

EPF's Response Statement

Public consultation on Data sharing in the EU – common European data spaces (new rules)

31 January 2021

Health is an area where Europe can benefit from the data revolution. Proper use and re-use of health data can improve health systems' sustainability, increase the quality, safety and patient-centredness of healthcare, improve access, 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 not yet developed with the patients' views at the centre. The EU can set the global standard when it comes to technological development, but it must do so while ensuring inclusivity, empowerment, and respect of fundamental rights.

Given the upcoming proposal for a European Health Data Space (EHDS), EPF welcomes the request for a regulation on European data governance (Data Governance Act), which will serve as a horizontal framework for data governance across the different sectoral data spaces. EPF welcomes that the EHDS framework will provide further legislation on the re-use of health data which will complement the general rules set out in the DGA and looks forward to the opportunity to comment on such legislative proposals in due course.

A solid governance framework, built on trust, data protection, ethical standards, transparency, and clear definitions will be fundamental to ensure the safe and efficient establishment of the health data space while increasing citizens' and patients' trust in data sharing.

Focusing on the contents of the Data Governance Act, EPF would like to address a set of elements included in the current version of the proposal that we believe require further attention, especially considering their potential impact on the field of health data.

While we are aware that several of these aspects will be tackled and better defined within the framework of the health data spaces, it is important to highlight them now in the context of the Data Governance Act proposal discussion.

Clear definition and concepts to improve understanding and trust in data sharing

EPF welcomes the efforts made in the current proposal to define some of the key notions related to data sharing in the EU. Clarity on concepts such as 'general interest', 'data altruism', and 'data intermediaries' are crucial to ease understanding of the key components of European data sharing while, at the same time, define clear boundaries for the application of the upcoming Data Space frameworks.

The proposal links several of its key elements to the notion of '**general interest**', for example, to be considered as an exception to the application of specific provisions or as an essential requirement (e.g., for the registration or 'data altruism organisations'). Whereas we are aware of existing

[definitions](#), and have already called for clarity in our response to the European Commission's Data Strategy where 'public good', 'common good' and 'public interest', are used interchangeably¹, we believe that better harmonisation of this notion would further clarify the scope of application of the Regulation. Furthermore, when designing the European Health Data Space framework, it will be important to dedicate additional attention to the specificity of health data and its use for 'general interest'. We note the inclusion of several examples of 'general interest' in recital 35 but suggest this could be complemented by further specification within the definitions set out in Article 2.

Facilitating **data altruism** emerges as one of the main objectives of the DGA. EPF welcomes the inclusion of a specific definition² in the proposal to increase clarity on a crucial concept that often leads, in particular for the healthcare sector, to confusion and misinterpretation (e.g., altruism vs. donation). Considering the importance of 'data altruism' in the healthcare sector however, EPF calls for additional focus on this concept in the application of the DGA provision to the European Health Data Space.

On **data intermediaries**, EPF calls for attention in applying the provisions included in the Data Governance Act to the definition of the European Health Data Space. Given the peculiarity of the health sector and the strong need for better trust and clarity, it will be important to provide users with additional clarification on the possible entities falling under this definition.

Increasing trust through labelling, clarity, and transparency

The current proposal on the Data Governance Act includes a focus on the role of 'data intermediaries' as providers of data sharing services, with the objective to reinforce citizens' trust in their activities. In this regard, EPF welcomes the provisions included in Chapter III of the proposal, setting up **mandatory notification requirements of data sharing service providers**. The mandatory notification process also includes specific measures in case of breaches or misconduct such as financial penalties, cessation, or postponement of the service.

EPF also welcomes the proposal for a **register of recognised data altruism organisations**. This registration activity, if supported by clear requirements to safeguard rights and interests of data subjects and monitoring of compliance, can improve transparency and trust. EPF notes however that such registration is voluntary. While this may be suitable for less sensitive information, EPF would urge the requirement of mandatory registration and oversight in the case of a data altruism organisation facilitating access to health data.

European data altruism consent form

To facilitate the collection of data based on data altruism, the Data Governance Act introduces the concept of a **European data altruism consent form, customisable for specific sectors and purposes**.

¹ https://edps.europa.eu/sites/edp/files/publication/20-06-16_opinion_data_strategy_en.pdf

² 'data altruism' means the consent by data subjects to process personal data pertaining to them, or permissions of other data holders to allow the use of their non-personal data without seeking a reward, for purposes of general interest, such as scientific research purposes or improving public services.

As highlighted in our response to the Data Strategy³, EPF welcomes more harmonisation and review of consent processes.

In view of the planned sectoral legislation for the European Health Data Space, EPF calls for a considered approach considering patients' views and experiences on this subject. Meaningful informed consent enables a person to make an "enlightened decision"⁴ about how, to whom and for what purposes they want to make their data available. It will therefore be fundamental to adopt a clear, transparent, and easily accessible consent mechanism to increase trust and confidence in data sharing. EPF also notes that consent and consent processes are already defined within the GDPR and urges the Commission to carefully assess both the draft DGA and planned legislation on the European Health Data Space to avoid confusion on the understanding of the term in the context of health data altruism.

Re-Use and data sharing to third countries

As stated in our response to the Data Strategy consultation⁵, re-use of routinely collected health data for the public interest is fundamental. However, data protection, privacy and property rights need to be fully ensured, clearly understandable by patients and adapted to the rapid evolution of technology. EPF welcomes the DGA's attention dedicated to the **full respect of fundamental rights** and calls for further discussion concerning the application of the DGA elements to the upcoming European Health Data Space.

As it concerns the transfer of health data to third countries, EPF echoes the suggestion by the European Data Protection Board on the EHDS⁶, enabling data sharing only towards countries that can guarantee a level of protection essentially equivalent to that guaranteed within the European Union.

European Data Innovation Board

EPF welcomes the proposal for the establishment of a European Data Innovation Board in the form of an Expert Group (Art. 26). Building on the possibility for stakeholders and relevant third parties to be invited to attend meetings of the Board and to participate in its work, **EPF calls for a structured inclusive approach** to be adopted for healthcare-related discussions within this expert group to ensure meaningful input from civil society.

Patient organisations must be able to play a fundamental role in conveying patients' experiences, needs and challenges in the field of health data sharing and ensure truly consultative processes.

³ https://www.eu-patient.eu/globalassets/library/data-strategy-consultation-response---epf-statement_finalversion.pdf

⁴ Words used in the Nuremberg Code, the 1947 precedent of the Declaration of Helsinki.

⁵ https://www.eu-patient.eu/globalassets/library/data-strategy-consultation-response---epf-statement_finalversion.pdf

⁶ https://edps.europa.eu/data-protection/our-work/publications/opinions/preliminary-opinion-82020-european-health-data-space_en