

## **ECL's feedback on the European Commission's proposal on a European Health Data Space**

The Association of European Cancer Leagues ([ECL](#)) welcomes the European Commission's proposal to create a European Health Data Space ([EHDS](#)) to unleash the full potential of data cooperation across borders for the benefit and improvement of care, research, care and health policy.

### **Patient involvement and protection**

ECL firmly believes that **patients' needs and wants should be at the heart of all EU health legislation** and that **patient involvement** should be among the main drivers.

The collection and exchange of patients' data should be done in full respect of fundamental rights and support for digital literacy, and within a robust regulatory framework, complying with the **highest standards of protection of patients' privacy**, and firmly condemning **data abuse**.

On the other hand, although the General Data Protection Regulation (GDPR) aimed to ensure both the privacy of citizens and stimulate innovation, the latter point was overshadowed by public discussions about privacy. While **patient privacy must be ensured, it must not compromise the effectiveness of the EHDS in stimulating innovation**. A balance should be maintained in political debates.

In terms of governance, **data authorities should be appointed transparently**, free from all sorts of conflicts of interest, and respect a strict code of conduct. Member States should make it possible for patients to appeal in case of difficulties accessing or protecting their data.

We support the setup of a **Board to facilitate info-sharing among member states** and promote the elaboration of common standards and requirements for the interoperability of health data sets. We also encourage the Commission to **meaningfully involve patients, patient advocates and researchers** in the **EHDS Board** and **any other key initiatives**.

Patient-centredness should be a key aim of the EHDS, and **interoperability is a means to this end**.

### **Interoperability and technical hurdles**

ECL is concerned about potential interoperability and technical hurdles given the considerable **discrepancies in digitalisation and digital skills** across and within EU member states, which might jeopardise the EHDS's implementation. User-friendly digital platforms can reduce the administrative burden only if (1) they are interoperable and integrated with the systems that are now in use and if (2) healthcare providers, healthcare professionals, data authorities, and citizens have access to trustable tools and training on how to best collect, store, and exchange data. It is, therefore, essential that:

1. EU and Member States facilitate interoperability between national systems and any new (EU) digital platforms. Member states and/or the European Commission should keep a tight rein to ensure vendor lock-in will not delay this process. Unifying and structuring the language used to collect data will form

an important step in reaching interoperability, one that requires collaboration from various member states. The EHDS can play an important role in the implementation of international standards.

2. EU and Member States generously invest in addressing deficiencies in interoperability and strengthening digital health skills, training healthcare professionals, and **ensuring that no EU patient is left behind**. Special attention and resources should be given to less digitalised countries to **avoid widening health inequalities**.

What is more, strengthening digital skills may not be sufficient to assure data of high quality. Other financial, and socio-cultural factors, such as a high workload, can influence the quality of data. A cultural shift is essential, and this could be facilitated by new tools and training. The **collective need to collect data in a structured manner** must be abundantly clear to all users and collectors of data, and collectors should be stimulated to do so (even monetarily). **Technical solutions** should be developed **to support their users** rather than letting the technical solutions shape their work processes for optimal utilization.

### Research & secondary use of data

ECL supports the initiative of pooling and sharing knowledge, experience, and EU-wide high-quality data to **make informed decisions based on real-world evidence**. However, cancer leagues carrying out and/or funding cancer research projects are **concerned about the uncertainties of conducting health research** under EU rules and its national adaptations. A fragmented implementation of data protection provisions would limit research collaboration and impede data exchanges, ultimately putting patients at risk.

ECL calls on the Commission to develop a solid regulatory framework for the secondary use of data, mitigating risks for EU patients, ensuring data altruism without impeding innovation, and that all **data protection legislations are interpreted and harmonised across Europe**. The success of the EHDS will depend on its **effectiveness in addressing legal ambiguities** created by the uneven interpretation and implementation of the GDPR and convincing researchers that they can reuse and share health data in a safe and legally compliant environment. The procedures that will be put in place to **regulate applications for data reuse must be efficient in supporting researchers in reusing real-world data**. It is thus very important to **involve researchers from the very beginning** of establishing these data access bodies to not run into the risk of delaying and discouraging them from reusing data.

### Interaction with other EU initiatives & funding

ECL would also like to stress that synergetic action and coordination with other digital health initiatives, such as the GDPR, Data Act, and DARWIN EU is key. The proposal is unclear about the scope and interactions of the EHDS with these. **Potential overlaps should be addressed to ensure legal clarity** and prevent these initiatives from becoming inaccessible or cumbersome for research purposes. In particular, the interplay between the GDPR and the EHDS will have to be clarified when it comes to the processing of personal health data.

Finally, **concerning funding**, ECL acknowledges that the successful rollout of the EHDS would require a **high level of political cooperation and investment** at the regional, national, and EU levels. Not only should sufficient funds be made available, but it will be important to identify who is best placed to receive those funds. Providing funding requires a comprehensive approach beyond domains, healthcare processes, and institutions, as the ones that are responsible for investing will not necessarily be the ones that benefit directly from the EHDS.