

# European Health Data Space implementation: Towards Citizen Information Points

## TEHDAS2 'M8.2 Draft Guideline for Health Data Access Bodies on informing natural persons about the use of health data – Citizen Information Point'

EPF welcomes the proposed Citizen Information Points (CIPs) under the European Health Data Space (EHDS) and the strong focus on patients' rights. This is essential for building a trustworthy and effective EHDS. EPF also urges stronger guidance on communication of the opt-out mechanism and of significant findings, ensuring that patients can make informed choices and receive appropriate support. Finally, EPF highlights the untapped potential of CIPs to improve digital health literacy, build trust in health data systems, and collaborate with existing patient-led initiatives to maximise outreach and engagement. In this respect, we regret that the emphasis is on citizen/patient engagement through information and transparency rather than participation in governance or decision-making of CIPs.

### Making information accessible and understandable for patients

EPF highlights that information provided by the CIP should be in lay language and patient organisations should be involved in the drafting and the development of the information to ensure it is fit for purpose. Initial suggestions include:

- Addressing practical questions and concerns, such as: "Will I be automatically included? What happens in an emergency? How secure is my data? Will my commercial insurer or employer have access to my data? How will this improve healthcare? What happens if I move or live in multiple EU countries? How to access my data? What is included in my EHR?"
- Designing step-by-step visual guides (flowcharts, infographics, video tutorials with captions) which are particularly valuable for patients managing multiple conditions with limited energy.
- Most people will not seek information about the secondary use of health data unless they become aware of its existence through routine interactions with the healthcare system. Therefore, we suggest that communication should also be integrated into patient portals, healthcare provider communications, public awareness campaigns and patient organisation activities.
- The guideline's recommendation for newsletters and subscription mechanisms (Section 6) is practical and welcomed; patient organisations can actively promote uptake of these among their communities.
- The suggestion for disease-specific or condition-grouped information layers (Section 6) is especially valuable for rare disease patients; we encourage Health Data Access Bodies (HDABs) to explore this and engage with patient organisations to ensure specific communities receive information that is tailored to their needs.

## Further guidance on the communication of the opt-out mechanism

Similarly, we would stress that further guidance and clear patient-facing information on the opt-out mechanism are crucial. Patients need to understand not only their rights, but also how to exercise them in practice, in a simple and accessible way. We highlight that:

- Patients should receive balanced information about the potential implications of their decision. The objective should not be to encourage or discourage opting out, but to enable individuals to make an informed choice by understanding both their rights and the potential benefits of health data use for research, innovation, public health planning and the development of future treatments.
- Information on opt-out should be easily accessible and visible to patients on the CIP and should answer practical questions that matter to patients in a neutral way, such as what secondary use of data means, what benefits and concerns relate to opt out, etc. In particular, the process for reversing an opt-out decision the conditions under which data may be accessed even after opt-out (“public interest” override), should be explained clearly.
- We welcome the emphasis on “non-electronic possibilities” for patients with low digital skills and would welcome further guidance on this matter. The CIP should provide clearly defined non-digital pathways (printed materials, assisted access points at hospitals and public service counters, as recommended in Section 6 of the guideline) for people with limited digital skills. Patients should be able to receive information and exercise their rights through healthcare providers, family physicians and public service centres.
- Communicating proactively through trusted intermediaries, including patient organisations — we strongly support the guideline’s Section 5 recommendation to engage patient communities as dissemination channels. Patient organisations can support making the information more tailored and fit-for-purpose and act as amplifiers in public communications campaigns. These campaigns should be co-created between health authorities and patient organisations to maximise impact. Their involvement and activities of patient organisations in this context should be remunerated.
- In Estonia, the opt-out mechanism is directly integrated into the national health portal (Terviseportaal), where citizens already access their health records and manage healthcare-related consents. This example could be further considered.

## Informing patients about significant findings

We also welcome the emphasis on informing patients about significant findings related to their data. This is fundamentally about transparency and trust. In this regard, it will be important for the EHDS Board, in consultation with relevant stakeholders, including patient representatives, to develop clear guidelines on what constitutes a clinically significant finding, and under which circumstances re-contacting individuals is appropriate and respectful of patients' preferences regarding the communication of such findings. We also point out that:

- Notifications regarding significant findings should not only be delivered through secure national digital health infrastructure, but they should be communicated by a healthcare

professional who can explain what the findings mean in lay terms and discuss possible next steps.

- Patients should be informed in advance about the possibility of receiving such findings, the types of findings that may be communicated, and the process that would follow. They should have the opportunity to consent to receiving this information.
- The 18-month deadline for health data users to report results to the HDAB (Article 61(4)) should be the maximum, not the norm; HDABs should actively incentivise earlier reporting.
- Patient organisations should be formally recognised as intermediary communication channels for significant findings — particularly for rare diseases where HDABs may lack direct patient contact infrastructure.

### An underused opportunity to improve patients' digital health literacy

We regret the non-mandatory nature of the information to be provided by HDABs under Section 5, especially considering the relevance of the topics addressed in this section (citizens' awareness, trust and engagement; enabling individual information; providing health data user information; patient communities; disease-specific information and educational features; and eHealth awareness).

In this context, we would also welcome a stronger synergy with digital health literacy activities and awareness raising campaigns, in accordance with articles 58 and 84 of the EHDS regulation. It is important to explain the benefits that patients can derive from data sharing.

Building awareness of the infrastructure or system through which patients share their data is also essential. Studies have shown that patients are more willing to share their data when they trust the institution requesting it. The CIPs could play a role in fostering this trust by providing clear information about the system.

As part of large-scale awareness-raising efforts and digital health literacy initiatives, patient organisations can help CIPs translate complex regulatory concepts into language that people understand and trust, while also helping to develop disease-specific educational materials.

### Drawing on existing patient-led initiatives

We encourage making full use of existing resources, such as the extensive work developed by patient organisations such as the [Data Saves Lives](#) initiative, including practical toolkits and webinars that can support the implementation of the EHDS. This information can be easily tailored and adapted to local contexts. CIPs should map existing initiatives and engage with relevant organisations to leverage their activities and expertise.

As highlighted in [previous EPF statements](#), it is important to ensure meaningful and coherent patient involvement in EHDS governance, building on effective coordination between HDABs, CIPs, and patient organisations, for example through Patient and Public Advisory Boards. Patient involvement should be embedded across governance structures and decision-making processes rather than limited to ad hoc consultation. Particular attention should also be paid to the implementation capacity of smaller Member States, where limited administrative, technical, and human resources may create

additional challenges for the establishment and operation of CIPs and related structures. In this respect, specific capacity building programmes and exchanges of best practices should be available.

## 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](http://www.eu-patient.eu)