



Startup Communities Call for a European Health Data Space That Stimulates Research and Innovation

Startup Communities welcome the European Commission's proposal for the creation of a European Health Data Space (EHDS), as it could become the runway for startups to scale life-changing innovations across the EU. It is an opportunity to introduce common standards and create an environment that could boost Europe's global competitiveness in medical research and innovation. Startups are most often smaller economic players - navigating complex regulatory barriers requires both time and resources. The current EU health data ecosystem differs across Member States, each having different levels of data centralization and standards of interoperability, which comes at a cost for startups. The EHDS promises to lay the ground-rules for harmonisation by creating well-governed pathways to access cross-border health data.

Startup communities are sharing three key recommendations to make the EHDS fit for purpose for patients, healthcare professionals and innovators.

1. Regulatory Harmonisation Across Borders

Coordinated approaches across Member States will help avoid a patchwork of interpretations of the EHDS, and create a more integrated cross-border Single Market in healthcare. Achieving EU health data interoperability will allow data to be properly pooled and compared, empowering innovators to build their solutions with interoperability compliance already in mind.

Ensuring legal certainty on the interplay between other data legislation including the GDPR, the Data Governance Act, the Data Act, and the AI Act is key to avoiding additional and unnecessary red tape. As horizontal frameworks, they cannot address the specificities of sensitive data such as health or genetic data, therefore the creation of the EHDS should complement these legislations with specific rules for the health sector.

The EHDS must also set out clear rules for the estimation of the **costs associated with the interoperability of data**. It must provide a clear and mandated space for researchers - a lack of clarity could hinder health data access for primary and secondary purposes, leading to a deviated approach of implementation - much like what we see today.

2. Maximising the Pool of Secondary Health Data

The current diverging views in the European Parliament has led to a compromise proposal of an opt-out model, where citizens can indicate if they would like to exclude the re-use of their health data. **The EHDS' goal should be to maximise the pool of high quality health data available for medical research which will serve as a catalyst to better predict, prevent and treat diseases, while preserving patients' privacy and**

trust in the system. The EHDS must provide the necessary safeguards to ensure the privacy of citizens is protected by facilitating data sharing for secondary use either in pseudo-anonymised or anonymised form in a secure, GDPR-compliant processing environment. If an opt-out model were to be introduced, we strongly recommend multi-stakeholder perspectives be involved to consult in this process.

Intellectual property (IP) rights and trade secrets are essential to stimulate the development and distribution of new products and services. It is important to avoid unintended consequences for businesses that depend on data as a key asset for their ability to grow and sustain their competitive advantage. **Maximising the pool of health data available is possible without infringing on the IP and the trade secrets of startup companies, however it is vitally important that the EHDS ensures this balance.**

3. Startup Representation in the EHDS

A multi-level governance approach that brings all actors (patients, medical establishments, health professionals, researchers, companies, NGOs, professional associations) to the table is vital for the successful rollout of the EHDS. As startups are both users and holders of secondary health data, startup feedback is essential in the EHDS implementation. Entrepreneurs can pinpoint barriers and changes needed on the ground and they can provide their technical expertise for the definition and application of interoperability standards. Startups can also make an informed contribution to the calculation of fees. It is important to strike the right balance between ensuring that the cost of making data available for public use is not prohibitive - while not discouraging to those with fewer resources seeking to access data. For these reasons, **startups should have a say in the decision-making and governance of the EHDS. Therefore, we call for the inclusion of startups and their representatives in the EHDS board.**

Conclusion

For the European Health Data Space to truly achieve its goal of building a stronger health union, policy makers should focus on designing this regulation with the smallest players in mind to give the clarity and flexibility startups need to scale across the EU and beyond. Startup communities look forward to engaging with the EU institutions in the upcoming legislative process of the EHDS.