Setting benchmarks to empower digital health innovation in Europe
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Executive Summary

Life-changing digital health innovations continue to pierce the European market, driving the digital revolution of health and care. Spotlighted by the Covid-19 pandemic, we’re seeing an unprecedented potential for what digital health innovation has to offer.

However, entrepreneurs continue to navigate what has been coined a ‘complex and fragmented’ European health policy landscape. Innovators face regulatory hurdles that oftentimes stifle innovation. In building a stronger Health Union, we ask policymakers to consider startup perspectives to ensure innovators feel empowered to bring transformative innovations to the market. Allied for Startups has therefore partnered up with leading innovators and key healthcare stakeholders across Europe to construct The HealthTech Charter.

Introduction

Digital health provides the unique opportunity to address some of society’s largest challenges. Through data-based treatment decisions, empowered patients and providers, and lower overall costs – the digital health revolution is rapidly expanding across the medical field.

Covid-19 has drastically accelerated the uptake of digital tools in health, revolutionizing access to care in times of social distancing. The third quarter of 2021 has seen a record increase in global health innovation funding - with $9.7B raised, this year’s total funding has just surpassed $30B, which is significantly higher than any previous full year on record. These numbers exemplify the steep growth and visibility of the health innovation sector.

However, all too often digital health innovators invest time and resources navigating complex regulatory measures across Europe. This, in turn, hinders digital health solutions from reaching their full potential. We believe the startup founders should be preoccupied only with what they do best – innovating. We urge policy makers and governments to adopt similar practices that eases the process of innovating and scaling across Europe.

With the COVID-19 pandemic placing a spotlight on digital health, this standard provides an opportunity to shape Europe into a hub for digital health scale-ups. Sharing best-in-class policies will not only improve individual ecosystems, it will also smoothen the pathway for a digital health startup that is successful in one country to be successful in the whole of Europe.
# The best practices

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The digital revolution of health has gained extraordinary momentum across European borders, redefining traditional methods of delivering care. Digital health solutions provide a myriad of benefits in terms of improving patient outcomes, reducing healthcare costs and transforming patient care through innovative technologies. However, a key barrier to the wider adoption of digital therapies and telehealth solutions is the lack of standardised pathways to reimbursement and prescription across European healthcare systems – where publicly-funded health systems are the norm. Digital health entrepreneurs often have to navigate complicated funding pathways at the national, regional, local or even hospital level – and in some cases, reimbursement is not possible at all.

Best practices

Germany

The German Digital Health Care Law (DiGA) paves a way for digital health applications to be prescribed and reimbursed within the German public health system. The law allows doctors to prescribe approved digital health apps to their patients, just as they prescribe medications today, and simultaneously allows entrepreneurs to be reimbursed by statutory health insurance for their applications. The DiGA offers a straightforward pathway to patients worldwide, as the inclusion of an app on the DiGA Directory equates to the prescription and reimbursement of this tool in the German market.

Belgium

The mHealthBelgium platform aims to integrate mobile health applications into the Belgian healthcare system with the overall goal of fostering affordable and better care and enabling validated health apps to be reimbursed by the Belgian Social Security. This public–private initiative classifies CE-marked health applications according to a three-tiered system that centralises information on digital health apps for patients, healthcare professionals and healthcare institutions to access on one single platform.
Longer development cycles, rigorous safety testing, and extensive R&D require our company and our investors to be confident that there is a substantially mature market for the final product. That’s where we see tremendous value in the potential of DiGA and similar initiatives in France and across the EU to create this needed confidence. A predictable set of rules on market entry and a transparent reimbursement mechanism, combined with growing market demand for digital health, currently allows us to work on a new, more ambitious product offering designed from the ground up to be used as a prescription-only solution.

From a financial perspective, DiGA and similar initiatives enable pharmaceutical level pricing and a reduction in payment friction, making it viable to address some of the rarer health conditions that would not be feasible in the conventional app economy. We at Velmio are especially motivated by this opportunity to utilise our unique technology in digital therapeutics for underserved women’s health and chronic health conditions. Increased user trust enabled by CE marking and clinical validation requirements of the apps distributed with DiGA approval can drive further adoption and growth benefits.

In a sense, what we see in the current implementation of the DiGA directory is a glimpse of the possible future of the app market for medical apps. The biggest challenge to DiGA, in our opinion, is discoverability. Both Google Play and App Store have dedicated sections for medical apps, yet the boundary between general-purpose wellness apps and medical apps is not well-defined. If you open a supposedly “medical” section of the App Store, you can easily find apps spreading harmful medical advice, propagating misinformation, and selling health data to marketing brokers. This erodes trust in the general concept of digital health. Imagine the benefits to safety and adoption if only the approved clinically validated solutions were displayed in front of the millions of users already in those stores. Combine that with increased use of similar regulations across the EU, and we would have a way of creating a new European medical app economy.

“\textit{What we see in the current implementation of the DiGA directory is a glimpse of the possible future of the app market for medical apps.}”
Since the Covid-19 pandemic, mental health has become a world crisis. Public and private stakeholders should ally in order to build bridges and design a more scalable, efficient and accessible way of helping patients. We believe the answer to the increasing demand only can come from the advantages that innovation and technology can bring.

From a Psious perspective, the main challenge digital health startups face today is the business model definition.

A federated Go-To-Market path for digital health solutions would help startups in their journey. The main points in this route would be a clear regulatory framework and a determined strategy for public systems to purchase or implement digital health solutions.

Most European countries have a public healthcare system. Access to these systems to validate a digital health solution is usually through non-paid pilots. In a large number of cases, this validation has already been conducted. On top of that, these pilots do not lead to a clear deployment of the solution where the startups or company will generate revenues from it. Startups encounter significant barriers to really define a clear business model to bring a product to the market.

The payment and reimbursement path is essential for companies to really scale, become world leaders, and reach patients at scale.

What we have seen is models such as the DiGA in Germany or the reimbursement system in the US can really make an impact in bringing a digital health solution to the market. The DiGA framework in Germany is a good structure for digital health companies to follow after the development phase. The main points of DiGA are the GKV reimbursement, a directory of certified medical devices processed transparently. In the US there is a clear roadmap to reimbursement whether this is through already existing CPT codes or generating new codes. In our opinion, both models can be and should be very good examples of how Europe should unify processes to ensure long term future for companies in the space.
Comunicare Case Study

Seraing, Belgium

A mobile companion for patients to provide data analytics to care providers in the context chronic diseases.

The mHealthBelgium platform is a federal initiative launched in 2019 with the aim of integrating mobile health apps with proven benefits in the Belgian healthcare system. The platform’s validation model is currently a pyramid of three levels that define comprehensive steps for software providers to demonstrate the quality, the safety and the benefit of their mHealth apps. The ultimate goal of this process is to foster affordable and better care by enabling validated apps to be reimbursed by the Belgian Social Security (e.g. INAMI/RIZIV).

Comunicare is one of the pioneers in this mHealthBelgium validation process. The company managed to reach the first and the second level right after these were made available for submission. The requirements of the platform followed a logical sequence of steps that Comunicare had already planned within its development milestones making it a streamlined process. This type of regulatory tool is key to building trust from users and the public, and puts the spotlight on relevant solutions paving the way for more personalised, predictive, participatory and preventive healthcare.

However, companies in the mHealth market are still facing different nascent regulations and reimbursement schemes in European countries (e.g. DiGA in Germany, LPPR list in France, DTAC in UK, etc.), the diversity of which generates strong barriers to innovation. We plead for the establishment of European standards and regulations to facilitate these processes, boost European eHealth innovation and generate expected benefits for patients.

"This type of regulatory tool is key to building trust from users and the public, and puts the spotlight on relevant solutions paving the way for more personalised, predictive, participatory and preventive healthcare"
Access to Secondary Health Data

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. However, the lack of common standards across Europe and diverging national regulations often makes accessing secondary health data extremely complex. This, in turn, prevents digital health technologies and solutions from reaching their full potential.

In its 2021 Work Programme, the European Commission announced its intention to reduce regulatory fragmentation and introduce common standards to facilitate an environment that empowers startups and other digital health innovators to scale. The development of European Health Data Space serves as a platform where data can be shared operationally with the full protection of citizens’ interests and rights while promoting research and innovation through secondary use of health data.

Best practices

Finland

The Finnish Act on Secondary Use of Health and Social Data (2019) provides a GDPR-compliant legal basis for health data processing and access, including for research and innovation in the health sector. This facilitates the secure and effective access to social and health data which streamlines developments in health research. The country is home to initiatives like FinnGen, a personalised medicine research project combining genome information with digital health care data.

Why is access to data important?

Data replaces guess work. It empowers researchers, patients, and clinicians to make informed decisions based on real-world cases.
eHealth Services and Interoperability

Overcoming much of the fragmentation of the eHealth market in Europe lies in fostering the adoption of interoperable solutions. This ensures that different eHealth systems can exchange information seamlessly within and between countries. In addition to providing physicians with a complete view of their patients, health data interoperability provides stakeholders across the care continuum with insights into demand for services, utilisation rates, population trends, and more. Access to fully interoperable, robust datasets also drives faster, more informed health research and innovation.

Enabling cross border e-prescriptions and exchange of Electronic Health Records across the EU would significantly improve the environment for health innovation. The adoption of Electronic Health Records (EHR) is key to the digitisation of healthcare services. Secure data sharing for patients and health care providers contributes to more effective and timely diagnosis, reliable prescribing and improved productivity. However, too often EHRs systems lack interoperability: data cannot be shared with other health care providers or lacks easy access for patients themselves. In 2019, the European Commission proposed a common European Electronic Health Record exchange format that would allow citizens to access and exchange their health data wherever they are in the EU – it is yet to be implemented by most EU Member States.

Electronic prescribing increases the safety, efficiency and transparency of prescribing practices. During the COVID–19 pandemic, the importance of e–Prescription systems has become evident as it enables doctors to easily prescribe the necessary medication to their patients during online consultations. While many EU countries are transitioning to e–Prescribing, some lack nationwide interoperability between prescribers and pharmacies. Lack of cross–border interoperability is especially apparent: as of early 2021, citizens from only 4 EU Member States can retrieve e–Prescriptions in at least two other EU countries (Electronic cross–border health services).

Best practices
Estonia

Estonia’s eHealth services include a fully interoperable, centrally–stored EHR system, covering all its citizens. Patients have electronic access to their medical records, referrals, and certificates and can easily and securely share them with any healthcare worker or institution. The country’s e–Prescription infrastructure ensures the retrieval of electronic prescriptions in all pharmacies, and any medical subsidy is accounted for automatically. Estonia is one of the 4 EU Member States that have joined the cross–border ePrescription service.
Artificial Intelligence in Health

Artificial intelligence has become a key technology in the digitalisation of health – transforming the delivery of care, expanding precision medicine and improving overall patient experience. As a defining technology of the future, AI has the opportunity to transform health systems into being proactive, predictive, and preventative. However, questions around scaling the use of AI in health have been largely debated in recent years – particularly on ethics, use of personal data and AI-related risks. Such debates have contributed to a heavily regulated framework that rigorously addresses the safety and clinical performance of digital health products in Europe. Although standards of regulation and certification are key, the regulatory complexity has presented itself as an enormous challenge for digital health and AI innovators, curbing the potential of the European AI and digital health market.

Best practices AI4Health.Cro

The European Commission’s Digital Innovation Hubs (EDIH) aims to foster the growth and success of digital companies by providing the necessary space for experimentation, testing, funding, and technical expertise. EDIH empowers digital health entrepreneurs with a sandbox to ‘test before investing,’ and stimulate the European uptake of artificial intelligence, among other areas, in health. Croatia’s AI4Health public-private consortium is a national candidate for EDIH and provides a platform for AI startups in health to test, learn, collaborate and fund their innovations, paving the way for MDR compliant, trustworth AI technologies to come to the market.

The Potential for AI in Health

Research & genomics, early detection, diagnosis, decision making, training – the potential is still untapped
Megi Case Study

Krapinske Toplice, Croatia

An AI digital health assistant for monitoring of chronic patients

The Medical Device Regulation (MDR), as a new set of regulation that more rigorously addresses the safety and clinical performance of digital products the same way as a new drug or hardware device, builds clinical credibility and necessary trust for healthcare providers to adopt the solution in their clinical practice. On the other hand, it is an enormous challenge for startups and innovators, and it could additionally slow down the European AI and digital health market, which already lags behind the US and China.

Learning from the example of the highly entrepreneurial Magdalena Clinic, which collaborates with AI experts and tech companies to build and test innovative digital health products, we wanted to scale up and further develop this concept. Coordinated by the Ruđer Bošković Institute, together with the Croatian AI association, we formed a consortium that brings together the key stakeholders (healthcare providers, technology companies, researchers, Croatian Healthcare Fund and Ministry of Health) and provides the pipeline that facilitates safe yet efficient adoption of AI innovation in the healthcare system.

EDIH’s mission is to select the most promising European AI solutions for digital health, provide all the necessary infrastructure and know-how for co-development, testing and funding, lowering the risk and accelerating the process of MDR, clinical roll-out and commercialization.

Healthcare is a highly conservative and change-averse industry, as with every change, it absorbs the risk of human lives. Therefore, we shouldn’t go against that process, but leverage the super-regulated European market, that has the best defined medical software regulation in the world, and a huge scientific and innovator community. Opportunities, such as AI4Health.Cro, are fundamental in bringing clinicians and innovators together, enabling lean development, evaluating clinical relevance and safety and implementing compliance with MDR expectations of new technologies early in their development. We strongly believe such hubs will enable the European Union to pave the way towards trustworthy digital healthcare and long term sustainability of healthcare worldwide.
The demand for telemedicine services reached an unprecedented peak during the Covid-19 pandemic. Tele-health solutions, such as online consultations or telemonitoring, enabled medical care to be provided remotely during times where access to services were limited. Entrepreneurs continue to develop telemedicine services that offer speedy, innovative, and flexible solutions to people all around the world. The availability of these digital solutions on a mobile phone, watch, or laptop contributes to the democratisation of healthcare and a step closer to making universal access to care a reality. However, the lack of clear frameworks, reimbursements and incentives creates barriers to wider telemedicine adoption in Europe.

Best practices
France

One of the first countries to adopt a dedicated legal framework for telemedicine (2018), which was amended in 2020 to furtherly reduce barriers. The law provides clear rules for online consultations, including diagnosis, follow-up, telemonitoring, prescriptions and tele-expertise. Moreover, it introduced reimbursements at par with physical visits. Doctors are incentivized to use telemedicine solutions: an annual payment of 350€ is provided to cover related costs such as computer equipment or subscription fees.

Check out our Telemedicine in Europe Report, where telemedicine startup founders and representatives from across Europe share the impact of COVID-19 on their business, and the barriers and challenges the sector is facing.
Public-Private Partnerships

Technological and scientific advances offer new opportunities to solve the health challenges of our times. Bridging the gap to address today’s health and translational challenges will require interdisciplinary public–private partnerships (PPP). PPPs have gained widespread acceptance as a strategy to achieve global health objectives. Cooperation between digital health innovators, healthcare providers, public institutions and patient groups is important in fostering innovation in healthcare. Combining the innovative potential of digital health initiatives with the public sector’s reach and private sector’s resources, can secure better health outcomes, increase healthcare systems’ capacity, and drive the digital transformation.

Best practices

Denmark

Denmark has a long history of public–private collaboration in healthcare. Private donations are made to innovation centers, research units and hospitals, while life science industries play an active role in developing innovative digital healthcare solutions. For example, multiple Danish municipalities invested in a digital platform developed by scale-up Liva Healthcare to provide their residents with access to a personal health coach. Herlev hospital and local authorities are collaborating with startup Qlife to trial a technology for home monitoring of kidney cancer patients. Denmark leads Europe in clinical trials per capita, and patient organisations play an active role in cooperation and decision-making.
Accelerators and Grants

Digital health accelerators play a pivotal role in the development of innovative technologies. Accelerators offer early-stage companies support to grow and scale their innovations through mentorship, education and financing. Startups take part in an accelerator for a fixed-period of time and are equipped with rapid, immersive support aimed at accelerating the potential of their company - compressing what would normally be years of education into months of learning-by-doing. With the right combination of funding, mentorship, and networking, accelerators can propel young startups and their innovations to be successful in the market.

Digital health innovators require financial backing to progress an idea into a marketable product. From research, growing a team, and operating costs, the importance of funding is crucial for the success of a startup and innovation. Creating more opportunities for accessing financial grants at the European and national level is key to the future of digital health innovation in Europe.

Best practices
United Kingdom

The NHS Innovation Accelerator (NIA) aims to boost the uptake of promising health innovations across the UK. This Accelerator places a unique focus on both the development of the innovation and growth of the entrepreneur. Innovators are empowered through education, mentorship and networking opportunities to equip them with the critical knowledge, relationships and skills to scale and succeed. Accelerators such as the NIA grant early-stage digital health startups a fast-track into the market - allowing life-changing innovations to be accessed by patients and providers, many of which may not have been able to make the same impact without the tools attained within the accelerator.

Best practices
Horizon 2020 & Horizon Europe

With nearly €80 billion in funding, Horizon 2020 was the biggest financial instrument of the European Union’s research and innovation funding programme between 2014 – 2020. It aimed to foster breakthroughs, discoveries and world-firsts by funding ideas from the lab to the market. Horizon Europe replaced H2020 in January 2021, increasing the budget to €95.5 billion - aiming to tackle climate change, achieve the UN’s Sustainable Development Goals, and boost the EU’s competitiveness and growth. Successfully securing funding from this program can be an incredible boost and push forward for digital health innovation. However, Horizon Europe grants are known to be highly prestigious and competitive - navigating application procedures are complex.
One key program helped us identify our potential, share our insights, and scale: the NHS Innovation Accelerator (‘NIA’). The NIA is an award-winning NHS England initiative, delivered in partnership with all 15 Academic Health Science Networks and hosted at UCLPartners. The NIA was created to deliver on the commitment detailed within the Five Year Forward View and more recently highlighted within the NHS Long Term Plan – helping to create the conditions and cultural change necessary for proven innovations to be adopted faster and more systematically through the NHS, and to deliver examples into practice for demonstrable patient and population benefit.

The NIA is designed to both speed up this process and also to learn from the experiences of Fellows participating in the Accelerator so that others can benefit from the knowledge generated. Bespoke support is delivered predominantly through the following mechanisms:

- Peer to peer support from the NIA Fellows
- Access to a bursary of up to £20,000 that can be used to support the scaling of your innovation and for travel and subsistence for your participation at NIA events.

Specifically, the access to a £20,000 bursary supported the design and launch of our What Patients Think Report in 2020, where we identify trends and variation across all NHS Trusts in England. This report enabled us to articulate to a national audience the power of our data and provided a platform for commercial engagement at several levels of the NHS and beyond that would have been difficult if impossible to reach beforehand. The report also validated our technology, generating wide reaching interest and commercial contracts across the NHS and beyond.

"The NIA... is helping to create the conditions and cultural change necessary for proven innovations to be adopted faster and more systematically through the NHS"
As a startup founded by the family of a patient, motivated by the frustration about the lack of solutions for low vision related mobility problems, we had to overcome many unfamiliar challenges, such as medical regulations, certification processes, reimbursement policies and raising funds. Thankfully, there are many extraordinary initiatives on the EU level, as well as on Spanish, Catalan, and even on municipality level, that support innovation and made it possible for Biel Glasses to grow to the point where we are at now.

Our most recent grant, the Tecniospring Industry Programme, co-financed by the H2020 Marie Sklodowska-Curie actions of the EU, is an international talent programme from the Government of Catalonia’s Agency for Business Competitiveness (ACCIÓ). The programme provides 100% funding to hire experienced researchers to develop a new technology and bring it to the market. The grant pays two years’ salary of the researcher. This is an example of a funding scheme that will help our company tremendously in the development of our product and its commercialisation. Without this grant, it would have been nearly impossible to hire senior researchers with this extent of experience for a small company like ours.

Although the many grants that we have received have helped us come a long way, there is still a clear need for improvement. We see an enormous bureaucratic hurdle when it comes to the application as well as the justification and reporting processes of EU grants.

To avoid corruption and be thorough in the selection process, many grants ask for long and complex proposals, to an extent that often overstains the capacities of young startups with limited resources. Often, it takes experienced consultants to navigate the platforms and formulate the answers in a way that satisfies evaluators. This needs to change if the goal is to foster innovation and not the consulting industry.

The other flaw we see is in justifications and reporting of grants. Often, the budgeting is rigid and requires an extensive level of detail. Startups often do not have the accounting expertise, and it creates the need to hire external accountants – this takes valuable funds and time away from innovating. We think, justification and reporting of grants need to be simplified and there needs to be more freedom to invest the funds according to business needs and adjust the budget afterwards.

To sum it up, Biel Glasses would have not come this far without the financial support of public institutions that foster innovation in the EU. There are a multitude of grants available for startups but accessing them often requires patients, time, and effort. The job is not done once the proposal was accepted and work that follows to justify the grant at the end of the project can come back and haunt you.
When Tired of Cancer (ToC), a Dutch company focusing on digital therapeutics in oncology was founded in 2013, the digital health landscape was still in a very early stage. Hardly any adaptation of digital care existed, let alone successful revenue models. However, visionaries saw that there would be a need for this cost-effective way of delivering care, in a world where the population is growing and aging. The demand for care at the patient’s home and self-direction would arise. Visionaries from governments and industry helped to initiate this new landscape. In the early years, ToC received several grants from the pharmaceutical industry (nonrestrictive) for the first development and first research.

Receiving a Horizon 2020 SME phase 2 subsidy (in 2017) was a real game-changer. The upside of such a grant is that it enables a company to invest, for example, in crucial research and in building a strong team. However, anyone who has ever worked with such a grant also knows; it can be a squeezing straitjacket that does not move with the changing insights you have as a startup. The challenge upfront lies in estimating in advance as best as possible what exactly the next few years will bring (and exactly when) and what exactly the plans and execution will look like.

Where, as a start-up, you need to have a certain degree of agility and that means that your scope and planning can change on the basis of progressive insight.

For example, when are you going to start? What is the best time? Deviating from the original plan is hardly possible, although with good communication and explaining there is at least some room for adjusting the original plan. So yes; we would like to see more of these stimulating European grants, and if possible also something with more eye on the changing world of digital healthcare.

Nowadays, a specific challenge for young startups in digital healthcare is meeting all the different regulatory and certification requirements. These are often FTE and financially intensive pathways. Both factors that are often rare in startups. However meeting regulation and certification requirements is indispensable for a successful digital startup. It would be helpful to have more grants to help young companies obtain regulation. And if we may dream; one applicable regulation in the EU would be a huge benefit and give the necessary development of digital healthcare a huge boost.
Conclusion

Digital health innovators continue to transform European healthcare systems by improving patient outcomes and enhancing clinical decision-making. However, the potential of digital health tools successfully entering European markets is often curtailed by having to navigate complex and fragmented regulatory frameworks. Building a stronger Health Union rests on creating inclusive policies that support entrepreneurs.

The HealthTech Charter compiles a set of 9 proven best practices that empower digital health innovators in their journeys of converting life-saving ideas into marketable products. It is an open consultation to consistently learn of what works according to entrepreneurs – but also a continuous conversation to set benchmarks and inform policy makers what innovators need to succeed.

Acknowledgements

We would like to thank the founding partners for their continued support in the development of The HealthTech Charter.
Interested in partnering and having a say in the future of digital health innovation?
Reach out to dt@alliedforstartups.org