The proposal for a European Health Data Space (EHDS) is part of the European Commission's efforts to harness the benefits of the data economy and unleash the full potential of health data.

The EHDS will put citizens in control of their own health data, whether in their country or cross-border, and help deliver the transformation of healthcare delivery.

The EHDS will also improve the use of health data for research, innovation, and policymaking and create a strong, secure, and trustworthy legal framework for the re-use of health data that will help deliver next-generation treatments.

EHDS marks a global first in providing federated access to important health data. Placing a central focus on citizens' control over their data, the EHDS seeks to implement a framework through which data access for primary and secondary use is both clarified and simplified.

The power of data in the healthcare sphere is evident. Realising the potential of healthcare data is a crucial step to ensure the EU is a leader in the development of next generational medicines. The biotechnology industry has stood at the forefront of using digital innovations for many years, having advanced alongside digital technologies.

The EHDS will play a central role in improving the availability of data within a transparent and secure infrastructure. Data collection from across the EU will be valuable in addressing the health challenges facing Europeans, allowing for research and innovation, and collection of insights not possible when necessary data is fragmented.
Priorities

We outline our core priorities for the use of healthcare data in the development of novel biotechnology derived medicines, reflecting on the EHDS legislative proposal:

- EuropaBio encourage the EHDS initiatives that promote the rights and accessibility of citizens to the use of their electronic health data;

- To ensure trust and understanding of healthcare data use, the EHDS implementation should continue to complement the overarching digital transformation [and relevant initiatives];

- Expansion of MyHealth@EU across Member States, and in terms of the services available, is a necessary step to support data portability;

- EuropaBio support standardisation of electronic health records to facilitate the core functioning of the EHDS and support a multi-stakeholder approach to establish relevant criteria;

- A clear framework for the provision of telemedicine services within the context of the EHDS should be explored to enable appropriate access to these necessary services in each Member State, and for all citizens;

- National digital health authorities should receive clear operational guidelines to ensure a harmonised experience across the EU, in particular when dealing with relevant national contact points for digital health to avoid unnecessary fragmentation of data;

- Industry should play an appropriate role as part of the functioning of the European Health Data Space Board;

- Access to the EHDS for private scientific research, and to support development and innovation activities by industry is a welcome recognition of the role the private sector plays;

- Maintaining strong intellectual property protections is necessary for a prospering data economy and vibrant innovation system for digital healthcare;

- We encourage the ability for the EHDS to further our ability to use real world evidence (RWE) in regulation of medicines.