

EIT Health Statement on the European Health Data Space

EIT Health welcomes the publication of the legislative proposal for the European Health Data Space (EHDS)¹, a key building block for the creation of a sustainable and resilient European Health Union, and an unprecedented opportunity to leverage the European power to innovate.

The EHDS creates a much-needed balance between the rights of patients to control and access their own data and the needs of healthcare professionals, providers, industry, researchers and decision-makers to use health data both for health care delivery and for public health, scientific and R&D purposes. Importantly, the ability for innovators to use high-quality health data is an indispensable requirement to transform health care and deliver more value to patients.

EIT Health will be closely monitoring the development of the proposal through the European Parliament and Council of the European Union. As outlined in its 2021 Think Tank Report report '[Learning from health data use cases: Real-world challenges and enablers to the creation of the EHDS](#)' it invites policymakers to consider the following elements for the creation of a truly operational EHDS:

- **The EHDS governance framework should effectively address the different roles that health data users may hold, and work with all stakeholders**

The way in which data can be accessed and used is determined by the user's role in the healthcare system. Roles are not static: a healthcare professional may also be a researcher, a public health insurance body can also be a policy maker, and a citizen may be a patient, a carer and also a data provider. It is important to ensure a regulatory landscape that embraces and effectively addresses the 'changing nature' of roles while keeping the rights and interests of patients front and centre. This demands that the legislators work collaboratively with all stakeholders.

- **Compliance with the new EHDS requirements on data interoperability should be facilitated and supported**

Practices and standards applied to health data collection, processing and storage vary among sectors and borders. This poses a challenge of interoperability – i.e., the ability of organisations and technologies to interact meaningfully without altering the content of data – which will not be easily surmounted given the currently fragmented landscape. As the EHDS legislation sets to establish common rules and obligations for interoperability, support should be foreseen for stakeholders to comply with the new requirements so that these represent an opportunity rather than a new challenge, particularly for smaller players such as start-ups and SMEs. If interoperability is not met, data will remain significantly under utilised.

¹ Proposal for a Regulation of the European Parliament and of the Council on the European Health Data Space
https://ec.europa.eu/health/system/files/2022-05/com_2022-197_en.pdf

- **Clarity on the interplay between the EHDS and connected legislation must be ensured, and compliance simplified as much as possible**

Unleashing the 'data economy' is paramount to accelerate Europe's digital transformation towards a Digital Single Market. Yet, challenges persist regarding the commercialisation of digital health solutions. In the evolving field of digital health, innovators often face difficulties in achieving widespread adoption, due to regulatory, reimbursement and procurement processes which are difficult to navigate and fragmented across Europe. Such barriers delay impactful solutions from reaching patients and citizens. Legal complexity and overlap between other legislation impacting the health sector – e.g., the Medical Devices Regulation, the Health Technology Assessment Regulation, the AI Act - must be addressed to ensure that overregulation is avoided and that the legislative landscape is as understandable and user-friendly as possible for innovators and early adopters of new technologies.

EIT Health and its network are a unique resource capable of supporting the development and implementation of the EHDS. Together, we are keen to make available the knowledge of our experts as well as best practice examples throughout the process so that the final EU law is fit for purpose, and that the resulting EHDS can bring real benefit in terms of empowering patients and unleashing the full European innovation potential.

About EIT Health

EIT Health is one of eight Knowledge and Innovation Communities (KICs) of the European Institute of Innovation and Technology (EIT), an EU body 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, its mission is to help overcome the well-known EU paradox whereby state-of-the-art education, excellent research and a dynamic industry seldom turn breakthrough ideas into new transformative products and services. Within the EIT Health network, ~150 partner organisations and institutions from academia, business, research and health care delivery collaborate across disciplines, borders and sectors to reinforce excellence, create knowledge and innovation and encourage greater investment in innovation that delivers the outcomes that matter to citizens and patients. www.eithealth.eu