

EPF's Response Statement

Public consultation on Digital health data and services – the European health data space

31 January 2021

Health is an area where Europe can undoubtedly benefit from the data revolution. Proper use of health data can improve health systems' sustainability, foster disease prevention, increase the quality, safety and patient centredness of healthcare, decrease costs and transform care into a more participatory process. Nevertheless, the road to fully exploit the potential benefits of data in health is only partially built, still extremely fragmented and undeveloped with and for patients.

EPF therefore welcomes the European Commission's plans for the development of a European Health Data Space as a positive step towards a more harmonised, interoperable, safe, and trustworthy environment for health data.

To drive the creation of a **patient-centred European Health Data Space**, EPF calls for:

Improved and harmonised health data access and control

As identified by the EPF community and confirmed by the Inception Impact Assessment (IIA), **exercising barrier-free access and control over their own health data is often difficult for patients**. For example, electronic health records (EHRs) are not yet a reality across the whole EU, and many patients cannot easily access and understand and use the information they contain, or transfer them between healthcare providers, including when they move across borders. These challenges lead to a fragmented approach on health data while exacerbating differences across and within countries and limiting patients' trust.

The EHDS should therefore be built **with patients and their data at the centre**, ensuring adequate data protection, clear rights, and instruments to grant **access and control over their personal health data, how it is used, and ensure data portability**. This objective could be reached through the development of user-friendly and co-designed tools and platforms, clear guidelines and information tailored to patients, carers, and the public.

EPF therefore welcomes the policy option 'C' identified within Objective 1 of the IIA '**Ensuring access and control of patients and citizens over their own health data**' and will collaborate with EU institutions to help map and address the challenges and needs of the patients' community.

A clear framework to improve transparency and trust in health data use and re-use

The European Health Data Space is a unique chance to increase clarity on several health data concepts towards a more harmonised approach. As highlighted in our response to the Data Governance Act

proposal,¹ it will be fundamental to address notions such as: the use of data for ‘general interest’, ‘data altruism’ and ‘data intermediaries’ to avoid fragmented interpretation and ensure clear health data sharing standards.

To create a more **ambitious, trustworthy, and safe environment for health data in Europe**, the EHDS will have to be shaped around an appropriate legal and governance framework to protect individuals. The framework will have to be robust, clear, and built-in line with EU data protection law. Furthermore, defining a clear framework is necessary to address the fragmentation of protection rules applied to health data and research across the EU, guaranteeing lawful and ethical use and re-use of the data within the EHDS. To achieve harmonisation, additional solutions such as the adoption of a dedicated code of conduct for health data, addressing main challenges and covering the key actors involved in health data sharing and processing, can therefore be considered a viable complement to robust EU level legislation on re-use of health data adopted as a sector specific parallel legislation to the Data Governance Act.

Furthermore, EPF welcomes the third objective identified by the IIA aimed at reinforcing safety, clarity (for example on liability rules) and supporting the development, deployment and application of trustworthy digital health operations, products, and services, including those based on Artificial Intelligence. This would also move the EU towards a more genuine single market for digital health, improving harmonised deployment of tele-health, tele-monitoring, and mobile health.

The build-up of best practices, synergies, and better investments

To ensure the efficient establishment of the European Data Space, the European Commission should look at building on the range of initiatives, projects, and collaborative platforms currently active, including the Cross-Border directive framework, the eHealth Network, the European Reference Networks, the eHealth Digital Service Infrastructure (MyHealth@EU). These should be complemented by the harmonisation and further integration with mandates and initiatives of other EU agencies in the field of health data (e.g., the ECDC’s activities, the EMA’s DARWIN project), the numerous EU funded projects, as well as national and regional best practices.

While designing the EHDS, the EU must also address the risks of **potentially exacerbating inequalities within and across Member States**, taking into consideration the digital divide and the different levels of digital preparedness of our health systems. This risk could be mitigated by ensuring adequate health systems receptiveness in research, analysis, and transfer of knowledge. Investments in infrastructure, technical innovation and tools, skills and health literacy should also be expected to drive and support the necessary systemic changes.

The use of the patients’ experience to address challenges and needs

¹ EPF, Response Statement - Public consultation on Data sharing in the EU, <https://www.eu-patient.eu/globalassets/epf-consultation-response---data-governance-act.pdf>

Despite the consensus on the need for patient-centredness, trust and ethics, there is a demonstrable lack of practical tools or suggestions to make the concept a reality.² This requires a broad systematic approach that should be at the centre of the EHDS discussions.

The **EHDS process should therefore incorporate the necessary mechanisms to guarantee meaningful involvement of patients'** already in the current design phase, including the patients' views in the EHDS consultation process and research initiatives, setting up inclusive governance structures with meaningful patients' representation and addressing ethical questions in a more harmonised way. Furthermore, the EHDS will have to ensure appropriate capacity-building measures and skills development on digital and data literacy to increase trust and to better inform on rights and benefits related to health data.

² EPF, EPF Congress 2019 – Report, <https://www.eu-patient.eu/News/News/epf-congress-2019-theres-nothing-forpatients-without-patients/>