European Health Data Space implementation

Data permit issuance by Health Data Access Bodies – EPF raises concerns and proposes solutions

The European Patients' Forum has been closely involved in shaping the European Health Data Space (EHDS) Regulation from the outset. Since 2019, EPF has actively engaged with EU institutions and stakeholders throughout the entire policy cycle—from the initial development phase and public consultations, to drafting amendments and position papers, and producing legislative analyses and Data Saves Lives toolkits to empower patients and patient organisations.

Further clarification on the implementation of the 'public interest' definition

Health Data Access Bodies (HDABs) are responsible for assessing whether the required criteria are fulfilled before granting access to health data[1]. More specifically, HDABs may only grant access to electronic health data for secondary use where the processing is necessary for one of the permitted purposes. This includes, among others, the 'public interest in the areas of public or occupational health'[2].

The EHDS sets out a non-exhaustive list of purposes that may be considered to serve the 'public interest' [3], yet it does not provide a clear definition of the concept itself. TEHDAS2 guideline[4] provides additional background information to support the interpretation of the concept, while also highlighting the gaps of the current definition: "*The lack of a clear, generally applicable definition is countered in the EHDS regulation, among others, by explicitly naming tasks or aspects that the legislator considers to be in the public interest*". In several countries, it was noted that the current definition may not provide sufficient guidance for assessing data access requests against this criterion.

The breadth of this concept allows for diverse interpretations – e.g. across sectors, research disciplines, countries and even time periods – potentially leading to fragmentation in the implementation of the EHDS. This challenge is likely to further increase the complexity of EHDS implementation as HDABs will most likely face a huge rise in the number, diversity, and complexity of data-permit applications to access and process health data. This is particularly true in smaller Member States, where limited administrative, technical, and human resources may create additional challenges.

Considering the critical importance of this concept and the uncertainty among stakeholders regarding the operationalisation of the definition, EPF calls for further clarification of the concept of 'public interest' at the European level. This should be accompanied by practical assessment criteria, common guidance, and illustrative examples to ensure clarity, consistency, and usability across HDABs.

[1] Article 68
[2] Article 68
[3] Article 53 "*such as activities to protect against serious cross-border threats to health, public health surveillance or activities ensuring high levels of quality and safety of healthcare, including patient safety, and of medicinal products or medical devices*"
[4] More specifically, paragraph 6.3.1 of draft guideline 5.2 of TEHDAS-2 ("M5.2 Draft Guideline for Health Data Access Bodies on Minimum Categories and Limitations on the Reuse of Health Data").

Examples from Member States

Spain – "*Spain does not have a clear definition of 'public interest'. In the absence of clear criteria, there is a risk that projects of a very different nature could be considered equally aligned with the public interest, even where their anticipated benefits for patients or the healthcare system have not been sufficiently demonstrated*" Spanish Platform of Patient organisations (POP)

Germany – "*The German HDAB allows access to health data to applicants demonstrating a scientific interest. This broad access framework has raised concerns regarding how scientific interest is defined and assessed, highlighting the need for a clearer European definition of public interest*." BAG Selbsthilfe

Czech Republic – "*The more complex framework for secondary use of health data has recently been postponed to a later phase of implementation, pending further EU-level guidance. While this step may be understandable from a legislative perspective, it also creates a risk that key safeguards related to secondary data use – including governance, access conditions, and patient oversight – are delayed or insufficiently defined at this stage*." NAPO - National Association of Patients' Organizations

In this context, structured patient involvement becomes particularly important to ensure that interpretations of public interest remain grounded in societal expectations, patients' rights, and public trust. TEHDAS2 guideline recognises that "*the definition of public interest could or even should be informed by the public themselves, including citizens and patients, as their values should guide what constitutes the common good*"[5].

Formalise patient involvement within governance structures

As the EHDS foresees an active cooperation between HDABs and patient organisations[6], EPF emphasises that the concept of 'public interest' can best be safeguarded through the integration of formalised Patient and Public Advisory Boards directly within the Digital Health Agencies (DHAs), the HDABs, and the EHDS Board itself from the outset. It is important that patient involvement is built into HDAB governance structures from the very beginning of EHDS implementation, rather than being added later as a corrective measure once concerns about legitimacy or trust emerge. If patient representation is not structurally planned and embedded from the beginning, there is always a risk that institutions later try to fill representation gaps quickly with "suitable" individuals through non-transparent processes.

Such structures should not amount to mere procedural participation but should instead be recognised as an essential governance function. Patient and Public Advisory Boards should be given a clear and mandatory mandate to contribute to defined operational areas, including public interest criteria, transparency (including management of conflicts of interest), sensitive data uses, communication with citizens, and the monitoring of patient and societal value.

[5] More specifically, paragraph 6.3.1 of draft guideline 5.2 of TEHDAS-2 ("M5.2 Draft Guideline for Health Data Access Bodies on Minimum Categories and Limitations on the Reuse of Health Data").
[6] Article 55

To make this institutionalisation a tangible reality, it is critical that Patient and Public Advisory Boards are adequately resourced and that patients are financially compensated for their time. As data permit applications become increasingly complex, ethically sensitive, and technically demanding, it is neither realistic nor sustainable to rely primarily on voluntary participation from patient representatives. Meaningful oversight requires a solid understanding of legal, ethical, scientific, and technical frameworks.

There is also a clear need for Member States to learn from each other's experiences. In this context, a European learning community bringing together future Patient and Public Advisory Boards could provide a valuable platform for the exchange of practices, challenges, and governance approaches. Coordination of such a community could be supported by the European Patients' Forum (EPF). This learning community could explore, among other areas, the successes and challenges identified both by patient representatives and by data holders in the implementation of the EHDS. The insights generated could help inform ongoing discussions with public authorities and institutions on the evolution of national legislation and governance frameworks in line with EHDS requirements.

EPF emphasises that patient engagement is not only a matter of legitimacy, but also of quality. Systems designed with patients' experiences and perspectives are likely to be more accurate, more trustworthy, and more sustainable over time.

Our members' voice

Netherlands – "*Patient representatives are actively involved and currently chair the Societal Advisory Board of a project focused on establishing the technical and governance components required for the future HDAB. However, it remains unclear whether patient representatives will be involved in the HDAB's governance once it becomes operational, and if so, what their mandate will be*." Dutch Patients' Federation

France – "*Patient representatives are part of the ethical and scientific committee responsible for examining data requests, particularly those concerning data from the National Health Data System (including reimbursements, hospital billing, and related data)*." France Assos Sante

Spain – "*There is not yet a clearly formalized and publicly defined mechanism to ensure the structured representation of patient organisations within the future Health Data Access Body*" Spanish Platform of Patient organisations (POP)

Czech Republic – "*At national level, patient organisations have been consulted, but this is still largely ad hoc*" NAPO - National Association of Patients' Organizations

Estonia – "*It is essential that involvement is not limited to institutionally convenient or state-aligned representatives, but instead includes independent voices with a clear mandate*" Estonian Inflammatory Bowel Disease Society

Sweden – "*There are examples of dialogue and consultation through patient and disability organisations, but participation does not always meet the requirements for active involvement, as it is often limited to public consultations, general stakeholder dialogues with authorities, or ad hoc meetings*." Swedish Disability Rights Federation

Protect robust ethical oversight to ensure patients' trust

HDABs vary in terms of their level of development across the European Union and are organised in different ways. The ambitious deadlines set out under the EHDS[7] together with the general call to simplify and shorten the timeframes for issuing data permits, raise concerns that this could place countries that rely on more rigorous ethical and scientific assessment processes in a difficult position, potentially undermining the trust that patients place in the system.

Ethical and scientific assessments are important to protect patients' fundamental rights, ensuring legitimate public interest and prevent the misuse of data. The EHDS also provides for the possibility of including an ethical assessment within HDABs[8]. It is crucial that, in practice, the implementation of the EHDS makes this possibility a tangible reality.

The time allocated for assessing data access applications is essential to ensure a thorough review, including a detailed description of the purpose for which the electronic health data are made available[9]; and ensuring that data permit are not used for purposes such as decisions detrimental to a natural person, advertising or marketing activities and developing products or services that may harm individuals, public health or society at large[10].

In the case of health data access applications requesting data from multiple Member States, EPF emphasises the need for strong collaboration between HDABs to ensure a smooth implementation of the EHDS that does not come at the expense of the quality and ethical integrity of data request reviews.

Robust ethical and societal evaluation should therefore not be viewed as an administrative burden slowing down implementation, but rather as one of the core conditions for the long-term legitimacy, transparency, and public acceptance of the system.

Our members' voice

France – "*Numerous measures are already being implemented to simplify access. Independent evaluation should not serve as an adjustment variable, especially as it is currently conducted within reasonable timeframes*." France Assos Sante

Spain – "*Spain has experience with ethical and scientific assessment in health research, particularly through Research Ethics Committees and CEIms for clinical studies involving medicines or medical devices. However, this experience does not automatically mean that equivalent procedures are already integrated into the future EHDS/HDAB framework for secondary use of health data*." Spanish Platform of Patient organisations (POP)

Czech Republic – "*We share the concern that pressure to simplify and accelerate data access procedures may come at the expense of robust ethical and scientific assessment."* NAPO - National Association of Patients' Organizations

[7] Article 57 "*All data permits issued or health data requests approved as well as refusal decisions, including their justification, within 30 working days of the issuance, approval or refusal*"
[8] Article 55 "*Where an assessment by ethics bodies is required under national law, those bodies shall make expertise available to the health data access body. As an alternative, Member States may provide for ethics bodies to form part of the health data access body*"
[9] Article 57
[10] Article 54

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The thorough delivery of data permits by HDABs is a matter of trust for patients. If patients agree to share their data, it should always be in their interest, whether to support better healthcare or to improve public health. When data are used to drive advancements in treatments, medicines, devices and services, they should lead to meaningful innovation and improved treatment, diagnosis and health outcomes for patients, including addressing unmet needs.

EPF therefore calls for:

1. Further clarification on the implementation of the 'public interest' definition: At European level, develop an operational definition of 'public interest' for the secondary use of health data, accompanied by practical assessment criteria, common guidance, and illustrative examples to support harmonised implementation across Member States, ensuring clarity, consistency, and practical applicability.
2. Formalising patient involvement within governance structures: Establish formalised and institutionalised mechanisms such as formalised Patient and Public Advisory Boards within HDABs to ensure meaningful, continuous and structured patient involvement.
3. Protecting robust ethical oversight: Ensure that the implementation of the EHDS places the values and rights of patients living in countries with robust ethical and scientific evaluation procedures at its core.

About EPF

The European Patients' Forum (EPF) is an umbrella organisation of patient organisations across Europe and across disease areas. Our 82 members include disease-specific patient groups active at the EU level and national coalitions of patients representing 24 countries across Europe. www.eu-patient.eu