sciences industry should contribute, for example through public-private partnerships, to covering the cost of implementation in light of the expected gains from access to data

Establish a monitoring system and ensure transparency of the use of resources and funding allocation

At national and regional levels

Structure support in such a way as to prevent any stakeholder group from bearing a disproportionate financial burden and avoid accentuating already existing inequalities in the health system

Avoid making investments or allocating resources to the EHDS to the detriment of investments in research, innovation and healthcare services

Do not neglect investments in human resources and skills and public communication when allocating public funds

Devise cost-efficient implementation strategies

At European level

Reuse technical building blocks from previous EU projects (EUCAIM, GDI, ELIXIR, DARWIN, etc.) for harmonised and cost-efficient infrastructure development across the EU

At national and regional levels

Set out a national strategy for health data collection and sharing, with clear timelines

Map all existing secondary use initiatives around health data to enable collaboration and synergies

Create financial incentives for regional cooperation, sharing lessons learned and good practice

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Ensure long-term sustainability of the EHDS

At European level

Ensure that public investment in innovation through the EHDS supports improved availability and accessibility of new products and services for all citizens

At national and regional levels

In collaboration with all data holders, define the return on investment and possible business models through which sustainable funding for data collection, quality management, curation and transfer can be established

Identify the mechanisms by which long-term funding for the EHDS can be secured from the stakeholders across society for whom benefits are generated

Current national landscapes

As the first of nine planned European data spaces, the EHDS is likely to be the most expensive to build, although the exact cost is difficult to quantify. In most cases, estimates for the national cost of implementation could not be made, and the question of who would shoulder which costs at government, regional and institutional level had yet to be clearly answered. It was generally expected that current levels of funding in most countries, particularly in smaller Member States, would fall short of the total investment needed. The human resources needed to implement the EHDS, including legal and administrative functions as well as technical support to manage IT systems, drive interoperability and enforce data standards, were also considered insufficient even in countries with established systems for secondary use of health data, such as Sweden.

In Germany, the federal government currently bears the primary responsibility for allocating funds towards the EHDS, but an initiative supported by the Bavarian state Ministry of Health and Care to financially assist SMEs with the implementation provides an example of the role that regional funding streams could play in the process. Another such example is digiOnko, a financial mechanism introduced by the same ministry in Bavaria to allow the remuneration of university hospitals that make their data available for secondary use. A valuable resource at national level is the Medical Informatics Initiative, which builds and operates infrastructure for data-sharing and secondary use, but this is also currently limited to university hospitals.

The Spanish national government has so far allocated € 100 million from both national and EU funding sources specifically to the implementation process, € 35 million of which have been distributed equally across the 17 Autonomous Regions to develop local services for the EHDS. The rest is serving to build a national data repository and computing infrastructure on the premises of the Ministry of the Economy, a choice called into question by some who argue that the federated data storage and computing capabilities already present throughout the country should have allowed investments to focus on the human capacities, skills and services needed to operate the national data space.

The biggest investments, currently, are seen in France, where the "Ségur du Numérique" programme has been endowed with € 2 billion over a five-year period to support the development of a comprehensive digital health offering. A part of the French 2030 recovery plan is also dedicated to the digital transformation, with € 650 million allocated to an acceleration strategy to help companies through this process. It aims, among other things, to promote the emergence of an eHealth ecosystem capable of competing on the global market and to facilitate secure and ethical use of health data with less reliance on a few major players. Going forward, sustainable funding will also be needed to improve the accessibility and usability of the data held by the country's health institutions, especially in a context where healthcare is delivered mainly outside of hospitals and data from community medicine, pharmacists and citizens themselves will need to be integrated.

Portugal, by contrast, will be challenged to finance and sustain the new EHDS governance structures, agencies and expertise-building in a context where substantial infrastructural upgrades and investments in its health information systems will also be required to prepare for the EHDS. Many institutions at all levels of the health system contend with outdated and inadequate

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equipment, undermining their ability to use health data effectively. A longstanding problem of structural underinvestment in both hardware and software compounds has resulted in a significant deficit in technological capabilities that obstructs even the simplest forms of network-based data-sharing.

Similarly, the investments required for Ireland to develop its national data space far exceed those of more digitally mature Member States. They include the creation of robust digital infrastructures for both primary and secondary use, data lakes, as well as filling the skills gap at all levels of the health system. The current freeze on recruitment of managers and administrators—including IT workers—within the country's Health Service Executive was a cause for concern in this context. Although government funding for the digitalisation of the health system has fallen short of expectations in the past, a paradigm shift has been observed since 2019 with the publication of cross-government national strategies for the digital transformation of healthcare, which could unlock more comprehensive financial support in the future.

Common challenges and potential solutions

A difficult cost-benefit analysis for payers

Securing sufficient funding for implementation is likely to run up against the challenge that returns in proportion to the investments required will take many years, if not decades to materialise for payers: governments, public agencies, healthcare institutions. Although an impact assessment by the European Commission has estimated that outputs of the EHDS could ultimately generate cost savings of up to € 11 billion over 10 years, including € 5 billion from secondary use (European Commission, 2022), not knowing when in the future they will "break even", as well as not being able to predict the exact nature of the rewards for different stakeholders as new possibilities emerge, for example to connect data across different European data spaces, could inhibit various actors' willingness to pay in the short term. This is all the more of a concern in a context where most national health systems are already struggling with issues of financial sustainability, and especially holds true for healthcare institutions. In addition to the expense incurred, these will likely see an increase in administrative workloads that cannot easily be absorbed by their already overstretched medical staff, and therefore want to see a defined return on the investment required to produce and share high-quality data for secondary use within the EHDS, in a setting where selling access to data for a profit will be explicitly prohibited.

Data collection is not just costly, it could also be counterproductive if the necessary quality standards for secondary use cannot be fulfilled in the process and if it leads to the creation of so-called data graveyards that, despite being expensive to maintain, ultimately go unused.

Defining precise data needs tied to clear secondary use cases and desired outcomes, such as improving early detection of diseases or health incidents, will be an important way to ensure funds for the EHDS are invested intelligently in better and more useful data through which real value can be unlocked. This type of approach that defines the expected benefit from the outset could also increase different payers' motivation to contribute to the funding effort.

At European level

Establish narrower, more precise data requirements tied to clear use cases and desired outcomes to increase payers' motivation and limit the cost of collection, storage and processing

Uncertainty persists around long-term financial sustainability

In addition to the upfront investment needed for the creation of the EHDS per se, uncertainty remains surrounding the financial models that can ensure the long-term sustainability of operating this extensive data infrastructure. In a setting where the data itself is not directly monetizable, finding a sustainable business model to translate the cost of running the EHDS to its users based on a defined benefit will be an important and challenging task. The Joint Action TEHDAS has highlighted the trust of key stakeholders—governments, data holders, data users and of course citizens—in the system and in the value it provides as a critical factor in motivating sustained efforts and investments to keep the EHDS operational long term. Work to identify the mechanisms through which investments in the healthcare system and in the EHDS generate value and cost savings in other areas of society could also foster the development of new socio-economic models to secure funding from the stakeholders willing to pay for the benefits they receive.

At national and regional levels

Identify the mechanisms by which long-term funding for the EHDS can be secured from the stakeholders across society for whom benefits are generated

Privately funded data holders will struggle to resource the change

For data holders in the private sector, who are not expected to receive any direct public funding to help cover the cost of implementation, complying with the new requirements will require establishing and resourcing new infrastructures and processes for the curation and provision of all the mandatory data categories beyond clinical trial data. While there may be internal benefits to investments in making data more findable, interoperable, and reusable—for example to create in-house possibilities to commoditise data based on patient consent—their feasibility for individual organisations will depend heavily on their size and financing model. Private hospitals and other healthcare providers, as well as SMEs and startups which are often major drivers of innovation in the health and digital health sectors, are likely to struggle the most to secure budgets for the changes in the absence of clearly defined expected returns in proportion to the investments required. With many European digital health companies already focused on the less fragmented and less complex US market, the imposition of additional requirements related to the EHDS carries a risk of further accentuating the relocation of businesses and the loss of opportunities for EU citizens to benefit from their innovations.

In France, concerns were also raised about what the new provisions will mean for the sustainability of its health cohorts, a number of observational databases tracking the health condition of a large population sample over time. Initially created with public funding, the cohorts rely on private investors to cover the cost of their long-term maintenance. If the governance and pricing rules introduced by the EHDS were to run counter to their established economic model, the cohorts could lose their industrial partners and see their viability threatened.

At national and regional levels

Clearly define the compliance requirements and penalties for data holders to prevent waste of resources

In collaboration with all data holders, define the return on investment and possible business models through which sustainable funding for data collection, quality management, curation and transfer can be established

Enablers and opportunities

A template for efficient investment: the European Genomic Data Infrastructure

A number of existing EU projects have already delivered solutions and infrastructures that could be leveraged for an efficient and harmonised implementation across Europe. In particular, the European Genomic Data Infrastructure provides both a technical building block for the EHDS and an example of best practice in terms of funding and incentive creation. With the European Commission and participating Member States contributing in equal measure to the financial investment, a pilot project and infrastructure elements were developed which countries can now reuse to build their own national node. This collegial approach to developing reusable solutions can make implementation significantly cheaper than if each Member State develops its own systems.

At European level

Create financial incentives for Member States and regions across Europe to collaborate and pool their resources on projects of common interest (e.g. the ELIXIR, European Genomic Data Infrastructure)

Reuse technical building blocks from previous EU projects (EUCAIM, GDI, ELIXIR, DARWIN, etc.) for harmonised and cost-efficient infrastructure development across the EU

Priorities for implementation

EU funding for a European data infrastructure

The funding so far allocated by the European Commission for the implementation at EU level was widely considered to fall short of the ambition of the original proposed regulation and of the budget and human resources that will be needed to operate the central infrastructure and services. In addition to increasing this core package, however, various other levers exist to channel available resources efficiently towards the EHDS. Requiring Europe's large ongoing public health projects in areas such as cancer, genomics or mental health to dedicate a share of their budgets to data collection, storage and interoperability for the EHDS, for example, would be one step towards a coherent EU funding policy in this area. Better coordination and more transparency in allocation decisions of EU funding streams such as the Recovery and Resilience Facility, Horizon Europe and EU4Health would further help to ensure that resources are not wasted on redundant projects. EU funding for the EHDS should also explicitly favour initiatives that support the development of an integrated European system, as a fragmented landscape of 27 national data spaces would both run counter to the framework's main objectives and run up the cost of implementation.

On the receiving end, clearer signposting is needed to help actors in the EHDS implementation navigate the multitude of EU funding instruments and facilitate timely access to the appropriate support for different national, regional, local, public or private entities. This is especially important given the significant differences observed between European countries', regions' and stakeholders' experience and knowledge of the procedures for securing EU grants, with those least attuned to the possibilities and requirements likely to be among those most in need of support. The role of organisations like EIT Health, which act as brokers and enablers for their network of partners and help them access funding while creating synergies and collaboration across various funding instruments, becomes increasingly relevant.

At European level

Provide adequate EU funding and better coordination of funding allocation for projects through which healthcare providers can invest in infrastructure for the EHDS and an integrated European implementation

Ensure that major ongoing EU public health projects allocate a given share of their budgets to data

Develop signposting and information materials on the different EU funding instruments and procedures available to help different actors in the EHDS implementation obtain timely support

Leverage lessons learned from the implementation of complex EU legislation, such as the Medical Device Regulation, and provide adequate financial support for countries to invest in infrastructure and resources

In addition to EU and national public funds, healthcare payers and the life sciences industry should contribute, for example through public-private partnerships, to covering the cost of implementation in light of the expected gains from access to data

Establish a monitoring system and ensure transparency of the use of resources and funding allocation

Dedicated resources to foster equal opportunities

Although EU co-funding is also planned to help Member States with the national implementation, the drastically different starting positions of individual countries in this process and the variability of human and financial resources available locally to collect and process data pose a serious risk of widening inequalities and creating a structural imbalance in the way nations can interact with and benefit from the EHDS. Even within individual Member States, significant regional differences were reported in terms of the digitalisation of healthcare institutions, the infrastructure available to technically implement the EHDS, as well as the expertise and human resources to manage and maintain health data to the standards necessary for its secondary use. These entail the risk that existing regional disparities will be reinforced through the implementation process, and that patients will not have equal opportunities to participate in the EHDS depending on the city and type of healthcare institution where they receive treatment.

Preventing the EHDS from creating or accentuating inequalities between European citizens in a context where health, digital and data literacy are also known to be highly heterogeneous will require significant and targeted investments at EU and national levels. In certain regions, access to basic infrastructures will need to be improved to ensure equal opportunities for electronic health data collection, sharing and use. Solutions will need to be developed, and human resources mobilised, to help people with low digital skills, healthcare-avoidant demographic groups, and other vulnerable populations such as minorities and immigrants to gain access to, understand and share their health data in an informed manner. Effective stakeholder processes, and especially patient engagement, are also time and resource-intensive and will need to be planned over the long term.

At European level

Dedicate funding and resources to ensuring equitable access to health data, data security and privacy and avoiding discriminatory outcomes, including through the enhancement of digital literacy and skills across the EU

At national and regional level

Structure support in such a way as to prevent any stakeholder group from bearing a disproportionate financial burden and avoid accentuating already existing inequalities in the health system

Do not neglect investments in human resources and skills and public communication when allocating public funds

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National budget allocation based on a clear understanding of responsibilities and resources available

In many Member States, regional authorities and actors will shoulder extensive responsibilities for implementing the EHDS in line with the decentralised organisation of their respective health systems. Governments will need to take this into account when allocating national budgets for this undertaking, making sure to sufficiently resource regional and local bodies and to prioritise where possible the scaling of existing structures over starting from scratch. Rather than leaving each organisation to take its own path to connecting local data platforms to the EHDS, national policymakers should incentivise the development of open and reusable solutions that will allow the integration of multiple platforms at minimal cost.

National funding plans should also take into account how the financial burden of implementation is going to be distributed, namely recognise that the most cost-intensive tasks will likely be data preparation and acquisition, compared to the costs of setting up administrative processes and secure processing environments that will be borne by health data access bodies. Both data holders and health data access bodies will need dedicated budgets to recruit and train skilled staff to curate, standardise and maintain databases as well as expedite data access procedures: experts on the interface between health and technology, data stewards, medical informatics specialists, lawyers, among others. These, however, should not be financed to the detriment of investments in healthcare services, research and innovation.

At national and regional levels

Set out a national strategy for health data collection and sharing, with clear timelines

Allocate national budgets for the EHDS based on a clear understanding of the geographical and organisational distribution of responsibilities for its implementation

Map all existing secondary use initiatives around health data to enable collaboration and synergies

Create financial incentives for regional cooperation, sharing lessons learned and good practice

Allocate public funds appropriately between infrastructure upgrades and human resources and skills

Avoid making investments or allocating resources to the EHDS to the detriment of investments in research, innovation and healthcare services

Clarity on the data fee mechanisms

The pricing of data and data access services is recognised as one of the most difficult questions to be resolved in the course of the EHDS implementation and which is surrounded by widely differing expectations. In the private sector, the financial burden associated with curating and making datasets interoperable for sharing within the EHDS will be greatest for those specialising in health data or otherwise carrying large data inventories—which include companies of all sizes. To help these actors plan and execute the steps required to comply with the future legislation, clarity needs to be provided on what fees data holders will be entitled to charge to health data access bodies for making their data available, and to what extent the fee structure will reflect the real cost of providing different types of datasets.

Conversely, the question currently remains open whether the fees charged by health data access bodies and data holders to data users will follow a common structure or be differentiated according to the profile of the applicant (public body versus private company, corporation versus SME) or the use purpose (policymaking versus commercial innovation). Some take issue with the possibility that their data could be used at a low cost by private companies which may then charge healthcare providers and public payers high prices for innovative solutions developed with that data. At the same time, it was noted that fees exceeding the financial capabilities of small businesses or publicly funded actors should be avoided to ensure a level playing field for research and innovation in the EU.

A critical issue yet to be addressed in this setting is how to define the value of different types of data in various use scenarios and research contexts. For example, data related to rare diseases can be considered more valuable due to its scarcity and potential impact on research and treatment advancements, but further distinctions could be made between continuous and one-time data use applications. Importantly, the worth of data and the value derived from its use may also vary between countries as it begins to be shared more systematically across borders, raising once more the question of whether all Member States will benefit equally from the EHDS.

At European level

Agree at EU level on the model to be applied for data access and define where the actual fees can be obtained in an open and transparent manner, before requesting access to data

Ensure that public investment in innovation through the EHDS supports improved availability and accessibility of new products and services for all citizens

CHAPTER 4

Data quality

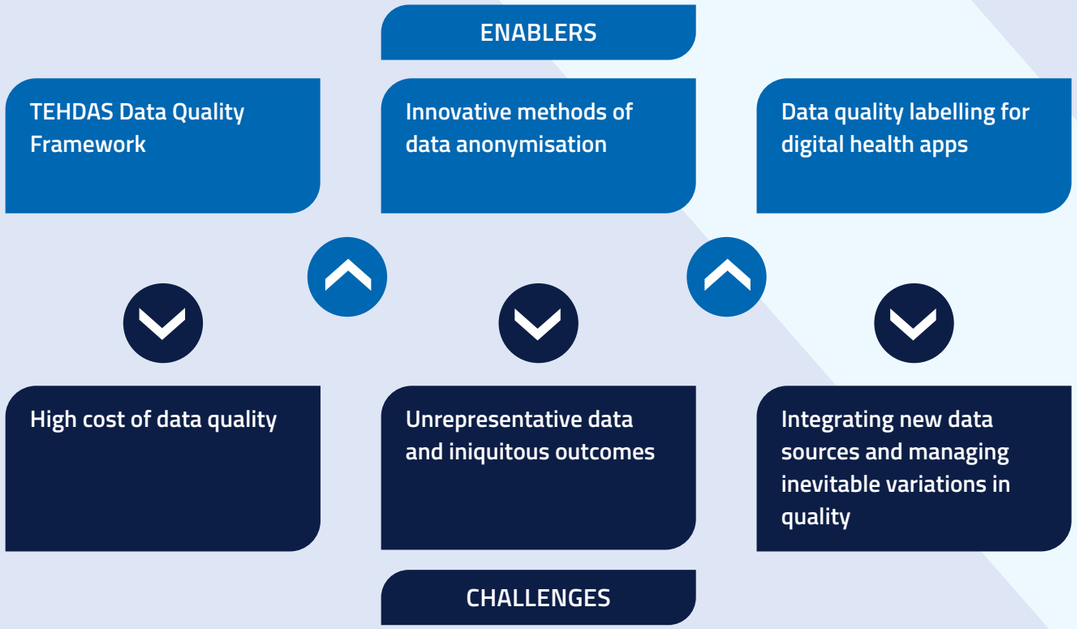
> The quality of data is always terrible until people start using it for a purpose
>
> Harald Wagener, Berlin Institute of Health, Germany

Summary

Main findings

- Vast disparities exist between Member States in the implementation of standards for health data
- Data quality is inconsistent across different categories of data holders within individual countries, and interoperability remains a universal challenge
- Capacities and budgets for quality improvement measures are particularly low in healthcare
- Patients and citizens could have a role to play in controlling and enriching their own data
- Extensive work is happening at EU level to help develop a common approach to quality

Challenges and enablers of implementation



Key findings, actors and potential solutions for implementation

Foster a common understanding of data quality

At European level

Agree on a common language, a common (logical) data model, a common semantic and a unified way of collecting metadata to improve system and data interoperability in consultation with relevant stakeholders

Further define EU-wide standards and concepts of data quality and data utility in the EHDS legislation or delegated acts, building on the data equity and FAIR principles

Establish a clear purpose and long-term vision for why which data should be collected, defining precise requirements for data from healthcare and from medical devices

Establish guidelines for robust data traceability across primary and secondary use systems, as well as data robustness and access across all society

At national and regional levels

Adopt and implement a common data quality framework (like the one created under the Joint Action TEHDAS) at national level to ensure a harmonised European approach to data quality

Adopt a coordinated strategy to educate clinicians on data standards to optimise the research potential of the data they record. Similar strategies should be adopted for researchers on data collection and analysis applied to healthcare and policymaking

Enforce an inclusive system of quality control

At European level

Define an efficient EHR certification system that companies of all sizes can cope with, including user-centricity and the standardisation of terms and coding systems (vocabularies) as evaluation criteria for health information systems' data quality

At national and regional levels

Establish legal obligations and financial support for the adoption and maintenance of EU and international data collection standards

Focus on making primary data reusable

At European level

Agree on common European health record standards in line with EU and international best practices, in consultation with industry and research actors

At national and regional levels
Healthcare providers

Ensure the consistent capture of metadata in the primary use setting

Contribute to developing standard approaches to improving primary data quality that are compatible with routine work processes

Leverage new technologies such as natural language processing to expedite the standardisation of legacy free text data in EHRs

Support appropriate use of different datasets

At national and regional levels
Health data access bodies

Establish data traceability across primary and secondary use platforms, especially with regard to where, how and by whom data was collected to help data users better understand and manage variability in data quality within the EHDS and ensure appropriate use of different datasets

Higher education providers

Educate secondary users of health data on the suitability of EHRs and other primary data sources for different types of research

Develop and validate data quality testing methods and algorithms, as applied in health research

Current national landscapes

As could be expected, the quality of the electronic health data available in national health systems was reported to vary widely between different data holders. While national data collections established with secondary use in mind, such as registries and official statistics, tend to be highly standardised and structured, this is not the case of the majority of data collected for primary use in healthcare. Both system and data interoperability were reported to be lacking in this sector across the countries involved in the roundtable series. Data silos that do not easily communicate with one another and datasets that have limited utility beyond the specific purposes for which they were collected are defining features of the health data landscape in countries such as Austria, Hungary or Poland.

In Austria, a lack of implementation of data standards—from data models and interoperability standards to a consistent way of measuring biological parameters in different practices—was highlighted across various healthcare professions and fields of medicine, especially in the community setting. Nurses in particular do not currently have access to the national EHR and therefore continue to work in unstructured data silos, such as basic spreadsheets. The technical possibilities for structured data registration are better in the country's hospitals, with some high-quality collections such as the billing datasets and their derived Inpatient Quality Indicators, however chronic staff shortages mean that few resources are available to focus on data curation and maintenance rather than clinical care delivery. In many instances, including at the level of national registries such as the SARI (Severe Acute Respiratory Infection) registry, the Austrian cancer registry or the official death statistics, suboptimal reporting practices related either to unclear data specifications or to paper-based submissions significantly undermine overall data quality. A more focused approach to secondary use of health data is expected to come out of a broad consultation process led by the national public health planning and research institute, GÖG, for the Austrian Ministry of Health, for the development of a national eHealth strategy in the course of 2024.

In Germany, the implementation of a nationwide EHR system has been ongoing for over a decade, but in 2023, its uptake by patients remained critically low (Schmitt, 2023). Current practices in updating it have resulted in the EHR becoming a collection of PDFs rather than structured data: for example, scanned printouts of individual institutions' EMRs featuring handwritten updates. In addition, there is little standardisation in the data itself, from semantic inconsistency and syntactic differences such as the way patients are asked about pain levels, to variation in methods of recording metadata. As a result, it is difficult to share and compare data between existing systems. As the majority of medical care is delivered in silos, with Germany ranking low on integrated care among OECD countries (Toth, 2020), the long-term view and incentive is lacking for most healthcare providers to improve data collection practices for the purpose of sharing data for either primary or secondary use.

In Ireland, healthcare institutions' reliance on paper records has also meant that data quality was a low priority in the past. Even where electronic data exists, quality control and improvement measures at the level required to make the entire medical record fit for secondary use was deemed to be well beyond the current capabilities or bandwidth of hospitals' data teams. Consistent with the lack of connectivity and data-sharing practices throughout the system, the overall quality of its national data collections has been found in national and international assessments to suffer from a lack of communication and harmonisation in the standards applied by the different data holders. However, identified instances of excellent practices, together with the advanced expertise of national organisations such as the Health Information and Quality Authority, the National Office of Clinical Audit, or Cancer Trials Ireland, provide a strong basis for the implementation of a unified national quality framework in the future. Some also see the country's digital immaturity as an opportunity to build an efficient system that integrates from the outset the need for standardised data collection and sharing across primary and secondary use environments: a relative advantage over Member States with established infrastructures that will need to be extensively adapted to meet the new requirements.

Although challenges related to data fragmentation and lack of interoperability equally affect France, Spain and Sweden's healthcare institutions, these countries have done extensive work and positioned themselves at the vanguard of efforts to set data quality benchmarks for secondary use. Sweden has been collecting health data for its national registries and statistics for the past 70 years, and accordingly has a solid established framework and a wealth of high-quality data available for secondary use. Spain, meanwhile, is considered a leader in the use of data standards throughout its health research ecosystem and even in clinical care. Among other things, this has allowed the scientific validation of EHR datasets from the country's primary care setting, including diagnoses of chronic diseases such as diabetes, hypertension and atrial fibrillation, for use in research. Spain is also one of the main providers of data in the European Health Data & Evidence Network (EHDEN).

In France, the "*Ségur du Numérique*" programme was launched in 2021 to introduce services that will strengthen the security and enhance the interoperability of existing health information systems. These services include a unified electronic health record, the DMP, a secure health data exchange and messaging service for healthcare professionals and patients, and e-prescriptions to be included in the DMP. Meanwhile the national SNDS claims database, which has the unique characteristic of covering the entire French population and thus being largely unbiased, is currently in the process of being converted to the OMOP format. This will ensure its syntactic and semantic interoperability with other standardised databases internationally. France's Health Data Hub has also been actively involved, including on the European stage, in work to define semantic interoperability standards for health data.

Common challenges and potential solutions

Obtaining high-quality health data is still too expensive

Even if the most up-to-date international data quality standards began to be applied to data collection throughout health systems, there would still be decades' worth of legacy data to structure, standardise and make available for secondary use. In addition, the use of standards and structured forms does not completely eliminate the intermediate processing steps necessary to make raw data suitable for secondary use, including cleansing, plausibility checks and quality control. For all of these reasons, the cost of generating and processing data to a high level of quality for secondary use purposes remains prohibitively high.

The fact that data holders, data controllers and data processors are usually distinct organisations raises the question of who will assume responsibility and, importantly, pay for this data curation and improvement effort. Some reports based on national experiences with secondary use in Estonia suggested that the time and resources required to retrieve and make data available tended to be split unevenly between data controllers and data holders, with the latter shouldering as much as 80% of the burden in spite of their main interest residing in primary use. Some therefore advocated starting with controlled pilots targeting specific data types and use cases.

Data (in)equity

One of the major challenges in relation to using the datasets that will become available through the EHDS for research and policymaking is the underrepresentation within them of vulnerable groups such as people living in low-income households, the homeless, immigrants, and others who rarely interact with the healthcare system, for instance rural populations or young adults. Another cause for concern is the prevalence of unstructured, free-text or even paper-based data unfit for secondary use in the records of senior citizens, who are also the most likely to suffer from chronic conditions and thus stand to benefit from the reuse of their data. Measures to maximise participation and inclusion in the EHDS will be needed to reduce the risk of biases in the data leading to bias in the policies, health interventions and especially data-driven commercial solutions it serves to develop.

Although empowering individuals to record and share data about themselves directly could be one way of increasing population coverage, this comes with its own quality control challenges and still limits participation to citizens with the digital skills and health literacy necessary to do so. On the side of data holders, the quality improvement measures that will be demanded must be materially and financially feasible for all organisations, in all EU Member States. An approach proposed by the Joint Action TEHDAS in this area would allow data holders to do a mere self-assessment in the earliest stages, before progressing to an external data quality audit for the most advanced organisations. Enshrining principles of data equity in the data quality framework for the EHDS, and in initiatives running in parallel to develop labels for data quality and utility, would further help to ensure

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Chapter 4 | Data quality

that these issues are systematically considered in the collection and handling of health data for secondary use.

With the EHDS slated to create unprecedented possibilities for quantitative data analysis, experts also cautioned that the new framework should not be allowed to eclipse the important area of qualitative research, which provides a further means of bridging gaps in datasets by specifically engaging with underrepresented groups.

At European level

Enshrine principles of data equity in the data quality framework and labels for the EHDS to ensure the unique needs of hard-to-reach populations are considered in data collection and secondary use

Enablers and opportunities

A European quality framework for the EHDS

The TEHDAS project, involving 25 countries and coordinated by the Finnish Innovation Fund – Sitra, dedicated one of its eight work packages to "Excellence in data quality" to develop guidance for a harmonised quality framework enabling the trustworthy secondary use of health data. Recommendations were published within the final TEHDAS data quality framework, covering both the technical quality aspects and the utility dimension and considering the entire life cycle of data from curation and preparation, through discovery, all the way to use, enrichment and publication (TEHDAS, 2023). These include, among others, a call to support data holders in the areas of data management and quality assurance, as well as a data holder maturity model to give data holders an audit model and roadmap to improve their data management and data quality. Further guidance pertains to the labelling of datasets and the publication of catalogues of available datasets, as well as metadata catalogues, following international standards.

A role for patients in data collection and sharing

The prospect of empowering patients to collect, edit and share their own data for reuse has been much discussed as a means of fostering participation in the EHDS, obtaining more complete datasets and generating patient-reported outcome measures in a more systematic way. The EU-funded Health Outcomes Observatory project, which is developing independent observatories for the reporting and assessment of health outcomes from the patient's perspective in four Member States, could chart the path for broader implementation of such approaches in the future.

While the possibility foreseen by the EHDS for patients to have access to, rectify and potentially enrich their electronic health records could be a further enabler for data accuracy and completeness, this is highly dependent on individuals' health and digital literacy, as well as on the quality, calibration and real use they make of wearables, devices and other health applications that produce data. The quality aspects, in this scenario, would need to be balanced against the usefulness of the information that can be obtained. For example, the fact that a patient's weight scale is inaccurate may be compensated by the fact that a measurement is provided on a daily basis. Improving data custodians' and data users' knowledge of how to deal with and use data of varying quality levels could also help to unlock the research value of patient-generated data.

At European, national and regional levels

Explore practical possibilities to increase patients' involvement in data collection, improvement and sharing

Implementing the European Health Data Space Across Europe
Chapter 4 | Data quality

A quality label for wellness applications

The EHDS proposal foresees that data from wellness apps, digital applications that have not received CE certification as medical devices, but which claim to be interoperable with EHR systems, will also be made available for secondary use. As things stand, this poses a considerable challenge with respect to measuring the quality of the eligible datasets, as there are currently no widely recognised assessment criteria or frameworks available. The Label2Enable project, funded by Horizon Europe, is creating an ISO 17000 series-compliant certification scheme for the ISO Technical Specification 82304-2 (health and wellness apps quality and reliability) which could become the voluntary label for wellness applications that claim to be interoperable with electronic health records. Like any voluntary scheme, however, the expectation is that it would not be taken up by the majority of developers, raising the question of whether integration of this type of data into the EHDS should be conditioned upon obtaining the quality label. The definition of standard data quality criteria and thresholds for inclusion remains an open issue that will need to be addressed.

Priorities for implementation

A common understanding of data requirements and overarching goals

Many anticipate that the EHDS framework will naturally act as a catalyst for data quality, with the proposed regulation foreseeing quality and utility labels for the datasets integrated in the system. An EU-funded project is expected to work on developing the data quality label for the EHDS in 2024. The adoption of the data quality framework developed by the Joint Action TEHDAS by all Member States would be another important step towards a shared understanding in this area. However, it was additionally recommended to further define the concepts themselves at European and national levels, building on the FAIR principles of findability, accessibility, interoperability, and reusability.

At national level, the health data access bodies could be given a legal mandate to issue clear guidelines on the basic data to be recorded. In particular, a common and consistent approach to registering metadata is needed to describe the environment in which data was collected and allow researchers to overcome the inherent variability across different practices and detect biases, which health data access bodies will need to publish in metadata catalogues alongside the dataset catalogues.

Concrete use cases could be developed to allow all stakeholders to contribute to a common, detailed understanding of the data needs, relevant quality criteria, and feasible improvement measures for the datasets they are most familiar with. For instance, medtech industry representatives caution against integrating large volumes of unprocessed device-generated data, due to the difficulties posed by its management and its limited utility for generating meaningful insights. Collaboration to define data quality in relation to specific practical applications could also help to uncover gaps in data collection and registration, as well as potentially unforeseen regulatory hurdles. The medical device sector provides another example here, as it was noted that the Medical Device Regulation (MDR) currently defines stringent but differentiated requirements for products' approval in a risk-based approach that will not be reflected in the way data is integrated into the EHDS, suggesting a need to homogenise the data quality standards across all product categories. In addition to medical device and EHR manufacturers, key actors should include academic and industry research communities, all categories of data holders, who have the necessary domain expertise to qualify their own datasets, health technology assessment bodies, which will ultimately use the evidence gathered through secondary use, data protection authorities, but also patients and ethicists, who can help ensure that values and ethical principles become an integral aspect of data quality.

At European level

Establish a common language, a common (logical) data model, a common semantic and a unified way of collecting metadata to improve system and data interoperability in consultation with relevant stakeholders

Further define EU-wide standards and concepts of data quality and data utility in the EHDS legislation or delegated acts, building on the data equity and FAIR principles

Establish a clear purpose and long-term vision for why which data should be collected, defining precise requirements for data from healthcare and from medical devices

Establish guidelines for robust data traceability across primary and secondary use systems, as well as data robustness and access across all society

At national and regional levels

Adopt and implement a common data quality framework (like the one created under the Joint Action TEHDAS) at national level and ensure a harmonised European approach to data quality

Mandate the health data access bodies to regulate data collection standards and establish advisory functions on data quality

EU-wide medical reporting standards based on international best practice

The implementation of data standards in all areas of medical reporting will become particularly important going forward, as the extensive standardisation performed for instance in the field of radiology in recent decades remains a relative exception in the healthcare sector. With an excessive number of different standards in the health domain and gaps in the knowledge of various stakeholders regarding data ontology[2] and coding systems posing a challenge to efforts to improve interoperability, choices will need to be made about which standards are instrumental to conducting the types of research that the EHDS aims to enable. These should also be in line with international best practices to avoid creating an EU exception that would increase complexity and block innovation. The field of genetics can serve as a role model in this area, with longstanding expertise and experience to be found within and international initiatives such as the Global Alliance for Genomics and Health. The European Reference Networks and European professional societies can provide further guidance in their specialised fields.

Implementation could then be accelerated through financial support to comply with the relevant data standards. However, it will also require a concerted effort to raise awareness of the necessity and rationale for the changes among healthcare professionals, and to design viable systems of primary data collection and improvement with adequate staffing and technology. Recognising that there are many other actors in the ecosystem who have an interest in and will benefit from data of the highest possible quality, possibilities for incentivisation should be explored, including non-financial benefits such as the creation of feedback loops in which the enriched datasets resulting from secondary use are returned to the holders of the original data.

At European level

Agree on common European health record standards in line with EU and international best practices, in consultation with industry and research actors

2 A data ontology enables the sharing of information between disparate systems within the same domain by standardising the vocabulary across that domain, for example the terms used to describe medical specialties or diseases in different healthcare systems.

Define an efficient EHR certification system that companies of all sizes can cope with, including user-centricity and the standardisation of terms and coding systems (vocabularies) as evaluation criteria for health information systems' data quality

At national and regional levels

Adopt a coordinated strategy to educate clinicians on data standards to optimise the research potential of the data they record. Similar strategies should be adopted for researchers on data collection and analysis applied to healthcare and policymaking

Establish legal obligations and financial support for the adoption and maintenance of EU and international data collection standards

Healthcare institutions

Ensure the consistent capture of metadata in the primary use setting

Contribute to developing standard approaches to improving primary data quality that are compatible with routine work processes

Leverage new technologies such as natural language processing to expedite the standardisation of legacy free text data in EHRs

Implementing the European Health Data Space Across Europe
Chapter 4 | Data quality

Support appropriate use of EHDS data

The inclusion of entirely new types of data in the secondary use ecosystem, including data from EHRs and medical devices, but also patient-generated data from wearables and wellness apps, means that there will be variations in the intrinsic characteristics and quality of available datasets even if standards are homogenised within each category. An essential aspect of ensuring appropriate secondary research and policymaking applications for this data will therefore be to provide users with transparency and guidance as to what types of questions and research methodologies different datasets are most suitable for.

As researchers increasingly apply new methods of data processing and analysis to large datasets or to data from multiple sources, quality issues within the EHDS will not be limited only to the data inventory but will also concern the ways algorithms connect and process the input information. For example, an evaluation of three different AI algorithms for breast cancer detection revealed biases such as equipment-associated variations in the assessment scores of mammography images (Salim, et al., 2020). This was expected to be a recurring issue with the secondary use of data from medical devices more generally, because input and output data are not currently harmonised across devices of the same categories. Standardised methods of testing algorithms' predictive value will thus need to be developed to measure specificity and sensitivity, similar to in vitro diagnostics.

At national and regional levels Health data access bodies

Establish data traceability across primary and secondary use platforms, especially with regard to where, how and by whom data was collected to help data users better understand and manage variability in data quality within the EHDS and ensure appropriate use of different datasets

Higher education providers

Educate secondary users of health data on the suitability of EHRs and other primary data sources for different types of research

Develop and validate data quality testing methods and algorithms, as applied in health research

CHAPTER 5

Closing the loop: The relation between primary and secondary use

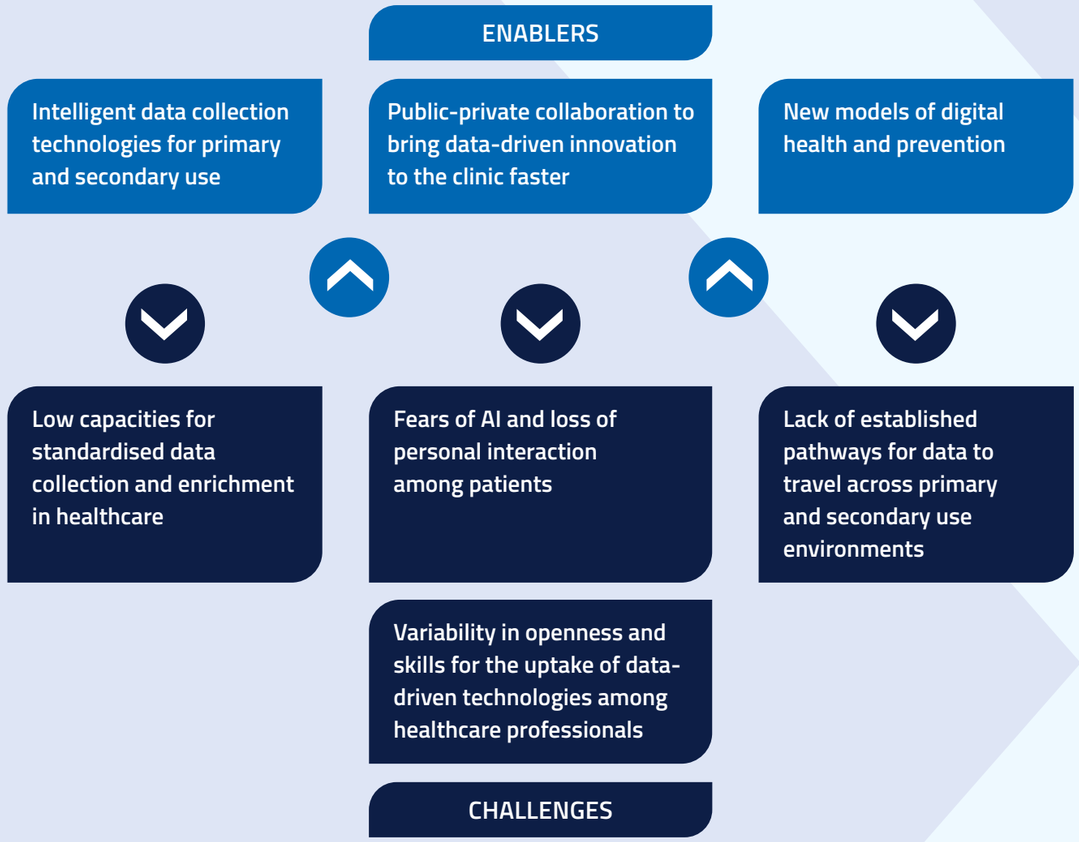
> The focus has to be on what we want [data analytics] to solve: that is where breakthroughs will come from
>
> David Van Laere, Innocens, Belgium

Summary

Main findings

- Healthcare providers' current workflows and data management structures are not geared towards the need for standardised collection and segregation of datasets for secondary use.
- The continued reliance on paper records in some regions and areas of healthcare keeps entire territories and categories of health data inaccessible for research.
- New technologies could facilitate data collection in clinical workflows, automate the data transfer across primary and secondary use environments, and motivate healthcare professionals to record high-quality data by generating direct insights and value for patient care.
- Some paths for the introduction of data-driven innovation into clinical pathways exist, but represent an emerging field lacking standardisation.
- Public-private and multistakeholder collaborations are accelerating the development of data-driven solutions based on unmet needs in healthcare.

Challenges and enablers of implementation



Key findings, actors and potential solutions for implementation

Facilitate the flow of data from primary to secondary use settings

At European level

Define which primary data needs to be collected for reuse and accelerate the adoption of international standards and coding for the relevant data categories in healthcare

At national and regional levels

Support technical-legal approaches and standard-setting to enable automatic transfer of EHR data from primary to secondary use systems and smooth integration with national health data access bodies

Establish joint systems and standardised contracts to decrease overhead costs of data provision and use

Healthcare institutions

Generate use cases to demonstrate to healthcare professionals the benefits and time savings that can be achieved for them through the digital transformation of healthcare and educate them on their role in entering high-quality data into health information systems

Develop guidelines and standard protocols for data collection that support healthcare professionals and integrate easily into their workflows

Build trust in the outputs of secondary use

At national and regional levels

Develop standard methods for evaluating data-driven health technologies' reliability and fitness for clinical practice

Establish step-by-step rules and processes to address ethical and other issues that arise from the use of AI in healthcare

Develop educational resources for all stakeholder groups (citizens, healthcare professionals, health institutions, insurance providers, public health and political actors) to improve knowledge of the new technologies being developed and deployed in the health sector

Health data access bodies

Facilitate data traceability to foster trust in the new outputs and technologies to be fed back into healthcare

Implementing the European Health Data Space Across Europe
Chapter 5 | Closing the loop: The relation between primary and secondary use

Chart the paths to closing the loop

At European level

Establish a standardised path for secondary users to comply with their obligation to report incidental findings in a timely manner, defining how, where and to whom the relevant information on patients must be provided

At national and regional levels

Develop structured paths to adoption and reimbursement of data-driven innovation by the healthcare systems, centred around defined patient or societal needs

Healthcare institutions

Specify the characteristics and type of data and/or analysis from secondary use that are relevant and useful to be provided to healthcare professionals

Current national landscapes

With very few exceptions, data collection processes in healthcare institutions across Europe today remain exclusively geared towards the needs of primary use. Neither medical professionals' clinical workflows, nor the data infrastructures and data management processes established within different organisations allow for the kind of highly standardised and structured data collection, processing and segregation from operational systems that secondary use requires. The continuing reliance on paper documentation, not only in Ireland but also as a widespread practice in Germany and parts of the Austrian healthcare system such as nursing and home care, keeps entire territories and categories of health data inaccessible for research and data-driven health policymaking. Even in countries like France, Spain and Sweden, where electronic medical and health records are ubiquitous, experts see a lot of work to be done to standardise reporting and improve data quality. According to some reports from Spain, for instance, only a small percentage of the input fields in EMR systems are actually filled out in routine practice and the majority of data is still entered as free text.

Discussions in Austria, Germany, Italy, Ireland and Spain additionally highlighted the lack of a data-sharing culture and fears surrounding the risk of data misuse within these countries' healthcare workforces, especially when it comes to releasing what many still perceive as their data (rather than the patient's) for secondary use purposes from which they receive no direct benefit. In Spain, which is among the globally leading countries for clinical trials, a large community of clinicians already accustomed to participating in research was seen as an important asset for driving cultural change in the profession.

On the other side of the data loop, the introduction of digital and data-driven solutions into clinical or patient pathways has begun in certain countries like Belgium, France and Germany, which have established assessment procedures and reimbursement schemes for digital medical devices. In Spain, Catalonia's bioregion BIOCAT is working on a fast-track for the adoption of new technologies, including for digital health, to help them reach the market and become eligible for reimbursement based on a defined health benefit. Meanwhile, Austria's statutory health insurance is considering the development of a "digital health pathway" that would allow citizens to manage their health data autonomously on a single platform and establish a hub connecting them with certified and quality-assured eHealth offerings. This is still an emerging field. At the level of healthcare institutions, the implementation of digital health solutions and services is inconsistent within and across countries, depending in large part on the budget available for piloting innovation and on the individual initiative of staff members.

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Common challenges and potential solutions

A disproportionate burden on healthcare providers

Healthcare professionals have a key role in contributing data in the primary use setting that will be reusable for secondary purposes and generate credible research results, yet the concentration of this responsibility in their hands is out of step with clinicians' rightful focus on delivering the best possible care to patients. Where the needs of primary use conflict with data requirements for secondary use, such as the registration of device-generated measures not as absolute values, but in a format that is more immediately evocative of their implications for diagnosis and treatment, prevailing practices could be difficult to change.

Beyond the use of data standards, making medical records suitable for research will often entail gathering additional data points that may not be immediately relevant to patient care, but which constitute essential explanatory variables in the reporting and interpretation of research study results. Current disparities in EMR and EHR systems, the lack of adequate workflows within healthcare institutions to support this contribute to such an effort could make the desired data enrichment challenging to achieve, thereby limiting the research applications for which patient records can be used.

A further difficulty here is that the time it takes to extract and transfer large volumes of data from health information systems, is time during which these systems cannot fulfil their primary function of supporting patient diagnosis and care. Especially in acute settings, healthcare providers cannot afford to keep their systems immobilised for extended periods just to allow the retrieval of datasets for research.

At European level

Define which primary data needs to be collected for reuse and accelerate the adoption of international standards and coding for the relevant data categories in healthcare

At national and regional levels Healthcare institutions

Develop guidelines and standard protocols for data collection that support healthcare professionals and integrate easily into their workflows

Cultural and practical barriers to the uptake of data-driven innovation

Rapid recent developments in the field of AI and their coverage in the media have increased public awareness of the possibilities, but also of the risks that come with these technologies. Among patients, the prospect of new data-driven solutions being deployed in healthcare has reportedly triggered fears related to the loss of personal contact with medical professionals and to the safety of the technologies themselves. Establishing trustworthy sources of information and guidance for the use of novel health technologies, as well as involving patients and their caregivers early in the development of concrete applications, could help to foster better understanding and build trust in this area. To

ensure acceptance, it will be particularly important for these developments to be driven by identified problems and defined needs in healthcare. Efforts should be made to address and include all parts of the population, not just the highly engaged and usually highly educated patients who typically participate in collaborative initiatives.

Reservations about the introduction of new technologies also exist among healthcare professionals themselves, although this was variable across countries: from early adopter mindsets reported in Austria, Ireland or the Netherlands, to more cautious attitudes or cultural barriers described in Spain. However, even in countries where healthcare professionals were deemed to be open to adopting data-driven innovation that integrates and adds value in the process of care delivery, the heterogeneity of digital skills both across and within different professions was expected to pose difficulties for a systematic implementation. Especially with AI, moving in small, manageable steps was recommended.

At national and regional levels

Establish step-by-step rules and processes to address ethical and other issues that arise from the use of AI in healthcare

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Chapter 5 | Closing the loop: The relation between primary and secondary use

Enablers and opportunities

Mutually beneficial data technologies

Novel technologies could provide an answer to the difficult question of how to motivate healthcare professionals to contribute to data collection for secondary use purposes. In a first step, more streamlined, structured, and user-friendly EHR forms aligned with the needs of clinical practice and designed around the principle of entering data only once, as well as possibilities for automated data collection and transfer from devices to medical records, could make the process of recording health data itself significantly easier for busy professionals. Going further, new intelligent systems could fulfil a double function by allowing a feedback loop and generating insights that can be directly applied in the primary use setting. In this setting, however, it would be important to precisely define what types of insights would be truly beneficial to healthcare delivery, to avoid drowning clinicians in information that they do not have time to process.

An example of this is provided by electronic data systems deployed in the USA, which intelligently define what information is needed and collect only data of the highest quality from different sources, then allow doctors to visualise their patients' characteristics as they compare to others through the creation of avatars. In situations not covered by existing clinical practice guidelines, physicians can then recommend treatment strategies with the highest chances of benefit based on similarities with historical patient profiles in the database. Although the economic and privacy models associated with the implementation of these systems are not transferrable to the European context, joint public tendering initiatives could be a way of fostering the development of solutions with the required scale. Previous initiatives like OncNGS, in which a consortium of European cancer centres collaborated to define needs and specifications for cancer diagnostic tools based on next-generation sequencing technology and launched a public call for tenders to incentivise more competitive offerings in a market dominated by large corporations, offer a template for how this can be done.

At national and regional levels, healthcare institutions

Specify the characteristics and type of data and/or analysis from secondary use that are relevant and useful to be provided to healthcare professionals

Data-conscious medical professionals

There is increasing recognition within the medical profession that not all knowledge can be obtained through clinical trials and that other types of data can be useful for informing clinical practice guidelines. Beginning to think prospectively about what data is needed for real-world research to address gaps in medical knowledge and questions left unanswered by the controlled clinical trial environment could be a powerful incentive for healthcare professionals to change the way they collect and record patient information in the primary use setting, and thus as an enabler of increasing data standardisation in line with the needs of secondary use. This could be mediated by coalitions of the willing, professionals with an interest in digital innovation and data who could help to mobilise their colleagues to

facilitate the adaptation of clinical workflows and the transformation of care processes. A valuable initiative in this area is the Data Value in Integrated Diagnostics educational programme carried out by EIT Health, Italy's IRCCS Synlab SDN, and other partners, which aims to create "data friend" professionals capable of informing patients and encouraging data-sharing, and familiar with the principles of data analytics and correct procedures for data collection.

At national and regional levels, healthcare institutions

Work with medical scientific societies to prospectively define research questions to be answered through the EHDS and the corresponding needs for real-world data collection

Dedicated infrastructures to make primary data reusable

In Germany, the Federal Health Data Lab (*Forschungsdatenzentrum Gesundheit*) placed under the responsibility of the Federal Institute for Drugs and Medical Devices (BfArM) is an infrastructure facilitating the secondary use of pseudonymised billing data from across the German statutory health system, through a central contact point that provides secure processing environments for research. The Health Data Use Act coming into force in 2024 expands the scope of the Health Data Lab to include new data sources and, going forward, will enable the organisation to support the process of making all primary data from the German EHR system reusable and accessible for secondary purposes.

A template for integrating the needs of primary and secondary data users within the same infrastructure can also be found in France, where the Data Collector Analyser (CAD) developed as part of the French Genomic Medicine Plan 2025 is currently being implemented. The infrastructure, to be hosted in two of France's national computing centres, will provide services for both healthcare delivery, helping practitioners to interpret genomic data for their patients, and for research, making the data collected for primary use available for secondary analyses.

Public-private collaboration on health research and innovation

Ireland is well known for being a hub to the life sciences industry, with more than 85 pharmaceutical companies operating in the country, and to the medical device sector, hosting 14 of the top 15 medtech companies globally alongside 300 smaller players, mostly startups and SMEs. Another key strength that will allow the country to benefit from the possibilities offered by the EHDS and translate these into valuable new health products and services, is the important contribution of its academic and public actors to the health research ecosystem. These include Ireland's world-class universities and the national health service.

Multistakeholder collaboration on new models of digital health and prevention

Making the best possible use of the insights and digital innovation resulting from the types of research that the EHDS will enable, implies a detailed understanding of the unmet needs that exist within different health systems and populations and a capacity to develop useful, viable solutions to address them. A best practice example in this area is Italy's DARE Digital Lifelong Prevention programme. The four-year initiative financed by the national Ministry of

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Higher Education and Research aims to develop a distributed knowledge community that can foster the emergence of new models and solutions for health promotion, monitoring, and disease prevention for the general population and subgroups such as children, pregnant women or chronic patients. A diverse network of partners including universities, research centres, local health authorities, foundations and private companies work together to harness the potential of digital technologies to bridge social and geographic disparities in the delivery of integrated health and care services.

Priorities for implementation

Streamlined processes enabling data use at scale

One of the biggest promises made by the EHDS proposal is that it will give researchers access to vast datasets including diverse patient demographics across EU Member States. If representativity of the real European population can be achieved, it will be instrumental to inform both policymakers and industry on the real healthcare needs across the Union and paves the way for the emergence of better medicines and effective digital health solutions, including ethical AI. However, long contracting phases and complicated legal processes currently make it difficult and expensive to provide the large data volumes that AI-based approaches and other health research methodologies require. Establishing joint systems and standardising the contracts for data use could support faster developments in this area. Importantly, these should be underpinned by clear ethical principles for data-sharing and processing.

Another critical factor will be to establish the technical and legal conditions for reuse of primary data at the earliest possible point of collection. For example, technical concepts could be developed on the basis of broad patient consent for secondary use, to allow context-specific pseudonymisation and linkage of datasets. Especially for the development of precision medicine, it was considered important to maintain connectivity between the datasets made available for secondary use and the clinical settings in which they were created. A standardised path is needed to enable secondary users to recontact patients via their healthcare teams, be it to request complementary information for research or to report incidental findings.

For some, the ultimate goal for integrating the primary and secondary data ecosystems should be the development of solutions to automate the extraction and transfer of data from standardised, interoperable EHRs to secondary use platforms—similar to the picture archiving and communication systems (PACS) now ubiquitous in the field of medical imaging—to ensure the sustainability of the process at scale. This, however, will require work to overcome legal, privacy and cybersecurity-related barriers.

At European level

Establish a standardised path for secondary users to comply with their obligation to report incidental findings. The finding should be reported in a timely manner, defining how, where, and to whom the relevant information on patients must be provided

At national and regional levels

Establish joint systems and standardised contracts to decrease overhead costs of data provision and use

Invest in connectivity between datasets and the healthcare setting in which they were generated, including a path to recontact patients

Support technical-legal approaches and standard-setting to enable automatic transfer of EHR data from primary to secondary use systems and smooth integration with national health data access bodies

Implementing the European Health Data Space Across Europe
Chapter 5 | Closing the loop: The relation between primary and secondary use

Healthcare institutions

Ensure pseudonymisation (by anonymisation of all personal identification information) of data at the data collection point to allow context-specific pseudonymisation and controlled use of privacy-preserving record linkage services when legal and ethical conditions are met

At national and regional levels, healthcare institutions

Generate use cases to demonstrate to healthcare professionals the benefits and time savings that can be achieved for them through the digital transformation of healthcare and educate them on their role in entering high-quality data into health information systems

Use cases around which all stakeholders can coalesce

An important finding during the first TEHDAS project was the need expressed in different countries to see concrete examples of how problems have been solved elsewhere. In a sector as fragmented as healthcare, multistakeholder projects centred around well-defined use cases will be crucial not just for understanding what each group expects and needs from the EHDS, but also for elucidating the inner workings of the interactions between them. Defining a moonshot project—a truly ambitious goal for EHDS stakeholders to coalesce around, akin to Europe's Beating Cancer Plan—was also suggested as a way of fostering engagement and collaboration for a common purpose. For doctors and nurses especially, defining a tangible purpose of the framework in this way could facilitate the emergence of viable solutions for standardised data collection in healthcare.

At European level

Define an ambitious overarching goal to be achieved through the EHDS to foster engagement and collaboration towards a purpose-driven implementation

Incentives to adopt digital health innovation

Many of Europe's healthcare systems are not prepared for the new developments that secondary use of data will bring. In particular, the majority have a pay-for-service system of healthcare reimbursement that does not easily accommodate solutions that improve quality of life, contribute to prevention of disease or health incidents, and allow a more efficient allocation of healthcare resources through predictive features. Value-based healthcare (VBHC) has been gaining traction in recent years as an approach to channelling public health systems' limited human and financial resources towards interventions that improve the health outcomes that matter most to patients. Adopting value-based models of healthcare financing that pay for results rather than services would incentivise keeping people healthy over treating the sick and thus be a powerful enabler for the adoption of predictive and preventive models of care that the EHDS is expected to make possible on a much larger scale.

Although the development of funding and reimbursement schemes for digital health innovation in various countries has been welcomed for its potential to ensure better and more equitable access for patients, EIT Health has previously highlighted that growing fragmentation

in this area, and in the application of the Medical Device Regulation, could undermine this very objective by delaying products' market entry as manufacturers turn first to the US (EIT Health, 2023). A harmonised European approach to the regulatory and health technology assessment of digital medical devices is needed, including common quality standards and evaluation criteria for real-world data studies. An important way in which the EHDS can support such assessments and foster trust in new technologies, is by ensuring the traceability of data across primary and secondary use platforms to allow its appropriate use in various applications.

At European, national and regional levels

Support health economics research to define the value of secondary use of data for public health

Develop structured paths to adoption and reimbursement of data-driven innovation by the healthcare systems, centred around defined patient or societal needs

Health data access bodies

Facilitate data traceability to foster trust in the new outputs and technologies to be fed back into healthcare

Healthcare and research institutions

Contribute to consensus-building towards a quality framework for real-world data analysis akin to the established standards for clinical trials

Change management to accompany the transformation of healthcare

As the digitalisation of healthcare workflows progresses and new insights and solutions are generated from the secondary use of primary data, the resulting transformations in care delivery could be immensely beneficial to patients, healthcare providers, and public health systems, but could also be met with great resistance if they are not well understood. In this area, active change management will be required not only to standardise the new solutions and patient pathways that are introduced, but also to define and communicate the benefits of new developments in a way that is meaningful for each stakeholder group. Understanding what matters to patients, healthcare professionals, healthcare managers and payers will be crucial to reconciling their different interests and implementing solutions with true added value.

At national and regional levels

Develop standard methods for evaluating data-driven health technologies' reliability and fitness for clinical practice

Develop educational resources for all stakeholder groups (citizens, healthcare professionals, health institutions, insurance providers, payers, public health, and political actors) to improve knowledge of the new technologies being developed and deployed in the health sector

CHAPTER 6

Awareness, education, communication: Towards a data-driven culture in healthcare

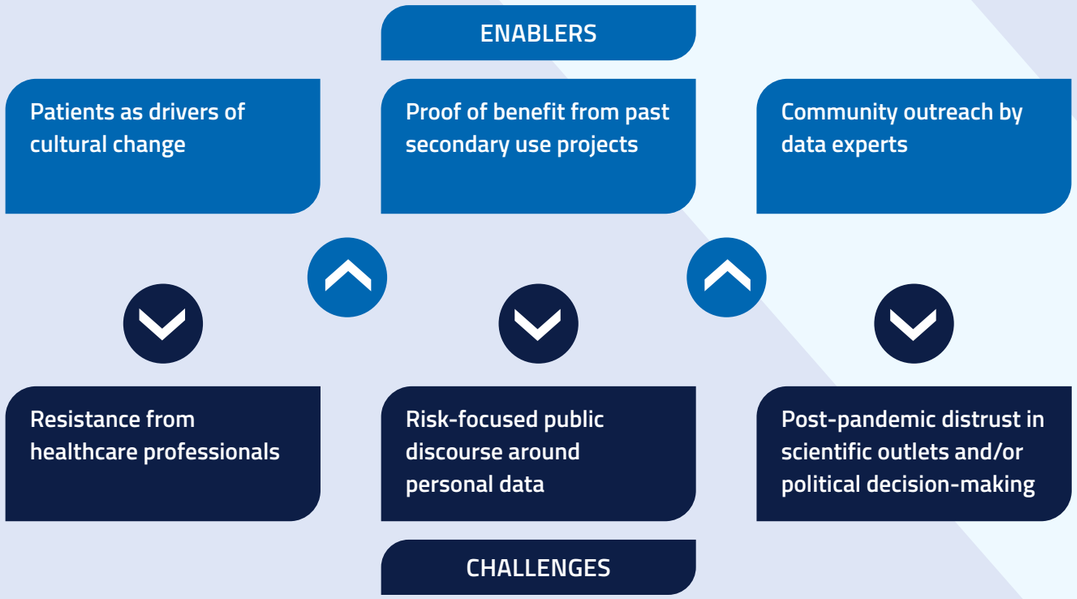
> Healthcare needs to understand patients better in order to be able to communicate better with them and make shared decision-making a reality
>
> Margareta Haag, Swedish Network Against Cancer, Sweden

Summary

Main findings

- Awareness of the upcoming EHDS regulation is low among key stakeholder groups, including healthcare providers. Most institutions are not currently taking any measures to prepare for their future role as data holders. Citizens' awareness of their health data and of their existing rights with respect to it are also insufficient.
- Citizens' acceptance of health data sharing for secondary use is variable between countries and conditioned upon factors such as data privacy and security, perceptions of benefit to the community, but also trust in the responsible governance bodies. Direct engagement of these bodies with the public is desirable.
- Patients are generally more conscious of the importance of data-sharing than the general public and can act as drivers of cultural change in healthcare and in society at large.
- Data-sharing initiatives and projects completed in the course of the COVID-19 pandemic can serve to demonstrate tangible results and benefits of secondary use and inform communication efforts around the EHDS

Challenges and enablers of implementation



Key findings, actors and potential solutions for implementation

Foster awareness and acceptance of the EHDS across society

At European level

Raise awareness early on the contents of and rationale for the legislation at all levels of healthcare, health policy and civil society

Develop appropriate communications around the cost effectiveness of high-quality data and proper use by different actors

At national and regional levels

Develop communication campaigns at national and regional levels to raise awareness of the EHDS among the general public and health professionals

Educate regional elected officials and decision-makers on the objectives of the EHDS and on their role in implementing the standards required to make it a reality

Communicate to all stakeholders how data security and patient privacy will be warranted and clearly publicise the penalties for misuse

Patient associations:

Mobilise patients as advocates for data-sharing towards the general public

Work closely with health data authorities to address inequalities and close the health data literacy gap

Provide practical answers to facilitate engagement with the EHDS

At European level

Provide clear guidelines for data holders on timelines for data-sharing and reassurance on the security of the data

Support transparent communication on the generation and use of health data to foster patients' and citizens' role as drivers of EHDS implementation

At national and regional levels

Develop a national implementation roadmap in consultation with all stakeholders, including the use of public debate

Make guideline information and processes transparent and user-friendly, taking into account the variety of stakeholders and different knowledge levels of the communities that need to understand and implement the guidance

Design inclusive (not only digital) educational resources to empower citizens to make informed decisions about their health data and make competent use of their opt-out rights, leveraging the know-how and reach of multi-stakeholder initiatives (such as Data Saves Lives)

Adopt measures to enhance digital literacy among all citizens through empowering all citizens with digital tools to manage their own health and health data

Explore ways to foster inclusion and empower populations with low digital and health literacy to engage in data-sharing through trusted health system actors such as primary care physicians, nurses and pharmacists

Empower all citizens with digital tools to manage their own health and health data and put in place measures and programmes to address inequities and enhance health and digital literacy

Cultivate trust in data-sharing long term

At national and regional levels

Emphasise the life-saving potential of data-sharing for citizens, while providing transparency around data collection, storage, use and the privacy safeguards in place to protect personal data

Engage with healthcare professionals and involve them in data-sharing platforms early on to demonstrate tangible value and foster trust and active participation in the EHDS

Health data access bodies

Warrant clear and timely communication to the public about which datasets are used in practice, for which purposes and with what results

Current national landscapes

Public awareness of the EHDS plan was consistently reported to be low in all regions covered by the roundtable series. In countries including France, Germany, Ireland, the Netherlands, Spain and Sweden, this lack of awareness was also noted among the healthcare professions and within healthcare management, with most providers having taken no preparatory actions in anticipation of their future obligations as data holders. Reports from Spain and Sweden further highlighted that knowledge of the upcoming regulation and of the actions required to implement it had not yet trickled down sufficiently from the national level to all regional elected officials and public decision-makers.

Attitudes towards sharing personal health data in general, especially among citizens, were variable and, as some suggested, correlated with the respective countries' regulatory landscapes for data protection as well as patient involvement in healthcare processes and health data management. Spain in particular stood out in an international comparison for its citizens' reticence to share their data for a variety of secondary use purposes, including scientific research and public health planning. In Germany, a discrepancy was described between the public's strong reservations about making data from the healthcare system available for research due to privacy and security concerns, and many people's willingness to share basic health data from wellness apps via social media. Austrian citizens' acceptance of the secondary use provisions of the EHDS was thought to be predicated on the perceived benefits to the community and data protection, while public trust would depend significantly on the choice of EU and national entities responsible for its governance.

In Luxembourg, by contrast, the public was reported to have a unique perspective on the importance of data-sharing in a context where cross-border healthcare is relevant for the majority of its 600,000 citizens and 200,000 daily commuters from neighbouring countries. Different stakeholders within the country's limited health ecosystem, which is centred around four large hospitals, also have an intrinsic motivation to engage in data-sharing on a European level. Similarly, the longstanding experience of Sweden's citizens and health system actors with health data being used for secondary purposes has resulted in a high level of acceptance and trust in data-sharing practices. In Ireland, too, findings of a national survey on health information found that participants overwhelmingly trusted and understood the importance of data-sharing for both primary healthcare delivery and secondary research (Health Information and Quality Authority, Department of Health and Health Service Executive, 2021), in spite of this not currently being a reality within the health system.

Assessments of population-level digital and digital health literacy varied across the countries represented, but there was consensus on the existence of significant domestic disparities: between regions, generations, healthcare professions, among others. In particular, awareness of the rights pertaining to personal health data that the GDPR provides was largely considered insufficient. In Sweden, high overall rates of digital literacy and use of mobile applications, including for health and wellness, have contributed to shifting the culture in healthcare, but gaps in health literacy, understanding of the health system, and communication with healthcare professionals tend to leave patients disconnected from their own care. Similar issues were highlighted in Austria and Spain.

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Chapter 6 | Awareness, education, communication: Towards a data-driven culture in healthcare

Common challenges and potential solutions

A history of risk-focused communication around data

In some countries, including Germany and Spain, political discourse and public debate surrounding use of data have traditionally been heavily focused on data protection and the risks of misuse. In Spain, widely publicised cases of past privacy breaches occurring in the country's healthcare institutions have only reinforced this tendency. Conscious efforts will be needed in these settings to help various stakeholders, especially the general public, make more accurate assessments of the risk-benefit balance of different forms of data use and normalise the practice of informed data-sharing. Demonstrating the benefits as tangibly as possible in different fields of health and healthcare will be important to convince citizens and medical professionals to participate actively in the implementation of the EHDS. One such attempt is being made in Italy, where the DARE Digital Lifelong Prevention programme is developing an initiative to allow individual patients to trace the use that is made of their data for the advancement of knowledge in the biological and medical fields.

At national and regional levels

Generate concrete evidence of the value of data-sharing and secondary use to inform and develop benefit-oriented communications for different stakeholders

The uncertain legacy of COVID-19 in public opinion

The COVID-19 pandemic is often credited with creating widespread political momentum and public acceptance for digital and data-driven approaches to public health policymaking and healthcare. Countries such as Italy, Ireland and Poland saw health data used in ways that were not possible before for research and rapid political decision-making, while the Spanish region of Catalonia witnessed the number of citizens registered on the MyHealth@EU platform for primary use skyrocket from 300,000 to 5.4 million in those few years. However, the health emergency and its management have also increased the polarisation of opinion on issues such as the imposition of lockdowns and personal protective equipment in public spaces, vaccine mandates, and the trustworthiness of research data and publications supporting different therapies against the virus. This erosion of public trust in political and health authorities should not be underestimated, and the task of convincing citizens to endorse and participate in the EHDS should not be treated as a secondary facet of the implementation effort.

At European, national and regional levels

Raise awareness early on the contents of and rationale for the legislation at all levels of healthcare, health policy and civil society

Develop appropriate communications around the cost-effectiveness of high-quality data and proper use by different actors

Resistance from clinicians

Although there has been a marked shift towards open data in academic circles in recent years, the reality reported by various representatives of professional associations is that in the wider health research ecosystem, and especially among most healthcare professionals involved in clinical research, data still tends to be jealously guarded. Reluctance to adopt the data-sharing principles of the EHDS is expected to be particularly strong in this field of research, where negative clinical trial results are rarely published.

A cause for greater concern is the possible resistance of healthcare professionals motivated by the perceived burden of the additional workload imposed on them by the EHDS, which featured prominently throughout the roundtable series, but also by feelings of frustration and exclusion from the current wave of innovation in healthcare coming from technology companies. Austrian experts in particular warned that failure to convince healthcare professionals and bring them on board early in the implementation process could cause them to become active detractors of the EHDS to patients, similar to what was observed during the rollout of the country's national EHR. Being some of the most highly trusted actors in the system, their buy-in and positive participation will be essential to the success of wider public awareness and communication campaigns.

At national and regional levels

Engage with healthcare professionals and involve them in data-sharing platforms early on to demonstrate tangible value and foster trust and active participation in the EHDS

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Enablers and opportunities

Patient-driven cultural change

Patients tend to have the greatest vested interest in data-sharing: to improve the continuity and quality of the care they receive, and to gain access to new treatment opportunities. It has been shown in various surveys across Europe that patients, as well as caregivers as a stakeholder group are more open to sharing their health data on average than the general population—likely because they perceive the direct benefits for them more easily than those who do not interact with the healthcare system as frequently. Often surprised to discover that data currently is not being shared in ways they would have taken for granted, patients have the personal experience and knowledge to illustrate to their fellow citizens, but also to healthcare professionals, why access to, use and reuse of health data are vitally important and what the consequences of disconnected primary and secondary data ecosystems can be. Communication and outreach programmes led by patient associations could thus be a powerful tool for conveying not just the benefits, but also the need for the EHDS. In Spain, for instance, the Platform of Patient Organisations has undertaken to launch a data lake dedicated to demonstrating the value of open data-sharing from the patient perspective.

Patient associations

Mobilise patients as advocates for data-sharing towards the general public

Work closely with health data authorities to address inequalities and close the health data literacy gap

Community outreach by data experts

France's Health Data Hub is endowed with a citizen department that engages in dialogue with civil society and provides useful information about how data is reused, trying to understand what they want to know. It also communicates intensively with data users and works to address the most commonly reported issues such as the length of time needed to obtain access to data. One of its tasks is explicitly to help foster a data culture throughout the ecosystem, which it fulfils for example by organising data challenges, AI for health summer schools, events to raise awareness about health data, and digital health training for medical professionals.

Tangible proof of benefit from past secondary use projects

In Poland, as in other countries, secondary use of electronic health data was facilitated during the COVID-19 pandemic. One use case, which began as a bottom-up project, concerned research among Polish children on the paediatric inflammatory multisystem syndrome (PIMS) caused by the coronavirus infection. The work was a boost to the research community, resulting in the publication of a number of scientific papers, and, importantly, it benefitted patients and their families by enabling the production of clinical practice guidelines for treating the condition. Further development of the project could eventually allow the modelling of future demand for related healthcare services and thus improve health policymaking in the country.

Showcasing such examples where results can already be measured can support the communication effort around the EHDS by making the benefits tangible for different stakeholder groups.

Priorities for implementation

Foster an ongoing, inclusive dialogue with all stakeholders

Dedicated efforts will need to be undertaken by the responsible entities at national level to raise awareness as widely as possible of the upcoming EHDS: the changes and, importantly, the possibilities and benefits it will bring, the compliance requirements and timelines for data holders and data users, as well as the penalties for non-compliance. An ongoing national dialogue should be initiated early on and cultivated with all relevant stakeholders: citizens and patients, healthcare and research institutions, healthcare professionals, healthcare payers, regional health authorities, legislators, EHR and other health information system manufacturers, as well as companies in the life sciences and health technology sectors. Each Member State will need its own roadmap for implementation taking into account the realities of its current landscape and reconciling the perspectives and interests of all those who will have a role to play in making the EHDS a reality.

At European level

Provide clear guidelines for data holders on timelines for data-sharing and reassurance on the security of the data

At national and regional levels

Develop a national implementation roadmap in consultation with all stakeholders, including the use of public debate

Develop communication campaigns at national and regional levels to raise awareness of the EHDS among the general public and health professionals

Educate regional and local decision-makers on the objectives of the EHDS and on their role in implementing the standards required to make it a reality

Make guideline information and processes transparent and user-friendly, taking into account the variety of stakeholders and different knowledge levels of the communities that need to understand and implement the guidance

Provide clear answers on data security, privacy and ethical governance

The main concerns surrounding the sharing and secondary use of health data that have been expressed by patient associations and observed in surveys of EU citizens pertain to data security, privacy, and the possibility of misuse. These are also relevant for data holders, who do not want to see breaches occurring with patient data they have, on their end, gone to great lengths to protect. Bringing clear and convincing answers to different stakeholders about how these risks will be prevented or minimised, as well as how ethical governance will be ensured, will thus be fundamental to building trust in the EHDS. Possible mediums for this include transparency reports and educational campaigns on major topics of interest such as AI, machine learning, or the risk that individuals, especially those suffering from rare diseases, could be reidentified even with limited data. Communications should also include the development of appropriate language surrounding the data economy that the regulation will give rise to, in which health data could effectively be attributed a price and traded, to prevent stoking long-held fears about its commoditisation.

Especially on sensitive or polarising issues, communication should not come only from the EU and the national ministries responsible for implementation, but rather from non-political actors such as the health data access bodies, statutory health insurances, doctors, as well as IT service providers or software manufacturers. Campaigns should also ensure universal access to knowledge by including non-digital channels such as telephone hotlines and information desks. Once data permitting and secondary use activities begin, regular and transparent communication by the health data access bodies about which datasets have been used, by whom, for which purposes and, ideally, with what results, could further help to cement citizens' trust and engagement over time.

At national and regional levels

Communicate to all stakeholders how data security and patient privacy will be warranted and clearly publicise the penalties for misuse

Emphasise the life-saving potential of data-sharing for citizens, while providing transparency around data collection, storage, use, and the privacy safeguards in place to protect personal data

Identify trusted system actors through which to channel information for different stakeholders

Health data access bodies

Warrant clear and timely communication to the public about which datasets are used in practice, for which purposes and with what results

Develop a checklist of frequently asked questions and publish clear answers for different stakeholders and the general public

Invest in health, data, and digital literacy

Lack of awareness among many EU citizens of what health data they possess, where it is located, and what rights they have with respect to it, was considered a significant obstacle to conveying to them the rationale for and benefits of gaining better access and control. Providing every citizen with a concrete way to visualise their health data and experience their ownership by controlling access or choosing to donate it will therefore be an essential condition for winning widespread acceptance. This should go hand in hand with measures to improve digital skills and, where necessary, include non-digital ways to bridge the gap between people and their data.

With as much as half of the EU population also considered to have poor health literacy, significant investment in education will be required to achieve widespread public engagement with the EHDS and prevent it from becoming a vector of further health inequities. Possible approaches include long-term campaigns targeting schools and workplaces to strengthen individuals' sense of responsibility for their own health and health data, as well as gamification approaches in the patient portals of EHRs and other digital patient spaces to encourage autonomous and proactive

management of healthcare and prevention. Leaning on trusted health system actors such as healthcare professionals and pharmacists to help vulnerable groups and people with low digital skills to share their data and engage appropriately with digital health applications, could be another way of fostering inclusion and participation.

Digital upskilling and digital health literacy programmes will additionally need to be developed and tailored to various other stakeholder groups, including doctors, nurses, elected officials, civil servants—not only as vectors of participation in the EHDS, but also as a means of reducing the data security and privacy risks arising from its implementation. With breaches in this area often attributable to a lack of understanding of how data should be managed or insufficient awareness of common fraudulent tactics like phishing, all individuals who will be expected to engage with the EHDS should be supported with educational measures which, by increasing individual competence and confidence, could also help to build collective trust towards data-sharing. Existing EU resources such as the Data.Europa Academy, which offers educational material on the topic of health data tailored to various stakeholder groups and skill levels, as well as existing platforms like the EIT Health Academy can be leveraged in this context to help prepare all parties in the respective Member States for the introduction of the new framework.

At European level

Support transparent communication on the generation and use of health data to foster patients' and citizens' role as drivers of EHDS implementation

At national and regional levels

Design inclusive (not only digital) educational resources to empower citizens to make informed decisions about their health data and make competent use of their opt-out rights, leveraging the know-how and reach of multi-stakeholder initiatives (such as Data Saves Lives)

Adopt measures to enhance digital literacy among all citizens through empowering all citizens with digital tools to manage their own health and health data

Explore ways to foster inclusion and empower populations with low digital and health literacy to engage in data-sharing through trusted health system actors such as primary care physicians, nurses and pharmacists

Empower all citizens with digital tools to manage their own health and health data and put in place measures and programmes to address inequities and enhance health and digital literacy

Glossary

Central platform for secondary use of electronic health data
An interoperability platform established by the European Commission, providing services to support and facilitate the exchange of information between national contact points for secondary use of electronic health data.

Data holder
Any natural or legal person, which is an entity or a body in the health or care sector, or performing research in relation to these sectors, as well as EU institutions, bodies, offices, and agencies, who has the right or obligation in accordance with the EHDS Regulation, applicable EU law, or national legislation implementing EU law, or in the case of non-personal data, through control of the technical design of a product and related services, the ability to make available, including to register, provide, restrict access, or exchange certain data.

Data permit
An administrative decision issued to a data user by a health data access body or data holder to process the electronic health data specified in the data permit for the secondary use purposes specified in the data permit based on conditions laid down in the EHDS.

Data user
A natural or legal person who has lawful access to personal or non-personal electronic health data for secondary use.

Dataset
A structured collection of electronic health data.

Dataset catalogue
A collection of dataset descriptions, which is arranged in a systematic manner and consists of a user-oriented public part, where information concerning individual dataset parameters is accessible by electronic means through an online portal.

Data quality
The degree to which characteristics of electronic health data are suitable for secondary use.

Data quality and utility label
A graphic diagram, including a scale, to be developed for the purpose of describing the data quality and conditions of use of a dataset.

Electronic health record (EHR)
A collection of electronic health data related to a natural person and collected in the health system, processed for healthcare purposes.

EHR system
Any appliance or software intended by the manufacturer to be used for storing, intermediating, importing, exporting, converting, editing, or viewing electronic health records. Designed to share information across different healthcare providers, including laboratories and specialists, it contains the same data categories as an individual institution's electronic medical record (see below) but compiles the information from all clinicians involved in the patient's care. Increasingly, EHR systems also offer patient portals that allow individuals to view their own health data.

Electronic medical record (EMR)
A digital version of the patient charts used by an individual healthcare institution to diagnose, treat and follow up with the patients in its care. It contains the medical and treatment history of patients specific to the relevant practice, but is not designed to allow the sharing of this information with other providers.

European electronic health record exchange format
A structured, commonly used and machine-readable format that allows transmission of personal electronic health data between different software applications, devices and healthcare providers.

HealthData@EU
The infrastructure connecting national contact points for secondary use of electronic health data and the central platform.

Implementing the European Health Data Space Across Europe
Glossary

Health data access bodies
According to the European Commission's original proposed regulation (2022), the health data access bodies are set up by the EU Member States to provide access to electronic health data to third parties for secondary use in a secure way, either as a new organisation or part of an existing organisation, building on the Data Governance Act.

Interoperability
The ability of organisations as well as software applications or devices from the same manufacturer or different manufacturers to interact towards mutually beneficial goals, involving the exchange of information and knowledge without changing the content of the data between these organisations, software applications, or devices, through the processes they support.

MyHealth@EU
The cross-border infrastructure for primary use of electronic health data under the EHDS, formed by the combination of national contact points for digital health and the central platform for digital health.

National contact point for digital health
An organisational and technical gateway for the provision of cross-border digital health information services for primary use of electronic health data, under the responsibility of the Member States.

National contact point for secondary use of electronic health data
An organisational and technical gateway enabling the cross-border secondary use of electronic health data, under the responsibility of the Member States.

Non-personal electronic health data
Data concerning health and genetic data in electronic format that falls outside the definition of personal data provided in Article 4(1) of Regulation (EU) 2016/679.

Personal electronic health data
Data concerning health and genetic data as defined in Regulation (EU) 2016/679, as well as data referring to determinants of health, or data processed in relation to the provision of healthcare services, processed in an electronic form.

Primary use of electronic health data
The processing of personal electronic health data for the provision of health services to assess, maintain or restore the state of health of the natural person to whom that data relates, including the prescription, dispensation and provision of medicinal products and medical devices, as well as for relevant social security, administrative or reimbursement services.

Registration of electronic health data
The recording of health data in an electronic format, through manual entry of data, through the collection of data by a device, or through the conversion of non-electronic health data into an electronic format, to be processed in an EHR system or a wellness application.

Secondary use of electronic health data
The processing of electronic health data for purposes other than the diagnosis, treatment and care of the patient. The data used may include personal electronic health data initially collected in the context of primary use, but also electronic health data collected for the purpose of the secondary use.

Wellness application
Any appliance or software intended by the manufacturer to be used by a natural person for processing electronic health data for other purposes than healthcare, such as wellbeing and pursuing healthy lifestyles.

Annex I

EIT HEALTH ROUNDTABLES	DATE	REPORT
Poland (Pilot Roundtable)	22 September 2022	**Polish EIT Health InnoStars Partners' roundtable on the European Health Data Space**
Hungary	18 April 2023	European Health Data Space Roundtable in Hungary
Italy	18 May 2023	**The power of health data: benefits and challenges for the European Health Data Space in Italy**
Ireland	30 May 2023	**Implementing the European Health Data Space in Ireland**
Portugal	9 June 2023	Implementation of the European health data space in Member States: is it feasible?
Spain	14 June 2023	**Implementing the European Health Data Space in Spain**
Sweden	27 June 2023	**Implementing the European Health Data Space in Sweden**
Austria	20 September 2023	**Umsetzung des European Health Data Space in Österreich**
Germany	10 October 2023	Implementing the European Health Data Space in Germany and Switzerland
BeNeLux	11 October 2023	Implementing the European Health Data Space in the Benelux Region
France	7 November 2023	How implementable is the EHDS?

Annex II

MEMBERS OF THE STEERING COMMITTEE	
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Leander Vranken	European Confederation of Pharmaceutical Entrepreneurs (EUCOPE)
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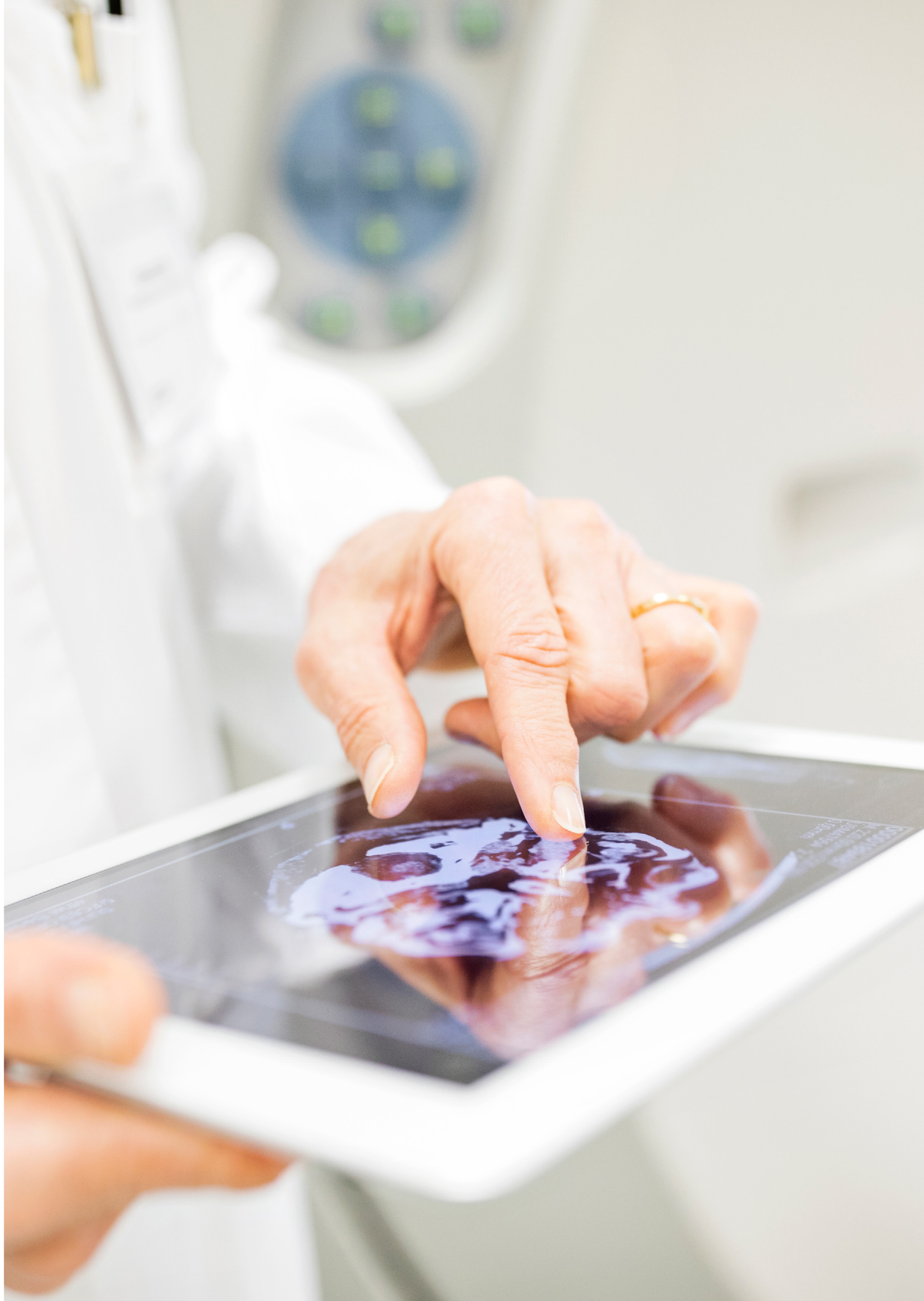

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