

ELF submission to the European Commission's proposal on the European Health Data Space

European Lung Foundation (ELF) appreciates the opportunity to give feedback on the proposal on the European Health Data Space for better healthcare, research and policy-making. Supporting the submission of the European Respiratory Society, ELF endorses their recommendations and would like to provide additional patient perspective on this proposed legislation.

The COVID-19 pandemic has clearly shown the need for electronic health data for the development of policy response to health emergencies and better preparedness of healthcare services, as well as for fostering research and innovation. It has been an undeniable catalyst for the digital transition in healthcare. Higher numbers of patients with chronic respiratory conditions such as chronic obstructive pulmonary disease (COPD) and asthma among others, used remote consultations and other online tools to ensure continuity of care at a moment of crisis.

The European Health Data Space should enable people's control over their electronic health data, and allow researchers to access and share relevant health data to promote better and person- and patient-centered diagnosis and treatment.

We fully support the Commission's vision to enable individuals' digital access and control over their health data and support free movement by ensuring the health data portability.

However, we believe there are some key pillars of the EHDS proposal that will need further work in order to fulfil its potential.

Primary and Secondary use of data: protecting privacy and security

First of all, appropriate Primary and Secondary use of data are fundamental for the success of the EHDS proposal. It is crucial to ensure a consistent and efficient framework for the secondary use of citizens' health data for research, innovation, policy-making and regulatory activities that cannot be sufficiently achieved by the Member States through coordination measures alone. Adequate processes must be created and implemented at local, regional, national and the EU level to bridge the activities of all involved stakeholders and avoid enhancing further health and social inequalities that might be rooted in lack of access to digital tools, health and digital literacy, access to medical programmes and funding. As the exchange of health data will rely on trust, it must be done securely and transparently. Strong safeguards should be implemented to ensure that the fundamental rights of data protection are respected. Health data access bodies aiming to ensure predictable and simplified access to electronic health should guarantee a high level of transparency, accountability, and security in the data processing. Individuals and patients should receive the required level of support in sharing, accessing and managing their own data in a secure and safe manner.

In this context, we are ready to work with the EHDS Board that will facilitate cooperation between digital health authorities and health data access bodies. We recommend the board to include in its meetings patients, patient organisations, healthcare professionals, medical

experts and societies. We believe that patients should be the driving force behind the creation and implementation of this initiative.

Avoid fragmentation and duplication

Secondly, the regulatory framework should be selected carefully to avoid legislative fragmentation and different rules and practices across the EU, through standardisation and improved data interoperability. The risk of regional fragmentation should be also taken into account as the initiative might be in the competence of regional rather than national authorities.

Data must be shared using a common language with a harmonised data quality, allowing its use within European countries. This should include easy-to-manage bridging between the WHO code systems ICD-10/11 and ICPC-2 (ICD-International Classification of Disease and ICPC-International Classification of Primary Care) to secure data quality and completeness.

The governance model should look at overlapping different regulations that are in place: Artificial Intelligence Act, Data Governance Act, Data Act, and European Health Data Space to seek clarity and avoid further burden and duplicity. The institutional architecture should bring under the same umbrella the technical and policy aspects of cross-border health data sharing, centred on an EU-level agency, connected to the national health data agencies.

The European Reference Networks (such as the ERN-Lung) need greater funding to support, implement and assess new health data governance models by leveraging their experience with health data sharing for primary purposes (experts' advice) and secondary uses (clinical practice guidelines, clinical decision support tools, clinical research).

Advancing the digital and health literacy and decision-making of patients and healthcare professionals

Patients should be able to manage their health data properly, have control over it, and understand their right to health data portability within the EU. Healthcare professionals should be well prepared to effectively use digital health innovations. As an example, digital respiratory wards proved to be effective to provide better care for patients during the COVID-19 pandemic. For that aim, healthcare professionals should be supported by training and awareness-raising activities through funding programs.

Overall, the opportunities provided by the EHDS are going beyond simple digitalisation of data. They can and should lead to a fundamental change in health systems, dynamics of patient-doctor relations, diagnosis and treatment processes and empowerment of the patients and population in general. Thus training on the use of new digital opportunities is essential for health professionals, patients and the general population.

Funding for all these aspects of the proposal needs to be considered and accessible as it is essential for its success. It will be important to introduce a mechanism for Member States to easily access funding for the EHDS. Moreover, we should keep in consideration the differences between Member States as they will require different approaches to efficiently and successfully implement the European Health Data Space.

Researchers: access to controlled data by 2030

We need an ambitious European Health Data Space with common and understandable rules in order to link health data at the EU level. We support the Commission's target that, by 2025, all citizens should be able to share their health data with the healthcare provider of their choice when travelling abroad in the EU. We suggest an additional target that by 2030 health

researchers have sufficient access to controlled data spaces to improve citizen health and ensure medical research can continue to thrive in the EU.

In Europe, we have vast amounts of data that can improve citizens' health. However, the different pockets of data are not accessible due to issues in data transparency, interoperability and uncertainty in Member States on how to ensure both privacy and, at the same time, accessible quality data. Health data is highly sensitive and cybersecurity is a critical concern, but we have seen during the pandemic that barriers can be overcome, and digital solutions can be found when there is a will. Some good examples are the opening of the European Reference Networks platform to COVID-19, the EU Digital COVID certificate and the Passenger Locator Form. We therefore urge the Commission to consider these factors to have an effective health data space.

Proper interconnection of health data - less political silos

We need to invest in a functional and comprehensive health data space now and not wait for the next health emergency to accelerate change. Importantly there has to be properly joined up interconnections between European Centre for Disease Prevention and Control (ECDC), European Medicines Agency (EMA), Health Emergency Preparedness and Response Authority (HERA), European Institute of Innovation & Technology (EIT), Health and other relevant bodies of the EU in the health data space. There should not be silos between acute and chronic, communicable or non-communicable and common or rare diseases. While it might be politically expedient to separate health data into silos, it is not sensible nor sustainable from a scientific or healthcare point of view. In a similar vein, EU health data cooperation should be as efficient in peacetime as it is during a pandemic. We appreciate the Commission's efforts to break down these silos.