Gesundheit Österreich GmbH

European Health Data Space: navigating the paradigm shift

Conference session report, European Forum Alpbach 2025

Alexander Degelsegger-Márquez, Melanie Maria Kuhrn, Herwig Ostermann
Oktober 2025

Context

The European Health Data Space (EHDS) is a comprehensive regulatory framework for sharing and accessing health data across the European Union. The Regulation (Regulation (EU) 2025/327) pursues two objectives: supporting the exchange of electronic health data for healthcare delivery (primary use) and enabling secure access to pseudonymised health data for research, innovation, policymaking and regulatory purposes (secondary use). In a nutshell,

- patients and healthcare providers will have digital access to relevant health data in a structured way, also across borders. In a hospital setting, for instance, care providers can quickly access the most relevant medical information via a patient summary across the entire EU;
- data users can apply for access to anonymised or, under certain conditions, pseudonymised health data for justified secondary use purposes including public health, research or education. This allows for better health policy, healthcare planning and quality.

Beyond its requirements for technical infrastructure, the EHDS constitutes a fundamental shift in European health data governance, establishing new legal foundations for cross-border data utilisation across the 27 EU Member States. With most of the secondary use provisions applicable from 2029, Europe finds itself in a critical preparatory phase. The EHDS Regulation will be implemented in several phases, given the breadth of preparatory work needed to set up the legal and technical infrastructure to operationalise the EHDS, making 2025 a pivotal year for the start of stakeholder alignment. Implementing the EHDS requires coordinated, multi-stakeholder engagement across policy, research, healthcare, IT infrastructure and civil society domains. The European Forum Alpbach (EFA) facilitates cross-sectoral dialogue between government representatives, researchers, patient advocates, data governance experts, interested and critical minds and stakeholder groups from different sectors that typically operate within separate institutional contexts, fostering perspectives that extend beyond traditional sectoral boundaries.

In this spirit, the Federal Ministry of Labour, Social Affairs, Health, Care and Consumer Protection (BMASGPK), Gesundheit Österreich GmbH (GÖG), the European Health Forum Gastein (EHFG) and the Complexity Science Hub (CSH) organised a structured 180-minute session at this year's EFA, examining the challenges and opportunities of implementing the EHDS. The format combined expert presentations, panel discussions and fireside chats with Austrian ministry officials, data users and patient representatives as well as national counterparts from Belgium and Slovenia. There were also thematic

breakout sessions to address both strategic and operational aspects of preparing secondary use within the EHDS.

Navigating the paradigm shift

The EHDS represents a fundamental transformation in European health data governance. Having entered into force in March 2025, it marks the beginning of a new era of health data use across member states. As State Secretary Königsberger-Ludwig underlined in her opening address, "I am convinced: if you don't have a data strategy today, you won't be able to ensure reliable care tomorrow. Health data are no longer merely an administrative affair: they are strategic to the future of our health system".

This transformation represents a fundamental evolution from a reactive, administrative approach to health data management towards a proactive, strategic model. This paradigm shift positions health data not as a mere byproduct of clinical processes but as a critical asset for systemic advancement. The EHDS provides a unified, cross-border framework that aims to break down data silos, enabling better care and a more holistic view of public health trends and individual patient journeys. This is a crucial step towards a data-driven health ecosystem where insights can be leveraged at scale to improve care, inform policy and accelerate innovation.

The EHDS Regulation: structure and objectives

The EHDS is an ambitious piece of legislation. Michael Fürmann (Head of Unit, Directorate-General VI, Human Medicine Law and Health Telematics, Federal Ministry of Labour, Social Affairs, Health, Care and Consumer Protection) introduced the text and explained its context and objectives. The European Commission presented a first draft of the Regulation in March 2022. After intense years of negotiation, it was published in the EU's Official Journal on 5th March 2025 and entered into force on 25th March 2025. The provisions will become applicable in phases from 2027 to 2035, with more than 30 implementing acts coming up in the next few years laying down additional details.

The Regulation is divided into three main sections:

Primary use (Chapter II): this concerns the use of health data for direct patient care including the availability and cross-border exchange of seven priority data categories: patient summaries, electronic prescriptions and dispensations, medical images and their reports, laboratory results and discharge reports. Patients are given the right to provide data and to rectify and restrict access to their data as well as several other related rights. Member States must establish a "Digital Health Authority (DHA)".

Requirements for Electronic Health Record (EHR) systems (Chapter III): EHR systems, a term which refers to all software handling the priority categories of health data defined in Chapter II, may only be placed on the market with two harmonised components: a European interoperability software component for common exchange formats and a European logging software component. Member States are required to establish a "Market Surveillance Authority (MSA)".

Secondary use (Chapter IV): this area governs the use of data for legitimate secondary purposes, including research, innovation and policymaking. This is only permitted under strict rules, with a strong emphasis on trust and transparency. Data are to be provided in anonymised form and, only under certain conditions, in pseudonymised form. Identifying personal data is never shared and any attempt at re-

identification is punishable by law. The data come from public and private data holders alike, including data in the priority categories from EHR systems but also socioeconomic and environmental data, data from public registries, medical device data, reimbursement data and clinical trials data, to name but a few examples. These data are to be made available through a common cross-border infrastructure in secure processing environments that tightly control data users' activities. For the facilitation of secondary use, Member States must establish a "Health Data Access Body (HDAB)".

Perspectives from the regulators, data users and patients

Following the State Secretary's opening and the Ministry's presentation of the Regulation, GÖG CEO Herwig Ostermann moderated a panel discussion on stakeholder expectations towards the EHDS. The panel discussion offered critical insights from key stakeholders on its implementation, revolving around several key themes and questions and exploring the benefits, challenges and necessary safeguards from diverse perspectives.

From a researcher's perspective, Peter Klimek, CSH, framed the EHDS as being crucial for addressing critical data gaps to improve health system resilience. The speaker highlighted that the increasing prevalence of diseases necessitates a focus on data-driven prevention and the early detection of disease progressions. The importance of using technology meaningfully was underlined, including the belief that the EHDS could help design health systems.

Representing the perspective of the Austrian Micro Data Center (AMCD), a national data holder, Regina Fuchs stressed that research requires high-quality, usable data. The importance of a feedback loop was also pointed out, where insights from research are returned to data holders and applications. The role of the Austrian Micro Data Center (AMDC) as well as the implementation of the EU's Data Governance Act are central to collaboration when implementing the EHDS and providing support to data users.

Representing a patient's standpoint, Valentina Strammiello emphasized that data protection should not mean data prevention, advocating for the proper use of data instead of blocking them. The speaker called for transparency and security in relation to how data outputs are managed and a well-designed opt-out mechanism to ensure that patients retain control over their health data.

Following up on the previous presentation, Michael Fürmann highlighted the importance of using EHR data for research and the need for common standards for cross-border use. The ultimate goal of the EHDS was underscored: improving healthcare provision. The key phrase "Data meet data" emphasised the importance of interoperability and the ability to link different datasets to enable more holistic insights.

National perspectives and experiences of implementing the EHDS

An EFA Fireside Chat allowed experts from Austria, Belgium and Slovenia to share where each country stands in their preparations for implementing the EHDS as well as to discuss common challenges and important preconditions with the audience.

The panel discussion provided a comparative overview of national approaches to health data infrastructure and EHDS implementation, highlighting both similarities and differences in strategy. The Austrian health data landscape, similar to the Belgian one, is characterised by a fragmented system with

many data holders. As Alexander Degelsegger-Márquez, GÖG, pointed out, Austria's approach is to put a focus on high value use cases and then gradually incorporate additional data holders depending on data users' demands. Other key areas in Austria's preparation work are the establishment of a user-friendly health data catalogue with interactive data exploration tools, an effective and agile ethics regime and a fair fee structure. The Belgian strategy concerning its fragmented health data landscape is to concentrate on progressively onboarding stakeholders, from smaller to larger data holders. Kathleen Janssens, Director of the Belgian Health Data Agency, also highlighted preparatory work on the EHDS already underway through her institution involving preparing health data training material and an AI-powered health data catalogue. Finally, Metka Zaletel from the National Institute of Public Health in Slovenia explained that, in contrast to Austria and Belgium, Slovenia has a more centralised data infrastructure but faces a significant challenge with data stored in outdated formats like PDFs. Their focus is on building infrastructure, establishing robust metadata structures and ensuring transparency through their opt-out procedure as well as continuous communication with patient organisations.

Implementing the EHDS's secondary use rules presents a multifaceted set of challenges alongside significant opportunities for systemic advancement. A key challenge is the potential for discriminatory monetary or non-monetary entry barriers for data users (fees too high, data quality not good enough, etc.) as well as a lack of capacity and/or compliance on the part of data holders. From an operational standpoint, bringing all data holders into a single, interconnected network represents a substantial hurdle, as does standardising data provided in such a way that facilitates exploration and analysis. However, these challenges also serve as a catalyst. The EHDS provides a framework to develop user-centric systems that streamline processes, drive interoperabliity, build public trust through robust data governance and transparency and foster a collaborative environment among diverse stakeholders, creating a more efficient European health data ecosystem.

Who stands to gain?

If implemented properly, there is plenty to gain from the EHDS both in primary and secondary use. In an interactive discussion with members of the audience, the potential gains were debated from four perspectives (society, policy, healthcare, research & innovation). The core questions revolved around the benefits, risks, control mechanisms and value associated with the secondary use of health data.

Society

There are both risks and benefits involved in the paradigm shift around the secondary use of health data. It was noted that this shift offers a better understanding of public health trends and an improved cost/benefit ratio for healthcare systems. Key societal benefits include enhanced transparency and patient empowerment through greater digital health literacy. To mitigate risks, discussions focused on establishing clear controls for citizens, such as an opt-out mechanism for specific data categories and a European-level secondary use registry. The importance of ensuring digital inclusion was also highlighted, aiming to prevent new inequalities across different demographic groups. Participants stressed the need for robust ethical bodies to oversee secondary use and the sharing of value back with society.

Policy

From a policy standpoint, the EHDS's secondary use rules are expected to provide concrete benefits by enabling more effective and efficient health policy design. The success of the EHDS by 2029 and beyond will be measured by its ability to provide access to high-quality datasets and by its connection to other EU initiatives, such as the Data Governance Act (DGA) and future additional sectoral data spaces. Discussions focused on ensuring that the implementation of the EHDS is adaptable and flexible, with a clear framework for data user fees to make data access sustainable. The need for basic agreements and public consultations on draft guidelines was also emphasised.

Healthcare

Healthcare providers stand to benefit from secondary data use through accelerated research and innovation, which can lead directly to improved treatment options. The discussion identified the need for specialised training for healthcare professionals on smart systems designed to reduce documentation burdens. To build trust, it is crucial to establish incentives and feedback loops that motivate providers to contribute high-quality data. The ultimate objective is to leverage data to improve health literacy and create a more efficient healthcare delivery system, thereby strengthening the trust relationship between patients and professionals.

Research & innovation

The EHDS can unlock economic and societal value. A key concern is the potential for high data access costs, which could hinder research, particularly for academia, where funding is scarce. Participants discussed the need for a balanced approach to data access fees, suggesting a low-cost initial period to foster early use and generate valuable results. The importance of establishing ethical review boards with knowledge of data ethics was also highlighted to guide decision making and ensure that researchers and authorities are not left to navigate complex ethical issues alone. To ensure Europe's competitiveness, it is crucial to balance the interests of academia and the private sector, possibly through a quota system for data access.

Key takeaways

- The paradigm shift: the EHDS signifies a move from reactive, administrative data management to a proactive, strategic model that views health data as a critical asset for systemic development.
- Data-driven healthcare: the EHDS promises to enable better disease prevention and more effective policy design as well as a higher quality and more resilient healthcare system by leveraging data for research and innovation.
- Trust and transparency: building trust is paramount. This requires providing patients with control over their data through a clear opt-out mechanism, ensuring ethics appraisal and transparency in how data are used and how benefits are shared.
- Interoperability and fragmentation: despite fragmented data landscapes in many countries, there is a shared commitment to building interoperable data infrastructures to enable seamless data exchange.

- Incentives and feedback: successful implementation of the EHDS depends on creating a system with clear incentives for healthcare providers to contribute high-quality data, along with feedback loops that demonstrate the value of their contributions.
- Cost of data: a significant challenge for the research and innovation sector is the high cost of data access. A balanced approach to fee structures is needed to support both academic and private-sector research.

Next steps in Austria

As the EHDS Regulation entered into force in 2025, with full applicability of secondary use rules from 2029 onwards, stakeholders in Austria and throughout the EU face a critical preparatory period. A few of the upcoming activities are listed below:

- Discussions with the data holder community: this is a crucial step to ensuring the integration of all data holders, from small to large, into the new data ecosystem. Data holders need information on the EHDS and how to be compliant so that preparatory work can be set in motion. GÖG will facilitate this with a variety of data holder communities.
- Secure Processing Environment (SPE) testing: the EHDS's secondary use rules require EHDS-compliant Secure Processing Environments that also tie into the cross-border HealthData@EU infrastructure. Tests are currently being conducted by GÖG and the BMASGPK as part of the HealthData@AT project to validate the technical infrastructure for secure data access.
- Establishing a Health Data Academy: this initiative aims to enhance data users' knowledge about health data and the EHDS.
- Piloting a data catalogue: also part of the HealthData@AT project, this initiative will work towards improving the discoverability of datasets.
- Work on the data catalogue as well as general secondary use infrastructure will be coordinated between the bodies responsible for implementing the Data Governance Act and the EHDS.
- EU Community of Practice: Austria will continue to play an active role in the Community of Practice of authorities in charge of implementing secondary use provisions within the EHDS. Discussions with international peers are essential for sharing experiences and best practices as well as avoiding duplication when implementing the EHDS.

As State Secretary Königsberger-Ludwig emphasised in her closing remarks, Austria is determined to make the implementation of the EHDS a success. The Federal Ministry will continue to work with relevant stakeholders in Austria and beyond.

Suggested citation: Degelsegger-Márquez, Alexander; Kuhrn, Melanie Maria; Ostermann, Herwig; (2025): European Health Data Space: navigating the paradigm shift. Conference session report, European Forum Alpbach 2025. Gesundheit Österreich, Wien

ZI: P6/35/5511

Commissioned by the Federal Ministry of Labour, Social Affairs, Health, Care and Consumer Protection