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## The European Health Data Space: Steps Forward and Critical Limitations

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**Abstract:** This paper analyzes the European Health Data Space Regulation as a pioneering framework within the EU's data strategy. It examines the dual objective of the EHDS: empowering patients through enhanced access and control over their health information (primary use) and fostering a robust ecosystem for research, innovation, and policymaking (secondary use). The analysis highlights how the Regulation seeks to dismantle existing data "silos" and regulatory fragmentation, while navigating the complex legal interplay with the GDPR and the AI Act. Furthermore, it addresses critical challenges regarding the governance of national Health Data Access Bodies, the necessity of maintaining public trust through "common good" justifications, and the geopolitical ambition of establishing European leadership in health data management. The study concludes by identifying key limitations that could impede the secure and efficient flow of data if not properly harmonized.

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### 1. Introduction: Health Data and the EHDS

Although health-related information accounts for **nearly a third of all data stored globally**, it remains a **vastly underutilized resource**. Despite the opportunities created by new technology to process health data for social benefit, **inconsistent regulatory environments** are acting as a structural barrier, stifling the full realization of these advancements<sup>1</sup>.

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<sup>1</sup> OECD, Facilitating the secondary use of health data for public interest purposes across borders, OECD Digital Economy Papers, June 2025, [https://www.oecd.org/en/publications/facilitating-the-secondary-use-of-health-data-for-public-interest-purposes-across-borders\\_d7b90d15-en.html](https://www.oecd.org/en/publications/facilitating-the-secondary-use-of-health-data-for-public-interest-purposes-across-borders_d7b90d15-en.html).

In the European Union, for example, this wealth of information is frequently trapped in isolated “silos” and lacks the structure necessary to unlock its full potential for improving healthcare outcomes<sup>2</sup>.

To address these problems, the **European Health Data Space Regulation<sup>3</sup>** is the first domain-specific common European data space established under the European Union’s data strategy<sup>4</sup>.

Its principal aim is to **improve individuals' access and control over their electronic health data (primary use)** and **increase data availability for secondary use purposes** such as research, innovation, and policymaking<sup>5</sup>.

The EHDS is designed to establish a common framework, standards, infrastructures, and governance for the use and exchange of electronic health data across the EU<sup>6</sup>.

The EHDS presents significant **opportunities** by:

- ★ **Empowering individuals** with increased access and control over their electronic health data (**primary use**), enabling them to obtain better care and make informed choices by reducing information asymmetries between healthcare providers<sup>7</sup>.
- ★ **Driving substantial economic and societal benefits** for **secondary use**, including faster and more cost-effective development of new drugs, medical procedures, and AI systems, and supporting evidence-based public health decisions<sup>8</sup>.

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<sup>2</sup> Petročnik T., Health data between health(care) and the data economy, Technology and Regulation, 2022, <https://techreg.org/article/view/13284>; Gwee S., The importance of increasing access to high-quality health data, OECD Forum Network, January 2021, <https://www.oecd-forum.org/posts/the-importance-of-increasing-access-to-high-quality-health-data>.

<sup>3</sup> Regulation (EU) 2025/327 of the European Parliament and of the Council of 11 February 2025 on the European Health Data Space and amending Directive 2011/24/EU and Regulation (EU) 2024/2847, OJ L, 2025/327, 5.3.2025.

<sup>4</sup> Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions, A European strategy for data, COM/2020/66 final, <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52020DC0066>.

<sup>5</sup> Li W., Quinn P., The European Health Data Space: An expanded right to data portability?, Computer Law & Security Review, April 2024, [https://www.sciencedirect.com/science/article/pii/S0267364923001231?ssrnid=4516769&dgcid=SSRN\\_redirect\\_SD](https://www.sciencedirect.com/science/article/pii/S0267364923001231?ssrnid=4516769&dgcid=SSRN_redirect_SD); Fåhraeus, E., Reichel, J., and Slokenberga, S., The European Health Data Space: Challenges and Opportunities, Sieps - Swedish Institute for European Policy Studies, February 2024, <https://sieps.se/en/publications/2024/the-european-health-data-space-challenges-and-opportunities>; Marcus, J.S. et al., The European Health Data Space, The European Health Data Space, IPOL | Policy Department for Economic, Scientific and Quality of Life Policies, European Parliament Policy Department studies, 2022, [https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=4300393](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4300393).

<sup>6</sup> See: Li W., Quinn P., The European Health Data Space: An expanded right to data portability?, cit.; Marcus, J.S. et al., The European Health Data Space, cit.

<sup>7</sup> See: Marcus, J.S. et al., The European Health Data Space, cit.; Fåhraeus, E., Reichel, J., and Slokenberga, S., The European Health Data Space: Challenges and Opportunities, cit.

<sup>8</sup> See again: Marcus, J.S. et al., The European Health Data Space, cit.

- ★ Expanding the scope of the EU General Data Protection Regulation (GDPR) by **mandating strong interoperability requirements** and **expanding the right to data portability** to cover **inferred data**, which is excluded under GDPR Article 20<sup>9</sup>.

However, the EHDS implementation faces numerous **challenges**, including:

- **High costs and complexity** associated with the mandatory implementation of interoperable Electronic Health Record systems, placing a burden on constrained national healthcare budgets<sup>10</sup>.
- **Regulatory incoherence and fragmentation** due to overlaps with the GDPR and other EU laws, and significant variances in national rules concerning data protection and health policies across Member States<sup>11</sup>.
- Risk of **decreasing legitimacy and trust** due to the weak role of the individual in exercising control over their data for secondary use purposes<sup>12</sup>.
- The potential for the **governance structure** to be **too centralized** or to place an overly **excessive administrative burden** on the designated national Health Data Access Bodies<sup>13</sup>.

## 2. Relationships with GDPR and Open Data Directive

### 2.1. Opportunities:

- ❖ **Expanded Data Portability (GDPR):** The EHDS reinforces and expands the right to data portability beyond Article 20 of the General Data Protection Regulation (GDPR)<sup>14</sup>.
  - The EHDS expands the right to cover **inferred data** (such as diagnoses derived from processing), which is excluded by GDPR Article 20, as the GDPR restriction was implemented to protect the commercial secrets of data controllers who derive inferred data through analysis.
    - The portability right applies to electronic health data **irrespective of the legal basis for processing**, unlike GDPR Article 20, which is limited to processing based on consent or contract.
- ❖ **Mandatory Interoperability:** The EHDS mandates strong interoperability requirements, requiring the creation of the **European electronic health record**

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<sup>9</sup> See again: Li W., Quinn P., The European Health Data Space: An expanded right to data portability?, cit.

<sup>10</sup> See: Fåhraeus, E., Reichel, J., and Slokenberga, S., The European Health Data Space: Challenges and Opportunities, cit.

<sup>11</sup> Kiseleva A., de Hert P., Creating a European Health Data Space. Obstacles in Four Key Legal Areas, European Pharmaceutical Law Review, June 2021, [https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=3846781](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3846781); Fåhraeus, E., Reichel, J., and Slokenberga, S., The European Health Data Space: Challenges and Opportunities, cit.

<sup>12</sup> See again: Fåhraeus, E., Reichel, J., and Slokenberga, S., The European Health Data Space: Challenges and Opportunities, cit.

<sup>13</sup> See again: Marcus, J.S. et al., The European Health Data Space, cit.

<sup>14</sup> See: Li W., Quinn P., The European Health Data Space: An expanded right to data portability?, cit.; Marcus, J.S. et al., The European Health Data Space, cit.

**exchange format** to facilitate data interchange. This format is laid down by the Commission through implementing acts, increasing legal certainty for data controllers, and going beyond the GDPR's minimum requirement for a "structured, commonly used and machine-readable format"<sup>15</sup>.

- ❖ **Synergy with Open Data Directive:** The EHDS complements the ODD, allowing researchers and policymakers to combine **aggregated, non-sensitive public data** with granular, individual-level health data to support robust, data-driven analyses and policy development<sup>16</sup>.

## 2.2. Challenges:

- **Ambiguity in Portability Scope:** The expanded portability right in Article 3(8) **may fail to take into account** the need for data portability for **secondary use** purposes. The most restrictive interpretation suggests that transfers are only possible between actors who fall within the definition of "primary use" - i.e., those in the health or social security sector - making it impossible for individuals to proactively channel their data to non-primary use actors, such as research institutions, through this mechanism<sup>17</sup>.
- **GDPR Alignment (Consent):** The reliance on portability requests under Article 3(8) may conflict with GDPR Article 9 requirements for processing sensitive health data. Since the data holder is not required to provide the relevant information needed for informed consent, a portability request alone would seemingly not meet the conditions for **explicit consent** under the GDPR<sup>18</sup>.
- **Re-Identification Risk:** Combining open data with granular EHDS data could potentially increase the risk of identifying individuals through cross-referencing<sup>19</sup>.

## 3. Challenges for Primary and Secondary Use of Data

### 3.1. Primary Use Challenges:

- **Implementation Burden and Costs:** The mandatory implementation of interoperable EHR systems requires significant investment in technology and staff training that must be absorbed within already constrained national healthcare budgets. These technical burdens may result in higher prices for mandatory software licences, which could negatively affect healthcare providers.

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<sup>15</sup> See again: See: Li W., Quinn P., The European Health Data Space: An expanded right to data portability?, cit.

<sup>16</sup> Grijsbach M., van der Zwaag J., Page M., The impact of the EHDS Regulation and the Open Data Directive on citizens, September 2025, <https://euagenda.eu/publications/the-impact-of-the-european-health-data-space-regulation-and-the-open-data-directive-on-citizens>; Marcus, J.S. et al., The European Health Data Space, cit.

<sup>17</sup> See: Li W., Quinn P., The European Health Data Space: An expanded right to data portability?, cit.

<sup>18</sup> See again: Li W., Quinn P., The European Health Data Space: An expanded right to data portability?, cit.

<sup>19</sup> See: Grijsbach M., van der Zwaag J., Page M., The impact of the EHDS Regulation and the Open Data Directive on citizens, cit.

- **Patient Safety and Liability:** Expanded patient rights, such as the right to insert data into their records or restrict access, may negatively affect the quality of care and patient safety, and raises complex liability questions for healthcare professionals if actions are taken based on restricted or low-quality information.
- **Subsidiarity Concerns:** Because healthcare organization and delivery are primarily national prerogatives (Article 168 TFEU), the extensive EU regulation of domestic primary use aspects within the EHDS could face challenges regarding the principle of subsidiarity<sup>20</sup>.

### 3.2. Secondary Use Challenges:

- **Legal Fragmentation:** Existing national legal frameworks governing health data reuse are highly divergent, particularly concerning consent requirements (e.g., specific consent, broad consent, or public interest derogations). This fragmentation complicates the creation of a uniform EU-wide mechanism<sup>21</sup>.
- **Intellectual Property and Trade Secrets:** There is a serious concern that the EHDS obliges the sharing of health data which may be protected by IP rights and trade secrets, essential assets for firms in the healthcare industry. Clarity is needed on how to balance data sharing mandates with the protection of commercially sensitive information<sup>22</sup>.
- **Reduced Incentives:** Mandating dominant firms to share valuable data might reduce their economic incentive to invest time and resources in collecting high-quality health data, potentially leading to decreased innovation and lower data quality in the market<sup>23</sup>.

## 4. Interplay between National HDABs and HealthData@EU

**HDAB Authority and Burden:** Member States must designate one or more **Health Data Access Bodies (HDABs)** to grant permits for secondary use. The HDABs are assigned a **wide array of complex duties**<sup>24</sup>, leading to concerns that this model is overly burdensome and centralized<sup>25</sup>.

**Complexity of Permit Procedures:** The administrative application procedure for accessing data for secondary use is elaborate, and the assessment of applications, especially multi-

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<sup>20</sup> See: Fåhraeus, E., Reichel, J., and Slokenberga, S., The European Health Data Space: Challenges and Opportunities, cit.

<sup>21</sup> See: Kiseleva A., de Hert P., Creating a European Health Data Space. Obstacles in Four Key Legal Areas, cit.

<sup>22</sup> See: Marcus, J.S. et al., The European Health Data Space, cit.

<sup>23</sup> See: Fåhraeus, E., Reichel, J., and Slokenberga, S., The European Health Data Space: Challenges and Opportunities, cit.

<sup>24</sup> Around twenty enumerated tasks.

<sup>25</sup> See again: Marcus, J.S. et al., The European Health Data Space, cit.

country requests, is expected to be **complex and demanding** due to varied national legal requirements<sup>26</sup>.

**Data Holder Participation:** Data holders - that is, the suppliers of data - lack a **formal role** in the administrative procedure before a data permit is granted, meaning they lack effective remedies to object to a data permit request<sup>27</sup>.

**Infrastructure Design:** The EHDS framework, which includes the Commission operating a core platform for **HealthData@EU**, may be too centralized.

Thus, it is recommended to clarify the degree to which centralized versus decentralized infrastructure is permissible, favoring a federated structure that maximizes security and minimizes cost, while reflecting current decentralized conditions in many Member States<sup>28</sup>.

**HealthData@EU Connection:** National HDABs are **not directly connected** to HealthData@EU; instead, designated national contact points for secondary use connect to the system, extending the system's reach across the Union<sup>29</sup>.

## 5. Issues of Data Processing with AI

**AI as an Accelerator:** Artificial Intelligence provides great promise to transform healthcare<sup>30</sup> and is an essential tool for processing massive amounts of data made available by the EHDS<sup>31</sup>.

Training, testing, and evaluation of AI algorithms are explicit permissible purposes for secondary use<sup>32</sup>.

**Training and Data Quality:** The reliability of AI systems depends on large quantities of **high-quality, non-biased, and representative training data**.

There is currently insufficient data available for the innovative re-use needed for AI development<sup>33</sup>.

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<sup>26</sup> See: Fåhraeus, E., Reichel, J., and Slokenberga, S., The European Health Data Space: Challenges and Opportunities, cit.

<sup>27</sup> See again: Fåhraeus, E., Reichel, J., and Slokenberga, S., The European Health Data Space: Challenges and Opportunities, cit.

<sup>28</sup> See: Marcus, J.S. et al., The European Health Data Space, cit.

<sup>29</sup> Ramozzi F., Data Solidarity in the Health Sector: The Challenges of "Giving Back to the Commons" under the Health Data Space Regulation, November 2025, [https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=5727225](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=5727225).

<sup>30</sup> See: Kiseleva A., de Hert P., Creating a European Health Data Space. Obstacles in Four Key Legal Areas, cit.

<sup>31</sup> Sánchez Frías I., Secondary Uses Of Health Data Under The European Health Data Space. Connections With The GDPR And The Impact Of AI, Revista General de Derecho Europeo, April 2025, [https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=5143418](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=5143418)

<sup>32</sup> See: Fåhraeus, E., Reichel, J., and Slokenberga, S., The European Health Data Space: Challenges and Opportunities, cit.; Ramozzi F., Data Solidarity in the Health Sector: The Challenges of "Giving Back to the Commons" under the Health Data Space Regulation, cit.

<sup>33</sup> See: Kiseleva A., de Hert P., Creating a European Health Data Space. Obstacles in Four Key Legal Areas, cit.

**Regulatory Integration:** The development of data space regulations must proceed hand-in-hand with the emerging AI legal framework, such as the EU AI Act<sup>34</sup>, to ensure compliance.

The indefinite status of general and sectorial AI rules might hamper the development of the EHDS<sup>35</sup>.

**Risks of Misuse and Identification:** The EHDS includes prohibitions aimed at preventing the use of health data for discriminatory or detrimental decisions, e.g. setting insurance premiums, and for unauthorized marketing<sup>36</sup>. Processing health data through AI raises many data protection concerns<sup>37</sup>.

A **symbiotic relationship** exists where AI benefits from health data for training but also plays an essential role in providing data security techniques like pseudonymization and anonymization<sup>38</sup>.

Despite protective measures, **residual risks of re-identification remain**, especially with rare diseases, making anonymization of certain data categories difficult<sup>39</sup>.

## 6. Consequences of the EHDS for EU in the Geopolitical Scenario

**Global Leadership and Innovation:** The EHDS is a key initiative aimed at making the EU a **leading actor in the global health sector**<sup>40</sup>.

Aggregating data at an EU level facilitates competitiveness in personalized medicine, drug discovery, and AI development<sup>41</sup>.

• **Policy Harmonization:** The EU with the EHDS and the US with the 21st Century Cures Act are simultaneously developing regulations, creating an unprecedented opportunity for

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<sup>34</sup> Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence and amending Regulations (EC) No 300/2008, (EU) No 167/2013, (EU) No 168/2013, (EU) 2018/858, (EU) 2018/1139 and (EU) 2019/2144 and Directives 2014/90/EU, (EU) 2016/797 and (EU) 2020/1828 (Artificial Intelligence Act), OJ L, 2024/1689, 12.7.2024.

<sup>35</sup> See again: Kiseleva A., de Hert P., Creating a European Health Data Space. Obstacles in Four Key Legal Areas, cit.

<sup>36</sup> See: Fåhraeus, E., Reichel, J., and Slokenberga, S., The European Health Data Space: Challenges and Opportunities, cit.

<sup>37</sup> See: Sánchez Frías I., Secondary Uses Of Health Data Under The European Health Data Space. Connections With The GDPR And The Impact Of AI, cit.

<sup>38</sup> See again: Sánchez Frías I., Secondary Uses Of Health Data Under The European Health Data Space. Connections With The GDPR And The Impact Of AI, cit.

<sup>39</sup> See: Ramozzi F., Data Solidarity in the Health Sector: The Challenges of “Giving Back to the Commons” under the Health Data Space Regulation, cit.; Sánchez Frías I., Secondary Uses Of Health Data Under The European Health Data Space. Connections With The GDPR And The Impact Of AI, cit.

<sup>40</sup> See again: Fåhraeus, E., Reichel, J., and Slokenberga, S., The European Health Data Space: Challenges and Opportunities, cit.

<sup>41</sup> See: Marcus, J.S. et al., The European Health Data Space, cit.

**international policy harmonization** regarding healthcare data and patient data sovereignty<sup>42</sup>.

**External Reach and Reciprocity:** The EHDS has international ambitions for cross-border data exchange<sup>43</sup>.

Third countries and international organizations will be able to apply to join HealthData@EU as authorized participants, provided they adhere to EU rules and offer equivalent access to their health data by March 2034<sup>44</sup>.

**Regulatory Flight Risk:** If EHDS regulatory demands are overly complex, there is a risk that AI developers and innovators may be driven toward regions with more lenient regulations, such as the USA.

Furthermore, cross-border data processing raises concerns about complying with GDPR requirements when data is transferred outside the EU, especially to jurisdictions with weaker data protection standards<sup>45</sup>.

## 7. Conclusion

The European Health Data Space represents a **commendable and ambitious legislative effort** to lay down a framework that significantly **enhances the portability and transferability** of health data across Europe, both for the individual's direct care and for broader societal benefit<sup>46</sup>.

In this perspective, first of all, it must be kept in mind that citizens/patients typically grant their approval on the **premise that their data will serve the collective interest**. Therefore, ensuring that health research yields tangible social benefits is a critical factor in the "balancing equation" of data governance<sup>47</sup>.

The EU Regulation successfully **expands patient empowerment rights**, such as extending data portability to inferred data and mandating interoperability, but **critical limitations persist regarding its scope**, particularly the **seeming exclusion of transfers for**

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<sup>42</sup> Rai P., Patient-Owned Health Records: A Policy Framework for Post-EHDS Healthcare Data Sovereignty, August 2025, [https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=5389475](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=5389475).

<sup>43</sup> See: Marcus, J.S. et al., The European Health Data Space, cit.

<sup>44</sup> Tolias Y.S., Unlocking Health Data for AI: Analyzing the European Commission's EHDS Proposal, Journal du Droit de la Santé et de l'Assurance - Maladie (JDSAM), 2023, <https://droit.cairn.info/revue-journal-du-droit-de-la-sante-et-de-l-assurance-maladie-2023-3-page-34?lang=en>.

<sup>45</sup> See: Fåhraeus, E., Reichel, J., and Slokenberga, S., The European Health Data Space: Challenges and Opportunities, cit.

<sup>46</sup> See: Li W., Quinn P., The European Health Data Space: An expanded right to data portability?, cit.; Fåhraeus, E., Reichel, J., and Slokenberga, S., The European Health Data Space: Challenges and Opportunities, cit.

<sup>47</sup> Skovgaard L.L., Wadmann S., Hoeyer K., A review of attitudes towards the reuse of health data among people in the European Union: The primacy of purpose and the common good, Health Policy, 2019, <https://www.sciencedirect.com/science/article/pii/S0168851019300818>; Petročnik T., Health data between health(care) and the data economy, Technology and Regulation, cit.

**secondary use purposes, such as data altruism and research**, from the expanded portability right<sup>48</sup>.

The success of the centralized permit procedure hinges on resolving the complex governance issues surrounding the **burdensome mandate of the national HDABs** and ensuring necessary **administrative and judicial safeguards for data holders** who currently lack a formal role in the process<sup>49</sup>.

Furthermore, achieving the EHDS's goals for AI innovation requires **harmonizing its rules with the GDPR and the evolving AI Act**, specifically clarifying the compatibility of portability requests with **explicit consent requirements** and creating consistent regulations to prevent fragmentation due to national derogations<sup>50</sup>.

Ultimately, the EHDS must navigate these tensions to realize its geopolitical ambition of becoming a global health data leader by ensuring that the framework is **consistently implemented, fosters trust among citizens/patients and innovators, and avoids regulatory complexity** that could impede the secure, efficient flow of data<sup>51</sup>.

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<sup>48</sup> See again: Li W., Quinn P., The European Health Data Space: An expanded right to data portability?, cit.

<sup>49</sup> See: Fåhraeus, E., Reichel, J., and Slokenberga, S., The European Health Data Space: Challenges and Opportunities, cit.

<sup>50</sup> See: Kiseleva A., de Hert P., Creating a European Health Data Space. Obstacles in Four Key Legal Areas, cit.; Sánchez Frías I., Secondary Uses Of Health Data Under The European Health Data Space. Connections With The GDPR And The Impact Of AI, cit.

<sup>51</sup> See: Fåhraeus, E., Reichel, J., and Slokenberga, S., The European Health Data Space: Challenges and Opportunities, cit.; Marcus, J.S. et al., The European Health Data Space, cit.