

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

The European Respiratory Society appreciates the opportunity to input to the proposal on the European Health Data Space for better healthcare, research and policy-making. The COVID-19 pandemic has clearly shown the benefits that better sharing and use of health data could bring to healthcare in the EU. The European Health Data Space should exploit the potential of ever-growing data in a trustworthy European framework where Member States are encouraged and supported to better align their use of health data, to stimulate research and enable data-driven healthcare for citizen benefits while protecting their privacy.

Objective 1: Ensuring access, sharing and use of health data for healthcare delivery purposes as well as re-use for research and innovation, policy-making and regulatory activities, in a privacy-preserving, secure, transparent and trustworthy way

Regulation must be agile and adapt to the revolution in digital health. We therefore fully support the Commission's vision to ensure access, sharing and use of health data not only for healthcare delivery purposes but also for research and innovation, policy-making and regulatory activities. As the exchange of health data will rely on trust, it must be done securely and transparently. Therefore, active participation of a broad range of stakeholders, including healthcare professionals, medical societies and patients, must be ensured in taking decisions around trustworthy data exchanges in the EU.

The impressive scientific response to COVID-19 illustrates the value and return on investment health research brings to society especially where data exchange is facilitated rather than restricted. A common or harmonised approach must be balanced with ensuring that there are not new or greater restrictions for necessary health research. We are ready to work with the European Commission and other relevant institutions to develop codes of conduct for data that address scientific research using health data. We also encourage the Commission to hold workshops and capacity building to see if the divergence in national ethical authorities could be addressed. Vital research using health data should not be impeded.

Objective 2: Fostering a genuine single market in digital health covering digital health services and products, including tele-health, tele-monitoring and mobile health

We welcome the proposed fostering of the single market in digital health. Concerted efforts should be made to ensure interoperability of digital health services and products as well as harmonising the methods of certification and authorisation, liability and reimbursement rules across all Member States. The fragmentation across infrastructures should also be addressed.

For this purpose, we need an institutional architecture to bring under the same umbrella the technical and policy aspects of cross-border health data sharing, centered around a EU level agency, connected to the national health data agencies. This EU body should have a well-staffed operational arm and would cover: data stewardship, data access policies, data management, tools to preserve rights of individuals, data standards and advice on ethical matters.

The European Reference Networks (such as the ERN-Lung) also need greater funding and support so they can be scaled up to the next level. ERNs are a testing environment ready to implement and assess new health data governance models by leveraging on their experience with health data sharing for primary purposes (experts' advice) and secondary uses (clinical practice guidelines, clinical decision support tools, clinical research).

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

The COVID-19 pandemic has shown the potential of digital health innovations such as digital respiratory wards to provide better care for patients more effectively. However, the deployment of trustworthy digital health products and services cannot happen without healthcare professionals being properly prepared to apply them. Training and awareness-raising among healthcare professionals is therefore essential for making sure they are adequately prepared for patient care using digital health tools. The opportunity provided by EU4Health (and other funding programmes) to support training of professionals must be utilised.

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 ECDC, EMA, HERA, EIT Health and other relevant bodies of the EU in the health data space. There should not be too many silos created between acute and chronic, communicable or non-communicable 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 co-operation should be as efficient in peacetime as it is during a pandemic. We welcome the Commission's efforts to break down these silos.