

## Allied for Startups Position on the European Health Data Space

Allied for Startups welcomes the European Commission's strategy for the creation of a European Health Data Space (EHDS), a core initiative for a united and healthy Europe. Startups are key actors in the digitalisation of health and care, as reflected in the global pandemic response. Our members are excited about the EHDS' potential to enable EU-wide collaboration for better healthcare, research and innovation - and boost the global competitiveness of healthcare startups in Europe and beyond.

Any entrepreneur is no more than an idea and a data-set away from a new startup. Access to secondary health data is a key enabler in the development of innovative healthcare solutions. Entrepreneurs rely on the access to quality health data sets for research and innovation purposes in order to develop health solutions and bring life-changing initiatives to the market.

Startups are also 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 often comes at a cost for startups.

The EHDS provides the opportunity to introduce common standards to facilitate an environment that empowers startups and other digital health communities. To ensure the EHDS fulfills its promise for startups, Allied for Startups is sharing four key priorities to consider:

### **Harmonization Across Borders - Not Additional Red Tape**

In order to fully realize the benefits of harmonization across borders, we urge for proportionate and fit for purpose legislation. This entails having clear definitions and concepts to avoid additional red tape. The EHDS must explicitly set out a framework on infrastructure development and 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.

We ask for interoperability standards to be clear and consistent to avoid the EHDS becoming an additional red tape for startups, Member States, and other key stakeholders in Europe's healthtech ecosystem. Coordinated approaches across member states must be established to avoid a patchwork of interpretations of the EHDS regulation. Achieving EU health data interoperability will allow data to be properly pooled and compared, granting

startups and other key innovators to build their solutions with interoperability compliance already in mind.

### **Startup Perspectives in the European Health Data Board**

As key players in digital health, startups should be represented in the European Digital and Health Board, which the EHDS is proposing to create. As the main users of secondary health data, startup feedback is important to consider in the EHDS implementation - entrepreneurs can provide first-hand expertise on some of the barriers and changes needed on the ground. A multi-level governance approach is vital for the successful rollout of the EHDS. We call for a continuous dialogue and inclusion of startups in this process.

### **Alignment With Relevant EU Policy Files**

The EHDS provides a pivotal step in regulating health data access and sharing, however, steps need to be taken to ensure legal certainty on the interplay between other data legislation including the GDPR, the Data Governance Act, the Data Act, the AI Act as well as forthcoming initiatives like Civil liability aspects of AI and more. As horizontal frameworks, they cannot address the specificities of sensitive data such as health or genetic data, therefore the creation of the EHDS complements these legislations and creates specific rules for the health sector. Consistency with other data related initiatives is imperative to avoiding additional bureaucracy for startups and other stakeholders in the healthtech industry.

### **Reimbursement of Digital Services**

Wide scale access to digital health tools will not be achieved until public systems embrace and integrate digital health products in their statutory health insurance schemes. A common EU approach for digital health reimbursement would be a quantum leap forward in tackling European health inequities. Developing uniform reimbursement schemes for digital health applications will empower patients to use these fully-insured tools and allow life-changing innovations to enter EU markets faster and more efficiently.

In creating the infrastructure for an EU wide health data interoperability and eHealth services, the EHDS provides the momentum to create reimbursement pathways across the block. We urge EU policy makers and governments to consider the German DiGA and mHealthBelgium platform as best practices of reimbursement systems that work.

### **Concluding remarks**

The European Health Data Space has the potential to harmonize the ground rules for health data sharing across the EU, and set a precedent for upcoming data spaces. We ask policy makers to consider startup perspectives in creating the EHDS. Standards should be designed with the smallest players in mind and give the flexibility they need to scale across the European Union and beyond. Allied for Startups and its members look forward to engaging with the EU institutions in the upcoming legislative process.

*Allied for Startups is a worldwide network of over 46 advocacy organizations focused on improving the policy environment for startups. We are working together to create a consensus on policies that can positively impact startups and grow the digital entrepreneurship and digital economy at large. Our mission is to ensure that the voices of startups are heard in government.*