



Report Summary Implementing the European Health Data Space in Sweden

Introduction to EIT Health, Think Tank & EHDS

EIT Health

EIT Health is one of eight Knowledge and Innovation Communities (KICs) of the European Institute of Innovation and Technology (EIT) and an Institutionalised Partnership under Horizon Europe's Pillar III – Innovative Europe. Established in 2015 to tackle the societal challenges of 'health, demographic change and well-being' within the EU.

Think Tank

The EIT Health Think Tank was established to address barriers and opportunities in adopting innovation and new health technologies. The Think Tank is a thought leadership forum that brings together experts to prepare the ground for life-changing innovation and to identify the next opportunity for a step-change in how health care is delivered. To facilitate this dialogue and its findings, EIT Health drives a range of activities to generate knowledge and insight, including research, expert Round Tables and interviews, publications, and dissemination of key information.

EHDS

The European Health Data Space (EHDS)¹ is a new framework intended to make it easier for individuals, doctors, researchers, and regulators to access and use information about the health of millions of citizens across the European Union. This data, accessed under strong safeguards for security and privacy, will also be a treasure trove for scientists, researchers, innovators, and policymakers working on the next life-saving treatment. The European Commission aims to have the EHDS finalised by mid-2024 and running by 2025.

Key objectives EHDS plan:

1. To give individuals better digital access to their personal health data and to support free movement by having that data follow them across the Union.
2. To promote the data economy by fostering a single market for digital health services and products.
3. To set up strict rules for the use of an individual's non-identifiable health data for research, innovation, policymaking, and regulatory activities.

In 2023 a pan-European, multi-stakeholder, initiative was conducted to support knowledge sharing and capacity building for a fully operational EHDS that is favourable to health innovation and research. The focus lays, in particular, on the secondary use of health data and to shed light on the needs of the individual countries in relation to adopting the EHDS. This report focuses on the feasibility of implementation of EHDS in Sweden only.

6 Dimensions of Implementation

1. Governance

The EHDS will introduce a common system of data governance, rules and guidelines for data exchange in the health sector. This will be coordinated at national level by Digital Health Authorities for primary use of patient data, and by Health Data Access Bodies for secondary use. The application of the EHDS regulation and cross-border data sharing will, among other things, depend on individual countries' conditions, including the availability and maturity of electronic health record (EHR) systems. It also depends on the countries' rules for health data anonymization, pseudonymization, privacy, and consent requirements under national interpretations of the GDPR.

The Swedish government and parliament support the European Health Data Space (EHDS) but face challenges in its implementation. While Sweden is making progress in building the necessary infrastructure, its legal readiness lags behind the technical readiness. An obstacle for instance is the national and regional allocation of EHDS roles and responsibilities. However, no comprehensive assessment has been conducted yet on the changes to regional legislation that will be required.

2. Capacity and skills

National health data access bodies have the responsibility to examine requests, issue permits, process relevant data in centralized pools, and deliver user access. Additionally, they need to network with counterparts in other Member States via the core platform HealthData@EU. These tasks require capacity building in the public administrations of individual countries.

Sweden has a strong track record of secondary use of data for research: national registries, statistics, and epidemiology, but there is a shortage of skills for extracting data from electronic health records (EHRs). As more data and new users enter the ecosystem, there will also be an increased risk of security and privacy breaches. Investments in data infrastructure are therefore needed as well as new types of collaboration and professional profiles.

3. Resources and funding

The EHDS is expected to be the costliest among European data spaces. Although health data access bodies (HDABs) and individual data holders will be entitled to charge access fees to users, these will likely cover only a small part of the total costs. The resources available for this will vary within organisations and could in practice limit their ability to comply with the new requirements. As healthcare professionals are already burdened, additional administrative tasks should be minimised.

Immediate investments are needed in data infrastructure to reduce data access time. Funding should be a collective effort across the health ecosystem, and socio-economic models should be developed to secure financing from stakeholders who benefit from the EHDS.

4. Quality of data

Collection, use, and storage of healthcare data varies between organisations and countries, making it difficult to compare data. A common framework is needed to ensure that the data being shared within the EHDS is reliable and meaningful to produce trustworthy and useful research results.

While Sweden has robust national data quality standards for secondary use, primary use settings lack mandatory data quality recommendations. The concepts of data quality and utility in the EHDS legislation should therefore be further defined, building on the FAIR principles, meaning that data should be Findable, Accessible, Interoperable, and Reusable. While the EHDS has the capability to improve data quality, it is essential to clarify the roles and responsibilities of data stakeholders to ensure effective implementation.

5. Closing the loop: The relationship between primary and secondary use of data

Secondary use of health data will impact the primary use, the clinical care process, for instance by accelerating the shift from treatment of illness to prediction and prevention. Conversely, effective secondary use depends on the quality of data collection in the primary use setting. Efforts to bridge the gap between primary and secondary data use are thus necessary, which includes the importance of providing incentives for healthcare professionals, automation of data recording, and improved digital literacy. Additionally, it is crucial to ensure electronic health record (EHR) interoperability and maintain strict standards for patient privacy.

6. Awareness, education, communication: Towards a data-driven culture in healthcare

Achieving the full potential and benefits of secondary use of health data through the EHDS will require support and approval across all stakeholder groups, including healthcare providers and payers, the academic research community, pharmaceutical and health technology industries, and patients and citizens.

At present, awareness and preparedness to participate differ across these stakeholder groups and give rise to varying educational and communication needs. Therefore, healthcare professionals should be involved in data-sharing platforms early on to foster trust and active participation in the EHDS. Moreover, both patients and healthcare professionals need training to understand the health system and improve communication. Demonstrating value for stakeholders, offering legal clarity, and providing guidance are essential steps.

Key take aways

- Broad support and a positive attitude towards EHDS from the Swedish government and the parliament.
- A challenge is the Swedish regions' decentralised responsibility for healthcare.
- Immediate investments are needed in data infrastructure to reduce data access time.
- The concepts of data quality and utility in the EHDS legislation must be further defined.
- Efforts need to be made to bridge the gap between primary and secondary data use.
- Training needs to be provided to both patients and healthcare professionals to understand the health system and improve communication.