European Federation of Pharmaceutical Industries and Associations

EFPIA responses to the European Strategy for Data

Author: EFPIA ● **Date:** May 2020 ● **Version:** submitted

Overview

EFPIA applauds the Commission's effort to create an EU policy environment that unlocks the value of the data economy. EFPIA supports the European Strategy for Data and the creation of a European Health Data Space (EHDS). As the Strategy highlights, data is at the core of digital transformation and it is the pivotal moment to act to create longer-term benefit, reinforcing the need for public and private sector actors to work together in new and innovative ways. EFPIA is committed to being a partner in this data ecosystem. We support the proposed vision and subscribe to the EU's intention to empower Europe through access to data and the creation of a Health Data Space, to improve health outcomes.

The connection and flow of data across the European Union is a critical enabler to a healthcare system that values positive clinical and societal outcomes. Indeed, a connected health data ecosystem has the potential to empower more effective and efficient research and development of new treatments and diagnostics. It would also ensure better planning and delivery of patient-centred care in the way of personalised medicine. This combined with value-based healthcare can result in better allocation of resources and more sustainable healthcare systems. A successful Health Data Space can also help inform policies towards better overall health outcomes.

For the EHDS to be successful and sustainable, the Commission will have to invest and allocate the required resources in its development, ensuring that appropriate governance structures are in place and creating frameworks which are built on the experience of data users. It should also enable 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 this important work proceeds, all stakeholders will benefit from a framework that is grounded in evidence and developed in consultation with them.

EFPIA's comments on the Commission Data Strategy

We call on decision makers to consider the following points in the implementation of the European Strategy for Data to fully realize its potential and Europe's position in the data economy as a leader:

- The introduction of new data sources (such as wearables, biosensors, remote tools) and **advanced transformative technologies** (e.g. AI and machine learning) offers the possibility to derive new/meaningful patient and disease level insights; greater specificity (e.g. gene decoding); enable medicines to deliver on their full potential, to radically innovate and help us to revolutionize medical science. With the emergence of these new technologies, there is a strong requirement for these **data to be of sufficient quality** in order for them to be accurate and avoid bias. These technologies also hold the potential to support Clinical Decision Support

tools to enable more effective and efficient care delivery, as well as optimize allocation of health system resources. **A roadmap is needed to work towards a solid framework of quality and interoperability standards for such advanced technologies.**

- **Establishment of a European Health Data Governance Policy:** Any data governance policy that the Commission and Member States were to consider should promote responsible data sharing across Europe and overcome existing barriers. It is important to create an ecosystem where data is generated in a timely manner, for example, to fight pandemics whilst safeguarding the core values of privacy. When considering access to and use of data, we must enable secure access to high quality health data in a format that allows it to be interrogated and integrated by a range of stakeholders at both regional and Member State level. The definition of scientific research on which governance is based should be inclusive of public and private sector research.

- The Commission's Communication proposes that the data governance of the European Health Data Space be elaborated at a cross-sectoral level and also in relation to specific sectoral data spaces. Data does not have to be physically pooled into one repository, but instead can sit as distributed data networks. A positive EHDS will scale up existing health data networks by connecting them and ensuring the system operates across Member States. The elaboration of an **EU-wide health data governance framework** would facilitate the expansion and connection of different data resources in a secure trust-based framework and should be addressed within each sectoral data space, in collaboration with stakeholders. For instance, a common data taxonomy, EU value guidelines and rules as well as guidelines for access to and use of data within the Health Data Space can help to build trust and incentivise data holders to share data. Further incentives to that purpose should be explored. The suggested governance framework can help to set the culture of the Health Data Space to achieve these elements. It will be particularly important to identify means by which the governance policy can overcome fragmentation within the Single Market, while respecting the prerogatives of the Member States. The Commission's commitment to a flexible and faciliatory approach to regulation is welcome and supportive of innovation, but should not obscure the need for the EU as a whole to endorse legally-robust, concrete trust-enhancing approaches to data-sharing.

- EFPIA endorses the Commission's description of the **social and economic** opportunity offered by the **enhanced responsible sharing of health data** and the recognition that researchers, regulators, health systems and patients need to be able to access the Health Data Space in ways that reflect their specific needs.

- The implementation of the Strategy should further emphasise the role of medicines regulatory agencies. The development of the European Health Data Space should be fully-**integrated with existing regulatory structures particularly in highly-regulated sectors**, such as pharmaceuticals. The European Network of Heads of Medicines Agencies is considering how adaptive/dynamic regulation and policy learning can be embedded in the current medicines regulatory framework. These concepts seem close to the concepts of "agile" regulation proposed in the Strategy as elements of the governance approach. EFPIA encourages the EU institutions to work together and explore whether the Data Space can be a resource for testing new regulatory approaches.

- There are various examples of successful data sharing obligations and voluntary initiatives, such as the IMI 'Big Data for Better Outcomes' program or the ClinicalStudyDataRequest.com (CSDR) consortium of clinical study sponsors/funders facilitating access to patient-level data from clinical studies. Although the current IP framework may not be fully adequate for the multiple possibilities and modalities of data sharing today, nor was it designed for this purpose, biopharmaceutical companies have been operating satisfactorily with contractual and technical measures. Whether the existing legal framework is sufficient to realise today's

opportunities and the Commission's ambition to create a data-agile economy, including a single European Health Data Space, should be further analysed. In particular, the development of robust voluntary data sharing competition exemptions and appropriate incentives to encourage widespread involvement should be explored with stakeholders, including EFPIA.

- In that respect, the Commission's proposal to conduct "**sectoral reviews**" that "should identify regulatory and non-regulatory obstacles to the use of data and data-enabled offerings" will provide an important baseline for further action including the development of "sector-specific legislative or non-legislative measures for the European health data space, complementing the horizontal framework of the common data space". EFPIA suggests that it will be valuable to base sectorial reviews **on real-life user experience**, as EFPIA's own research has indicated that formal reviews of regulation do not fully reveal where the roadblocks are to data sharing. The specificities of the safeguards, ethical oversight, regulatory structures and existing transparency measures that are unique to the health research sector provide a strong basis for governance at the sectoral level.

- For a European Health Data Space to be trusted and relied upon, to provide insights to those beyond the individual that it relates to, the data must be of high quality. **Well defined standards for data quality** can yield more consistent data sets and drive interoperability, leading to insights for revealing unmet needs, and developing innovative care pathways and treatment paradigms. International cooperation for high quality interoperable data standards enable more effective response to and ideally prevention of future global health issues such as pandemics.

  Therefore, EFPIA supports the emphasis that the Commission places on **advancing the EHR exchange format** in the Communication and also the plans to strengthen the European Reference Networks. We also welcome the EU's commitment to "prioritise interoperability requirements and standards within and across sectors, while taking into account the need for sectoral authorities to specify sectoral requirements". As well as supporting core platforms such as the EHR format, EFPIA believes that the EU should also be supporting user-driven standardization and best-practice initiatives, in relation to interoperability, data governance and cybersecurity. EFPIA welcomes the Commission's recognition of the advantages of decentralized data networks. Through IMI (EHDEN[1]) and other programmes and initiatives like Data Saves Lives[2], valuable experience is being built regarding the robustness of data and the management of privacy. Many valuable initiatives are unable to progress beyond pilot stage due to the lack of long-term funding. EFPIA encourages the Commission to consider how such support can be scaled up and integrated with funding available from other sources.

  We suggest adoption of the **FAIR principles**[3] to enable high data quality. The FAIR Principles were developed to enable generation of scientific insights and driving more informed clinical decisions and are a first step to higher quality data management and effective adoption of data quality standards. Further data quality standards adopted should consider some of the following key aspects: completeness of case ascertainment, completeness of the items, prevention of duplicate records, validity, usefulness, and timeliness.

- EFPIA agrees with the need to invest in building public understanding of, and trust in, how health data is used in research. We are committed to working with the Commission to develop **Codes of Conduct** for the sector and believe that users of the Health Data Space should be

[1] EHDEN (also part of BD4BO) - Electronic health data in a European network - make large-scale analysis of health data in Europe a reality. The project is building a federated data network of allowing access to the data of 100 million EU citizens standardised to a common data model.
[2] https://datasaveslives.eu/
[3] https://www.nature.com/articles/sdata201618

strongly encouraged to develop self-regulatory frameworks for the use of the data, identifying the safeguards that should be deployed to minimize harms to subjects. For these frameworks to deliver benefits in terms of improving data-sharing, they would need to be recognized by data custodians as providing legal certainty.

- Support for development of the appropriate **skills and competencies** for both data consumers and producers including patients is key to building trust and advancing the Health Data Space
- In concluding, EFPIA wishes to underline the importance of all key stakeholders being engaged in this initiative at the highest level and encourages early agreement on a **multi-stakeholder platform** to drive the proposal forward.