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Implementation of European Health Data Space in Spain: is it really feasible?

THINK TANK

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Executive summary

Introduction

In its proposal, the Commission explains that while the EU health sector is rich in data, it is poor in making it work for people and science. For this reason, the EHDS aims to harness the wealth of health data across the Union to help prevent, diagnose, and treat diseases, support research, improve healthcare delivery, and speed up the development of new medical products and treatments—all while adhering to its strong principles of data privacy and control.

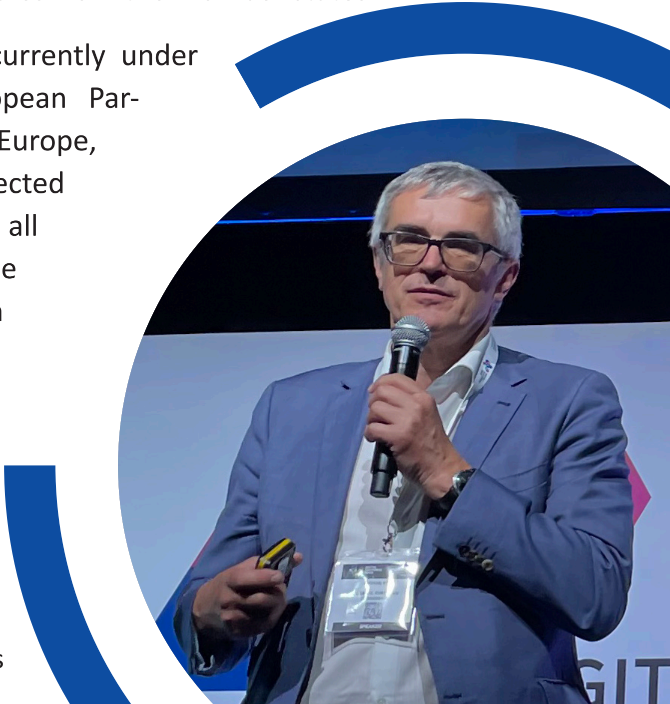
The Commission's EHDS plan covers the use of primary data, secondary data, common governance, and synergies with other health policy priorities. In terms of primary data, the EHDS aims to enable the millions of citizens of the EU to access their own health data and make it available to a health professional of their choice, including when abroad and in other languages, and also enable health professionals to update those records via the common myHealth@EU platform.

In terms of secondary use of data, the EHDS aims to set out a common EU framework allowing for use of anonymised or pseudonymised health data of EU citizens for research, innovation in public health, policymaking, regulatory activities, and personalised medicine. It will draw on the creation of a new and decentralised EU infrastructure for secondary use of health data, HealthData@EU, which will connect health data access bodies in all EU member states.

This infrastructure, piloted in five concrete use cases under the leadership of the French Health Data Hub[2], includes plans for permits governing the access to anonymised health data and how it can be used as well as closed, secure processing environments with clear standards for cybersecurity. The data will not be allowed to be used to make decisions that could be detrimental to individuals, to increase insurance premiums, to market health products toward health professionals or patients, or to design harmful products or services.

The proposal will also aim to reinforce the governance of health data at national and EU level. It will build on the current cooperation for primary use of data within the eHealth Network, which helped to build, in record time, two EU-wide infrastructures during the COVID-19 pandemic: the EU Digital COVID Certificate and contact tracing and warning apps. This will include the creation of a new European Health Data Space Board to oversee the system, chaired by the Commission and staffed by representatives of digital health authorities and health data access bodies from the member states.

The proposed regulation is currently under negotiation within the European Parliament and the Council of Europe, whose final positions are expected by the end of this year. Once all institutions have agreed on the final regulation, the European Commission aims to have the EHDS finalised by mid-2024 and running by 2025.



Andrzej Rys

How implementable is the EHDS? EIT Health assesses countries’ readiness for the legislation

To assess the feasibility of implementing the EHDS in different EU regions and member states, EIT Health is conducting a pan-European, multi-stakeholder public affairs initiative focusing in particular on provisions relating to the secondary use of health data. The initiative is gathering experiences and real-world insights of EIT Health's Partners and other relevant agents of the EU healthcare innovation ecosystem to shed light on what the realities and needs are in the individual countries in relation to adopting the EHDS, but also to distil lessons learnt and best practices from previous experiences of health data sharing for secondary use.

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

In Spain, a national roundtable was held on 14th June in Málaga as part of the health track co-organised by EIT Health Spain at the Digital Enterprise Show 2023. Three panels bringing together 10 experts representing the fields of public health, healthcare, academia, the life science industry, and patient advocacy convened to discuss Spain’s readiness for the upcoming EU legislation under six dimensions of implementation: Governance; Capacity and skills; Resources and funding; Data quality; Closing the loop: The relation between primary and secondary use; and Awareness, education and communication: Towards a data-driven culture in healthcare. Complementary insights and background were obtained through in-depth interviews with individual participants.

Six dimensions of implementation

Governance

The EHDS will introduce a common system of data governance along with rules and guidelines for data exchange in the health sector. This will be coordinated at national level by digital health authorities for primary use of patient data, and by health data access bodies for secondary use. The ability of different stakeholders in Europe's health ecosystems to apply this framework and engage in cross-border sharing of data will, among other things, depend on the conditions prevailing in individual countries in terms of access to electronic health records (EHRs), definitions of data anonymisation and pseudonymisation, authorised use purposes, and consent requirements under national interpretations of the General Data Protection Regulation (GDPR). Further challenges of data governance previously identified by EIT Health include the different policies and practices surrounding the use of health data within individual organisations.[3]

How ready is Spain?

Comprehensive digital policies are in place, but a legal framework for health data is missing

At national level, a strategic focus on digital transformation across all public and private sectors of Spain's economy and society has been materialised in comprehensive national policies such as Digital Spain 2026,[4] which leverages the funding made available through Europe's Next Generation EU stimulus package. It includes the National Artificial Intelligence Strategy, which, among other things, seeks to promote scientific research in this field, accelerate the development of digital skills, and establish data platforms and technological infrastructures to support AI.[5]

However, participants argued that efforts to tap into the potential of data have so far been undercut by the lack of an adequate legal framework for its use, as Spain's national interpretation of the GDPR is among the most restrictive in Europe and no specific national provisions exist for the governance of health data. According to **Joaquin Cayón, Director of the Research Group on Health Law & Bioethics at IDIVAL-University of Cantabria,** different institutions' reluctance to share health-related data has often been rooted in a fear of liability resulting from insufficient legal awareness and certainty as to how it can and should be done.

Lack of political coordination and continuity could hinder implementation at scale

Dr. Francisco José Sánchez Laguna, CIO of Andalusian Health Service, cautioned that although the EHDS would provide a complete framework to enable the sharing of health data on secure legal ground, the ability to adopt it in practice could be jeopardised by a lack of continuity in political action that has often been observed in Spain. It was noted that the national implementation of the EHDS is overseen by three different ministries, each with specific competencies—the Ministry of Health, the Ministry of the Economy, and the Ministry of Science—which would need to align closely with each other and with all of the regional governments across partisan lines.

In particular, coordination from the top down was said to be missing in order to be able to make the most of valuable experience in health data governance gained throughout Spain by many local initiatives which have already begun working with health data and deriving value from its secondary analysis. **Carlos Tellería, TEHDAS representative at Gaia-X Spain. Aragon Health Sciences Institute,** attributed this delay in developing a harmonised, scaled approach to the lack of a data culture and insufficient recognition of the value of data within the ministries of the regional governments. While political alignment across the country's 17 Autonomous Regions was deemed essential, the possibility for each of its 17 health systems to follow its own implementation roadmap and timeline was not considered an obstacle, but a practical advantage.

Insufficient patient involvement in data governance

Another potential challenge related to data governance under the future EHDS was highlighted by **Pedro Carrascal, Director of the Spanish Platform of Patient Organisations**: the lack of patient empowerment and participation in existing government, academic, and clinical data governance bodies. “There is a gap in regulation here, compared to other member states and European institutions which are more advanced,” said Carrascal. “We need to use the EHDS as an opportunity to change this—not only in the name of democratic participation, but also because the transformation of the healthcare system will require the active involvement of patients and patient organisations.”

According to Carrascal, the principle enshrined in the EHDS that citizens are the owners of their health data could equally help to overcome barriers related to healthcare providers' practices and policies around data-sharing. “Chronic patients are facing a lack of interoperability, there is a need to transform the health system to ensure more continuity of care throughout their lifetime. As data is increasingly collected outside of hospitals and patients obtain better access and control, citizens can become true enablers of data-sharing, including for secondary use purposes,” he said.

At the same time, Cayón warned that the notion of data donation as it is commonly formulated in Spain does not sufficiently acknowledge that data-sharing is also a matter of public interest. In this context, he highlighted the need for a health-friendly regulation. Therefore, he proposed a legal shift from the traditional ‘Helsinki model’ (based on the primacy of the consent of data subjects) to a new model which should rely on the primacy of public interest. To this end, Spanish regulation should take advantage of the new legal possibilities laid down by the EHDS regarding and the secondary use of collected data for medical purposes.

> *“Hardware becomes obsolete within a few years, knowledge does not"*
>
> **Carlos Tellería**

Priorities for implementation

Overall, participants agreed that Spain is not only in a good position to adopt the EHDS, but could even act as a leader in its implementation. “The diversity seen across Europe is not just a matter of different countries’ starting points, but also a matter of the directions they are taking. In Spain we have EHRs implemented nationwide, we have digitalised health systems, so we should also make the political decision to seize this opportunity and lead the way in Europe,” said **Montserrat Daban, Director of Science Policy and Internationalisation at BIOCAT, the bioregion of Catalonia.**

In defining the priorities for action at national level, there was consensus around the need to clearly identify which bodies would assume which responsibilities within the EHDS, as well as determine the roles of the national Ministry of Health and of the regional public health services in its governance. In this context, Cayón advocated for strong, centralised coordination at the national level and for specific national legislation governing the use of health data: “The implementation of the EHDS will likely be handled by the health-specialised legal sector rather than the general legal sector which implemented the GDPR. That’s why I am calling for a specific digital health act here in Spain,” he said. Due to the regional organisation of healthcare, however, it was suggested that data pools should be managed by data holders in the regions, and that regional data access bodies may also be needed in addition to the national contact point required by the EHDS proposal. “The national health data space project is currently being piloted with the creation of a large-scale national data infrastructure hosted by the Ministry of the Economy, but this is not in line with the structure of the Spanish health system,” Tellería explained. “Data holders should be at the regional level, with the national contact point being within the Ministry of Health purely as a coordination body.” Attention was also called to the need to resolve the crossover that currently exists in Spain between data holders, users, and access regulators, as the proposed regulation stipulates that health data access bodies should be distinct entities from the two other categories.

At European level, collaboration and harmonisation on a number of key issues were recommended for an effective implementation that would strengthen Europe's global position in the area of health data. Tellería suggested that in light of the different motivations and needs underpinning each of the secondary use purposes provided for in the EHDS—policymaking, research, and innovation—it would be necessary to design specific models of governance and potentially establish distinct data access bodies for each use case. "Policymaking is a primary focus of the regulation from the perspective of the European Commission, which during the COVID-19 pandemic found itself having to make political decisions on public health based on poor quality, incomplete data. Access to data needs to happen in real time to support public health monitoring and decision-making, whereas for research purposes, the timeline and the way data is selected and processed are quite different," Tellería explained. "Different users will have very different ways of interacting with the EHDS, therefore the rules for how data access applications are submitted, evaluated, and how access to data is provided should be adapted to these distinct needs and goals."

He also stressed the importance of ensuring agility in the data access process by guaranteeing the validity of data access permits issued in one country across all other member states based on a principle of mutual recognition.

Lastly, the need for member states to work towards EU-wide harmonisation of the GDPR was identified as a prerequisite to enable a unified system of EHDS governance, in particular with regard to the feasibility of adopting an opt-out model of informed consent. "There is a difference between the 'right to data protection' and the 'right to data privacy'. The last one is just non-interference right. This distinction is also made in the Treaty of Functioning of the European Union," said Cayón. "We have to provoke a shift from the 'privacy' model to a 'data protection' model, which allows for positive obligations of the data subject to share data in instances of an overriding public interest."

Key recommendations

- *Assign the responsibilities of data holders and data access bodies at regional level and a strong coordination function to the common contact point at federal level*
- *Build on existing regional initiatives and experiences in health data governance to allow efficient implementation*
- *Develop specific national legislation governing the use of health data*
- *Ensure patients and patients' organizations participation in data governance, not only in terms of management and guidelines but also in implementation of the EHDS itself.*
- *Agree at EU level on distinct models of governance for policymaking, research, and innovation purposes*
- *Ensure EU-level collaboration and mutual recognition between national health data access bodies*
- *Work towards EU-wide harmonisation of GDPR implementation to allow a common model of secondary use of health related 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 the national health data access body 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 its counterparts in other member states via the core platform HealthData@EU, will require some degree of capacity-building in the public administration. Single data holders such as hospitals, research organisations, and private sector companies will also be required to standardise and make their health data available to users either via a national data server or by establishing secure processing environments in-house. Finally, the EHDS will bring about significant changes and new opportunities in the way users can interact with health data. For instance, the possibility to bring together large numbers of independent datasets for analysis or the potential to conduct studies on an unprecedented scale with millions of patients will require new skills and changes in existing practices on the part of research communities, innovators, and policymakers.

How ready is Spain?

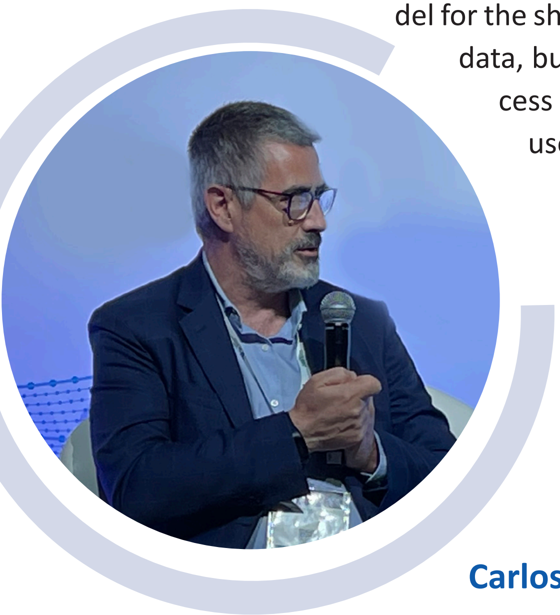
Spain has one of the world's most advanced digital healthcare systems

Although regional differences exist, the Spanish health system overall has reached a high level of digital maturity and was ranked among the top five out of 17 OECD countries with the most advanced digital healthcare systems in the Bertelsmann Foundation's 2019 Digital Health Index [6].

Key strengths were reported to be the implementation of basic standards at regional level, the capacity of regional EHR systems to export data to a national patient summary system, and the country's comprehensive electronic prescription infrastructure. Weaknesses included a lack of effective central coordination, variability in regional implementation of financing measures, and insufficient adaptation to digital health needs. Participants were therefore generally optimistic regarding Spain's technical and human capacities to implement the EHDS, pointing to the variety of digital solutions already available and to the high levels of investment in the digitalisation of both public and private healthcare. "In absolute terms, we are still far from where we need to be to fully realise the EHDS in the future, but if we compare Spain's situation to that of other countries in Europe, our starting point is favourable," said **Pedro Luis Sánchez, Director of the Studies Department at Farmaindustria,** the national association of pharmaceutical companies.

A strong foundation for secondary use of data

With respect to secondary use of health data, Sánchez cited the findings of a 2021 report[7] by the Open Data Institute that included Spain in the group of leading countries for policy and implementation especially in the subcategory of infrastructure, with progress similar to known role model countries like Denmark or Finland. Examples of Spain's extensive experience with and infrastructure for the use of federated data for health research include the Spanish Biobank Network[8], which links data from 39 biobanks for the benefit of the wider research community. "If you have a relevant project, you can apply to access both the data and the samples held by the biobanks," reported **Pablo Serrano, Planning Director at University Hospital 12 de Octubre in Madrid**, who saw this initiative as a model for the sharing of research and other proprietary data, but anticipated that creating paths to access primary healthcare data for secondary use would be more challenging.



"Instead of moving data to the people who want to process it, users should bring their computing to the data to avoid actually transferring it to a foreign jurisdiction whenever possible."

Carlos Tellería

Tellería echoed the sense of confidence that the technical infrastructure already distributed throughout the country's regions for data storage and computing would provide a robust foundation on which to build the EHDS. Even in the area of supercomputing, which may be needed for specific projects such as developing AI-based prediction models from the analysis of thousands of medical images, he argued that existing public research infrastructure like the Barcelona Supercomputing Centre or the University of Zaragoza's Institute for Biocomputation and Physics of Complex Systems (BIFI) would offer sufficient capabilities. In this context, Tellería lamented the national government's decision to build a new, central computation node within the Ministry of the Economy rather than investing in the human capacity and skills needed to make the EHDS come to life: researchers, data maintenance specialists, experts in AI, among others. "Hardware becomes obsolete within a few years, knowledge does not," he emphasised.

Interoperability of data in the healthcare system is a challenge

The main capacity gap Spain will likely face pertains to gathering and enabling secondary use of the primary data generated during healthcare provision. According to Daban, although this data is being recorded electronically in hospitals and in many other facilities, it is generally not standardised even within single institutions.

"In some hospitals there might be as many as 800 different information silos that need to be aggregated to support decision-making and research," Daban reported, expressing concern over the extent of data fragmentation considering that this scenario is repeated in various hospitals in the region and elsewhere in Spain, and that multiple different actors involved in managing data simultaneously add a further layer of complexity. She also highlighted a need to modernise the data infrastructures within healthcare, some of which date back to the 1990s. Against this backdrop, it was noted that the EHDS provisions for the interoperability of health data, including a mandatory certification for EHR systems, could be an enabler for implementation if extended as a requirement to all healthcare providers. Common terminology to underpin this interoperability, one participant reported, has already been developed in Spanish by various private companies and public-private partnerships, an effort which has also been picked up by the national Ministry of Health.

An example of best practice in this area came from the Autonomous Region of Aragon, where 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 Aragon Health Sciences Institute (IACS), was largely facilitated by a 15-year process of connecting and integrating the information systems within the public health service and to the introduction of a single health identifier for each citizen in Aragón. "There are still several systems in use today, but both the solutions and the data have undergone a process of standardisation: for example, when our 10 hospitals' labs were digitalised, we implemented 10 instances of the same solution, which significantly facilitated the creation of the data lake," Tellería reported. "We now have information from hospitalisations, emergency room visits, primary care, laboratory tests, radiology and medical imaging, drug prescriptions, and more, across the entire territory, which can be accessed upon application for research, public health planning, and quality management purposes. We support about 50 research projects each year, and when the COVID-19 pandemic started we were able to build a patient cohort in just two weeks in March 2020." The experience gained with the BIGAN platform has been studied by the Joint Action Towards a European Health Data Space (TEHDAS)[9] and allowed the development of recommendations on how to build and manage a federated data lake for Europe, and could serve as an implementation template for other regions in Spain.

A strong skillset for health data, but emerging needs to be addressed

While panellists generally considered Spain to have a rich talent pool in the field of data analytics and digital health, Daban warned against displaying excessive confidence in this area. The sharing mindset around health data and the different business models connected to it, she argued, are new to the healthcare sector and will require the development of novel skillsets—among the current healthcare workforce, but also among other professional groups entering the sector and thus the future EHDS through emerging fields of research and innovation like applied AI.

Carrascal also pointed to a gap in capacity and skills for the collection and use of new data streams like patient-reported outcome measures (PROMs) and other types of real-world data (RWD), which he linked to a disconnect between patients and the healthcare system. “There needs to be engagement and transparency at the macro, meso, and micro levels, to explain to patients how this kind of data can be used and how they can become active participants in its collection and sharing,” said Carrascal.

Andrzej Rys and Cristina Bescós, Growth Office Director, *ad interim* at EIT Health

Priorities for implementation

There was agreement among panellists that efforts to further improve Spain’s infrastructural readiness for secondary use of health data under the EHDS should focus mainly on creating the paths and the capacities to collect, aggregate, access, and reuse the data generated within healthcare. There was particular emphasis on the need to modernise obsolete data infrastructures in various institutions with a strategic orientation towards open systems capable of adapting to future developments, interoperability of both data and technologies, and connectivity to facilitate data-sharing with primary and secondary use environments.

With various infrastructures for secondary use of health data already in operation, it was recommended to build on open solutions that have previously been developed there, from data storage to analytics, and scale them up to a nationwide federated health data space for an efficient implementation. The main priority in this setting, according to Tellería, would be to adequately resource the processes needed to ensure secure data transfers and privacy-preserving processing. “In the queries submitted by the BIGAN platform to the primary data systems, all personal data is provided, the single identifier is public but it is encrypted and the key is held by the public health service. When we translate this data to our systems, we encrypt it a second time, and pseudonymise it differently for each research project in which it is used, meaning it cannot be linked across different projects,” he explained. “Data can still be reidentified, for example if incidental findings need to be reported back to the patient, but this requires both encryption keys and the collaboration of two organisations.”

Ángeles Barrios, Andrzej Rys and Cristina Bescós

At the level of the public bodies that will be responsible for managing data access within the EHDS, the need was identified to invest in the creation and staffing of all the services that will be required, and which do not exist today. These include the publication and maintenance of a data catalogue to make available datasets findable at national and European level, the development of an infrastructure and procedures through which to channel and process data permit applications, and the creation of a public interface that will act as a one-stop shop for users to obtain access to data. A further valuable service would be to curate and publish models from validated requests for other researchers and innovators to reuse in their applications.

Measures to address current skills gaps as well as the need for new skillsets in the future were considered necessary throughout the Spanish health ecosystem. “The EHDS framework will tell us how to share data properly, but sometimes doing things properly requires more effort and more resources, with the risk that shortcuts will be taken. To avoid this we need to upskill all participants of the future EHDS to enable them to work according to the applicable standards,” said Sánchez Laguna. This ranges from improving the data proficiency of healthcare professionals, through bringing in data maintenance specialists to curate individual data holders’ collections, training and attracting data scientists to work within the organisations responsible for managing the national health data space, all the way to developing expertise in AI and algorithm development for health research. The EIT’s ongoing Deep Tech Talent Initiative[10] to skill 1 million deep tech talents in support of the New European Innovation Agenda[11] was cited as an important enabler in this area.

Lastly, a need for new methodological approaches and models of collaboration was identified to overcome the potential ethical and legal risks associated with secondary use of datasets from multiple countries within the EHDS. “Instead of moving data to the people who want to process it, users should bring their computing to the data to avoid actually transferring it to a foreign jurisdiction whenever possible,” Tellería argued. Research questions could then be answered in international collaborative research projects where participating institutions analyse the necessary data in their own country. An example of this kind of EU-level collaboration is provided by the PHIRI[12] project, which is articulated around several use cases and developed in a federated way with different countries contributing to the same studies by analysing national datasets using a common analytics code. “Of course, this requires all participants to have the same data models and processing environments,” Tellería added, highlighting the importance of pursuing standardisation at European and national levels simultaneously.

> *“If you have a relevant project, you can apply to access both the data and the samples held by the biobanks."*
>
> **Pablo Serrano**

Key recommendations

- Develop and resource public data services for the EHDS: data catalogues, infrastructure for processing applications, a streamlined user interface, and a public knowledge base and guidance
- Increase public investment in the modernisation of data infrastructures in healthcare to improve interoperability and connectivity
- Build on existing regional experiences to develop open, scalable solutions that can be integrated into a federated health data space at national level
- Learn from existing European initiatives to establish models of international standardisation and collaboration on cross-border research projects
- Train and recruit data-proficient professionals in healthcare and public health services
- Leverage the EIT's Deep Tech Talent Initiative to develop and source the technical skillsets needed for the EHDS
- Anticipate future skills needs in healthcare, industry, and society: develop training in new business models related to health data, novel approaches to recording primary data with secondary use needs in mind, as well as health and data literacy for citizens

Resources and Funding

Although health data access bodies and individual data holders will be entitled to charge access fees to users, these will likely recover only a small part of the total cost incurred to transform, pool their data and make it accessible within the EHDS. The resources available for this will vary from one organisation to another and could in practice limit their ability to comply with the new requirements. In its position statement on the EHDS,[13] EIT Health therefore called for support to ensure that the framework represents an opportunity rather than a challenge for stakeholders.

> *“Patients’ lack of knowledge about data is partly due to the lack of connection to the health system and the processes within it—that’s why patient participation is so key.”*
>
> **Pedro Carrascal**

How ready is Spain?

Abundant public funding is available but allocation is contested

As part of the Digital Spain 2026 policy and investment programme[14], the digital chapter of the main Strategic Projects for Recovery and Economic Transformation (PERTEs) was launched with initiatives for the creation of large, shared data lakes in strategic sectors including health. Under the Vanguard Health PERTE approved by the Council of Ministers on 30 November 2021, €982 million in public funds were allocated to the incorporation of personalised precision technologies and medications into the national health system. With funding coming from both national, but also EU sources thanks to the digital health component of the Recovery and Resilience Facility and additional support for the EHDS to be provided through programmes including EU4Health, Digital Europe, the Connecting Europe Facility, and Horizon Europe,[15] it was estimated that €100 million have already been made available specifically for the implementation of the EHDS in Spain.

Although these levels of public investment were widely considered to be sufficient for these purposes, Tellería nonetheless objected that allocation decisions have so far lacked the right strategic focus, with disproportionate spending on hardware. “The project coordinated by the Ministry of Health, the Ministry of the Economy, and the Ministry of Science has distributed €28 million equally across the 17 regions to develop the local services for the EHDS, and the remaining €45 million are being used to build this redundant national repository and computing infrastructure," he said. Tellería warned in this context that insufficient provisions for the training and recruitment of technically skilled professionals able to deal with large data volumes and drive the standardisation of data across the system would jeopardise Spain's ability to operate the EHDS in practice.

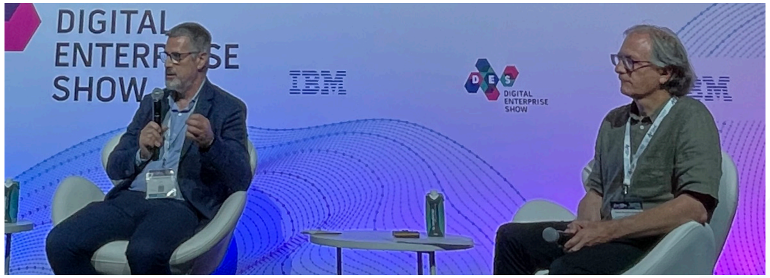
Uncertainty persists around long-term financial sustainability

In addition to the upfront investment needed for the creation of the EHDS per se, there was uncertainty surrounding the financial models that could ensure the long-term sustainability of operating this extensive data infrastructure in a context where the data itself is not monetizable.

Serrano reported from the Madrid region's experience with Infobanco[16], a public innovation tender for the development of a health data network combining information from different clinical, research, and administrative systems to provide services and tools for knowledge generation and decision-making: "We invested 2.5 million euros just for the first, research and development phase of this project which includes data from half a million people, but now the problem is finding a sustainable business model to translate the cost of running the platform to its users based on a defined benefit," he said. Serrano also questioned the availability of funding for the work that will be required to connect local platforms such as Infobanco to the EHDS.

Priorities for implementation

To optimise the allocation of available funds and ensure an efficient implementation, participants once again highlighted the importance of clearly defining which bodies at national and regional levels will play which roles within the EHDS in order to understand where new solutions will need to be developed and how much financial support will be required in each instance. "If the data holders and data producers are mainly in the regions, that is where we need to invest in data standardisation and storage. Meanwhile, to establish a centralised catalogue of services in Europe and in each country, we should allocate the appropriate amount of money at national level," said Tellería. In addition to technical solutions and services, there was consensus that a significant share of the total investment in the EHDS should be directed towards building up human capacities and skills within all stakeholder organisations to ensure its scalability at national level. With multiple data lakes already in operation throughout the country, it was also recommended to prioritise the development of open and reusable solutions for these platforms to integrate with the European infrastructure at minimal cost, rather than leaving each organisation to take its own path to technical implementation.



Carlos Tellería and Pablo Serrano

Key recommendations

- Optimise the allocation of available funds based on a clear understanding of which bodies will need to develop new solutions to fulfil their assigned roles
- Prioritise investment in the human capacities and skills needed to operate the EHDS
- Minimise the costs of integrating existing data lakes in the EHDS by supporting the development of open, standard solutions

Data Quality

Collection, use, and storage of healthcare data varies between organisations and countries, making it difficult to compare data across different sources and across borders. A common framework is needed to ensure that the data being shared within the EHDS is reliable and meaningful in order to produce trustworthy and useful research results, yet standards and auditing requirements must be inclusive enough as to allow every member state to participate. In particular, the possibility to use data from EHRs or medical devices for secondary research purposes requires that the reliability of the relevant datasets be scientifically validated.

How ready is Spain?

Leadership in data standardisation can be built on to improve usability of EHR data

Sánchez Laguna reported that although Spain's public health system has evolved significantly over the last few decades, the data stored in its now ubiquitous EHR systems is still overwhelmingly made up of free text which is difficult to use for secondary purposes in its unstructured form. This legacy data is especially prevalent in the records of older patients, who are more likely to suffer from chronic conditions and would stand to benefit from the reuse of their data. "We have technology to help us structure all of this information, but it will take time because we have to move carefully when it comes to health," Sánchez Laguna explained. "Consider how many years it took to achieve the European Patient Summary, which is just a simple report that to this day only a handful of countries have implemented—including Spain."

> *"Too often, once a law is passed we try to enforce the new requirements without making the effort to convince people of the rationale rather than simply mandating the change."*
>
> **Francisco José Sánchez Laguna**

Notwithstanding these challenges, participants rated Spain as being in a good position to implement a framework for the quality and interoperability of data shared within the EHDS, based on its extensive experience with the use of data standards in both clinical care and throughout its health research ecosystem. Of note, various studies in Spain have already confirmed the scientific validity of EHR datasets including diagnoses of chronic diseases such as diabetes, hypertension, and atrial fibrillation in the primary care setting. Further illustrating the country's leadership in this area, Serrano highlighted that Spain is one of the main providers of data in the European Health Data & Evidence Network (EHDEN).[19]

Collaboration between regions is now coordinated nationally

As the Autonomous Regions are not all equally advanced in the process of implementing quality improvement measures for their health data, panellists particularly welcomed the recent creation of a General Secretariate for Digital Health, Information and Innovation in the Healthcare System[20] to support and coordinate their efforts at national level, including with EU funding. "The 17 regions used to work separately, sometimes even competing for leadership. Now there is collaboration for a common purpose, which is going to make us unique as a country and places us in a very privileged position to move forward on the EHDS," said Sánchez Laguna.

Joaquin Cayón, Montserrat Daban and Pedro Carrascal

Priorities for implementation

With solid foundations in place for Spain to contribute high-quality data to the EDHS, participants wished to see a common national data quality framework formally established through this new General Secretariate. "The standards already exist, we don't have to invent anything, but ultimately working and making the decisions together is important for implementation to follow," said Sánchez Laguna.

Standardising EHRs and the legacy data they contain was considered by several panellists to be the main priority. Initiatives such as openEHR[21] were cited as offering affordable, alternative solutions to achieve system interoperability, while the HealthData@EU pilot project to demonstrate the feasibility of reusing health data from multiple European countries was expected to provide valuable lessons and guidance in data standardisation, data quality, and data labelling.

In general, engagement and collaboration with medical staff were deemed essential to the success of data quality improvement efforts in the healthcare setting. “Even though we are now working in information models and have better standards, our healthcare professionals need to be more aware of their importance and take the time to introduce high-quality data into our systems. It should be made clear that this is also a precondition for developing effective decision-support systems that can make their daily lives easier,” said Sánchez Laguna. He added that awareness and educational measures on this topic would need to be accompanied by efforts to make EHR systems more user-friendly and better aligned with clinical practice: “Ultimately, you still have people on the user end who need to examine their patients, touch and talk to them, do many things that technology cannot, and they sometimes feel that the information systems work against them rather than for them.” Daban argued that the process of standardisation could be an opportunity to simplify EHRs and thereby increase the chances of data being entered correctly for later reuse in a context where, as she reported, many healthcare professionals routinely use less than 20% of the spaces in the forms.

A further factor in achieving lasting improvements was said to be the choice of an appropriate implementation timeline, both to allow healthcare institutions and staff to continue focusing on their core business of taking care of patients, and to ensure the security of the data in the transformation process. “It takes time and resources to convince people to pursue a common goal, especially when that goal is subordinate to the requirements of daily patient care,” said Sánchez Laguna. To facilitate this shift in consciousness, Daban saw a role for patients to demand that their medical histories be recorded in useful, sharable form, and thus a need to raise awareness of the limited potential for reuse of the majority of current electronic health data among this stakeholder group.

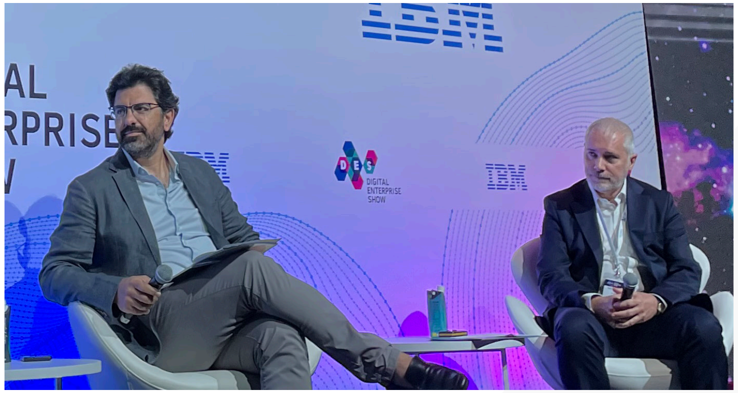
> *“We invested 2.5 million euros just for the first, research and development phase of this project which includes data from half a million people, but now the problem is finding a sustainable business model to translate the cost of running the platform to its users based on a defined benefit".*
>
> **Pablo Serrano**

Key recommendations

- *Formalise a national data quality framework through the General Secretariate for Digital Health, Information and Innovation in the Healthcare System*
- *Integrate lessons and guidance from the HealthData@EU pilot in the national framework*
- *Leverage new technologies to expedite the standardisation of legacy free text data within EHRs*
- *Educate healthcare professionals on their role in entering high-quality data into health information systems and the resulting benefits for their clinical practice*
- *Engage and collaborate with healthcare professionals to develop quality improvement approaches compatible with routine work processes*
- *Allow enough time for implementation to minimise risks to patient care and data security*
- *Mobilise patients to drive attitude shifts towards data collection in healthcare*

Closing the loop: The relationship between primary and secondary data use

Secondary use of health data will impact the primary use, clinical care process, for instance by accelerating the shift from treatment of illness to prediction and prevention in the way health- care is delivered. Conversely, effective secondary use depends on the quality of data collection in the primary use setting, as HealthData@EU will interface with MyHealth@EU and interoperable EHRs. The level of detail and choice of semantic standards used when health data is documented in the process of delivering care will determine whether it is reusable for secondary purposes at later stages. In general, a successful integration of data across the primary and secondary use ecosystems will require different actors within these ecosystems to play an active role beyond the interconnected technical infrastructure to be provided at EU level.



Francisco José Sánchez Laguna and Pedro Luis Sánchez

How ready is Spain?

Healthcare providers will be slow to adapt to data collection requirements for secondary use

The interaction between primary and secondary use of health data was anticipated by several participants to be a particularly challenging aspect of EHDS implementation in Spain. Panellists saw a cultural reluctance to share data at various levels of the health ecosystem, but especially among healthcare providers when it comes to releasing data collected for primary use to third parties for secondary use purposes. “This is a problem because the EHDS only makes sense if all possible health data is put on the table to derive value from it,” said Tellería. He reported that while research organisations are usually open to sharing the data from their patient cohorts and even integrating it into data lakes in the context of projects from which they can derive a benefit, it is harder to convince healthcare providers to release their data due to the difficulty of creating direct value or feedback for them. “This is one of the pending issues to be resolved: how can we bring value to the primary users of data from its secondary use?” Tellería emphasised.

Sánchez Laguna additionally highlighted the tension that exists between data needs in the secondary use setting and the daily business of healthcare provision: “If I need just three data points to be able to diagnose and treat the patient effectively, why should I waste precious clinical time collecting more information for research, innovation, or policymaking?” he emphasised. In this area, too, Sánchez Laguna expected that the changes required in clinical workflows, information systems, and physician behaviour to bridge this gap would take significantly longer than foreseen by the European Commission’s proposal. “The law may require us to complete the implementation in two years, but it simply will not happen because we have other essential things to do in parallel. In healthcare we have an obligation to move forward without failing,” he said.

One enabling force for reconciling the perspectives of primary and secondary users, according to several panellists, could be Spain’s large community of clinicians who already participate in research and therefore have an understanding of the information needs there. Spain is among the globally leading countries for clinical trials, the majority of which are concentrated in Catalonia. “The hospitals and healthcare professionals here who have experience with recruiting patients and handling data could be mobilised to help drive the change among their colleagues,” said Daban.

> *“All the stakeholders need to have a say in designing the roadmap for implementation, because the EHDS will have to reconcile their different interests if it is to achieve its dual ambition of improving the health, care, and quality of life of European citizens, and making Europe more innovative and competitive on the global stage”.*
>
> **Montserrat Daban**

> *“The hospitals and healthcare professionals here who have experience with recruiting patients and handling data could be mobilised to help drive the change among their colleagues.”*
>
> **Montserrat Daban**

Introducing innovation from secondary data use back into healthcare faces cultural barriers

Evaluating the potential for primary data users in healthcare to integrate insights and innovation from its secondary use into healthcare delivery, both Sánchez and Sánchez Laguna pointed to significant cultural barriers and to the time that would be needed to overcome them. “When we are on the verge of a significant breakthrough, we tend to overestimate its possibilities in the short run, but underestimate its impact in the long run,” said Sánchez. “Everyone wants this now, but we will have to take our time because introducing radical innovation like AI-driven models of prediction and prevention in our models of care has to be done right.”

Sánchez Laguna, who has been tasked by the regional Ministry of Health with overseeing the digital transformation of Andalucía’s public health system, explained that this transformation process has begun in Spain but cautioned that it must remain person rather than technology-led. “The vision is for technology to fade into the background and for people to spend less time engaging with it,” he explained. On the patient side, this could materialise as intelligent systems capable of automatically booking patients in for their next relevant appointments based on their medical history and records. On the clinician side, it could translate as voice-to-text solutions that drastically reduce the time spent typing up patient charts. Engaging with healthcare professionals and citizens to understand their needs would be critical, according to Sánchez Laguna, to ensure data-driven innovation is introduced with a purpose. “In a public challenge we organised around the management of diabetes in schoolchildren, for example, we realised that what children overwhelmingly wanted was for other people not to notice that they are diabetic,” he reported. “Rather than a connected blood glucose tracking device beeping all the time and drawing attention to them, they preferred to have a friend in the know who would recognise the symptoms of hypoglycaemia and help them if needed. We should not let technology pull us into things we do not want or need to do.”

Priorities for implementation

There was consensus among participants that healthcare professionals and healthcare managers should not only be educated on the new data needs they will be called on to fulfil under the EHDS, but also supported with clear guidelines, allocated time, and standard protocols for data entry. “We should design the guidelines around the priorities in each given situation: in the clinic, what the doctor needs to treat the patient must come first, and then additional data points that would be useful for research if they have time to collect them should be predefined in their systems,” said Sánchez Laguna. “If healthcare professionals are going to make that extra effort, the procedure for consenting the patient and recording the information must be made as easy as possible for them.” In this context, Sánchez highlighted the importance of designing a consent model that allows a broad range of potentially relevant information to be included, such as socio-economic background and environmental data as suggested in the regulation proposal.

To convince and motivate clinical staff to assume this role, panellists called for targeted efforts to demonstrate to healthcare providers how facilitating the secondary use of data will ultimately make their own work easier and improve patient care, including through practical use cases. The potential to gain new insights into rare diseases, for example, is one of the most highly anticipated benefits of the EHDS as it will allow small case numbers in different countries to be connected and studied in new ways.

Demonstrating tangible benefits was deemed equally important for citizens to have confidence in the system and volunteer comprehensive information for secondary use. In particular, the possibility for patients to have different privacy tiers within their records and control who can access each of them with much more transparency than is the case today was highlighted both as an immediate benefit of moving from free-text data to standard information models in the implementation process, and as an enabler of public trust in the EHDS.

From the perspective of the health research and innovation community, Daban underlined the need not just for clarity regarding where data will be gathered and how it may be accessed and used, but also for a structured path to adoption by the healthcare system of new solutions developed on this basis. “BIOCAT, which includes 1,500 companies and 100 research organisations within its network, 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 if they are able to demonstrate a health benefit,” she reported. “Currently though, businesses do not have a clear vision of what the Spanish data space is going to look like and how they will be able to close this loop from secondary use back to the healthcare setting.”

Key recommendations

- *Develop guidelines and standard protocols for data collection that support healthcare professionals and integrate easily into their workflows*
- *Agree at EU level on a consent model for secondary use of data broad enough to include both health and relevant health-related information*
- *Generate use cases to illustrate to healthcare professionals and managers how data-driven innovation can improve work processes and patient care*
- *Provide patients with transparency and control over who can access different categories of data within their health records to foster positive attitudes towards data-sharing*
- *Develop structured paths to adoption of data-driven innovation by the healthcare systems, centred around defined patient or societal needs*

Awareness, education, 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 and health technology industries, all the way to patients and citizens at large. At present, perceptions and preparedness to participate may differ between these groups and between countries, giving rise to varying educational and communication needs. One of the most salient needs in this area is the empowerment of individual citizens to exercise their rights in an informed manner, be it to engage in data altruism or to oppose further use of their personal health data.

> *"The implementation of the EHDS will likely be handled by the health-specialised legal sector rather than the general legal sector which implemented the GDPR. That's why I am calling for a specific digital health act here in Spain."*
>
> **Joaquín Cayón**

How ready is Spain?

Awareness of the upcoming legislation is low

While the national and regional governments in Spain may know broadly what to expect from the upcoming EHDS regulation, Sánchez Laguna warned that this is far from being the case for the various public health actors in the Autonomous Regions. Again, he anticipated that the swift implementation foreseen in the legislative proposal would be challenging in a context where awareness of the future EHDS is lacking and important stakeholders have not begun preparing for the change. Among these, the cultural readiness for open data-sharing of healthcare institutions was rated as particularly low.

Citizens are reticent to share their data for secondary use purposes

The preparedness of citizens to participate in the EHDS was another area of concern. Panellists reported on various opinion surveys in which Spanish respondents displayed low willingness to share their personal data for secondary use, especially with pharmaceutical, insurance, and digital health companies, but also for scientific research and public health purposes[22]. Sánchez rated these results as surprising for a country which displays a lot of solidarity in other areas, such as organ donation. "If patients don't see sharing their data as part of their citizens' rights and obligations, it means we are doing something wrong and we will face an issue of legitimacy with the implementation of the EHDS if we fail to address this," he argued.

An important barrier to overcome in this regard was reported to be widespread public distrust related to the risks of data theft and data misuse, something which one panellist attributed in part to a number of highly-publicised privacy breaches in hospitals that had admitted well-known public persons. At the same time, Sánchez was hopeful that the final EHDS regulation itself would help to allay some of these concerns by providing a binding legal framework for data to be shared according to defined quality, security, and ethical standards. Daban, meanwhile, highlighted the cultural shift provoked by the COVID-19 pandemic as a positive development and an enabling factor in obtaining the buy-in of citizens: "In Catalonia, the number of patients registered on the MyHealth@EU platform skyrocketed from 300,000 before the pandemic to 5.4 million afterwards. Sometimes it takes a major event to help us see the value of sharing data, and I think things are changing rapidly as a result."

Priorities for implementation

First and foremost, participants agreed that raising awareness of the upcoming regulation throughout the healthcare system and across society would be key to fostering acceptance of the EHDS ahead of its implementation. "Too often, once a law is passed we try to enforce the new requirements without making the effort to convince people of the rationale rather than simply mandating the change," said Sánchez Laguna. "If we change the EHR systems, for example, without explaining to healthcare professionals why and for what expected benefit, we are sure to trigger frustration, resistance, and non-compliance." Another important aspect of building trust across stakeholder groups, according to Sánchez Laguna, would be clear communication of the measures that will be in place to ensure data security and protect patients' privacy, including well-defined and enforceable penalties for data misuse.

Meanwhile, others identified a need for education in various areas to accelerate the broader transition towards a culture of data-sharing and reuse in health: from the legal and moral bases for secondary use of health data, through its possible applications, value, and limitations, all the way to the risks and opportunities of disruptive innovations like AI in healthcare. This was held to be particularly important for patients, who as a stakeholder group were identified as potential drivers of change in the healthcare culture. "Patients' lack of knowledge about data is partly due to the lack of connection to the health system and the processes within it—that's why patient participation is so key," said Carrascal, reporting that the Platform of Patient Organisations would be launching a data lake this year to show the value of open data from the patient perspective. "Patient organisations have not discussed the opportunities of data much in the past. Now we need to hit the ground running and launch practical programmes around data utilisation and data culture."

Some of the big open questions about how the EHDS will be implemented pertain to the composition of its different governance bodies and stakeholder representation on these, the decision-making processes within them, and the degree of legal flexibility that will remain for national interpretations of the final regulation. Daban therefore called on the Spanish and upcoming Belgian presidencies of the Council of the European Union to continue to prioritise this topic politically, and advocated for an open, ongoing national dialogue with all stakeholders: citizens and patients, hospitals and research institutions, healthcare professionals, health insurances and regional authorities, legislators, EHR and other health information system manufacturers, as well as companies in the life science and health technology sectors. "They all need to have a say in designing the roadmap for implementation, because the EHDS will have to reconcile their different interests if it is to achieve its dual ambition of improving the health, care, and quality of life of European citizens, and making Europe more innovative and competitive on the global stage," she concluded.

"When we want to make a very big change, it cannot be a quick change. The change management will require leadership, coordination, and looking to existing initiatives as role models. The task will likely never be complete, but Spain has the capacity to make the EHDS a reality in a not so distant future."

Ana Miquel

Key recommendations

- *Foster acceptance by raising awareness early of the contents of and rationale for the legislation at all levels of healthcare and society*
- *Communicate to all stakeholders how data security and patient privacy will be warranted and clearly define penalties for data misuse*
- *Plan and execute communications campaigns at EU, national, and regional levels*
- *Develop educational measures around the basis for, applications and limitations of health data use, including the risks and opportunities associated with AI in healthcare*
- *Target educational programmes via patient organisations to mobilise patients as drivers of cultural change in healthcare*
- *Keep the topic high up on the political agenda during the Spanish and Belgian presidencies of the Council of the European Union*
- *Involve all relevant stakeholders in designing an implementation roadmap through an open national dialogue*

Conclusion

Spain is, in many respects, starting from a privileged position to implement the EHDS. Its healthcare system is among the most digitally mature in Europe and has—its regionally segmented structure notwithstanding—provided fertile ground for many initiatives in data networking and secondary use to flourish over the past decade. As a result, extensive experience and expertise in data standardisation are present throughout the country and can inform the technical implementation and the quality framework for a federated EDHS infrastructure not just in Spain, but EU-wide. Funding for the national implementation effort is adequately provided by a cross-ministerial project dedicated to the EHDS, as well as by broader national policy programmes leveraging EU funding to accelerate digital transformation across the economy and society.

“In absolute terms, we are still far from where we need to be to fully realise the EHDS in the future, but if we compare Spain’s situation to that of other countries in Europe, our starting point is favourable.”

Pedro Luis Sánchez

Still, a lot of work remains to be done that will require a strategic allocation of resources at national and regional levels, starting with the distribution of roles and responsibilities for data governance in a way that reflects the decentralised organisation of public health and healthcare in the country. In a context where physical infrastructure for data storage and processing is already available across the Autonomous Regions, focus in implementation will need to shift to more complex tasks such as developing the services and technical solutions to allow data holders and users to interact efficiently with the EHDS, or transforming decades’ worth of legacy electronic records and fragmented information systems in healthcare into standardised, interoperable data collections fit for secondary use. The capacities and skillsets needed for this undertaking should not be underestimated—neither should the time it will take to achieve a transformation that facilitates rather than hinders the work of healthcare professionals and the continuity of patient care.

Both patients and doctors can be driving forces of this change, which will unleash the power of real-world data to help develop safer, more effective therapies and design more sustainable, patient-centred public health services. However, this will require profound cultural shifts in healthcare and across Spanish society, from privacy-centric approaches towards legally, ethically, and security enabled sharing of health data in the public interest.

These challenges are not small, but a sense of optimism emerged from the discussions that with cross-partisan political commitment and early involvement of all stakeholders in designing and preparing for implementation, Spain has all the makings of a leader in the process of adopting the EHDS across Europe. In the concluding words of steering committee member **Ana Miquel, responsible for innovation and international projects at the Ministry of Health of the Community of Madrid:** “When we want to make a very big change, it cannot be a quick change. The change management will require leadership, coordination, and looking to existing initiatives as role models. The task will likely never be complete, but Spain has the capacity to make the EHDS a reality in a not so distant future.”

Ángeles Barrios, Public Affairs & Stakeholder Relations Lead,
Izabel Alfany, Managing Director at EIT Health Spain and Ana Miquel

Participants

Ana Miquel - Responsible for innovation and international projects at the Ministry of Health of the Community of Madrid

Carlos Tellería - TEHDAS representative at Gaia-X Spain. Aragon Health Sciences Institute.

Francisco José Sánchez Laguna - CIO of Andalucía’s public health service

Joaquin Cayon - Director of the Research Group on Health Law & Bioethics at IDIVAL-University of Cantabria

Montserrat Daban - Director of Science Policy and Internationalisation at BIOCAT and President of The Council of European BioRegions (CEBR)

Pablo Serrano - Planning Director at University Hospital 12 de Octubre in Madrid

Pedro Carrascal - Director of the Spanish Platform of Patient Organisations

Pedro Luis Sánchez - Director of the Studies Department at Farmaindustria

Participants

From left to right: Pedro Luis Sánchez, Pedro Carrascal, Pablo Serrano, Carlos Tellería, Francisco José Sánchez Laguna, Izabel Alfany, Andrzej Rys, Montserrat Daban, Ana Miquel, Ángeles Barrios, Cristina Bescós and Joaquin Cayón.

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EIT Health Spain
Barcelona Science Park
Baldiri Reixac 4-8 Tower I Floor 3
08028 Barcelona Spain

T: +34 93 402 08 00

E: clc.spain@eithealth.eu

W: eithealth.eu
eithealth.eu/in-your-region/spain

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LinkedIn: linkedin.com/showcase/eithealthspain

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