

EPF's recommendations on the European Health Data Space (EHDS)

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The European Patients' Forum (EPF) welcomes the proposal to establish a European Health Data Space (EHDS). The EHDS provides a framework for the exchange of health data to support healthcare delivery and facilitate research, innovation and policy making. The digital transformation of healthcare driven by the EHDS can bring enormous benefits and improve patients' lives, but only if it is shaped with and for patients.

Patients must be at the very heart of the EHDS initiative. As outlined in EPF's amendments to the Commission proposal, trust, transparency, meaningful involvement of patients and their representatives, security, and data protection are elements that will impact the success of the EHDS and must be reflected in the regulation from the outset.

9 EPF's key recommendations for a patient-centred regulation:

1. Patient organisations must be included in the governance and decision-making structures of the EHDS Board, national digital health authorities and health data access bodies.
2. Patients should receive their data in a common MyHealth@EU format with option to include disease-specific data.
3. Patients should have the right to opt out if they do not wish their health data to be processed for secondary use.
4. Purposes for secondary use of health data should bring benefits to patients, and these purposes must be defined in partnership with them.
5. At the request of individual patients or patient organisations, data access bodies should provide information about the use of health data, including who has been authorised to access data, for which purpose, and under which legal basis.
6. Data users should report the results or findings of projects for which data were used within a maximum of 12 months and in lay language.
7. Misuse of health data must be sanctioned with fines, which should be transparent, proportionate, effective, and harmonised between Member States.
8. The Regulation should include provision on effective access to justice in cases of misuse of health data.
9. The EU and Member States should invest sufficient resources in developing digital health literacy, digital skills, access to digital means and infrastructure to support the implementation of the EHDS.

Ensure patients' control over the primary and secondary use of health data

EPF believes one of the main aims of giving patients better access and control over their personal health data should be to empower people in managing their own health. This is why EPF recommends establishing **a common EU MyHealth@EU data format that allows for the inclusion of disease-specific data**. A common framework, in line with the EU Directive 24/2011 on cross-border healthcare, will help patients manage their care between providers and self-management, and will contribute to better data quality, increased patient empowerment, and data portability.

EPF supports the Commission's proposal to ensure the **selective sharing of health data by patients**. The right to request rectification is also essential to improve data quality as outdated, incomplete, or incorrect information can lead to misdiagnoses and errors in care delivery, care planning, policy, and research.

Regarding the secondary use of data, EPF calls for stronger safeguards on data protection and **patients' ability to fully exercise their rights over their health data**. The proposal leaves a substantial leeway for interpretation on the purposes of re-use of health data, which opens the door to new bases for secondary processing of health data and to potential misuse, undermining patients' trust. These purposes need to be defined in partnership with the patient community, healthcare professionals, and health administrators. The increased access to data should result in more affordable and accessible healthcare services, treatments, medicines, and technologies that address unmet patient needs.

An essential precondition for accessing patients' data is to ensure informed consent in an accessible and easily understandable way. Patients are generally willing to give access to their data provided that appropriate and informed consent is granted¹, especially given the large number of health data categories made available under the EHDS. For this reason, EPF **calls for the introduction of an opt-out mechanism** in the framework for health data processing for secondary use, which would ensure the Regulation's objective to strengthen the individuals' control over their electronic health data.

Informed consent requires **clear, transparent, and easily accessible information on the use of patients' data**, which could be developed with patient representatives. Member States should inform the public not only about the role of health data access bodies but also about the potential benefits and consequences of sharing health data. More specifically, patients should be provided with the record of who has been granted access to the data, the legal basis, and the purpose, in accordance with Union and national law. Patient or patient organisations should be able to request such specific information from health data access bodies.

Next to this, EPF calls for **additional safeguards to ensure that patients are informed about the results or outcomes of projects** for which electronic health data have been used. Applications for data permits should include a communication plan defining the audiences and tools for informing the public about the results or outcomes. Data users should make the results or outcomes public within 12 months at the latest and in lay language that facilitates understanding and contributes to patients' health and digital health literacy.

Patients' data must be given the highest possible level of protection. The regulation should ensure that strong sanctions and dissuasive rules can be applied in case of data protection and security breaches

¹For more information see [Electronic Healthcare Records survey](#), EPF, 2020, and [Share and protect our health data!](#), EURORDIS, 2019.

and misuse. **Fines must be transparent, proportionate, and harmonised** between Member States to ensure the same level of protection for all patients across the EU. Patients should also be guaranteed **appropriate and effective access to justice** through a dedicated provision in the regulation, which could be impeded when the right to information is not respected.

Patient organisations have a central role to play in the regulation

Patients and patient representatives need to have a clear role in the governance of the EHDS Board, and not just through ad hoc participation in certain meetings depending on their sensitivity, as suggested in the current proposal. Similarly, they should be included in the governance and decision-making structures of the national digital health authorities and health data access bodies, as is already the case in some Member States such as France. **Concrete and meaningful involvement of patients** in the governance of the EHDS is essential to ensure transparency, build a high level of trust, and make sure that patients' needs are fully taken into consideration.

The unique expertise that patients can bring is fundamental to ensuring the effective implementation of the EHDS. For example, patient organisations could help in developing **educational material to enable patients to make the best use of this data**.

Substantial investments are vital in the implementation of the EHDS

The EHDS Regulation should be accompanied by substantial European and national investments to ensure the successful uptake and implementation of the EHDS, targeting **digital health literacy, digital skills, digital infrastructure, and access to digital means**, among others. Sharing of best practices between countries should further be encouraged.

A **one-size-fits-all approach to the EHDS risks exacerbating existing inequalities** and disparities between Member States, which will have a negative impact on patients' lives. For some EU countries, digitalisation of the health system is far from being a reality and it will take decades to reach the same point across the Union.

ABOUT EPF

The European Patients' Forum (EPF) is an umbrella organisation of patient organisations across Europe and across disease areas. Our 78 members include disease-specific patient groups active at EU level and national coalitions of patients representing 19 countries and an estimated 150 million patients across Europe. www.eu-patient.eu

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