



Nurturing the Digital Health Startups' Ecosystem in the EU

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Digital health startups are transforming healthcare across the EU by improving access to services, streamlining operations, and enabling preventive care. Leveraging AI, telemedicine, and data analytics, digital health startups address challenges in accessibility and efficiency while empowering patients.

To maximise their impact, a supportive EU ecosystem is essential, including regulatory harmonisation, accessible funding, and cross-border scalability. The upcoming European Health Data Space (EHDS) regulation will provide a cohesive framework for secure health data access fostering also startups' innovation. EU supported accelerator programs and incubators are invaluable resources that connect startups with essential mentorship, expertise, and access to real-world testing environments.

Digital health startups in Europe are emerging as **key players in modernising healthcare** through technology-driven solutions. They are addressing a range of healthcare challenges, from improving access to services and reducing wait times to enabling remote patient monitoring and personalising treatment plans. Digital health facilitates remote consultations, telemedicine, and mobile health applications, especially important in underserved areas and countries with dispersed populations. An increasing number of digital health solutions are using AI, machine learning, and big data analytics to assist in diagnostics, predictive healthcare, and personalised treatment plans. By digitising processes, from scheduling to patient record management, digital health tools help healthcare providers streamline operations, reduce administrative burdens, and cut costs. Digital health innovations often focus on preventive measures, helping individuals manage chronic diseases or monitor lifestyle factors, such as fitness and nutrition, to prevent illness.

The startup ecosystem is a critical catalyst in accelerating the invention of novel digital health technologies across the EU. By driving rapid innovation, agility, and tech-focused solutions, startups are uniquely positioned to propel transformative digital advancements in healthcare, addressing challenges in accessibility, efficiency, and patient empowerment. To fully leverage these innovations, **fostering a supportive ecosystem**

through harmonised regulatory frameworks and robust resource allocation is essential. This includes ensuring the single market concept applies to digital health and is accessible to start ups. Simplifying and aligning regulations across Member States — especially in areas such as data privacy, healthcare device certification, and AI usage — would reduce administrative burdens and facilitate cross-border scaling for startups. Cross-border alignment at HTA level on evidence standards and cross-recognition of approvals is another vital enabler of the single market. Such regulatory cohesion would not only streamline market entry and adoption but also support the rapid scaling of technologies, ensuring compliance with EU standards while maintaining innovation momentum.



Funding remains a critical enabler in the development and scaling up of digital health solutions. **Addressing the financing gap through EU-backed investments, grants, and venture capital match programs** can lower investment risks and attract private capital to the sector.

These mechanisms, combined with tax incentives for R&D in digital health, would support early-stage companies in bridging the gap between concept and market-ready solutions, reinforcing Europe's position as a leader in health technology innovation.

Moreover, **accelerator programs and incubators** are invaluable resources that connect startups with essential mentorship, expertise, and access to real-world testing environments. By facilitating pilot programs across diverse healthcare systems within the EU, the EU could enable startups to validate their technologies in varied regulatory and operational contexts. This not only provides startups with critical market insights but also ensures that their solutions are adaptable, scalable, and better aligned with the diverse healthcare needs and regulations across Member States.

Collaborative platforms are another cornerstone of success, enabling startups to refine and adapt their technologies through direct interaction with healthcare professionals and patients. These platforms can foster feedback loops where startups can iterate based on real user experiences, ensuring the development of solutions that are practical, user-friendly, and aligned with healthcare providers' operational needs.

Cross-border collaboration offers an essential pathway for startups to pilot and refine their innovations in multiple markets, capturing diverse insights that inform product refinement and scalability. By demonstrating the efficacy of their solutions in multiple settings, startups can build a case for broader adoption, accelerating their path to market readiness. Furthermore,

such collaborations facilitate knowledge sharing, help startups navigate regulatory differences, and foster resilience by enhancing the adaptability of solutions to various healthcare environments.

Corporate partnerships are also crucial, bringing together the agility and innovative strengths of startups with the resources, infrastructure, and market reach of established corporations. These collaborations enable startups to leverage corporate networks, funding, and expertise, which help them navigate regulatory complexities and scale their technologies more efficiently. For corporations, these partnerships bring new, cutting-edge technologies into their portfolios, ensuring competitiveness in a rapidly evolving digital health landscape. Jointly developed products emerging from these collaborations are typically more refined and user-centric, supporting smoother integration into existing healthcare systems and promoting widespread adoption of digital health solutions.

Additionally, **collaborations extending to academia and public institutions can drive a multidisciplinary approach** that incorporates technological, medical, and regulatory insights.

This integrated model ensures that new health technologies not only align with clinical standards but also meet regulatory requirements and patient care needs, enhancing the EU's capability to lead in digital health innovation.

Finally, **leveraging the EU's industrial synergies and cross-border networks** can accelerate the development and deployment of digital health technologies across

Member States. Establishing unified technical standards and protocols simplifies regulatory approvals, enabling a seamless integration of new technologies within healthcare systems across the EU. Furthermore, coordinated



efforts ensure that digital health policies support innovation while addressing critical privacy, security, and ethical considerations. Cross-border collaborations also streamline supply chains, enhance crisis response capabilities, and facilitate the pooling of resources, insights, and infrastructure — strengthening the EU's resilience in healthcare delivery, as demonstrated during the COVID-19 pandemic.

The upcoming **European Health Data Space (EHDS)** Regulation represents a significant step forward in enabling a more cohesive and data-driven healthcare ecosystem across the EU. Designed to streamline health data access, improve patient care, and drive healthcare innovation, EHDS has direct implications for the digital health startup ecosystem. The EHDS will enable a more integrated approach to health data utilisation, crucial for digital health startups as they bring transformative solutions to market.

The EU has a unique opportunity to support a **thriving, innovation-driven digital health ecosystem** by creating a cohesive regulatory environment, investing strategically in funding mechanisms, promoting collaborative platforms, and nurturing cross-border partnerships. These measures will not only reinforce healthcare systems across the EU but also ensure the EU's leadership in digital health on a global scale, delivering substantial benefits in healthcare quality, accessibility, and efficiency.

Recommendations at a glance

- ▶ **Harmonise regulatory frameworks** including uniform standards across Member States for data privacy, AI, and medical device certification, easing compliance and enabling startups to scale their solutions across borders.
- ▶ **Expand Funding Mechanisms** such as EU-backed investment funds, grants, and tax incentives for digital health R&D to reduce financial barriers, support early-stage growth, and attract private capital.
- ▶ **Support Cross-Border Collaboration and Pilot Programs:** Facilitate pilot programs and cross-border partnerships that allow startups to validate solutions across diverse healthcare systems, refining products for scalability and adaptability.
- ▶ **Encourage corporate and academic partnerships:** Fostering collaborations between startups, corporations, and academic institutions allows to combine technical, clinical, and regulatory expertise, creating solutions that meet both healthcare and compliance needs.