



ALLIED FOR STARTUPS

DTx

The European digital health startup ecosystem: an overview

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Healthcare is transforming, with increasing demands for better quality care, lower costs and more innovation. Startups meet this demand through their patient-centric and disruptive healthcare solutions.

Startups address the gaps of conventional healthcare, but they often face complex regulatory hurdles – and unlike big industry players, startups have little to no resources to devote to red tape.

Allied for Startups DTx brings together startups, policymakers and other healthcare stakeholders, with the aim of enhancing the policy environment and supporting innovation for startups in the European healthcare ecosystem.

Our mission is to build a network of startups and other healthcare stakeholders to:

- Ensure that EU policies benefit startups in healthcare,
- Connect stakeholders, discuss challenges and share best practices,
- Lead policy dialogues around digital health,
- Facilitate and enhance cooperation among startups and stakeholders.

To do so, we:

- Monitor and identify opportunities for startups to engage with the European Parliament, Commission and Member State representatives,
- Bring startup entrepreneurs and communities together to raise awareness about EU policies and initiatives,
- Engage with and create opportunities for startups to engage with policymakers to raise awareness about the needs of startups in EU digital and health policies,
- Speak on behalf of startup communities to promote digital health.

Startup Champions



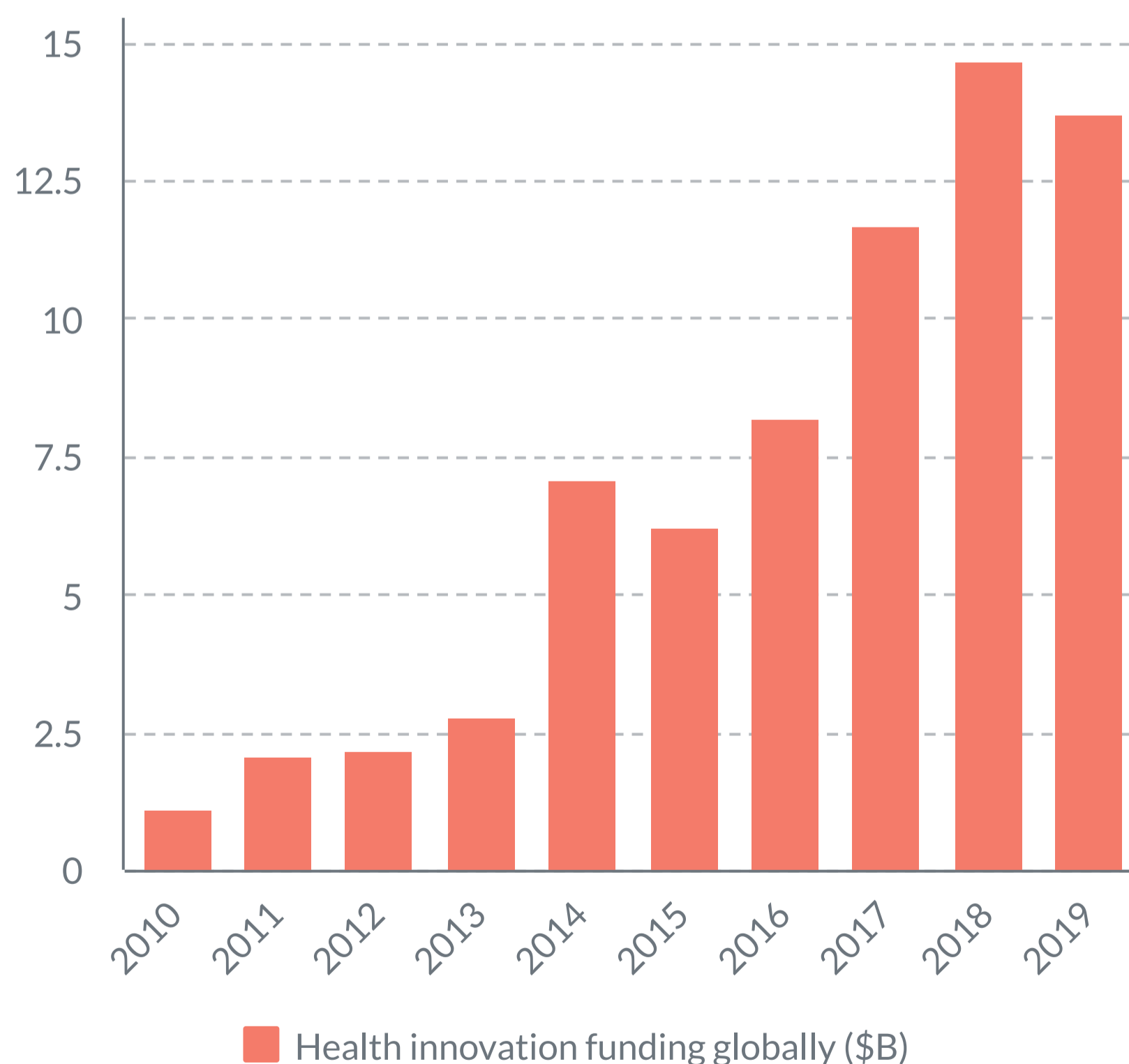
The digital health landscape: Present and future

Startup hubs in Europe are booming in all things digital. According to Atomico's State of European Tech 2019 report, European tech companies reached more than \$30 billion in funding in 2019, up from \$25 billion in 2018. Funding has more than doubled in five years, which includes more than 40 \$100+ million deals.

At the same time, digital health solutions are becoming more and more incorporated into healthcare systems at a very fast pace. For example, the World Health Organisation (WHO) released its first-ever guidelines on digital health in 2019. In November 2019, Germany introduced a law allowing the prescription of digital health applications that can then be reimbursed by the national health insurance system.

Startups have been key to the growth in the healthcare sector. Early January 2020, Sweden-based KRY -Europe's largest digital healthcare provider- raised \$155 million (€140 million) in a Series C round, with the aim of further expanding across Europe. According to the StartUp Health Insights 2019 Year-End Report, 2019 was the second-most funded year ever globally, with \$13.7 billion in total funding across 727 deals in health innovation. \$70 billion has been raised in health innovation since 2010. London and Paris were the second and third most funded non-US digital health startup hubs, raising \$777 million and \$456 million respectively in 2019.

According to the 2019 Global Health Care Outlook report by Deloitte, global healthcare expenditures are expected to continue to rise as spending is projected to increase from \$7.7 trillion in 2017 to \$10 trillion in 2022. A report by Global Market Insights predicts that the digital health market will grow at 29% compound annual growth rate from 2019 to 2025.



Source: StartUp Health Insights 2019 Year-End Report

Digital health startups in Europe: The regulatory landscape

With increasing amounts of groundbreaking treatment methods and investments into the industry, more entrepreneurs and investors are looking to expand into the healthcare sector. Startups' innovative solutions are reshaping practices and perspectives in this area.

But many startups struggle because of the highly specialised and regulated nature of the healthcare sector. As discussed by startup entrepreneurs at an AFS DTx roundtable in the European Parliament in November 2019, startups need to go through complex clinical and regulatory processes even before entering the market. On top of that, many scientific, regulatory and financial hurdles come up in the process of bringing solutions to patients. Since regulations are implemented differently across EU member states, there is a large amount of fragmentation between the national markets, too.

According to Atomico's State of European Tech 2019 report, 83% of European tech scale-ups that have reached \$1B+ valuations or more have internationalised, compared to 70% in the US. The most popular countries to set up international offices by European tech scale-ups are other European countries - mainly the UK, Germany and France. Yet, the same report states that 40% of founders and startup employees surveyed did not feel informed about the European Commission's digital priorities. According to one of its surveys exploring policy support priorities for European tech founders, the leading priority was to create the conditions that make it more appealing for companies to attract, retain and replace talent. The harmonisation of tech-related regulation across Europe was another leading priority. While founders find these regulatory areas difficult to navigate in, there is a desire to build bridges between the tech and policy spheres in Europe.

Building up on our exchanges with digital health startup entrepreneurs in Europe, there are 3 overarching topics where there is room for improvement in legislation: Access to a European single market in healthcare, a common European data space in healthcare and AI in health.

Sources:

- Atomico the State of European Tech, <https://2019.stateofeuropeantech.com/>
- WHO Guideline: recommendations on digital interventions for health system strengthening, <https://bit.ly/2RBMmVM>
- KRY, <https://www.kry.se/en/>
- StartUp Health Insights 2019 Year-End Report, <https://www.startuphealth.com/2019-q4-insights-report>
- Deloitte 2019 Global Health Care Outlook Report, <https://bit.ly/3aUpG51>
- Global Market Insights Digital Health Market Size By Technology, <https://bit.ly/2OaLm94>

Further reading:

- A Day Of Collaboration Among Startups, Policymakers And Healthcare Stakeholders In The EU, <https://bit.ly/318jXtu>
- 3 Topics That Matter For Startups In The European Digital Health Ecosystem, <https://bit.ly/2u1yOtP>
- The EU's New Health Agenda: Challenge Or Opportunity For Startups?, <https://bit.ly/317Kilv>
- The Rise Of Startups In The European Digital Health Ecosystem: Opportunities And Challenges, <https://bit.ly/37G17g0>
- 6 Reasons Why Sandboxes Are An Underrated EU Policy Instrument, <https://bit.ly/36GirA9>

1. Access to a European single market in healthcare

More harmonisation of regulatory requirements at the EU level: This can reduce market fragmentation, costs and increase the overall healthcare quality among Member States. Clear and manageable health regulations and a pan-European interoperable system (such as the European Reference Networks and the eHealth Digital Service Infrastructure) can maximise patient-centred outcomes.

The implementation of regulatory sandboxes: Sandboxes can be a powerful tool where conventional methods are too costly or prove ineffective. A European framework on regulatory sandboxes could provide guidance and incentivise innovation.

A more differentiated approach by the new Medical Device Regulation: The new MDR is coming into effect in May 2020 and only a limited number of notified bodies are ready to operate to certify devices. The new regulation is also very resource-demanding from a startup perspective. Strong support from policymakers for the smooth implementation of the new MDR is vital.

More collaboration: Providing more avenues for partnership between corporations, healthcare institutions, policymakers and startups from the design to the marketing stage can allow startups to better integrate into and innovate within healthcare systems.

2. Access to a European single market in healthcare

Better access to more data: There is need for improving access to public data and fostering measures to encourage private data sharing. The legislation on the secondary use of health and social data that came into effect in Finland in May 2019 is a great example, while respecting data privacy of individuals. Here, the issue of trust also needs to be addressed by a wide range of stakeholders, including policymakers.

Widespread use of Electronic Health Records: Widespread use of EHRs for the exchange and use of health data in the EU can facilitate cross-border interoperability and reduce the cost of healthcare significantly. This will allow better and faster innovation, while respecting citizen privacy.

3. AI in health

Flexible regulation: While a principle-based approach to ethical AI is necessary, a regulatory regime that provides enough flexibility for AI development in Europe can enable more innovation and investment in AI.

More funding opportunities: More funding can make the EU an AI champion. Initiatives such as the Commission's plan to support the development of a common database of health images (anonymised and voluntary) in 2020 to improve diagnosis and treatment of common forms of cancer can boost the uptake of AI in Europe.

Outlook for 2020

Which topics should be on the radar in 2020? This year, the new Medical Device Regulation will go into effect on May 26. There is a grace period for the application of the new law on certain products. But since the application of the regulation will affect apps and wearable developers, the discussions around the new MDR is worth following for startups.

Commission President von der Leyen promised AI legislation within her first 100 days in office (until March 2020). While many interest groups have been vocal about not rushing the legislation, this is likely to define the future of AI applications in Europe.

On the cancer research front, European Health Commissioner Kyriakides announced that the Commission will present “Europe’s beating cancer plan” on 4 February, while the action plan is expected towards the end of 2020. This is likely to drive more funding and collaboration opportunities for startups in the area of cancer prevention.

Products and legislation in the area of digital health share the ambition to empower patients. Startups realise this ambition by giving patients more governance over their health and health data.

Digital health startups have a proven value in improving patients’ quality of life, but need a stronger and more unified voice to demonstrate their economic value and to push for fundamental improvements in regulation. This is the aim of Allied for Startups DTx – to be the bridge between startups, policymakers and stakeholders in the European healthcare ecosystem in order to lower regulatory barriers, enhance growth and support innovation for startups. This will lead to innovative solutions for creating the healthcare of the future in Europe.

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