

Allied for Startups

Allied for Startups welcomes the European Commission's efforts to create the European Health Data Space, a core initiative for a united and healthy Europe. Startups are key actors in solving global health challenges and in revolutionising the digitalisation of care. Our members believe in the EHDS' potential to enable EU-wide collaboration for better healthcare, research and innovation - and boost the global competitiveness of healthcare startups in Europe.

Startups are key actors in the digitalisation of health and care, as reflected in the global pandemic response. Startups are also most often smaller economic players - navigating complex regulatory barriers requires both time and resources. The EHDS provides the opportunity to reduce regulatory fragmentation and introduce common standards to facilitate an environment that empowers startups and other digital health communities.

To complement our consultation feedback, we are sharing three key priorities to consider in the development of the EHDS:

Access to health data

- Currently, access to health data is fragmented and opaque. The EHDS provides the opportunity to establish a harmonised framework for secondary health data sharing and re-use in the EU. Ensuring harmonisation at the EU level makes it easier for innovators to access secondary data for research and innovation, a key premise for patient-centric innovation.
- Enabling interoperability and standardised, quality data sets at the EU level and beyond is fundamental in building global health databases and exchanging information between institutions and across borders.
- Making health statistics publicly available can help startups and other innovators determine the market and costs of their products (eg. statistics on Europeans living with particular diseases)
- **Best Practice:** Finish Act on the [Secondary Use of Health and Social Data](#): applies to data collected in social and healthcare organisations and governs processing for secondary purposes, including statistics, scientific research, and other activities.

Common EU framework for reimbursements

- Currently, pathways for reimbursement vary greatly amongst Member States, placing large regulatory barriers on startups in the digital health space. Developing an EU-level framework for the reimbursements and insurance coverage of digital health products and services would provide enormous benefits to digital health innovators.
- Most Europeans rely on publicly funded healthcare - wide scale access to digital health innovations will not be achieved until public systems embrace and integrate

digital health products in their reimbursement schemes. A common reimbursement EU approach would be revolutionising in tackling European health inequities.

- **Best Practice:** [Estonia's](#) nationwide eHealth services include a fully interoperable, centrally-stored EHR system, covering all of its citizens.
- **Best Practice:** [German Digital Health Care Act](#): provides a dedicated route to national reimbursement of digital applications. The law allows doctors to prescribe approved health apps to their patients, reimbursable by their statutory insurance.

AI & health

- AFS recognises the vast opportunities for AI in health. As a defining technology of the future, AI has the opportunity to transform health systems into being proactive, predictive, and preventative. Our world is facing growing challenges that call for extraordinary capabilities only AI can offer.
- Our members urge the importance of enabling more innovation & investment in AI across Europe, which underpins the need for synchronised AI legislation that provides clear pathways for startups and other innovators to scale in the EU (considering the 'high risk' classification of AI in health).
- Example: [Corti.ai](#) showing the potential for AI in health

The COVID-19 pandemic has accelerated the digital transformation of health and care, but has simultaneously also revealed several barriers for cross-border health innovation. The EHDS has the potential to play a crucial role in addressing challenges the digital health ecosystem is facing. At Allied for Startups, we will continue to provide feedback on behalf of digital health startups and engage our members in the discussions shaping the EHDS and the path towards a stronger Health Union.

As a worldwide network of over 45 advocacy organisations, Allied for Startups aims to improve the policy environment for startups to innovate and thrive. Allied for Startups DTx brings together startups, policymakers and other healthcare stakeholders to enhance innovation for startups in the European healthcare ecosystem.