

Position on a European Health Data Space

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EFPIA applauds the European Commission's (EC) effort to create an EU policy environment that unlocks the value of the data economy and creates a beneficial European Health Data Space (EHDS). It has a potential to enable better measurement of outcomes, empower patients and create new ways of communication between health care professionals and patients. If successful, the EHDS will enable exchange of data across the full continuum of care from development of medicines and treatments through the full patient journey. As the Commission's strategy highlights, data is at the core of digital transformation and it is the pivotal moment to act to create long-term benefit, reinforcing the need for the public and private sectors to work together in new and innovative ways. EFPIA is committed to being a partner in this data ecosystem.

EFPIA's vision supports European federated data networks that contribute to optimal research, development and healthcare delivery. We advocate for the following points to be addressed in the upcoming legislation on EHDS to initiate essential enablers accelerating the shift towards patient-centered, outcomes-focused access and sustainable healthcare in Europe:

Data governance is fundamental

Data Access challenges must be overcome and **EU legislation must support data access for healthcare purposes.** The functioning of existing legislative and regulatory frameworks e.g. General Data protection Regulation (GDPR)¹ should be explored and in particular its contribution to supporting data access for all research and healthcare stakeholders from private and public sector, the extent to which the legislation governs access to the key data sets and how access to high-value data sets can be enhanced through legislative initiatives. Existing legislation is often based on a centralized data model framework, where data access and movements are converging. Any new legislation and soft law /guidance would need to be developed to **govern and enable distributed and decentralized data models.**

In addition, EU and national programs should be set up to further enable individual's ability to exercise their **data portability** rights and to invest in **education in digital literacy**, building public understanding of, and trust in, how health data is used in research for the benefit of the overall European community.

The GDPR assigns a special regime to scientific research, but there have been few guidelines or comprehensive studies on the application of data protection rules to research. In the light of the divergence of interpretations, a **clearer definition of Secondary data use vs Primary data collection would be valuable.** EFPIA encourages the EC and Member States to support and endorse public or private initiatives aiming at clarifying and harmonizing the applicable legal framework.

¹ <https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1532348683434&uri=CELEX:02016R0679-20160504>

EC and Member States should consider providing a mix of **financial and non-financial incentives** for data holders to share their data, both with public and private market participants. Such incentives could potentially include traceability of the data, financial rewards/tokenization², reciprocity in access to data, giving credit to data providers and curators in publications that are based on the data, as well as IP-based incentives.

Interoperability increases the value of data

For data from multiple distributed sources to be valuable it must be able to be compared based on an **interoperability framework**. EFPIA is committed to working with the EC and other relevant institutions to develop **Codes of Conduct for Data that address scientific research using personal health data** and is a supporter of the principles being established in EH DEN (European & Health Evidence Network)³. Codes of Conduct would harmonize the rules applying across Europe and therefore equalize the rights of citizens from one country to another and reduce the complexity of cross-border projects. Users of the Health Data Space should be encouraged to develop self-regulatory frameworks for the use of the data, identifying the safeguards that should be deployed to minimize harm to subjects. EFPIA supports the development of general principles for standardized data visiting, collection and use that enable subsequent credibility of the insights gained. Any rules or principles that would needlessly impede the flow of data into or out of the EU must be avoided.

The framework must be flexible to future data sources and technologies

EFPIA anticipates that emerging and future technologies will bring significant opportunities for enhancing the health of European citizens, improving healthcare and saving lives. The healthcare sector is already developing further tools for healthcare professionals and saving money for healthcare systems. The potential gains in efficiency and efficacy strongly depend on how new data sources and technology is adopted by the healthcare sector. Healthcare decisions can be critical and therefore oversight of developments in this 'high-risk' domain require adoption of data quality standards and strong ethical and governance rules. In order to maximize the great potential of emerging data sources and new technologies in healthcare, while not compromising healthcare standards, we call the Commission to **develop risk-based policy** with oversight proportionate to the intended use and led by defined risk categories and that is aligned to existing good practice guidelines and regulations. It should reflect the inherent concerns of using health data and foster innovative uses and uptake of the technology.

Deployment and enforcement of solutions

It is likely that novel tools will be initially evaluated within certain Member States or in specific disease settings. For the broadest benefit throughout Europe, EFPIA believes that learnings should be rapidly shared, pilots should be expanded quickly and deployment and implementation appropriately supported. EFPIA supports **investment in upscaling and a mechanism for coordination** to maximize learning from outputs.

European citizens must feel that their data is secure and being used with a positive healthcare intent.

Guiding principles outlined in the Strategic Research and Innovation Agenda of the European Open Science Cloud (EOSC) referring to data being "as open as possible and as closed as necessary" operating on FAIR principles and envisioning new types of incentives and skills to share data openly, improve data management, and develop literacy and data stewardship skills can be exemplary and replicated.⁴

² https://uploads-ssl.webflow.com/5d9b5166166f623025995da7/5da8ccbaa4b9136a3fce2ad1_Whitepaper-HIT-foundation-2019.pdf

³ <https://www.ehden.eu/>

⁴ https://www.eoscsecretariat.eu/sites/default/files/open_consultation_booklet_sria-eosc_20-july-2020.pdf

The Commission should invest in wider adoption and implementation of guiding principles such as those listed by EOSC. EFPIA finds these principles as indispensable for establishing greater trust in data sharing and generating high quality of data.

Simple clear language and available education tools will be required for universal trust and use of data. Education about the existing safeguarding mechanism will enhance trust and encourage sharing of health data for a positive health benefit. Resources such as schematics presenting the Data Spectrum (which provides a tool for the continuum of data accessibility ranging from closed, to shared, to open) developed by the Open Science Institute (OSI) could be used to help to understand the common language of data. OSI work towards unpacking data's challenges and its benefits and they recognise that for that there needs to be precision about what these things mean. They should be clear and familiar to everyone, so we can all have informed conversations about how we use them, how they affect us and how we plan for the future.⁵ EFPIA supports **adequate resourcing for relevant education** at every level in the EU.

To create a positive environment for health data in Europe there will need to be focused political leadership and well as technical expertise. EFPIA calls for **European political leadership as a catalyst for focused development of harmonized principles on data governance, quality and interoperability throughout Europe.** We believe that there will need to be coordination between the European networking of institutions and Member States, facilitating the exchange of information, expertise and best practices and more importantly championing the implementation of the European Health Data Space. We envisage the **establishment of a European Health Data Institute** that plays the following pivotal roles:

1. Establish governance of the Health Data Space;
2. Define data quality and interoperability standards;
3. Provide resources to upskill both data consumers and data producers with the necessary competencies to understand their data and manage it appropriately.
4. Take learnings from the multiple digital health data pilots in member states or disease areas to create a positive environment that builds a sustainable ecosystem of health data utilization.

The full scope, role and activities of the proposed Institute should be determined in dialogue with all stakeholders.

EFPIA remains committed to work with the Commission and Members States to support the development and implementation of crucial components of the European Health Data Space that will be pivotal to the ongoing modernization and enhancement of European Healthcare.

⁵ <https://theodi.org/about-the-odi/the-data-spectrum/>