

EuropaBio position on the European Health Data Space proposal

EuropaBio welcomes the European Commission's bold ambition to make Europe the most competitive data economy globally. The power of data in the healthcare sphere is evident and 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 European Health Data Space (EHDS) marks a world 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, 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.

While we encourage bold moves for the region, it is important to ensure gradual steps in building the EHDS avoid unintended consequences for a data-intensive research industry that operates globally. Data is a key asset for large and SME biotechnology companies alike in the healthcare sphere, supporting their ability to grow and sustaining their competitive advantage. Maintaining strong intellectual property protections is also necessary for a prospering data economy and vibrant innovation system for digital healthcare.

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 complement the overarching digital transformation;
- 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.



Data Portability

EuropaBio supports the initiatives under the EHDS which seek to promote the rights and accessibility of citizens to the use of their electronic health data. By increasing the ability for cross-border access to health data from a patient, physician, clinical, and research perspective European healthcare as a whole will benefit.

Citizens, healthcare professionals, and industry need appropriate support to build digital literacy skills, and in turn trust in the shift towards digitalised healthcare. It is essential that we invest collectively to build societal understanding of, and trust in, health data and how it can contribute to improving health and wellbeing. While implementing the EHDS is critical, rapid expansion of services must coincide with other appropriate frameworks such as Europe's Digital Decade, which aims to provide European citizens with access to their medical health records as well as digital ID solutions and where the importance of the EHDS is recognised.¹ The Commission's Digital Transition also recognises the importance of the EHDS to foster targeted research, diagnosis and treatment for European patients, and its digital education action plans to ensure that 70% of adults have basic digital skills by 2025.²

Scale-up of MyHealth@EU, both in terms of use by Member States and an expansion of existing services, is a necessary step to achieve true portability of health data for citizens. EuropaBio is pleased to see that MyHealth@EU will facilitate the cross-border exchange of health data to the benefit of patients, and support standardisation of electronic health records to facilitate the core functioning of the EHDS. A sustained multi-stakeholder approach will be necessary to define adequate standards to ensure the compatibility and comparability of data for primary and secondary use. Harmonising the collection of healthcare data and ensuring interoperability will better facilitate data analysis and relevant outcomes.

The EHDS represents a significant opportunity to entice the international healthcare research community to focus on Europe as a hub for data-driven innovation. To achieve this the EHDS should not impede the international research community to access the data and ensure the ability to share relevant data outside of the EU with trusted third parties who recognised our data privacy standards. In this regard it is imperative to keep striving for semantic interoperability not just across the EU, but in alignment with international standards, to support global data development and exchange. We encourage European policymakers to continue work with third countries to enable

¹ [Legislative proposal COM/2021/574 establishing the 2030 Policy Programme "Path to the Digital Decade"](#).

² Available [here](#).



international data transfer in a burdenless environment for all the stakeholders, strengthening scientific collaborations with researchers around the world and driving biotechnology innovation forward.

Telemedicine

Telemedicine can provide health expertise to remote areas of the EU, which may be distant from specialised healthcare professionals (HCPs), or centres of excellence. Often, HCPs with expertise in a particular condition are not available in all Member States. This was one of the founding principles of the European Reference Networks, for example, to provide patients with access to medical expertise across the EU. The ability to provide digital healthcare services would greatly benefit for many populations across the EU, particularly those with limited mobility, or hard to diagnose/treat conditions. The EHDS proposal recognises that different reimbursement policies should not constitute a barrier to the free movement of digital health services, including telemedicine. EuropaBio encourage a clear framework for the provision of telemedicine services within the context of the EHDS to ensure appropriate access to these necessary services in each Member State, and for all citizens.

Governance

The EHDS proposal builds in a number of frameworks to support appropriate governance and functionality. Transparent governance structures that clearly outline data use and accessibility will in turn build trust among citizens as data use increases across the EU. European policy-makers must also continue to work with like-minded international partners towards a standardised and robust framework for data privacy, as this will also help build citizen trust globally, ensuring Europe retains a leadership position in shaping healthcare digitalisation.

EuropaBio supports the appointment of national digital health authorities in each Member State to facilitate the provision of cross-border digital health and access to health data by stakeholders. Cooperation between these health authorities and supervisory authorities under the GDPR should be efficient from launch, to avoid the creation of bottlenecks in data moveability through the EHDS. Clear guidelines will also be necessary to ensure a harmonised experience across the EU in dealing with digital health authorities to achieve the spirit of the EHDS to create a unified data space and experience. This will be particularly relevant when dealing with relevant national contact points for digital health to avoid unnecessary fragmentation of data.

The inclusion and accessibility of 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 in driving forward



innovation in healthcare. EuropaBio considers it important that industry should also play an appropriate role as part of the functioning of the European Health Data Space Board. Currently, the proposal does not make reference to the inclusion of industry stakeholders or representatives.

Secondary Data Use

The EHDS represents a significant opportunity to reverse the declining trend of international research conducted in Europe. Aggregated data can provide new information and insights on diseases, treatments, health outcomes, and unmet needs. All these elements are vital for future innovation and to position the EU as a world leader delivering excellence in scientific research to improve citizen health and treatment options for patients. Improving access to data for research and innovation is crucial, and the EHDS presents an opportunity to realise Europe's potential.

As stated above, the ability for industry to access the EHDS will be critical to support future research and innovation. The provisions within the EHDS proposal supporting scientific research as a secondary use of health data will allow the biotechnology industry to engage in cutting edge innovation. It is important therefore that implementation of the EHDS, and crucially its interplay with existing legal frameworks and authorities, is transparent with clear pathways for access to necessary data permits for industry stakeholders. Applications for access across the EU must be harmonised. However, the advance towards the future European data economy should not come at the expense of Intellectual Property (IP) rights. Compelling private industry to share data, particularly highly valuable datasets such as those resulting from clinical trials, may negatively impact their competitive advantage. Furthermore, this may put Europe-based companies at an unfair disadvantage compared to other regions, reducing Europe's attractiveness for investment and future growth.

The HealthData@EU platform presents an opportunity to gain deeper insight to impacts on the healthcare system in a holistic manner. EuropaBio would also encourage necessary coordination with EMA's DARWIN EU. We encourage the ability for the EHDS to further our ability to use real world evidence (RWE) in regulation of medicines. RWE collection, generation and use in decision-making will be critical to increase healthcare decision-makers' confidence in its quality and usefulness. Adoption of fit-for-purpose RWE for regulatory benefit-risk assessment to drive clinical development and provide pivotal evidence of treatment benefits of new therapies, to complement possible evidence gaps is also of increasing importance. Transparency and consistency in how HealthData@EU is used by regulators, HTA bodies, and other stakeholders is necessary.





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 79 corporate and associate members and bio-regions, and 17 national biotechnology associations in turn representing over 2,300 biotech SMEs. Read more about our work at www.europabio.org

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