



# 2023 Annual HealthTech Report

The voice of digital health startups in  
policy and government



# Welcome letter

As we embrace a new year, we are thrilled to share the Allied For Startups HealthTech Report, a reflection on our achievements within the digital health space over the past year, coupled with an exciting glimpse into our plans for the upcoming year and beyond.

2023 began with a remarkable milestone in January – the largest and most successful DTx Startup Congress to date. This event served as a catalyst, uniting Europe's healthtech startup ecosystem, industry experts, and policymakers through engaging panel discussions and networking possibilities. We delved into the future of DTx in Europe, exploring topics ranging from health data access, to reimbursement schemes, and the role of artificial intelligence in shaping a more digital health-friendly Europe.

During the event, we proudly announced the winners of the EU Patient Digital Health Awards, a collaboration aimed at identifying and celebrating Europe's most patient-centric innovations. Chosen from a pool of 17 semifinalist projects, three outstanding startups were recognised for their remarkable contributions to the field.

On the policy front, our focus extended to the European Health Data Space and the Medical Device Regulation, with active engagement around these legislative files. Recognising the importance of harmonising policies across the EU, we've conducted Fitness Checks in Germany, France, and Spain, offering insights into the regulatory healthtech landscape within

each nation. Additionally, we provided policymakers with recommendations to promote a patient-centric and technologically advanced union.

As we enter 2024, we are celebrating the fifth anniversary of the AFS HealthTech Project, rebranding from AFS DTx to AFS HealthTech. This transition underscores our commitment to inclusion and innovation, aiming to represent a broader spectrum of healthtech startups. Moreover, our anticipation grows for the upcoming EU Elections, as we join forces with other digital health players to craft the HealthTech Manifesto, an initiative geared towards revolutionising healthcare through patient-centric innovation.

The coming year holds promise for impactful collaborations, active engagement, and dedicated support for startups. As the digital transformation of healthcare advances at such an unprecedented pace, we remain eager to ensure that the voices of digital health startups echo widely at the policy table, and extend our gratitude for your unwavering support. Here's to a year filled with innovation, growth, and meaningful impact!

**Founder & CEO of Allied  
For Startups,**

A handwritten signature in blue ink that reads "Melissa Blaustein".

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# 01 About Allied for Startups HealthTech

Established in 2019, [Allied for Startups HealthTech](#) unites digital health startups, policymakers, and various healthcare stakeholders to bolster the regulatory landscape and foster innovation within the global healthcare ecosystem. While startups seek to bridge the disparities in traditional healthcare, they frequently encounter regulatory hurdles, and unlike larger players, startups typically possess limited resources for navigating complex and fragmented processes. As the digitisation of healthcare progresses at an unprecedented pace, we bring the voice of digital health startups to policy-making.

## Our Mission



Ensure that policy empowers digital health startups to scale



Facilitate and enhance cooperation among startups, policy makers, and key health stakeholders



Lead policy dialogues around digital health from a startup lens



Establish a European-wide network of startup champions and supporters to share best practices and discuss challenges

## What we do



Bring startup perspectives to the decision-making table



Create opportunities for startups to engage with policymakers and key healthcare stakeholders

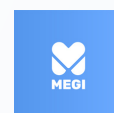
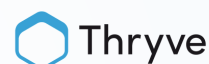


Collaborate with the DTx Network to promote advocacy, research and opinion on digital health

## Ecosystem Partners



## Member Organisations





## 02 2023 in Review

### HealthTech Rebrand

This upcoming year, we are thrilled to be celebrating the fifth anniversary of the AFS HealthTech Project. Over the past half-decade, this initiative has witnessed remarkable growth and has seen a rich array of startups being embraced under its umbrella. Consequently, to better align with this evolving landscape and more accurately represent the diversity of health technologies now supported, we are delighted to announce our rebranding from the DTx to the HealthTech Project. This new name embodies our commitment to encompassing a broader array of innovative health technologies and reflects our mission to champion startups at the forefront of healthcare innovation. We are excited to embark on this fresh chapter and look forward to continued collaboration and progress within the dynamic field of health technology.

### The HealthTech Charter: Fitness Checks ✓

The HealthTech Charter provides an opportunity to shape the EU into a hub for digital health scale-ups and creates benchmarks to inform policy makers what innovators need to succeed.



Recognising that healthcare remains a primary competence of individual EU Member States, it is key to maximise the alignment and harmonisation in both national and European policies. In pursuit of this objective, AFS is zooming in at the Member State level, conducting Fitness Checks to assess the regulatory healthtech landscape within each nation.



## Fitness Checks ✓

# France: Tele-chic innovation with ETAPES

The empowerment of healthtech innovators in France lies in the **establishment of a transparent and all-encompassing regulatory framework for reimbursement**, extending beyond just telemedicine operators. The ETAPES programme has played a pivotal role in introducing a sandbox for public procurement in telehealth solutions. This initiative aims to **empower patients by enabling them to access reimbursable telemedicine services**, creating a viable pathway for telehealth entrepreneurs to gain reimbursement for their innovative solutions, and providing regulators with essential data demonstrating the advantages of implementing a dedicated framework for telehealth reimbursement within the French healthcare system.



## Fitness Checks ✓

# Germany: Pioneering DTx solutions through DiGA

Germany's commitment to the digitalisation in health paves the way for the accelerated adoption of digital therapeutics across Europe. **The German Digital Health Care Law (DiGA) allows doctors to prescribe approved digital health apps to patients, enabling entrepreneurs to be reimbursed by statutory health insurance, streamlining reimbursement and providing a predictable entry route for digital health startups.** Additionally, regulations were introduced to facilitate access and use of health data, including the Health Data Use Act, the Research Data Act, and the Register Act, aiming to centralise data access for research and enhance data quality. Germany is also transitioning from an opt-in to an opt-out approach for the **Electronic Patient Record (ePA)** program to increase data availability while safeguarding patients' rights and privacy, although implementation faces challenges related to data privacy and clinician scepticism.



## Fitness Checks ✓

# Spain: Charting a course for European innovation leadership

Healthtech innovation in Spain has recently experienced a significant surge, yet several challenges remain as we look ahead. Crafting regulations with the specific needs of startups in mind holds the potential to not only enhance the innovation landscape in Spain but also propel Europe into a central hub for digital health scale-ups. **Empowering healthtech entrepreneurs in Spain rests on the development of a robust telemedicine framework, intricately linked with a well-defined reimbursement pathway.** Given the widespread adoption of telehealth services during the pandemic, we eagerly anticipate the establishment of permanent regulations for these transformative solutions, both within Spain and on a broader European scale.



# The HealthTech Congress

The [HealthTech Startup Congress](#) seeks to unite digital health startups, healthcare stakeholders, and policymakers on a global scale to harmonise entrepreneurial perspectives in healthtech policymaking and governance. The 2023 Congress, held in Brussels, featured an array of roundtable and panel discussions, startup exhibitions, and networking opportunities.

This event provided a platform for dialogue surrounding the prospects and obstacles in the realm of future healthtech innovation, both within Europe and worldwide. This annual gathering not only serves as an opportunity to spotlight the initiatives of the AFS healthtech project but also extends an invitation to our healthtech network and partners in Brussels.

## Panel I: Compare and Contrast - Digital Health Ecosystems Across Europe

This roundtable discussion brought together entrepreneurs and ecosystem players to compare & contrast the current state of digital health innovation in Member States and across the Bloc. From health data access, reimbursement schemes, to artificial intelligence in health - where are we now, and how do we transition towards a more digital health friendly Europe?

### Our speakers:



**MEP Tomislav Sokol**  
European Parliament



**Fulvia Raffaelli**  
European Commission



**Dominik Haller**  
derma2go



**Agata Hidalgo**  
France Digitale



**Vincent Keunen**  
Andaman7

## Panel I: A European Health Data Space Fit for Startups

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. The EHDS provides the opportunity to introduce common standards to facilitate an environment that empowers startups and other digital health communities - but how can we ensure the EHDS fulfils its promise for startups?

### Our speakers:



**Dimitar Georgiev**  
Paralax Life Sciences



**Milla Marinova**  
R8ER



**Marion Cassiau**  
Implicity



**Andy Bleaden**  
ECHAlliance

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## HealthTech Policy

### The European Health Data Space

As part of its European Strategy on Data, the European Commission put forward a regulation proposal for the European Health Data Space (EHDS) on 3 May 2022. As a key pillar of a European Health Union, the EHDS aims to provide European citizens control of their health data across borders and facilitate the uptake of the re-use of health data for research, innovation and policy-making. The EHDS promises to become an ecosystem of common standards and governance frameworks.

## Our engagement around EHDS

- Public campaigns
- Blogposts
- Global Startup Association Open Letters
- Participation and consultation in the European Commission's eHealth Stakeholder Group
- Bilateral meetings with Members of the European Parliament
- A dedicated panel discussion with the EHDS Co-Rapporteur MEP Tomislav Sokol and DG SANTE's Head of Unit for Digital Health Fulvia Raffaelli (European Commission).

## The Medical Device Regulation

In an effort to establish a robust regulatory framework ensuring safety and innovation, the EU Medical Device Regulation (MDR) replaced the Medical Devices Directive (MDD) and the Active Implantable Medical Devices Directive (AIMDD) on 26 May 2021. This change aimed to modernise safety and performance requirements while creating consistent certification standards across the EU. However, certification delays and capacity issues in notified bodies raised concerns about shortages of medical devices in the EU market. To address this, the European Commission amended the MDR's transitional provisions with Regulation (EU) 2023/607, extending deadlines for high-risk devices to comply by the end of 2027 and medium and lower-risk devices to the end of 2028, allowing more time for recertification.

## Our engagement around MDR

- Global Startup Association Open Letters
- Participation and consultation in the European Commission's eHealth Stakeholder Group
- Public campaigns
- Blogposts

 **Check out our [blog](#)**



## 03 A Glimpse Into 2024

In the upcoming year, our anticipation is centered around the EU Elections, which offer a significant opportunity for the European Union and its policymakers to shift their attention towards the much-needed digitalisation of healthcare. In partnership with fellow digital health stakeholders, we have crafted a HealthTech Manifesto that will make its debut on your screens very soon. Through this initiative, in the coming months, we will be advocating for a resilient and innovation-centric approach to shaping the digital health strategy that will ultimately improve access, quality, and continuity of care offered to all European citizens.

We would like to express our appreciation to all entrepreneurs, partners, and policy makers who have significantly contributed to a productive year within the digital health startup ecosystem. Thanks to you, the Allied for Startups HealthTech community has evolved into a dynamic global network with a steadfast commitment to fostering a unified voice for startups in the realm of policy and government across the globe.

We will continue our advocacy efforts to make sure 2024 is filled with even more promising collaborations, active engagement, and unwavering support for startups. As the digital transformation of healthcare continues to advance, we remain dedicated to ensuring that the voices of digital health startups resonate in policy-making.

Until next year!

The Allied For Startups Team

Don't hesitate to reach out by dropping us a line at [healthtech@alliedforstartups.org](mailto:healthtech@alliedforstartups.org).

# Subscribe to our **HealthTech Newsletter**

Want to stay up to date with the latest European policy developments for digital health startups? We've got you covered!

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