



The European Health Data Space Regulation: opportunities and challenges

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The **European Health Data Space Regulation** is the first domain-specific common European data space established under the European Union's data strategy [Li, Wenkai, and Paul Quinn, "The European Health Data Space: An expanded right to data portability?", Computer Law & Security Review 52 (2024); Marcus, J.S. et al., "The European Health Data Space", Policy Department for Economic, Scientific and Quality of Life Policies, European Parliament, December 2022].

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** [Li, Wenkai, and Paul Quinn, "The European Health Data Space: An expanded right to data portability?", Computer Law & Security Review 52 (2024); Fåhræus, E., Reichel, J., and Slokenberga, S., "The European Health Data Space: Challenges and Opportunities", European Policy Analysis, February 2024:2epa; Marcus, J.S. et al., "The European Health Data Space", Policy Department for Economic, Scientific and Quality of Life Policies, European Parliament, December 2022].

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 [Li, Wenkai, and Paul Quinn, "The European Health Data Space: An expanded right to data portability?", Computer Law & Security Review 52 (2024); Marcus, J.S. et al., "The European Health Data Space", Policy Department for Economic, Scientific and Quality of Life Policies, European Parliament, December 2022].

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 [Marcus, J.S. et al., "The European Health Data Space", Policy Department for Economic, Scientific and Quality of Life Policies, European Parliament, December 2022; Fåhraeus, E., Reichel, J., and Slokenberga, S., "The European Health Data Space: Challenges and Opportunities", European Policy Analysis, February 2024].

The Regulation reinforces patients' rights to access their data immediately and free of charge, eliminating previous challenges like providing data in paper form or charging fees for access [Fåhraeus, E., Reichel, J., and Slokenberga, S., "The European Health Data Space: Challenges and Opportunities", European Policy Analysis, February 2024].

- **Expanding the scope of the General Data Protection Regulation (GDPR)** by mandating strong interoperability requirements and extending the right to data portability to cover inferred data, which is excluded under GDPR Article 20 [Li, Wenkai, and Paul Quinn, "The European Health Data Space: An expanded right to data portability?", Computer Law & Security Review 52 (2024)].

- **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 [Marcus, J.S. et al., "The European Health Data Space", Policy Department for Economic, Scientific and Quality of Life Policies, European Parliament, December 2022].

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 financial burden on constrained national healthcare budgets [Fåhraeus, E., Reichel, J., and Slokenberga, S., "The European Health Data Space: Challenges and Opportunities", European Policy Analysis, February 2024].

- **Regulatory incoherence and fragmentation due to overlaps** with the GDPR, the Data Act, and the Data Governance Act, compounded by significant variances in national rules concerning data protection and health policies across Member States [Kiseleva, Anastasiya, and Paul de Hert, "Creating a European Health Data Space. Obstacles in Four Key Legal Areas" (undated preprint, SSRN: 3846781); Fåhraeus, E., Reichel, J., and Slokenberga, S., "The European Health Data Space: Challenges and Opportunities", European Policy Analysis, February 2024].

- **Risk of decreasing legitimacy and trust** due to the limited role of the individual in exercising control over their data for secondary use purposes [Fåhraeus, E., Reichel, J., and Slokenberga, S., "The European Health Data Space: Challenges and Opportunities", European Policy Analysis, February 2024].
- **The persistence of legal ambiguities regarding intellectual property** protection and the duty to disclose research outputs ("giving back to the commons"), which could deter innovative commercial actors from participating in secondary use [Ramoszi, Francesco, "Data Solidarity in the Health Sector: The challenges of 'giving back to the commons' under the Health Data Space Regulation" (undated preprint, SSRN: 5727225)].

Conclusion

The EHDS establishes a **foundational framework** intended to transform healthcare data governance in the EU, leveraging data as a source of innovation and public good [Marcus, J.S. et al., 2022].

Its success hinges on the **delicate process of implementation**, which must resolve the structural tension between harmonizing data flow across borders and respecting the existing fragmentation of national health systems and legal traditions [Fåhraeus, E., Reichel, J., and Slokenberga, S., 2024; Kiseleva, Anastasiya, and Paul de Hert, undated preprint].

Achieving the ambitious goal of making health data seamlessly accessible requires not only **political will, but also** the successful, **technically sound application of the mandatory interoperability standards** and **administrative procedures that are intended to foster trust** while maximizing economic and societal gains [Li, Wenkai, and Paul Quinn, 2024].

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