

EFPIA reply to the consultation for the inception impact assessment on the intended initiative in a European Health Data Space



EFPIA welcomes the proposal to create sectoral and horizontal legislative frameworks to unlock the value of data, support the use, re-use and exchange of health data at the EU level and ensure coherence between the operation of the different legislations contributing to the functioning of the Data Space.

EU policy should promote data sharing and harmonize applicable national rules removing technical and legislative barriers to the potential opportunities across Europe. **Clear guidance on how each stakeholder may gain access to health data and for what purpose**, needs to be transparently articulated and understood by all data partners participating in this data ecosystem. The associated processes to obtain and maintain access to this data ecosystem need to be clearly defined.

EFPIA welcomes the proposal in the draft Data Governance Act to establish competent bodies who may act as a gateway to national data resources. As also noted in the Act, sectoral bodies dealing with secondary use of data, including data altruism, should be set up. We believe that the actions of such bodies should be substantially harmonized at EU level to avoid complexity and duplication of groups at Member State level, charged with data access requests, particularly regarding the secondary use.

EFPIA considers that it is important that other potential legal bases (beyond consent) in particular for secondary use of data for scientific research are considered and that any consent form (as proposed in the Act), as well as providing for subjects to exercise specific control over the use of their data, should also permit individuals to agree for example to very broad categories of use (e.g., health research), both for primary and secondary use.

The GDPR assigns a special regime to scientific research, intended to foster innovation. However, in light of divergent interpretations amongst and within Member States, renewed efforts to clarify and harmonise the rules would be valuable. EFPIA agrees with the need to further review an individual's ability to exercise their **data portability** rights and to invest in building public understanding and trust in how health data is used in research. We are committed to working with the Commission and other relevant institutions to develop **Codes of Conduct** for the sector that would harmonize the rules across Europe, ensuring equal rights of citizens between countries. Users of the EHDS should be encouraged to develop self-regulatory frameworks for the use of the data, identifying the safeguards that should be deployed to minimize harms to subjects.

Investment in an interoperable data infrastructure is a prerequisite to allowing processing and analysis of different data sources. Data should not have to be physically pooled into one repository in a single format, but instead can sit as distributed data networks provided appropriate safeguarding mechanisms are in place. A positive European health data space will **scale up existing health data networks to connect them and ensure the system operates at scale across Member States**. Standardised outcome measures as well as expansion of common data models and quality standards are fundamental in consolidating multiple datasets and overcoming differences between the sources while at the same time ensuring a high level of data protection and generation of credible insights for research.

EFPIA welcomes the proposal to strengthen coordination at the EU level. In order to ensure the validity of the proposed EU system and that the data to be collected can be used to achieve EHDS objectives including the establishment of (mandatory) common requirements covering certain key issues such as interconnectivity, comparability of the collected data, data quality and the promotion of data protection. EFPIA supports **investment in a mechanism for coordination** to maximize learning from outputs and its eventual **upscaling** in order to benefit all EU residents.