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Citizen Information Point Position Paper 2026

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"CITIZEN INFORMATION POINT" DRAFT GUIDELINE FOR HEALTH DATA ACCESS BODIES ON INFORMING NATURAL PERSONS ABOUT THE USE OF HEALTH DATA UNDER THE EHDS REGULATION

Recommendations from the viewpoint of Patient and Public Advocates and Representatives

The purpose of this position paper is to provide recommendations on the draft guideline on the development and implementation of the "Citizen Information Point" under EHDS regulation from the viewpoint of patient and public advocates and representatives.

Introduction

The European Health Data Space (EHDS) regulation, under Article 58, highlights the obligations of the Health Data Access Bodies (HDABs) towards natural persons, to make information publicly available through electronic means and ensure that natural persons have access to information regarding the conditions under which electronic health data are made available for secondary use. These obligations also include informing natural persons about their rights under EHDS regulation and the mechanisms available to exercise those rights. To fulfil these responsibilities, HDABs should establish and maintain a public information system, named under the current draft guideline provided by TEHDAS as "Citizen Information Point."

This position paper presents the recommendations and concerns of patient and public advocates and representatives regarding the development and implementation of the "Citizen Information Point".

This paper reflects the joint efforts of patient and public advocates and representatives from patient organisations and civil society groups that are members of the BBMRI-ERIC Stakeholder Forum – Patients and Citizens' Pillar and has been developed in collaboration with BBMRI-ERIC.

The recommendations presented in this paper are solely from the perspective of patient and public advocates and representatives and are intended to contribute to the development and implementation of an effective, accessible and trustworthy "Citizen Information Point" under the EHDS Regulation.

Recommendations

1. **The development of EHDS "Citizen Information Points" must be based on continuous multi-stakeholder involvement from the earliest stages of design through implementation and evaluation. Stakeholder engagement should not be a one-time exercise but an ongoing, structured process throughout the lifecycle of the "Citizen Information Points".**

   Patient organisations, citizens, healthcare professionals, researchers and data holders each bring distinct perspectives that can help ensure the portals are trusted, relevant and accessible.

   In particular, patient organisations and civil society groups can play an important role in providing feedback on the structure and content, testing them and ensuring that information responds to citizens' real concerns and information needs.

2. **The guideline developed by TEHDAS working group should include a harmonised portal structure template for the design and implementation of "Citizen Information Points" across Member States.**

   Establishing a harmonised portal structure is essential to ensure consistent, accessible and understandable information for citizens across the EU, regardless of where they reside or where their data is used. A harmonised approach would improve transparency and trust by enabling citizens to encounter similar terminology, navigation pathways, rights-related information, and descriptions of secondary use processes across Member States. It would also support cross-border consistency within the EHDS ecosystem, reduce fragmentation, facilitate comparability of information, reduce duplication of efforts for national authorities, and promote more efficient implementation.

   To ensure that harmonisation reflects the needs and expectations of intended users, we urge the TEHDAS working group to organise dedicated multi-stakeholder workshops involving patients, citizens, public representatives, healthcare professionals, researchers and other relevant stakeholders to jointly discuss and develop a harmonised portal structure.

3. **HDABs responsible for the "Citizen Information Points" must establish a transparent governance framework for the development, maintenance and review of Citizen Information Points, with meaningful and ongoing participation of citizen and patient representatives.**

   The governance model should clearly define how European and national patient and citizen organisations are involved. Such involvement is important to ensure that the "Citizen Information Points" reflect and respond to the needs of the citizens and people living in Europe. Moreover, it contributes to fostering ownership and strengthening the legitimacy, trust and public acceptance of the EHDS.

4. **"Citizen Information Points" must explicitly address how datasets made available for secondary use can be disaggregated by sex, gender, age, disability, ethnicity and socioeconomic status.**

   The health needs of women, gender-diverse people and other underserved populations need to be disaggregated to be visible. Sex- and gender-specific differences in disease presentation, diagnosis and treatment response go undetected, and the secondary use of health data risks entrenching the very inequities it seeks to address. Disaggregation is also important to enable individuals to receive information on health-relevant significant findings, in line with the rights foreseen under the EHDS framework.

   Citizens have the right to know whether the data ecosystem built on their contribution is capable of serving everyone. Equity must be designed into the EHDS from the outset. At the same time, disaggregation must be accompanied by robust safeguards against the stigmatisation or discriminatory profiling of small and vulnerable groups, and these safeguards must be communicated transparently.

   We expect gender and equity considerations to be embedded in the harmonised portal structure as a core requirement, not an optional feature, so that no community is asked to contribute its data to a system that does not adequately recognise them.

5. **"Citizen Information Points" must explain not only how and by whom health data is used, but also why secondary use matters and what is the public value created by citizens' data contribution.**

A clear articulation of benefits is essential for creating trust. Citizens are more likely to engage with information when they understand its contribution to societal and health-related value of data use for better prevention, earlier diagnosis, improved treatments, healthcare planning and research. The public value of data use must therefore be clearly presented alongside information on governance, safeguards and access procedures and data protection measures.

6. **Information must be presented in plain language and designed to be accessible and understandable for all citizens, including people with all different disabilities (e.g., blind people, intellectual disabilities, etc.). It must be adapted to different levels of health and digital literacy and should be available in several languages.**

Layered information, infographics, visual explanations, and practical examples can help citizens understand complex concepts without oversimplification. Patient organisations and civil society groups should be actively involved in the co-development and testing of these materials, building on their experience in creating inclusive and accessible information resources for diverse populations, including the underrepresented groups.

7. **Transparency should extend beyond legal compliance.**

Citizens should be able to understand who may access health data, for what purposes, which uses are prohibited, and what safeguards and oversight mechanisms are in place to protect THEIR interests.

8. **“Citizen Information Points” should be viewed as trust-building tools rather than simply repositories of information.**

Maintaining public confidence in the secondary use of health data requires ongoing engagement, transparency and responsiveness. Attention should be given to addressing misinformation and disinformation relating to health data sharing. Information portals can serve as trusted reference points by providing clear explanations of common concerns and misconceptions, together with accessible information on safeguards and citizens' rights: right to opt-out, right to be informed, right to receive information about significant findings and right to lodge complaints.

9. **HDABs are responsible for ensuring that all information provided through "Citizen Information Points" is accurate, reliable and consistent across language versions.**

   If AI tools are used to support translation, HDABs must ensure appropriate quality assurance measures are in place to guarantee that translations are as close to the original content and do not introduce errors, ambiguity or distortions of the information provided.

10. **Finally, consideration should be given to creating mechanisms for continuous two-way communication, enabling citizens to ask questions, provide feedback and access information on their rights, complaint procedures and available support mechanism.**

    HDABs must ensure that the feedback channels and contact points provided in the "Citizens Information Points" are responsive and operate within defined and appropriate timelines for addressing citizens' input and their enquiries. This is important to ensure that citizens' rights are not only formally available but also practically exercisable.

We call on TEHDAS and Health Data Access Bodies to ensure that the recommendations set out in this position paper are systematically considered and implemented, so that "Citizen Information Points" truly reflect and address the needs, rights, and expectations of citizens and people living in Europe. This is instrumental to secure trust, legitimacy and equitable benefit from the European Health Data Space.

About the Stakeholder Forum

The BBMRI-ERIC Stakeholder Forum is the main interface for European patients' organisations, citizens, public representatives, industry, and academia to interact with the biobanking universe. It is an integral part of BBMRI- ERIC's governance and culture. Through the Stakeholder Forum, we are building a sustainable, bidirectional relationship between the biobank community and its stakeholders. The objective is to increase each other's awareness of needs and expectations about key issues related to biobanking, such as data protection, informed consent in health research, health research priorities, secondary use of healthcare data, involvement of patients and public in biobanking governance structures and research, and other ethical, legal, and societal issues. The Stakeholder Forum is enshrined in the BBMRI-ERIC Statutes and was put in place upon the inception of BBMRI-ERIC in 2009 (read the report: https://www.bbmri-eric.eu/wp-content/uploads/stakeholders-forum-report-1.pdf).

The Stakeholder Forum is a place for active dialogue, sharing, two-way communications, delivering the views of stakeholders, and maintaining trust between stakeholders and the biobanking community. The Stakeholder Forum is structured into 3 pillars: (1) Patients and Citizens' Pillar, (2) Industry Pillar, (3) Scientific Pillar.

The Patients and Citizens' Pillar of the Stakeholder Forum currently includes 27 patient and civic society organisations from 18 Member States and 9 European-wide patient and civic society organisations. Patient and civic society organisations that have been actively involved in addressing biobanking issues have demonstrated a longstanding interest in BBMRI-ERIC and have made significant contributions to the advancement of this research infrastructure. The strategic aims of the Patients and Citizens' Pillar are grouped in three large themes: (i) Data & digital solutions: AI in biobanking, trusted research environments (commercial access), EHDS, tools to follow-up on the use of samples in research; (ii) Informed consent: automated consent, future of consent; (iii) Patients' involvement & engagement: involvement of patients and citizens in biobank oversight committees, research projects, ethics committees. All three themes support wider pan-European projects and initiatives, and all three reflect the interests and concerns of patients, citizens and patient organisations.

This position paper was endorsed by the Management Committee composed of National Node Directors from BBMRI-ERIC Members and Observers and the below patient and civic society organisations.