Understanding the European Health Data Space: Actors, Data Flows and Governance Mechanisms

By Pankaj Raj

Pankaj Raj is a Research Engineer specializing in European governance, with a focus on the intersection of AI regulation, data protection, and ethical governance. He is a PhD candidate in health data and its secondary use, working at the intersection of the GDPR, the European Health Data Space (EHDS), and the AI Act.

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Abstract

The European Health Data Space (EHDS) is one of the European Union's most ambitious initiatives to improve the access, exchange, and reuse of electronic health data across Member States. By addressing longstanding challenges such as fragmented healthcare systems, limited interoperability, and barriers to data sharing, the EHDS seeks to enhance healthcare delivery while enabling the responsible use of health data for research, innovation, public health, and evidence-based policymaking. This article provides an accessible overview of the EHDS by examining its objectives, the key actors involved in its implementation, the journey of electronic health data through its primary and secondary uses, and the governance arrangements, safeguards, and operational mechanisms that support its functioning. Rather than focusing solely on the legal provisions of the Regulation, the article adopts an operational perspective to explain how the EHDS works in practice and how its various components interact to create a trusted and interoperable European health data ecosystem. By presenting the EHDS as an interconnected ecosystem, the article aims to provide readers with a clear understanding of one of the European Union's most significant digital health initiatives and how it is intended to transform the use of health data across the Union.

Key Takeaways

- The European Health Data Space (EHDS) creates a common framework for sharing and reusing electronic health data across the European Union.
- It enables individuals to access and control their electronic health data while supporting healthcare professionals in delivering safe and continuous care, including across national borders.
- The EHDS also allows health data to be reused for research, innovation, public health, and policymaking under strict legal and governance safeguards.
- A network of actors, digital infrastructures, and governance bodies work together to ensure that health data is exchanged securely, responsibly, and transparently.
- Understanding how these components interact is essential to understanding how the EHDS is intended to improve healthcare and strengthen Europe's digital health ecosystem.

1. Introduction

Health data has become one of the most valuable resources in modern healthcare. Every interaction between an individual and a healthcare provider generates data that can support not only the diagnosis and treatment of patients but also medical research, public health surveillance, healthcare planning, and the development of innovative medicines and medical technologies. As healthcare has become increasingly digitalised, the volume and diversity of electronic health data have expanded rapidly, creating new opportunities to improve healthcare delivery and population health (World Health Organization, 2021).

Despite these opportunities, Europe has long struggled to make effective use of health data. Healthcare systems across the European Union have traditionally developed independently, resulting in different legal frameworks, technical standards, and digital infrastructures. As a consequence, electronic health information is often stored in separate or incompatible systems that cannot easily communicate with one another (OECD, 2023). A patient receiving treatment in another Member State may find that their medical history is not readily available to the treating physician, while researchers seeking access to health data for studies addressing diseases or public health challenges frequently encounter legal, organisational, and technical barriers. Consequently, substantial amounts of valuable health data remain underused despite their potential to improve healthcare outcomes, strengthen health systems, and generate broader societal benefits (European Commission, 2022).

The importance of overcoming these barriers became particularly evident during the COVID-19 pandemic. Although discussions on establishing a European Health Data Space had already begun before the pandemic, the public health emergency highlighted the need for timely, secure, and reliable access to health data across national borders. Effective pandemic surveillance, scientific research, vaccine development, and coordinated public health responses all depended upon the ability to share and analyse health information efficiently. The experience reinforced the need for a more coordinated European framework capable of supporting both healthcare delivery and the responsible reuse of health data while respecting individuals' rights (European Commission, 2022).

In response to these longstanding challenges, the European Union adopted the European Health Data Space (EHDS), establishing a common framework for the access, exchange, and reuse of electronic health data across Member States. The EHDS represents one of the European Union's most ambitious initiatives in the field of digital health governance. Recent scholarship has described it as a transformative step towards a more integrated European health data ecosystem, while also recognising that its success will depend on effective implementation, interoperability, and public trust (Azzopardi-Muscat & Sørensen, 2022). It seeks to empower individuals by giving them greater control over their electronic health data, facilitate the secure exchange of health information for healthcare purposes, and enable the responsible secondary use of health data for scientific research, innovation, public health, regulatory activities, and evidence-based policymaking (European Commission, 2022). These objectives reflect the growing recognition that health data is not only essential for the care of individual patients but also represents a strategic resource for improving healthcare systems and generating knowledge that benefits society as a whole.

The EHDS does not replace existing European data protection legislation, particularly the General Data Protection Regulation (GDPR**)**. Rather, the two frameworks serve complementary purposes. While the GDPR establishes general rules governing the protection and processing of personal data across all sectors, it does not provide detailed mechanisms for the cross-border exchange and reuse of electronic health data within healthcare systems. The EHDS builds upon the GDPR (European Commission, 2022) by introducing sector-specific rights, obligations, governance structures, and digital infrastructures specifically designed for health data. In doing so, it seeks to facilitate the secure and trustworthy use of electronic health information while maintaining the high standards of data protection established under European law.

Understanding the EHDS therefore requires more than simply examining its legal provisions. The Regulation establishes an interconnected ecosystem involving individuals, healthcare professionals, healthcare organisations, data holders, data users, national authorities, European institutions, and digital infrastructures. Together, these actors support the generation, exchange, access, reuse, and governance of electronic health data throughout the EHDS ecosystem. Understanding how these different actors, infrastructures, and governance mechanisms interact is essential for understanding how the EHDS will function in practice and how it seeks to balance the benefits of wider health data use with the protection of individuals' rights and interests.

This article provides an accessible overview of the European Health Data Space by examining its objectives, the principal actors involved in its operation, the movement of health data through its primary and secondary uses, and the governance mechanisms that underpin the framework. Rather than focusing solely on the legal provisions of the Regulation, the article adopts an operational perspective to explain how the EHDS functions in practice. By following the journey of health data through the various actors, infrastructures, and governance arrangements established under the Regulation, the article aims to provide readers with a clear understanding of one of the European Union's most significant developments in digital health governance.

2. Objectives of the European Health Data Space

The European Health Data Space seeks to establish a common framework for the access, exchange, and reuse of electronic health data across the European Union. While health data has become increasingly important for healthcare delivery, scientific research, innovation, and policymaking, its effective use has often been hindered by legal fragmentation, technical incompatibilities, and organisational barriers between healthcare systems and Member States. The EHDS aims to address these challenges by creating a harmonised framework that enables the secure and trusted use of health data while safeguarding the rights and interests of individuals.

The objectives of the EHDS are reflected in the way the framework is designed. Rather than simply setting policy goals, the Regulation establishes a network of actors, digital infrastructures, governance arrangements, and safeguards that work together to achieve them. Understanding these objectives provides the foundation for examining how the EHDS operates in practice. The actors and mechanisms introduced in the following sections are therefore not isolated components of the framework; rather, each contributes to achieving one or more of the EHDS's overarching objectives.

2.1 Citizen Empowerment

A central objective of the EHDS is to place individuals at the centre of the European digital health ecosystem. The Regulation seeks to strengthen citizens' control over their electronic health data by improving transparency, facilitating access to health information, and enabling individuals to participate more actively in decisions relating to their healthcare and the use of their data[1].

This objective is reflected throughout the EHDS framework, particularly through mechanisms that enable individuals to access their health information, exercise control over certain forms of data processing, and benefit from improved continuity of care across healthcare providers and Member States[2].

2.2 Improving Healthcare Delivery Through Primary Use

The second objective of the EHDS is to facilitate the use and exchange of electronic health data for healthcare purposes. By improving access to relevant health information, the Regulation seeks to support more efficient, coordinated, and patient-centred healthcare delivery across the European Union[3].

This objective is pursued through a primary-use framework that enables individuals and healthcare professionals to access and exchange health data for purposes directly related to healthcare delivery. The actors, infrastructures, and governance arrangements that support the primary use of health data are involved throughout the journey of electronic health data within the EHDS ecosystem[4].

2.3 Enabling Secondary Use of Health Data

The third objective of the EHDS is to unlock the societal value of health data by enabling its responsible reuse for purposes beyond the direct care of the individual. The Regulation recognises that electronic health data can contribute to scientific research, innovation, public

[1] Regulation (EU) 2025/327, Recitals 8-18; Articles 3-17.
[2] Regulation (EU) 2025/327, Articles 3-17 and 23-26.
[3] Regulation (EU) 2025/327, Recital 19; Articles 2(2)(d), 15-26.
[4] Regulation (EU) 2025/327, Articles 15-26 and 64-66.

health activities, healthcare planning, regulatory activities, and evidence-based policymaking[5].

To achieve this objective, the EHDS establishes a governance framework that enables authorised users to access health data under clearly defined conditions and safeguards. The actors, infrastructures, and governance mechanisms supporting the secondary use of health data are explored in the subsequent sections of this article[6].

3. Understanding the EHDS Ecosystem

To understand how the EHDS operates in practice, it is useful to examine the actors involved throughout the journey of electronic health data within the EHDS ecosystem. The EHDS ecosystem comprises individuals, healthcare professionals, healthcare organisations, access authorities, data users, and European governance bodies. These actors perform distinct but interconnected functions within the EHDS ecosystem, supporting the generation and collection of health data, its primary use for healthcare delivery, its secondary use for research and innovation, and the governance mechanisms that ensure accountability, interoperability, and trust.

3.1 Health Data Generation

Every health data journey begins with the generation of information. Within the EHDS, health data originates through interactions between individuals, healthcare professionals, and digital health technologies before being recorded in electronic health record systems. These actors collectively create the foundation upon which both the primary and secondary uses of health data depend.

3.1.1 Individuals

Natural persons are the individuals about whom health data is generated and collected within the EHDS ecosystem. Health data is generated throughout an individual's interactions with healthcare systems and, increasingly, through the use of digital health technologies in everyday life. When a person seeks healthcare services, health-related information is created and recorded by healthcare professionals involved in their care. Physicians document symptoms, diagnoses, treatments, and medical histories during consultations. Specialists record clinical assessments and treatment plans, while nurses collect and update patient information throughout the care process. Laboratories generate diagnostic data such as blood test results, imaging reports, and other clinical measurements. Together, these records contribute to the creation and maintenance of an individual's electronic health record.

Beyond traditional healthcare settings, health-related data is increasingly generated through wellness applications, wearable devices, and other digital health technologies. These tools may collect information relating to physical activity, sleep patterns, heart rate, body weight, and other health indicators. Where data generated by such technologies is incorporated into electronic health records or otherwise falls within the scope of the EHDS under applicable

[5] Regulation (EU) 2025/327, Articles 53-56.
[6] Regulation (EU) 2025/327, Articles 67-90.

legal and national implementation requirements, it may become part of the broader European health data ecosystem[7]. In addition, health-related information may be generated through interactions with health insurance systems, which maintain records of reimbursements, prescribed medications, medical consultations, laboratory tests, and therapeutic interventions. Through their interactions with healthcare providers, digital health technologies, and related healthcare services, natural persons are the individuals about whom health data is generated, collected, and maintained within the EHDS ecosystem. The data generated through these interactions forms the foundation upon which both the primary and secondary uses of health data are built[8].

3.1.2 Health Professionals

Health professionals play a central role in the generation, validation, and maintenance of health data within the EHDS ecosystem. As the primary providers of healthcare services, they are responsible for documenting information relating to patients' health conditions, diagnoses, treatments, medications, and care pathways. During the delivery of healthcare services, physicians record clinical observations, diagnoses, prescriptions, and treatment decisions. Specialists document detailed assessments and recommendations within their respective fields of expertise. Nurses contribute by recording vital signs, patient histories, care plans, and observations made throughout the treatment process. Similarly, pharmacists, laboratory personnel, and other healthcare practitioners generate and record information relevant to the provision of care. The categories of healthcare professionals authorised to create, record, or update electronic health data within the EHDS are determined in accordance with the Regulation and the national legal and organisational frameworks of each Member State[9].

Health professionals not only create new health data but also verify, update, and maintain the accuracy of existing records. Through their interactions with patients and healthcare information systems, they ensure that health data remains relevant, accurate, and useful for supporting continuity of care. As a result, health professionals serve as a critical link between patients and electronic health records, transforming clinical encounters and healthcare interventions into structured electronic health data that can be used throughout the EHDS ecosystem[10].

3.1.3 Electronic Health Record (EHR) Systems

EHR systems constitute the technological infrastructure through which health data is collected, stored, organised, and managed. While EHR systems do not generate health data themselves, they provide the digital environment in which information generated by patients, healthcare professionals, laboratories, and other healthcare actors is recorded and maintained. EHR systems enable healthcare providers to create and update electronic records

[7] Regulation (EU) 2025/327, Article 2(2); Annex I (priority categories of electronic health data),
[8] Regulation (EU) 2025/327, Recital 6; Article 2(2)(a).
[9] Regulation (EU) 2025/327, Articles 15-17 and 20-22.
[10] Regulation (EU) 2025/327, Recitals 19-21; Articles 15-17.

containing a wide range of health information, including patient summaries, diagnoses, prescriptions, laboratory results, medical images, discharge reports, and other clinical documentation. By consolidating information from multiple healthcare encounters, these systems facilitate the creation of comprehensive and longitudinal patient records.

Within the EHDS framework, EHR systems serve as one of the principal environments in which electronic health data is recorded, managed, and exchanged. They support the structured collection of health information and enable healthcare professionals to access relevant patient data during the provision of care. Consequently, EHR systems represent a key component of the health data generation and collection stage, ensuring that information generated through healthcare activities can be securely stored, maintained, and made available for subsequent primary and secondary uses within the EHDS ecosystem[11].

3.2 Primary Use of Health Data

Once health data has been generated and recorded within electronic health record systems, it can be used to support the provision of healthcare services. Within the EHDS, the primary use of health data refers to the access, exchange, and use of electronic health data for purposes directly related to healthcare delivery, including diagnosis, treatment, continuity of care, and patient management. To facilitate such use, the EHDS establishes several technical and governance mechanisms that enable patients and healthcare professionals to access relevant health information both within and across Member States[12].

3.2.1 Electronic Health Access Services (EHAS)

The EHAS enable natural persons to access and manage their electronic health data. These services serve as the primary interface through which individuals can view information contained within their electronic health records and exercise greater control over their health information. These services are provided through the national digital health infrastructure established by Member States and operate under the supervision of the relevant Digital Health Authorities (DHA) in accordance with the EHDS[13].

Through these services, individuals may access key health data categories such as patient summaries, electronic prescriptions, laboratory results, medical reports, and other health records made available under national implementations of the EHDS. By providing direct access to health information, the EHAS promote transparency, patient empowerment, and informed participation in healthcare decisions. These services play an important role in ensuring that health data remains accessible to the individuals to whom the data relates, thereby supporting one of the fundamental objectives of the EHDS: placing citizens at the centre of the digital health ecosystem[14]. These services also support the exercise of certain rights established under the EHDS relating to access, transparency, and control over electronic health data.

[11] Regulation (EU) 2025/327, Articles 2(2)(k), 14, 27-39.
[12] Regulation (EU) 2025/327, Articles 15-26.
[13] Regulation (EU) 2025/327, Articles 15-26 and 63-66.
[14] Regulation (EU) 2025/327, Articles 3-12 and 15-17.

3.2.2 Health Professional Access Services (HPAS)

The HPAS enable authorised healthcare professionals to access electronic health data required for the provision of healthcare services. These services facilitate the retrieval and exchange of relevant patient information, allowing healthcare professionals to make informed clinical decisions and ensure continuity of care. Like the EHAS, these services form part of the national digital health infrastructure established by Member States and operate under the oversight of the relevant DHA.

When providing treatment, healthcare professionals often require access to information generated by other healthcare providers, including diagnoses, medications, laboratory results, imaging reports, and previous medical interventions. The HPAS provide mechanisms through which such information can be accessed in a secure and controlled manner. Access is subject to applicable legal, professional, and organisational requirements and must be linked to the provision of healthcare services. By enabling timely access to accurate and comprehensive health information, these services support coordinated healthcare delivery, reduce information fragmentation, and improve the quality and safety of patient care within and across healthcare organisations[15].

3.2.3 Digital Health Authorities (DHAs)

The DHAs are national authorities designated by Member States to oversee the implementation and operation of the EHDS for primary use purposes. They play a central role in ensuring that the infrastructure and services required for accessing and exchanging electronic health data function effectively and in accordance with the Regulation.

Among their responsibilities, DHAs oversee the operation of national digital health services, coordinate the implementation of interoperability requirements, and facilitate cross-border exchanges of health data through the EHDS infrastructure. They also contribute to ensuring that individuals and healthcare professionals can effectively access and use electronic health data within their respective Member States. As the principal national authorities responsible for the primary-use dimension of the EHDS, DHAs act as key governance actors supporting the secure and efficient exchange of health data across the European Union[16].

3.2.4 MyHealth@EU

MyHealth@EU is the cross-border digital infrastructure established under the EHDS to facilitate the exchange of electronic health data for primary-use purposes across Member States. It enables authorised healthcare professionals and individuals to access relevant health information when healthcare services are provided in a Member State other than the one in which the data was originally generated.

[15] Regulation (EU) 2025/327, Articles 15-26, together with Articles 11-14 where applicable.
[16] Regulation (EU) 2025/327, Articles 63-66.

The infrastructure supports the cross-border exchange of priority health data categories, including patient summaries, electronic prescriptions, electronic dispensations, medical images, laboratory results, and discharge reports. By connecting national digital health services and infrastructures, MyHealth@EU enables healthcare providers to access relevant information needed for the continuity of care when patients receive treatment abroad.

Participation in MyHealth@EU enables Member States to support the cross-border exchange of priority categories of electronic health data in accordance with common European standards and interoperability requirements. Through the establishment of a common European infrastructure for health data exchange, MyHealth@EU contributes to improving healthcare accessibility, patient mobility, and the continuity of care across the European Union[17].

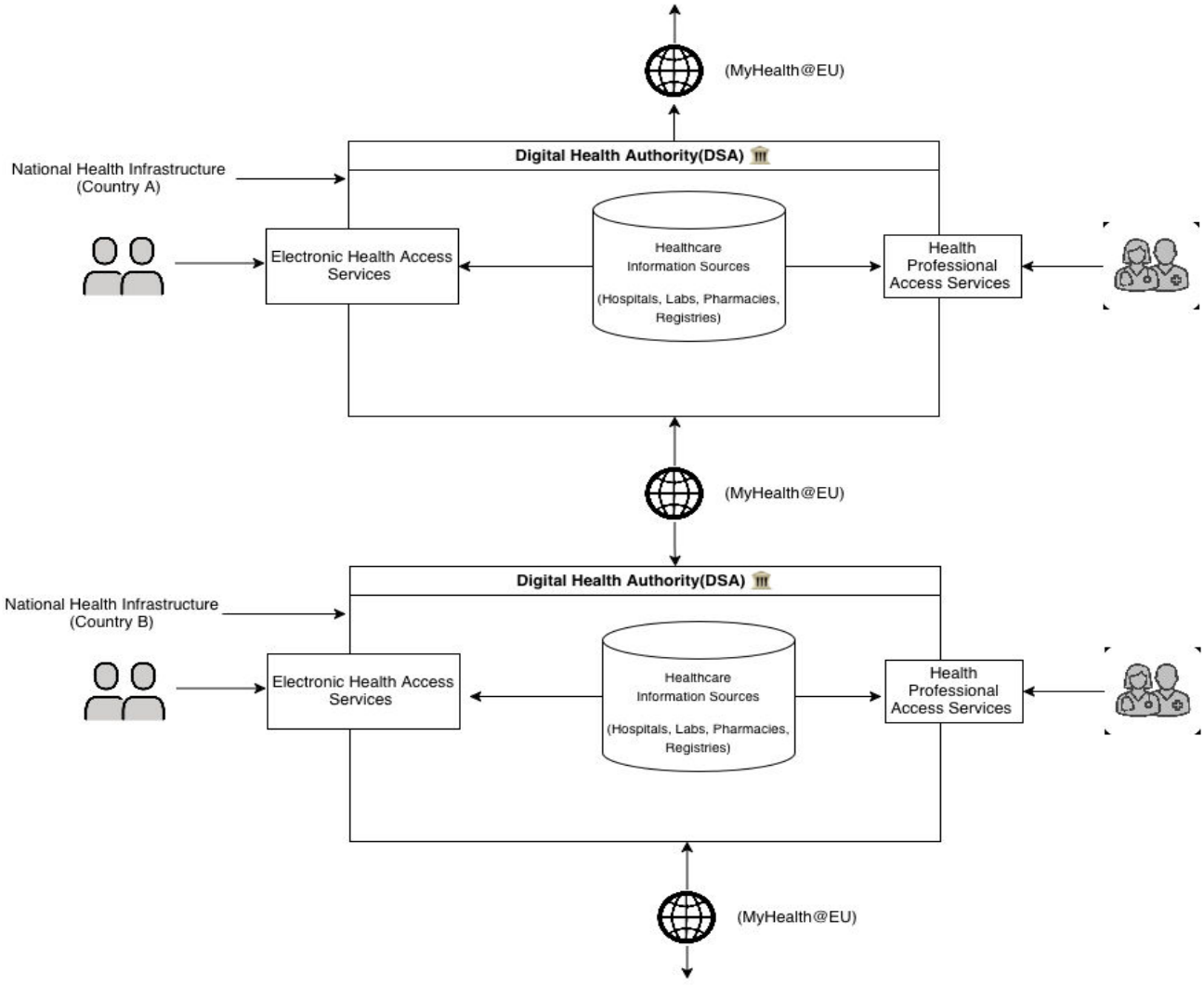

Figure 1. Primary-use architecture under the EHDS. Simplified representation of the national digital health infrastructure established under the EHDS. Health data generated and maintained by healthcare providers (such as hospitals, laboratories, pharmacies, and health registries) is stored within electronic health record systems. Individuals access their own electronic health data through the EHAS, while authorised healthcare professionals access patient data through HPAS. The Digital Health Authority supervises the national infrastructure, and MyHealth@EU enables the cross-border exchange of health data between Member States.

[17] Regulation (EU) 2025/327, Articles 23-26.

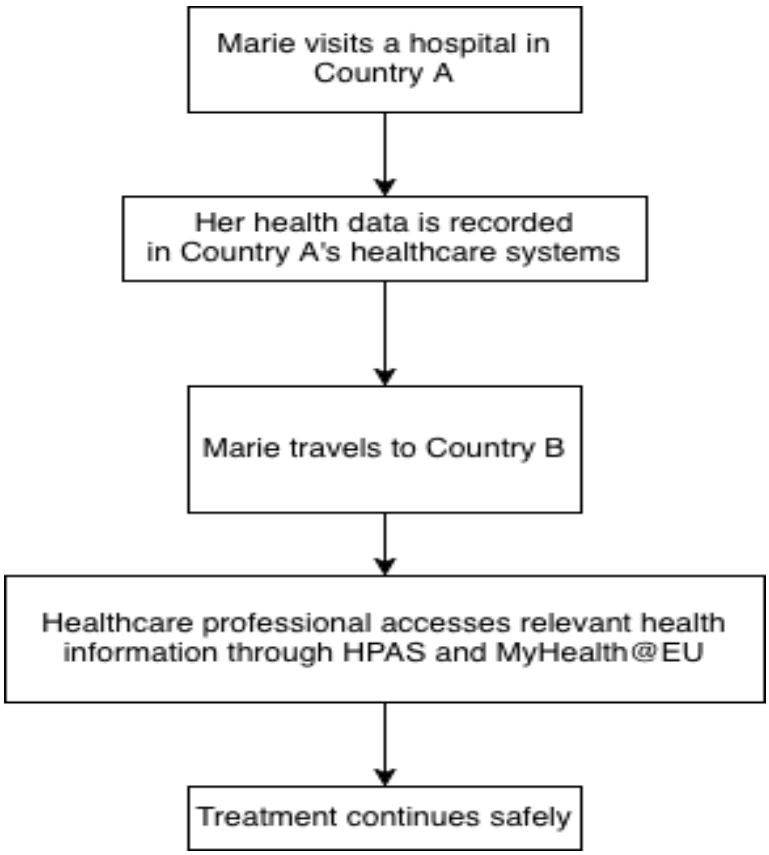

Figure 2. **Example of cross-border healthcare under the EHDS.** Illustrative example showing how electronic health data recorded in one Member State can be securely accessed by authorised healthcare professionals in another Member State through the HPAS and MyHealth@EU, supporting continuity of care across borders.

3.3 Secondary Use of Health Data

While the primary use of health data focuses on the provision of healthcare services, the EHDS also establishes a framework for the secondary use of electronic health data. Secondary use refers to the processing of health data for purposes other than the direct care of the individual to whom the data relates. Such purposes include scientific research, innovation, public health activities, policymaking, regulatory activities, statistical analysis, and the development of healthcare products and services.

To facilitate the responsible use of health data for these purposes, the EHDS establishes a governance framework involving data holders, HDABs, data users, and the HealthData@EU infrastructure. Together, these actors enable access to health data while ensuring that appropriate safeguards, transparency measures, and oversight mechanisms are maintained[18].

[18] Regulation (EU) 2025/327, Articles 53-90.

3.3.1 Data holders

Data Holders are entities that possess or control electronic health data and are responsible for making such data available for secondary-use purposes under the conditions established by the EHDS. They constitute the principal providers of datasets within the secondary-use ecosystem.

Data holders may include healthcare providers, hospitals, laboratories, public health authorities, health registries, research institutions, and other entities that collect or maintain health-related data as part of their activities. Depending on national implementation and the categories of data covered by the Regulation, additional organisations may also qualify as data holders. Within the EHDS framework, data holders are responsible for responding to requests transmitted through HDABs and for making relevant datasets available when a valid data permit or data request has been authorised. In this way, they play a crucial role in transforming health data generated during healthcare activities into a resource that can support research, innovation, and evidence-based policymaking[19].

3.3.2 Health Data Access Bodies

The HDABs are national authorities designated by Member States to administer and supervise access to electronic health data for secondary-use purposes. They serve as the central gatekeepers of the secondary-use framework established under the EHDS.

HDABs are responsible for evaluating requests for access to health data, assessing whether the requested use complies with the objectives and conditions established by the Regulation, and issuing data permits where appropriate. They also coordinate with data holders to facilitate access to authorised datasets and ensure that data users comply with applicable requirements. By acting as independent intermediaries between data holders and data users, HDABs contribute to transparency, accountability, and trust within the secondary-use ecosystem. Their role is fundamental to ensuring that access to health data is granted only for legitimate purposes and under appropriate safeguards[20].

3.3.3 Data Users

Data Users are natural or legal persons that obtain access to electronic health data for authorised secondary-use purposes. They represent the demand side of the secondary-use ecosystem and utilise health data to generate knowledge, develop innovative solutions, and support public-interest objectives.

Potential data users include researchers, universities, public authorities, regulatory agencies, healthcare organisations, pharmaceutical companies, medical device manufacturers, and

[19] Regulation (EU) 2025/327, Articles 51 and 57-61, together with Annex II where applicable.
[20] Regulation (EU) 2025/327, Articles 67-74.

other entities engaged in activities permitted under the EHDS. Depending on the nature of the project, data users may seek access to health data for scientific research, public health monitoring, healthcare planning, policy evaluation, regulatory decision-making, or the development of innovative healthcare technologies. Access to health data is not granted directly by data holders but is subject to authorisation through the governance mechanisms established under the EHDS. Consequently, data users operate within a regulated environment designed to balance the societal benefits of health data use with the protection of individuals' rights and interests[21].

3.3.4 HealthData@EU (Union Health Data Access Service)

HealthData@EU is the European cross-border infrastructure established to support the secondary use of health data across Member States. It connects national HDABs and other authorised participants, enabling data users to discover and request access to datasets held in different countries through a coordinated European framework[22].

HealthData@EU facilitates the discovery of datasets and the coordination of cross-border access requests between participating Member States. It is important to distinguish this infrastructure from the SPEs used within the EHDS secondary-use framework. While HealthData@EU supports the identification of datasets and the management of access procedures, authorised secondary-use activities are typically conducted within SPEs that provide controlled conditions for accessing and analysing health data. The infrastructure facilitates the exchange of information relating to available datasets, data permits, and access procedures, thereby reducing fragmentation within the European health data landscape. Among its functions, HealthData@EU supports the operation of a common European dataset catalogue that enables prospective data users to discover datasets held across participating Member States and identify the conditions under which those datasets may be accessed[23]. Figure 3 summarises the governance workflow through which electronic health data is made available for authorised secondary use under the EHDS.

[21] Regulation (EU) 2025/327, Articles 53-56 and 78-82, together with Articles 67–74 governing authorisation procedures.
[22] Regulation (EU) 2025/327, Articles 91-95.
[23] Regulation (EU) 2025/327, Articles 77 and 91-95.

Illustrative Example

Understanding Secondary Use Through a University Library Analogy

The secondary-use framework of the EHDS can be understood through a simple analogy. Imagine a university library that contains a large collection of valuable research materials.
The **data holders** are comparable to the various libraries and archives that possess the materials. **Researchers** who wish to use those materials are the **data users**. Before gaining access, researchers must submit a request to the library administration explaining the purpose of their work. In the EHDS, this role is performed by the **Health Data Access Body (HDAB)**, which evaluates requests and determines whether access may be granted.

If the request is approved, the researcher receives a form of authorisation comparable to a library access permit. Within the EHDS, this authorisation takes the form of a **data permit** specifying the conditions under which data may be used.
HealthData@EU can be compared to a shared catalogue that allows researchers to discover materials held in libraries across multiple countries. The catalogue helps users identify relevant resources but does not itself contain or provide unrestricted access to the underlying materials.

Finally, the **Secure Processing Environment** is comparable to a supervised reading room where authorised researchers may consult sensitive materials under controlled conditions. Rather than removing the materials from the library, researchers conduct their work within a secure environment designed to protect the information while enabling legitimate research activities.

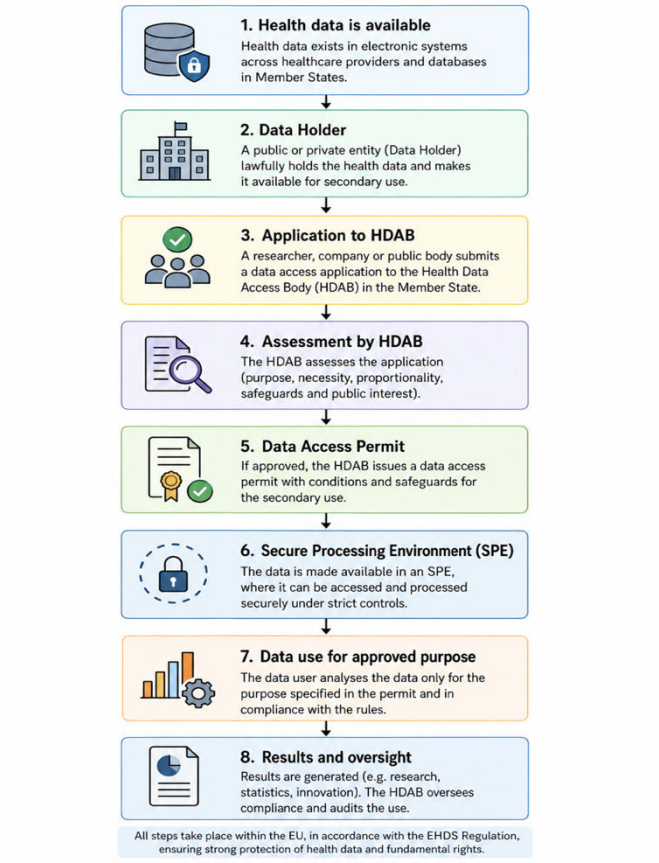

Figure 3. Secondary-use governance workflow under the European Health Data Space (EHDS). Simplified illustration of the pathway through which electronic health data is accessed for authorised secondary-use purposes. Following submission of a request by a data user, the Health Data Access Body (HDAB) assesses the application and, where the legal requirements are satisfied, issues a data permit. Approved users access and analyse data within a Secure Processing Environment (SPE), ensuring that secondary use takes place under the governance, security, and accountability mechanisms established by the EHDS Regulation.

3.4 Governance Across the EHDS

The previous sections have explained how electronic health data moves through the EHDS ecosystem, from its generation by individuals and healthcare professionals to its primary use in healthcare and its secondary use for research, innovation, public health, and other societal purposes. For these activities to operate effectively across the European Union, they must be supported by a governance framework that ensures health data is accessed, exchanged, and reused in a secure, consistent, and trustworthy manner. Governance is therefore not a separate stage in the operation of the EHDS; rather, it provides the organisational, legal, and institutional foundation that underpins every aspect of the framework.

To achieve this, the EHDS distributes governance responsibilities across both the national and European levels. At the national level, DHAs oversee the implementation of the primary-use framework, ensuring that individuals and healthcare professionals can securely access and exchange electronic health data. The HDABs perform a complementary role within the secondary-use framework by assessing requests for access to health data, issuing data permits, and supervising compliance with the conditions established by the Regulation. Together, these authorities help ensure that the EHDS operates consistently within each Member State while safeguarding individuals' rights and promoting the responsible use of health data.

Building upon these national governance arrangements, the EHDS establishes a broader European governance architecture that promotes regulatory consistency, interoperability, accountability, and coordinated implementation across Member States. Through cooperation between national authorities and European institutions, this governance framework supports the harmonised implementation of the EHDS and helps ensure that electronic health data can be exchanged and reused securely and efficiently throughout the European Union.

At the European level, two institutions play particularly important roles in coordinating and supporting the implementation of the EHDS: the European Commission and the EHDS Board. Together, they provide strategic direction, promote cooperation among Member States, and contribute to the consistent development of the European Health Data Space.

3.4.1 European Commission

The European Commission plays a central role in the governance and coordination of the EHDS at the European level. As the institution responsible for overseeing the implementation of the Regulation, it develops common rules, technical specifications, and interoperability standards necessary for the effective functioning of the EHDS.

In addition, the Commission adopts implementing acts, facilitates cooperation among Member States, and supports the development and operation of the European digital infrastructures MyHealth@EU and HealthData@EU**.** Through these regulatory, coordinating, and supervisory responsibilities, the Commission helps ensure that electronic health data can

be exchanged securely and consistently across the European Union while promoting the harmonised implementation of the EHDS framework[24].

3.4.2 EHDS Board

EHDS Board serves as the principal cooperation and coordination body supporting the implementation of the EHDS. It brings together representatives from Member States and relevant European institutions to promote the consistent application of the Regulation and facilitate cooperation among the many actors involved in the European health data ecosystem.

The Board provides a forum for exchanging expertise, sharing best practices, and discussing implementation challenges. It also contributes to the development of guidance, recommendations, and coordinated approaches that support the consistent operation of the EHDS across Member States. By strengthening cooperation between national authorities and European institutions, the EHDS Board promotes regulatory consistency, interoperability, and the long-term development of a trusted European health data ecosystem[25].

Together, the governance actors described in this section complement the operational actors and digital infrastructures presented throughout this article. While healthcare professionals, data holders, access bodies, and digital infrastructures enable the generation, exchange, and reuse of electronic health data, governance mechanisms ensure that these activities are conducted within a common regulatory framework that promotes accountability, interoperability, and trust.

Effective governance alone, however, is not sufficient to maintain public confidence in the EHDS. Individuals must also be assured that their health data is protected, that access is transparent, and that appropriate safeguards exist against misuse. The following section therefore examines the principal safeguards and protections established by the EHDS to support the secure and trustworthy use of electronic health data.

4. Safeguards for Individuals

The actors, infrastructures, and governance arrangements described in the previous sections enable the exchange and use of electronic health data throughout the European Health Data Space. The effective functioning of such a system, however, depends not only on the availability of data and the interoperability of digital infrastructures, but also on the existence of safeguards that protect individuals' rights and maintain public trust. Recognising the sensitive nature of health information, the EHDS establishes a range of mechanisms designed

[24] Regulation (EU) 2025/327, Articles 96-103 (Commission powers) together with Articles 23-26 and 91-95 where appropriate.
[25] Regulation (EU) 2025/327, Articles 97-103.

to ensure that health data is accessed, shared, and reused in a secure, transparent, and accountable manner.

4.1 Transparency and Access Logs

A key safeguard established by the EHDS is the requirement for transparency regarding access to electronic health data. Individuals are entitled to know when their health information has been accessed and by whom. To support this objective, access to electronic health data through EHDS services is subject to logging mechanisms that record relevant access events.

Through the EHAS, individuals may be able to view information concerning access to their health data, including which healthcare provider or authorised entity accessed the information and when such access occurred. These transparency measures help strengthen accountability within the digital health ecosystem and enable individuals to exercise greater oversight over the use of their health information[26].

4.2 Rights to Access and Control Health Data

The EHDS seeks to strengthen individuals' control over their electronic health data by complementing existing rights under European data protection law. Individuals are provided with mechanisms that facilitate access to their electronic health records and support their active participation in healthcare decisions.

In practice, this means that individuals may access important categories of health information through the EHAS, including patient summaries, prescriptions, laboratory results, and other health records made available under the Regulation. The framework also supports mechanisms through which individuals may request the correction of inaccurate information and, in certain circumstances, supplement their health records with additional information. Together, these measures contribute to the broader objective of placing individuals at the centre of the European digital health ecosystem[27].

4.3 Restricting Access to Health Data

The EHDS recognises that individuals may wish to limit access to particularly sensitive categories of health information. To address this concern, the Regulation allows mechanisms through which individuals may restrict access to specific elements of their electronic health data.

Such restrictions may be relevant where health information concerns particularly sensitive matters, including aspects of mental health, sexual health, reproductive healthcare, or other information that individuals may consider especially private. At the same time, the EHDS seeks to balance individual preferences with the need to ensure safe and effective healthcare delivery. For this reason, certain limitations or exceptions may apply, particularly where

[26] Regulation (EU) 2025/327, Articles 9 and 12; Recitals 16 and 19.
[27] Regulation (EU) 2025/327, Articles 3-8; Recitals 8-15.

access to health information is necessary to protect the vital interests of the individual in emergency situations[28].

4.4 Opt-Out Mechanisms

In addition to access restrictions, the EHDS allows Member States to establish opt-out mechanisms that provide individuals with an additional degree of control over the sharing of their electronic health data. The precise scope and operation of these mechanisms may vary depending on national implementation choices.

Where such mechanisms are available, individuals may be able to limit the availability of their health data through certain EHDS services. The Regulation nevertheless seeks to balance individual autonomy with broader public-interest objectives, including continuity of healthcare and the effective functioning of health systems. As a result, the availability and consequences of opting out may differ between Member States[29].

4.5 Secure Access for Research and Innovation

The EHDS not only protects health data used for healthcare delivery but also establishes safeguards for the secondary use of health data. Access to health data for research, innovation, public health activities, and other authorised purposes is subject to governance mechanisms designed to ensure that data is used responsibly and only for legitimate purposes.

Rather than granting unrestricted access to health datasets, the EHDS requires data users to obtain authorisation through HDABs and comply with the conditions specified in data permits. In many cases, authorised activities are conducted within SPEs that restrict how data may be accessed, analysed, and used. These safeguards help reduce the risk of unauthorised disclosure while enabling health data to contribute to scientific research, innovation, evidence-based policymaking, and improvements in healthcare delivery[30].

Taken together, these safeguards form an essential component of the EHDS framework. By combining transparency, individual control, regulatory oversight, and technical protection measures, the EHDS seeks to foster trust in the use of health data while enabling the societal benefits that can arise from its responsible use.

[28] Regulation (EU) 2025/327, Articles 10-11; Recital 17.
[29] Regulation (EU) 2025/327, Recital 18.
[30] Regulation (EU) 2025/327, Articles 67-90.

5. Operational Mechanisms of the EHDS

While the previous sections introduced the actors, digital infrastructures, governance arrangements, and safeguards that form the EHDS ecosystem, the effective operation of this framework also depends on several supporting mechanisms. These mechanisms provide the technical, organisational, and procedural foundations that enable health data to be exchanged securely, discovered efficiently, and accessed under clearly defined conditions. Together, they help translate the objectives of the EHDS into practical operation across Member States.

The following sections examine four key mechanisms that support the functioning of the EHDS: interoperability requirements, dataset catalogues, data permits, and SPEs.

5.1 Interoperability Requirements

Interoperability is one of the fundamental principles upon which the EHDS is built. Because health data is generated and stored across numerous healthcare organisations, digital systems, and Member States, meaningful data exchange is only possible if these systems can communicate using common technical, semantic, and organisational standards.

To address this challenge, the EHDS establishes interoperability requirements for electronic health record systems, digital health services, and cross-border infrastructures. These requirements ensure that health data can be exchanged, understood, and reused consistently across different systems and jurisdictions. Interoperability is particularly important for the operation of MyHealth@EU and HealthData@EU, enabling health information generated in one Member State to be accessed and used in another. By promoting common standards and technical specifications, the EHDS supports the development of a more integrated and connected European health data ecosystem.

In practice, these interoperability requirements are achieved by ensuring that electronic health record systems, digital health services, and cross-border infrastructures use common technical standards, shared terminology, and harmonised data formats. This enables health information recorded in one healthcare system to be accurately exchanged, interpreted, and reused by another, even when the systems operate in different healthcare organisations or Member States. Without interoperability, infrastructures such as MyHealth@EU and HealthData@EU would not be able to support the secure cross-border exchange and reuse of electronic health data. Interoperability therefore provides the technical foundation upon which the other operational mechanisms of the EHDS, including dataset catalogues, data permits, and SPEs, can function effectively[31].

[31] Regulation (EU) 2025/327, Articles 27-39, 67-90 and 91-95.

5.2 Dataset Catalogues

Dataset catalogues are designed to improve the discoverability and transparency of health data available for secondary use. Rather than storing health data themselves, they provide structured information describing datasets held by data holders, including their content, characteristics, and conditions for access. By making information about available datasets easier to find, catalogue services help prospective data users identify relevant resources before submitting requests for access.

At the national level, HDABs are responsible for maintaining and making available information relating to datasets that may be accessed through the EHDS framework. At the European level, the Regulation requires the establishment of a common dataset catalogue through the HealthData@EU infrastructure. This catalogue is intended to enable prospective data users to identify relevant datasets across Member States and facilitate cross-border secondary use of health data. By improving transparency regarding available data resources, dataset catalogues help reduce fragmentation, simplify data discovery, and support the development of a more integrated European health data ecosystem. According to the implementation timeline established by the EHDS Regulation, the European Commission is expected to make the European dataset catalogue operational by March 2027[32].

5.3 Data Permits

Access to electronic health data for secondary-use purposes is not automatic. To ensure that health data is used only for legitimate purposes and under appropriate safeguards, the EHDS requires prospective data users to obtain authorisation through a data permit before access to datasets is granted. Data permits therefore serve as an important governance mechanism, balancing the societal benefits of health data use with the need to protect individuals' rights and maintain public trust.

To obtain a data permit, prospective data users must submit an application to the relevant Health Data Access Body (HDAB), describing the intended purpose of the request, the datasets required, and how the data will be used. The HDAB assesses whether the proposed use falls within the purposes authorised by the Regulation and whether the request complies with the applicable legal and procedural requirements.

Where these conditions are satisfied, the HDAB may issue a data permit specifying the authorised purpose, the datasets to which access is granted, the duration of access, and any conditions governing the use of the data. Through this structured authorisation process, data permits ensure that secondary use of health data occurs in accordance with the objectives, safeguards, and oversight arrangements established by the EHDS, promoting transparency, accountability, and responsible data use across the European Union[33].

[32] Regulation (EU) 2025/327, Articles 77 and 91-95.
[33] Regulation (EU) 2025/327, Articles 67-82.

5.4 Secure Processing Environments (SPEs)

The SPEs are controlled digital environments in which authorised users can securely access and analyse electronic health data for approved secondary-use purposes. Rather than allowing datasets to be downloaded or transferred freely, these environments enable authorised analyses to be conducted under predefined technical, organisational, and security safeguards, thereby reducing the risk of unauthorised disclosure or misuse of sensitive health information.

Within the EHDS, SPEs play an important role in protecting confidentiality while enabling valuable research, innovation, public health activities, and evidence-based policymaking. Access to these environments is limited to authorised users operating under the conditions specified in a data permit, and activities undertaken within them are subject to appropriate monitoring and security controls.

By providing a secure environment for analysing health data without compromising individuals' privacy, SPEs support the broader objectives of the EHDS. They enable the responsible secondary use of health data while reinforcing accountability, data protection, and public trust in the European Health Data Space[34].

6. Conclusion

The European Health Data Space represents a significant milestone in the evolution of digital health governance within the European Union. By establishing a common framework for the access, exchange, and reuse of electronic health data, the EHDS seeks to address longstanding challenges associated with fragmented healthcare systems, limited interoperability, and barriers to the secure and effective use of health data across Member States. In doing so, it aims to create an environment in which electronic health data can support not only high-quality healthcare but also research, innovation, public health, and evidence-based policymaking.

This article has examined the EHDS by following the journey of electronic health data through the framework. Beginning with the generation of health data by individuals, healthcare professionals, and electronic health record systems, it explored how data is used to support healthcare delivery through primary use and subsequently made available for research, innovation, public health, and other societal purposes through the secondary-use framework. It also examined the governance arrangements, safeguards, and operational mechanisms that enable health data to be exchanged, accessed, and reused in a secure, transparent, and trustworthy manner.

Viewed collectively, the EHDS is more than a framework for data sharing or a collection of legal provisions. It is an interconnected ecosystem in which individuals, healthcare professionals, healthcare organisations, data holders, data users, national authorities,

[34] Regulation (EU) 2025/327, Articles 73-82.

European institutions, and digital infrastructures work together to support the responsible use of electronic health data. The success of this ecosystem depends not only on the effective operation of its actors and technical infrastructures but also on robust governance, strong safeguards, interoperability, and public trust.

The significance of the EHDS therefore extends beyond technology and regulation. At its core, the framework seeks to balance two complementary objectives: enabling the wider use of health data to improve healthcare, research, innovation, and public health while ensuring a high level of protection for individuals' rights, privacy, and data security. Achieving this balance will depend on consistent implementation across Member States, effective cooperation between national and European authorities, and the willingness of citizens, healthcare professionals, researchers, and public institutions to engage with and trust the framework.

As one of the European Union's most ambitious digital health initiatives, the EHDS has the potential to transform the way electronic health data is accessed, exchanged, and reused across Europe (Azzopardi-Muscat & Sørensen, 2022). While its long-term success will depend on effective implementation and continued collaboration among its many stakeholders, it provides the foundations for a more connected, interoperable, and data-driven European health ecosystem. By bringing together common rules, shared infrastructures, governance arrangements, and operational mechanisms within a single framework, the EHDS represents an important step towards a more integrated, patient-centred, and innovative future for healthcare in Europe.

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