

EuropaBio draft response to the IIA on European Health Data Space

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EuropaBio welcomes the European Commission's plan to begin a discussion with stakeholders to develop the EHDS. Science is evolving fast and digital tools are accelerating our ability to conduct research. For the biotechnology industry, it is imperative quality data sets are collected and analysed, while protecting privacy and maintaining trust in how the data are used.

This initiative is an opportunity to accelerate innovations that will optimise diagnostic and treatments, increasing cost-effectiveness of healthcare systems. The EC should work with the MSs to develop/harmonise the infrastructures required to make this feasible. While the EHDS would enable sharing data among research organizations within the EU, this should not distract from also developing ways to effectively share such data with research organizations internationally. The success of the EHDS should be measured on its capacity to increase the competitiveness in the EU health sector and to create health innovations to the benefit of researchers, healthcare professionals and citizens.

Objective 1: Ensuring access, sharing and use of health data for healthcare delivery purposes

Access/exchange of health data for research, including secondary use health data, is today too limited in the EU. EuropaBio supports the intention to reduce fragmentation of legislation through introducing a governance framework to clarify the rules across the EU with regards to collecting, accessing, and analysing health data. As a research-based industry with a history of handling patient data, access to such quality data would accelerate the sector's ability to develop innovations in diagnostics and therapeutics.

Interoperable data infrastructures should be developed. The value of such a network lies in the participation of all MSs and their ability to create such infrastructures. It will be equally important that all MSs, supported by the EC, maintain these to a common standard, including through appropriate funding mechanisms and sharing of relevant expertise. It will also be important to ensure local HCPs, as a key part of the system, are also trained on the harmonised system for entering and reading the data.

Furthermore, patient trust in sharing their data is key to the success of any initiative to harness data for healthcare purposes and research. Citizens must be assured their data is protected



and only used for purposes within the principle of data altruism. Patients should remain owners of their data, and research entities should remain the owners of the data resulting from their research.

Objective 2: Fostering a genuine single market in digital health covering digital health services

Digital health services are an essential part of the Digital Single Market. Improved access to digital health services and products, including tele-health and mHealth, have the potential to greatly improve access to healthcare and patient ability to manage their own health. Other key initiatives, such as cross-border healthcare, are enabled by such digital infrastructures.

Objective 3: Enhancing the development, deployment, and application of trustworthy digital health products and services, including those incorporating AI in the field of health

The adoption of digital technologies in health, in particular AI, will play a critical role on how healthcare is delivered in the future. It will support process efficiencies, and help overcome staff shortages. Telemedicine can provide health expertise to remote areas of the EU, which may be distant from specialised HCPs or centres of excellence but can also serve in situations of emergency and, in general, simplify patients' lives by avoiding unnecessary movements, speed up time to diagnoses and make available expertise.

In conclusion, EuropaBio is ready to serve as a constructive partner in exploring all options and co-designing a framework to ensure we can harness the data revolution in the interest of citizens, society, and the economy.

About EuropaBio

EuropaBio, the European Association for Bioindustries, promotes an innovative and dynamic European biotechnology industry. EuropaBio and its members are committed to the socially responsible use of biotechnology to improve quality of life, to prevent, diagnose, treat and cure diseases, to improve the quality and quantity of food and feedstuffs and to move towards a biobased and zero-waste economy. EuropaBio represents corporate and associate members across sectors, plus national and regional biotechnology associations which, in turn, represent over 1800 biotech SMEs. Read more about our work at www.europabio.org.

