

Challenges and enablers for implementation

As the first of nine planned European data spaces and the only project of its kind in the world to date, the EHDS is widely expected to come at a high cost of implementation. The precise amounts of the short and long-term investments needed in each country, however, are difficult to estimate. What did emerge clearly from the roundtable discussions is that many smaller Member States will be dependent on EU co-funding to be able to shoulder the financial burden. In this context, the budget so far allocated by the European Commission to the implementation effort was considered to fall short of the ambition level of the regulation proposal.

An efficient and just allocation of the resources and funding available at both EU and national levels will be key to building a system that is viable for all stakeholders and which works in the interest of all EU citizens. This will require a detailed understanding of who is going to incur which costs, and to what extent the relevant organisations have a stake in and the capabilities for making the necessary investments. Health institutions, in particular, cannot be expected to bear the brunt of the financial and human effort needed to make their electronic health data available for secondary use when their main interest resides in its primary use. It will also be important to ensure that resources allocated to implementing the EHDS in the healthcare sector do not subtract from those dedicated to ensuring patient safety and quality of care. In the private sector, the costs of complying with the obligations of a data holder will be equally difficult to cover for the numerous European SMEs

which tend to be the drivers of innovation in areas such as digital health. On the side of data users, the question of the fees for data access will be central to ensuring a level playing field for research actors small and large, public and private. Templates for a cost-efficient implementation can be found in existing European projects of common interest, which have already begun developing technical building blocks and transnational data infrastructures that could be leveraged for the EHDS. Pooling available resources across different organisations and Member States also has the advantage of supporting the emergence of standard solutions and a harmonised implementation, a critical success factor for the system's operation. In addition to the resources needed in the short term to warrant the kind of swift implementation envisioned by the European Commission, work will also be needed to identify the long-term financial mechanisms and new business models to ensure the sustainability of the EHDS over time.

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

- ▶ Provide sufficient funding for the implementation of the EHDS
- ▶ Devise cost-efficient implementation strategies for the EHDS
- ▶ Ensure long-term sustainability of the EHDS

At European level

Provide adequate EU funding and better coordination of funding allocation for projects through which healthcare providers can invest in infrastructure for the EHDS and an integrated European implementation.

Leverage lessons learned from the implementation of complex EU legislation, and provide adequate financial support for countries to invest in infrastructure and resources.

Dedicate funding and resources to ensuring equitable access to health data, data security and privacy and avoiding discriminatory outcomes, including through the enhancement of digital literacy and skills across the EU.

Create financial incentives for Member States and regions across Europe to collaborate and pool their resources on projects of common interest (e.g. the ELIXIR, European Genomic Data Infrastructure).

In addition to EU and national public funds, healthcare payers and the life sciences industry should contribute, for example through public-private partnerships, to covering the cost of implementation in light of the expected gains from access to data.

Reuse technical building blocks from previous EU projects (EUCAIM, GDI, ELIXIR, DARWIN, etc.) for harmonised and cost-efficient infrastructure development across the EU.

Establish a monitoring system and ensure transparency of the use of resources and funding allocation.

Ensure that public investment in innovation through the EHDS supports improved availability and accessibility of new products and services for all citizens.

At national and regional levels

Set out a national strategy for health data collection and sharing, with clear timelines.

Map all existing secondary use initiatives around health data to enable collaboration and synergies.

Establish joint systems and standardised contracts to decrease overhead costs of data provision and use.

Create financial incentives for regional cooperation, sharing lessons learned and good practice.

In collaboration with all data holders, define the return on investment and possible business models through which sustainable funding for data collection, quality management, curation and transfer can be established.

Identify the mechanisms by which long-term funding for the EHDS can be secured from the stakeholders across society for whom benefits are generated.

Structure support in such a way as to prevent any stakeholder group from bearing a disproportionate financial burden and avoid accentuating already existing inequalities in the health system.

Avoid making investments or allocating resources to the EHDS to the detriment of investments in research, innovation and healthcare services.

Do not neglect investments in human resources and skills and public communication when allocating public funds.

▶ EXAMPLE

In Germany, the federal government currently bears the primary responsibility for allocating funds towards the EHDS, but an initiative supported by the Bavarian state Ministry of Health and Care to financially assist SMEs with the implementation provides an example of the role that regional funding streams could play in the process. Another such example is digiOnko, a financial mechanism introduced by the same ministry in Bavaria to allow the remuneration of university hospitals that make their data available for secondary use.