

## Challenges and enablers for implementation

The EHDS will introduce a common system of data governance and rules and guidelines for data exchange in the health sector, but as this roundtable series has brought to light, the adoption of this common framework will run up against diverse national realities. In some instances, overly restrictive or unclear legal provisions will need to be revised along with the data-sharing policies and practices (or lack thereof) that they have led to in different organisations over the years.

Structural differences between centralised national health systems and those with a strong regional component to healthcare planning and provision appear to call for some flexibility in the model of governance adopted from one country to another.

These questions and others—related to how intellectual property of both private companies and academic researchers will be protected, how citizens' rights as the owners of their health data will be materialised in practice, or how actors in non-EU countries will interact with the EHDS—will require a lot more work to be effectively implemented.

In a landscape as fragmented as Europe when it comes to secondary use of health data, harmonising the rules and practices for its secure and ethical sharing provides an opportunity to reduce inequalities in European citizens' access to healthcare. The possibilities include more informed policymaking tailored to real public health needs in different countries, better identification

of individuals for prevention and screening measures, more effective patient monitoring and earlier diagnosis of health incidents and diseases, improved access to clinical trials for patients treated outside of research centres, better and safer pharmaceuticals developed using real-world data, and the democratisation of personalised medicine. In most countries included in the roundtable series, there is political will and momentum to drive the digital transformation of healthcare, as well as a positive, proactive stance of national governments towards the creation of a common EHDS.

**Disclaimer:** This text reflects only the point of view of the experts and stakeholders involved in the Think Tank roundtable series and consultation processes held in 2023 based on the European Commission's first legislative proposal

### Solutions should aim to

- ▶ **Define clear policies and implementation frameworks**
- ▶ **Collaborate towards a harmonised implementation of the EHDS**
- ▶ **Involve all stakeholders and support data driven culture throughout the EU**

## At European level

Provide detailed guidance for fulfilling data anonymisation and pseudonymisation requirements with a focus on harmonising the rules across the EU.

Minimise the risk of exploitation, intended or not, of secondary use of health data by providing a more specific definition of health data, as well as evidence-based definitions of the expected benefits for citizens and society.

Foresee safeguards to avoid non-legitimate use of health data for commercial purposes through oversight and control mechanisms.

Ensure meaningful patient and civil society input on EU-level data governance bodies.

Define an opt-out/opt-in model that balances the interests of data users with practical feasibility for data producers, (for example by allowing accumulation of historical data while minimising administrative burden,) which is broad enough to include both health and relevant health-related secondary use of data and which is easy to use and understand by patients and citizens of all levels of digital health literacy.

Agree on a protected interval of time during which research and other entities retain exclusive access to health data they have collected and processed, in alignment with existing rules for data protection and intellectual property (for example, as seen in the EU Clinical Trials Regulation).

Foster harmonised implementation through collaboration and mutual recognition of national health data access bodies and EU-level oversight by the EHDS Board.

Support collaborative initiatives between Member States for sharing best practices and lessons learned for designing national governance frameworks.

Leverage lessons learnt from existing pilot projects (like the HealthData@EU pilot) to answer practical questions surrounding data governance and use.

## At a national and regional levels

Assign roles and responsibilities for data governance in line with the degree of (de)centralisation of the health system, and develop clear guidelines for the national (and regional) EHDS bodies.

Clearly define how the local, regional or national health systems will connect to the health data access bodies, from a both procedural and technical perspective.

Ensure multistakeholder and cross-government collaboration, including involvement of regional lawmakers, hospital managers, in developing a national framework for EHDS governance, processes and systems.

Engage patients and healthcare professionals at all levels, including in pilot projects and local governance structures.

Mandate governance bodies to implement data quality, interoperability and cataloguing, in a consistent way with existing EU regulations.

Launch and collaborate in multi-country, multistakeholder and cross-regional collaboration projects for sharing and secondary use of health data.

Establish a transparent system of ethical oversight for all secondary use applications, networking and supporting in existing ethics committees as needed.

Provide citizens clear communication, transparency and control over who can access different categories of data within their health records, taking into account varying levels of digital and health literacy and openly addressing both the risks and benefits of the EHDS.

## EXAMPLE

In Sweden, health data collected nationally has been made available and used for research for decades, and its integration in the EHDS is not expected to pose any difficulties (EIT Health Scandinavia, 2023). The wealth of healthcare data held in its regions, however, has so far remained largely untapped due to the fragmentation of data infrastructures and the complexity of regional data governance structures preventing its extraction and aggregation at national level.

In France, a harmonised model of local governance of access to health data was introduced in early 2023 by the health data strategic committee. The "Governance of access to health data" working group aims to provide health institutions with a health data warehouse (EDS), a harmonised model of local governance of access to health data that is consistent with national governance. This includes a set of "turnkey" deliverables such as a framework for internal policies, an admissibility form, an evaluation sheet and a CSE opinion template.