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In a push to foster innovation, growth, and competition within the European Union's (EU) Single Market, in 2020, the European Commission (EC) announced its data strategy to create a more equitable and legally secure framework for data sharing. To operationalize this overarching vision within a specific sector, the EU initially prioritized the healthcare industry (European Commission, 2021). The seven-year long political process began in 2018 with the communication on common European data spaces (European Commission, 2018). This was followed by the publication of the European Health Data Space (EHDS) proposal in May 2022 that initiated an open stakeholder consultation (European Commission, 2022). Followed by the trilogue between the EC, the European Parliament (EP), and the Council of the European Union (EUCO), the EHDS was finally adopted as the first sector-specific data space regulation on March 26, 2025 (Regulation (EU) 2025/327; in the following EHDS (2025)). The EHDS (2025) will become directly applicable across all 27 EU member states starting in March 2029, with implications for all healthcare actors regarding the future use and sharing of health data within the EU (Schurig, 2025b).

More specifically, the EHDS (2025) introduces ex-ante rights, rules, and obligations, and thereby articulates its vision of a European health data market in unprecedented detail (Hoeyer et al., 2024). It establishes a comprehensive framework encompassing the necessary legal foundations, technical infrastructure, and governance model to create a unified EU-wide economy for data-driven healthcare services and products (Kari et al., 2023b), along with associated EHDS-compliant business models (Kari et al., 2025). Thereby, the EU seeks to enable more personalized and predictive medicine, anticipates cost savings of nearly €11 billion over the next ten years through improved utilization of health data, and expects an overall 20–30% growth in the digital health market by 2033 (European Commission, 2023). However, the legislative process for the EHDS also raised concerns about a potential loss of data sovereignty, as extensive health data sharing could result in patients losing control over their personal data (Hoeyer et al., 2024; Marelli et al., 2023).

Structurally, the EHDS (2025) distinguishes between the primary (chapter 2 of the EHDS (2025)) and secondary use of health data (chapter 4 of the EHDS (2025)): the primary use of health data encompasses the direct use by healthcare providers for patient care, including treatment, prescriptions, and rehabilitation. Here, the EHDS (2025) aims to empower individual EU citizens by granting them the right to access, control, and share their health data immediately and free of charge in the commonly agreed-upon interoperable European Electronic Health Record Exchange Format (EEHRxF). The EHDS (2025) enables the sharing of primary health data between healthcare professionals (HCPs) both within and across EU member states – for example, in cases of accidents during vacations in foreign EU countries. To address concerns about excessive data sharing, the final

EHDS (2025) includes an opt-out option for EU citizens to refuse access to their electronic health data, including its secondary use.

Similar to the figure in Kari et al. (2023a), which was based on the EHDS proposal and did not differentiate between the primary and secondary use of health data, Figure 1 illustrates the institutions, actors, and tasks involved in the primary use of health data, as outlined in EHDS (2025). This figure depicts in blue the roles and relationships of the EU Stakeholder Forum and the EHDS Board, as well as the MyHealth@EU data-sharing infrastructure, all of which are established exclusively at the EU level. All other institutions and functionalities are shown in grey and black. They will be implemented within each EU member state starting in March 2029, yet they must remain fully interoperable across the EU. Patients and healthcare professionals (HCPs) will gain access to personal health data through a national health data access service and a corresponding HCP access service, with identification managed via authorized national electronic ID authentication services (eIDAS).

Furthermore, HCPs from a member state in which the patient is a non-resident will be able to connect to the national HCP access services through a national contact point and the MyHealth@EU infrastructure. In addition, each member state must establish a Digital Health Authority (DHA) to monitor the primary use of health data and serve as the central point of contact for filing complaints.

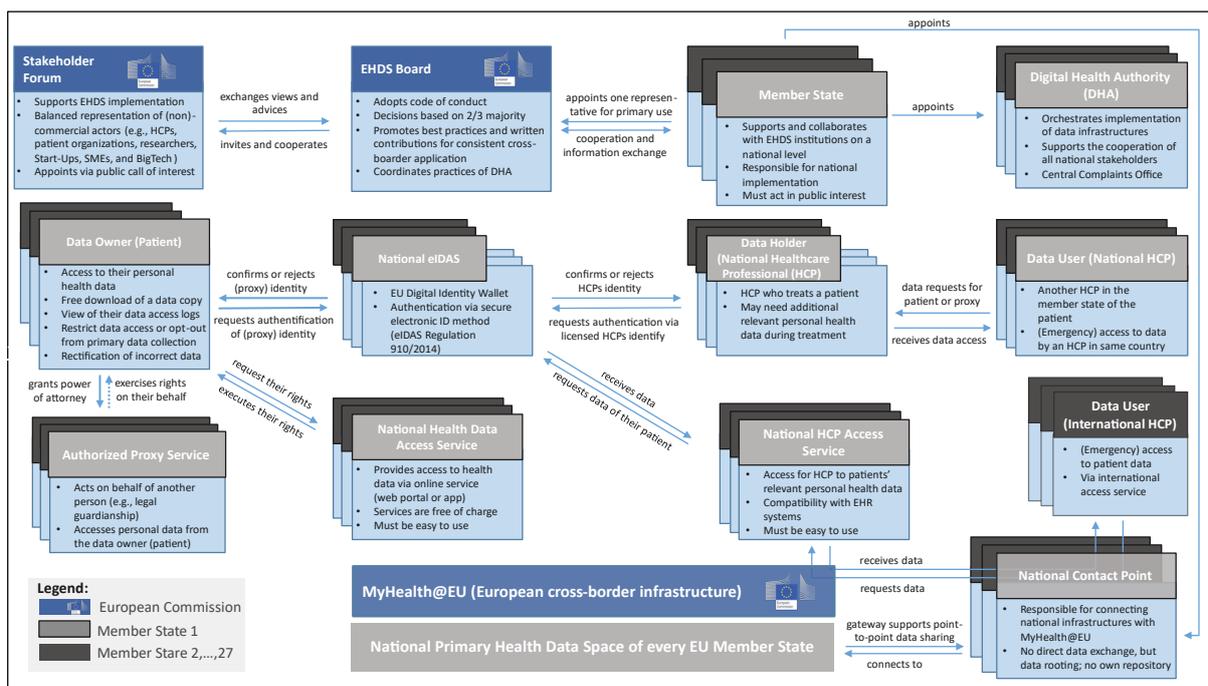


Figure 1: Primary Use of Health Data in the EHDS (2025) Regulation (taken from Schurig, 2025a).

The secondary use of health data occurs outside primary healthcare delivery and aims to enable large-scale reuse for research, innovation, and evidence-based policymaking (Kilgus et al., 2024). Figure 2 illustrates the institutions, actors, and tasks involved in the secondary use of health data, as defined in the EHDS (2025) regulation. Similar to the primary use, the Stakeholder Forum, EHDS Board, and HealthData@EU infrastructure are established only once at the EU level. In contrast, the remaining institutions and infrastructures must be implemented at least once in every EU member state:

The introduced reference infrastructure aims to facilitate the secure, privacy-preserving, and trustworthy reuse of anonymized, or, when anonymization of the data is not appropriate for the

as semantic and technical interoperability, data portability, and user accessibility. The goals are to reduce market fragmentation, promote fair competition among EHR system developers, and enhance trust among HCPs and patients (EHDS, 2025).

To summarize, the EHDS (2025) will fundamentally reshape the future of the data-based healthcare industry in the EU, with broad implications for all stakeholders (Hoeyer et al., 2024; Schurig, 2025b). The EHDS (2025) introduces the HDAB and DHA as new organizations with which all health data holders and potential health data users must cooperate. In addition, the EHDS (2025) mandates the use of specific interoperability standards based on EEHRxF and requires top-down implementation of an opt-out consent model (Schurig, 2025b). Furthermore, the EHDS (2025) will impose far-reaching obligations on dominant platforms to share health data, in stark contrast to their present focus on locking health data in siloed infrastructures. The EHDS (2025) will challenge the ability to protect the strategic value of data, as it enforces openness by defining purposes for the secondary use of health data. All this will be subject to intellectual property (IP) rights and trade secrets (Article 52, EHDS 2025). Finally, the EHDS (2025) will limit the pricing autonomy of health data holders, as national HDABs will be able to set prices for specific datasets if data holders and users cannot agree on a fee within a specified timeframe (Article 62, EHDS 2025). Consequently, the value generated from health data will shift from exclusive control and monetization toward participatory and secondary usage scenarios (Schurig, 2025b).

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