

## European Health Data Space (EHDS), Gaia-X and Health-X dataLOFT

Arthur Kari<sup>1</sup>, Tim Schurig<sup>1</sup>, Martin Gersch<sup>1</sup>

<sup>1</sup>Freie Universität Berlin, Germany

In 2020, the European Union (EU) allocated a budget of up to two billion euros for federated data infrastructures and common data space investments (European Commission, 2018, 2020). Initiatives such as Gaia-X and the European Health Data Space (EHDS) (European Commission, 2022a) have underpinned the willingness of policymakers to create an alternative to dominating American digital platforms. In May 2022, the European Commission finally published the EHDS proposal (European Commission, 2022a). It constructively frames an emerging health data sharing economy that establishes the required infrastructure, governance model and interoperability framework (Hussein et al., 2023) and at the same time builds on and promotes European values such as citizen-centricity, data sovereignty and transparency. It represents the emergence of the first sector-specific data space in an overarching European digital strategy. The EHDS proposal could become a “fundamental game changer for the digital transformation of healthcare in the Europe”. The goal is to “foster a single European market for digital health services and products” to realize the potential of the health data economy. Until 2025, the EU member states shall create the necessary technical, organizational, and regulatory prerequisites.

The regulatory framework will apply to all European member states, with other sector-specific data space regulations to follow (Ferretti, 2022; Genovese et al., 2022; Horgan et al., 2022). Hereby, the EU tries to combine previous attempts for regulation (e.g., General Data Protection Regulation, Data Service Act, Data Governance Act) and further specifies the data holder’s and data user’s rights, requirements for a fair data exchange, institutional framings and governance aspects (Shabani, 2022). The underlying rights and rules apply to all individuals and institutions that meet the requirements (e.g., data protection and data security requirements as specified in the regulation) and use data for public benefit (i.e., research or improving healthcare). For usage scenarios that are beneficial to the public, it establishes an obligation for data holders to make health data available. It also prohibits data usage for reasons that are harmful to individuals such as marketing or increasing insurance premiums. In essence, the EHDS promotes European citizens to take electronic control of their own health data while enabling a fair and transparent primary and secondary data usage (European Commission, 2022b). Secondary data usage areas are for example facilitating research, creating innovations, policymaking, AI development, and personalized healthcare. Specifically, the EHDS proposal defines generic roles (such as Data Holder, Data User, Health Data Access Point, Health Data Space Board, and Digital Health Authority), rights and associated tasks that need to be nationally institutionalized, implemented and orchestrated by the individual member states. This is illustrated in Figure 1.

The Health Data Access Body (HDAB) occupies a central role in operating the national data space by providing inter alia data access management, data permit management, monitoring and policing services for public and private stakeholders (European Commission, 2022a). Additionally, the EHDS portrays tasks and functions for the different roles and institutions. For example, the Digital Health Authority (DHA) needs to define penalties and potential data space exclusion criteria for data

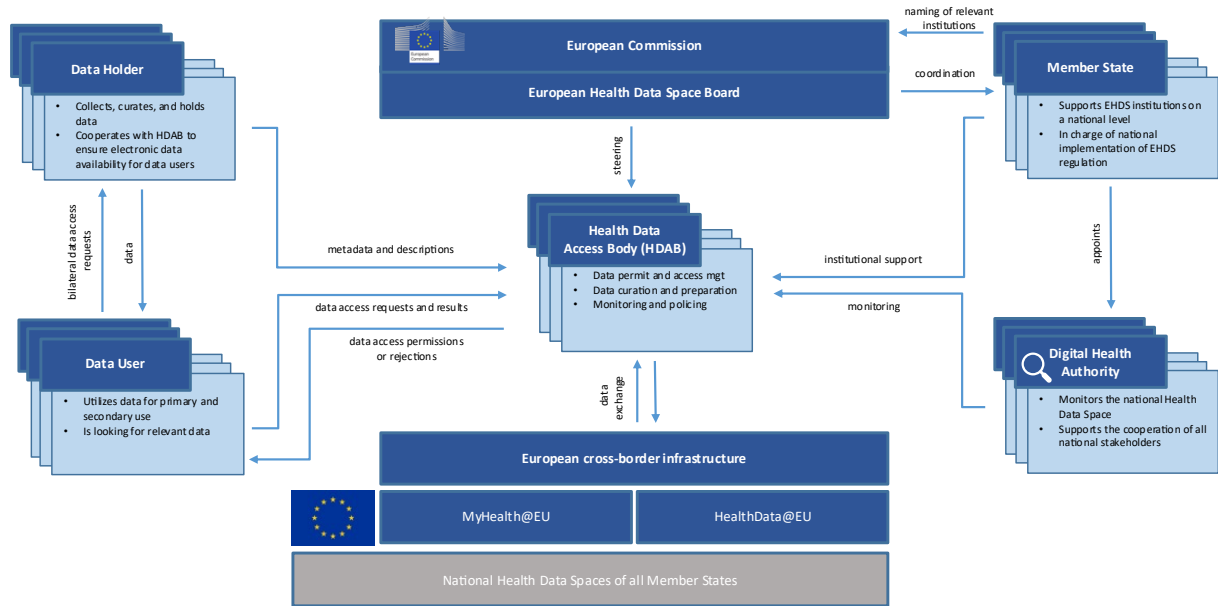


Figure 1: Own Illustration. Roles, Institutions and Functions of the EHDS

misuse and the DHA has the obligation to monitor and supervise the activities of the HDAB. A list of functions is depicted in Figure 2, which additionally also locates them within the illustrated landscape of EHDS roles and institutions.

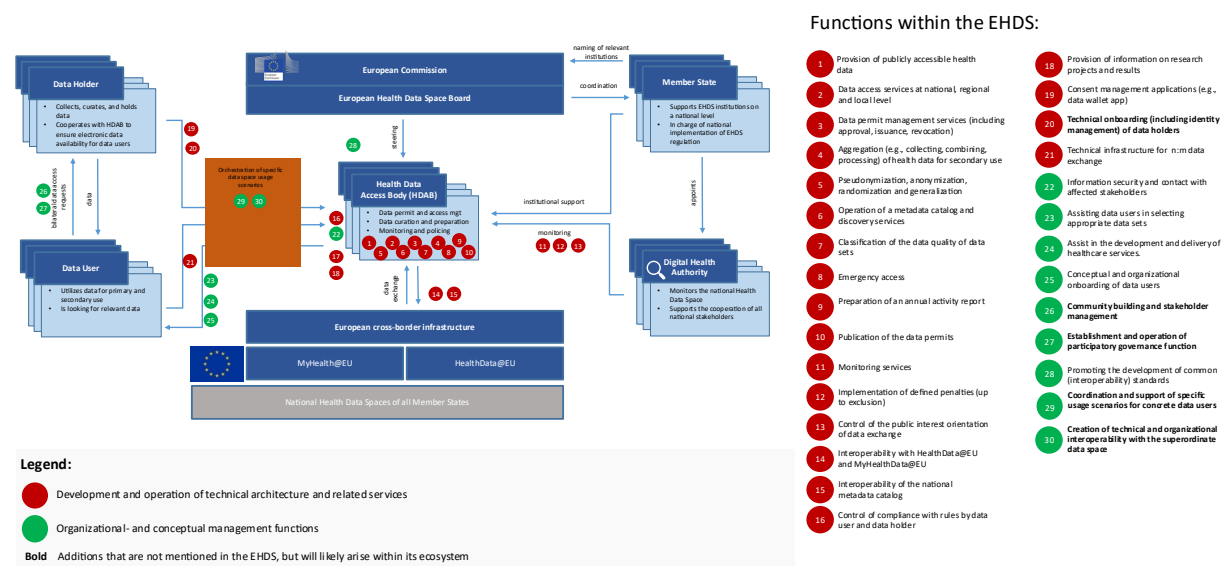


Figure 2: Own Illustration. Mapping of EHDS Functions to Roles and Institutions

While the EHDS proposal provides a regulatory framework, it is agnostic to the technical implementation that the member states shall build on. The budget that the European Commission allocated includes European cross-domain initiatives such as Gaia-X (European Union, 2020; Federal Ministry for Economic Affairs and Climate Action, 2021). Gaia-X develops a specific open-source technical reference architecture (including source code for, among other things, identity and trust services, connectors, and different kind of catalogue services) for federated data spaces. Thus, the Gaia-X initiative aims to realize a joint infrastructure for decentralized federated data spaces that enable data exchange in accordance with European values (Federal Ministry of Economic Affairs and

Climate Action, 2020; Otto & Burmann, 2021) and could be used as a technological foundation for the EHDS. Together, the EHDS and Gaia-X offer technical, organizational, and regulatory frameworks that represent a paradigm-shifting episode shaping the national and European healthcare landscape, but are yet to be implemented on a large scale (Gersch & Wessel 2023). Consequently, Health-X dataLOFT is building on top of Gaia-X to develop a first realization of a currently national, but prospectively also European health data space in alignment with the EHDS proposal. Thereby, Health-X dataLOFT could orchestrate specific application scenarios and provide the sector-specific technical capabilities by e.g., offering the provision and operation of critical technical services to EHDS institutionalizations, such as the HDAB, which are imperative to a functional and sustainable operation of the national health data space. This will foster a sovereign, citizen-centered data exchange that will improve healthcare and produce healthcare innovations in accordance with EHDS and European values.

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