# Towards harmonised EU Landscape for Digital Health:

## Summary of the roundtable discussions in selected EIT Health InnoStars countries

# Table of contents

# Introduction

## A new element of the European digital health

In 2019, the German Digital Healthcare Act *(Digitale Versorgung-Gesetz)* introduced a completely new approach to market access for reliable and safe digital health apps and platforms. The legislation aimed to separate digital health solutions with proven clinical benefits for patients from over 400 000 other health and wellness apps available on the market[1]. Since then, digital therapies have become a new form of medicine called *digital therapeutics (DTx)*. DTx can be prescribed by doctors and reimbursed by public payers.

Even though the evaluation process for digital health solutions already existed in other European countries, for example, Belgium and the UK, the regulatory framework adopted in Germany was considered as one of the most progressive.

## DiGA opened the door for digital therapeutics

New opportunities for digital health have begun in Europe. The "Fast-Track" pathway established market access for certain categories of digital health applications (DiGA) that meet the definition of lower-risk medical devices and are primarily used by patients rather than physicians. When such solutions meet requirements related to safety,

functionality, quality, data protection, data security, and interoperability, they are eligible for regulatory review and subsequent entry into a DiGA Directory maintained by the German Federal Agency for Drugs and Medical Devices *(Bundesinstitut für Arzneimittel und Medizinprodukte).* The positive care effects of a DTx can be demonstrated in two ways: in a 12-month 'fast-track' or if a developer delivers evidence, for example, clinical trial results. When all the criteria are met, the digital solution enters the healthcare system and can be reimbursed by all of Germany's statutory health insurers.

## Other European countries look to the same direction

The German fast-track system triggered interest in Europe. Already several European countries are considering similar frameworks to allow for the wide adoption of digital health solutions within their national healthcare systems. France is the most forthcoming – the DiGA-based model is expected to be launched in early 2023.

Meanwhile, the EU is advocating for the implementation of its Data Strategy. The last building block – the EU Data Act – was presented on 23 February 2022 and is expected to play a critical role in the digital transformation in line with the 2030 digital objectives. Another driver for DTx could be the

---

[1] https://www.economist.com/technology-quarterly/2022/05/02/apps-interpreting-data-from-wearable-devices-are-helping-people-to-live-better

European Health Data Space (EHDS)[2], which among others will give the developers better access to data needed to train algorithms applied in AI-driven health apps.

On the other hand, there are growing expectations from EU Member States to regulate the digital health market. The existing regulatory framework, covered by the Medical Devices Regulation (MDR), only partly addresses the challenges regarding adopting digital solutions in the healthcare market. For Europe to become an attractive and thriving market for digital health innovations and start-ups operating in this field, pan-European initiative and harmonisation are essential.

It must consider the differences in the EU Member States' healthcare systems, the existing digital legislation, and regulation regarding health technology assessment and gaps in digital (health) literacy. At stake is the future of European start-ups and the competitiveness of Europe in the global innovation market.

## DTx discussion in the EIT Health InnoStars countries and regions

**EIT Health InnoStars** is one of the nine geographical areas of EIT Health. It covers half of Europe, including Hungary, Italy, Poland and Portugal, and additional regions included in the EIT Regional Innovation Scheme –

Croatia, Czechia, Estonia, Greece, Latvia, Lithuania, Slovakia, Slovenia, and Romania.

We bring together 25 Core and Associate Partners from research, academia and business. Working with them, we focus on promoting entrepreneurship, innovation and education in the domain of healthcare, healthy living and active ageing. Also, we concentrate on closing the gap between regions that are leaders in innovation and those that are still progressing.

The purpose of the EIT Health **Regional Innovation Scheme** is to improve innovation capacity in countries which are considered emerging and modest innovators in Europe. By coordinating the scheme, we promote EIT and EIT Health opportunities, support the education of students, entrepreneurs and healthcare professionals and raise awareness of the innovations among citizens and patients. One of the main pillars is also the acceleration of early-stage ideas and support in business creation and technology transfer. Additionally, we aim to match and facilitate collaboration between healthcare innovators from emerging regions with the broader EIT Health network. We regularly organise expert discussions and events to exchange best practices and discuss the most pressing healthcare topics with pan-European relevance.

In 2022, among others, InnoStars organised six roundtable discussions about the directions of the development of digital therapeutics and possible reimbursement models. This report summarises key

---

[2] The European Commission's proposal for a Regulation on the European Health Data Space was published on 3 May 2022.

takeaways from discussions which took place in Italy, Estonia, Romania, Greece, Hungary and Portugal. EIT Health InnoStars organised them under the umbrella of Morning Health Talks.

# ITALY

" **The DTx round table promoted by EIT Health Italian Partners, in collaboration with InnoStars, has favoured an excellent opportunity for discussion with the main national public and private stakeholders. As InnoStars, we're glad to have contributed to suggesting possible next actions to be undertaken, with the main aim of promoting the development of new policies to support the use of digital therapeutics by NHS.**

*Chiara Maiorino, Ecosystem Lead for Italy, EIT Health InnoStars*

" **Creating value from healthcare data is the next challenge for digital innovation. The EIT Health Partners are aware of the role they might have in this scenario, favouring an alignment with EU indications and the initiatives promoted on the national landscape, leveraging the pillars of the knowledge triangle and patients' engagement.**

*Dr Marco Aiello, Medical Imaging Researcher at IRCCS Fondazione SDN, EIT Health InnoStars Supervisory Board Member*

## DTx landscape

Italian digital health plan has been recently introduced within the national strategic agenda for digital growth *(Strategia per la crescita Digitale)* and the national IT (Information Technology) three-year plan in the Public Administration *(Piano Triennale per l'informatica Nella Pubblica Amministrazione)*, indicating intervention actions dedicated to the digital health ecosystem and the main solutions aimed at improving health services, limiting waste and inefficiencies, improving the cost-quality ratio of health services, reducing gaps between territories.

However, this digital health plan, which includes some services like Single Health Record, Single Booking Center, and Health Card *(Fascicolo Sanitario Unico, Centro Unico di Prenotazione, Tessera Sanitaria)*, is still not defined enough and doesn't introduce any information about the use and implementation of digital therapeutics (DTx) in the Italian healthcare system (*Servizio Sanitario Nazionale, SSN*).

In order to understand the entire scenario and regulatory landscape, it's necessary to analyse different legal acts regarding digitalisation in general, data protection rules, and regional administrative-legal arrangements. Indeed,

each of the 20 regions individually defines and manages digital health implementation, leading to significant regional gaps and inconsistencies in regulations.

Several entities are discussing with the Italian Ministry of Health to contribute to developing an implementation policy for the use of DTx and, therefore, the definition of a reimbursement pathway for the national SSN. The most important and active on the matter (Fondazione Smith Kline, daVI Digital Medicine srl, Healthware Group as member of Digital Therapeutic Alliance, Agenas – Agezia, *Agenzia Nazionale per I Servizi Sanitari Regionali*) have successfully contributed to the EIT Health InnoStars Italian roundtable focused on discussion around DTx and promoted by EIT Health Italian Partners and InnoStars.

It's worth mentioning that, already in 2021, la Fondazione Smith Kline, in collaboration with a network of national experts, published an in-depth study dedicated to digital therapies and the possible beneficial use by the SSN *(Terapie digitali, un'opportunitià per l'Italia).* However, despite the insightful debate, the first cases of DTx, and some studies that have triggered the discussion about the use of DTxs in Italy, there are no DTx marketed, used or reimbursed to date.

## DTx market access

DTx in Italy are aligned with Regulation (EU) 2017/745 on medical devices. That means that DTx should provide evidence-based therapeutic interventions to prevent, manage or treat a medical disorder or disease. However, no specific authorisation and reimbursement regulations exist in this field. As a result, national DTx companies prefer to relocate to countries with a more favourable legislative landscape, further exacerbating the shortfall in innovation for health.

Those who want to offer DTx-related solutions on the national market must follow data protection and cybersecurity regulation – it's one of Europe's most restrictive regulated privacy frameworks grounded in the *Digital Administration Code (DAC).* The DAC deals with data security and other general and relevant aspects such as the rights of citizens and enterprises on public administration, rules for digital signatures and legal validity, contracts, payments and accounting deeds, and development, acquisition and reuse of software.

Due to existing data protection regulations that are stricter than the GDPR, data can hardly be processed without patient consent. This is another barrier for DTx to grow since their development requires access to data in order to ensure personalisation and improvements of their functionality.

A regulatory body that could be responsible for regulating DTx is the Italian Medicines Agency *(Agenzia Italiana del Farmaco, AIFA).* In February 2019, the Ministry of Health – in collaboration with AIFA, Agenas – the Italian Agency for Regional Healthcare Services and representatives of the regions – published the National Health Technology Assessment Plan for Medical Devices. However, it does not

cover mobile health applications or platforms that could be qualified as DTx.

During the COVID-19 pandemic, digital health technologies experienced a significant acceleration. Health and digital health are among the main pillars of the Italian Recovery Plan (PNRR), with a budget of €15.63BN. It aims to strengthen community-based prevention and care, guarantee equal access to treatment and healthcare services, and promote innovation and digitalisation within the Italian National Health Service.

## Recommendations for DTx use in favour of Italian SSN

Digital health, including DTx, represents an essential step in the management of chronic diseases also in light of the reform of proximity care that is intended to be implemented as part of the PNRR. Some recommendations formulated during the roundtable referred to general suggestions, such as:

- Strengthening awareness of the advantages of the use of DTx on the political level;
- Creating an enabling environment for the adoption of innovative solutions like DTx, informing citizens and training professionals working in the field;
- Promoting multi-stakeholders consultation and confrontation also involving trade and patient associations;
- Improving the overall level of the digital economy – Italy ranks 18th out of 27 EU Member States in the 2022 edition of the Digital Economy and Society Index (DESI);
- Reviewing existing data protection regulations that block the development of DTx.

**Experts representing Italian stakeholders gathered together during the EIT Health InnoStars Italian DTx round table and suggested to:**

- Start the discussion by clarifying the taxonomy related to DTx (differences among digital health, digital medicine and digital therapeutics), which is still poorly known by ordinary citizens and, unfortunately, by field professionals;
- Develop specific legislation for digital health based on solid scientific evidence;
- Design a new regulatory process, understanding the limitations of the few Randomised Clinical Trials (RCTs) that have included DTx, to overcome them and provide guidance on how to generate solid evidence for these tools as done for drugs (pharma and biotech therapies);
- Include DTx in the existing Health Technology Assessment (HTA) regulatory framework as a part of public health interventions;

- Include the digital health tools, and thus DTx, in the care pathways *(Percorsi Diagnostico-Terapeutici Assistenziali)*, defining the correct phases to insert such digital health tools, as well as the ways to implement this insertion;
- Engage with the patient along the whole development process of DTx, not just at the end of it as a mere end-user, guaranteeing correct digital literacy and thus reducing inequalities.

## Italian DTx examples

For the time being, Italy has no DTx marketed, used or reimbursed. However, there are different tools in a developmental phase, for example:

- DTx to treat Chronic Insomnia, developed by daVi Digital Medicine srl, in collaboration with Cloud-R, Milan and the University of Verona. This tool, which is still in the research phase, is a digital application with the purpose of Digital Therapeutic, in association or combination with a drug or dietary supplement based on melatonin, for the treatment of chronic insomnia;
- DTx to treat Arterial Hypertension, developed by daVi Digital Medicine srl, in collaboration with Polifarma Spa. This tool, which is still in the research phase, is an application for Digital Self-Management, Education & Support DSMES, in association or combination with an antihypertensive drug, in order to enable better management of arterial hypertension;
- AuReha, developed by DigitalRehab Ltd.: a Digital Therapeutic Device for neuromotor rehabilitation, will make possible innovative models of remote rehabilitation, where it will no longer be necessary for the patient to reach the rehabilitation centre to access therapy with the required continuity.

Many other digital solutions proposed by innovative Italian start-ups might be listed among DTx; however, the knowledge about these technologies and the distinction with the other medical devices is still needs improvements. Therefore, it is difficult to indicate which digital solutions will be counted as DTx in the near future.

Even if it's not a digital therapeutic tool, it's also important to mention the training course for "Patient Expert in Digital Technologies for Health." Promoted by *UnitelmaSapienza* in cooperation with the EUPATI programme (supported by EIT Health) and Fondazione Smith Kline, the course aims to encourage the development of patients' experts in digital technologies for health in Italy, with the final goal of improving – through the contribution of the patient expert in digital therapy – the quality of the technology offered to the patient, to lead their life in the best possible health state.

**References:**

Outcomes of the EIT Health InnoStars DTx roundtable with Partners and stakeholders from Italy
https://www.unitelmasapienza.it/paziente-esperto-in-tecnologie-digitali-per-la-salute/
https://pianotriennale-ict.italia.it/
https://www.agid.gov.it/sites/default/files/repository_files/documentazione/strategia_crescita_digitale_ver_def_21062016.pdf
https://iclg.com/practice-areas/digital-health-laws-and-regulations/italy
https://www.sciencedirect.com/science/article/pii/S0168851021000750
https://www.tendenzenuove.it/2021/07/29/digital-therapeutics-hta-and-reimbursement-in-italy/
http://www.passonieditore.it/doi/tendenze/2021/numerospeciale04/TendenzeNuoveNS04202107.pdf
https://www.tendenzenuove.it/2021/07/29/digital-therapeutics-hta-and-reimbursement-in-italy/

# ESTONIA

**"**

**The webinar provided very practical, thorough and revealing overviews by the experts who presented innovation initiatives in hospitals both in Estonia and Finland and specifically, described the development of Finnish social and healthcare innovation activities at Oulu University Hospital. I think that Oulu is a bit ahead of us as an innovation ecosystem. I really liked the good examples and initiatives provided that we can also learn from. The detailed insight into the ongoing Health and Social Care reform in Finland was very intriguing and so was the overview of the current trends and challenges of healthcare innovation in Sweden.**

*Liis Kruus, Estonian Health Insurance Fund*

## Digital health landscape

Although Estonia is ranked among European digital health leaders, clear regulations regarding DTx are not in place. Thus, similarly to many other EU Member States, general, EU-wide rules for medical devices apply. If the solution is a medical device according to the MDR or In-Vitro Medical Regulation (IVDR), it can be marketed in the EU and also in Estonia after the evaluation and receiving a CE mark.

However, the process doesn't cover the complexity of digital health solutions.

There are first initiatives aiming at creating a regulatory framework that will harness the potential of DTx. For example, in 2020, the Estonian Health Insurance Fund *(Eesti Heigekassa, EHIF)* launched a pilot programme in which four telemedicine solutions were selected to be reimbursed. The solutions had to meet MDR-related technical requirements

and undergo a validation process that involved assessing the economic, clinical and usability features. The developers of selected solutions should submit the required studies and evidence by the end of 2022. Based on this, EHIF will decide if the funding continues and on what terms.

The EHIF project aims to support the development, early implementation, and healthcare impact assessment of new integrated service models. Even though it's focused on remote solutions enabling better access to care, it's the first of this kind of initiative that could result in developing a DTx evaluation and implementation blueprint for evidence-based and reimbursable digital health applications. Especially since EHIF already covers the use of digital health solutions addressed to healthcare professionals. For example, drug-drug interaction solutions and Evidence-Based Medicine Electronic Decision Support.

## DTx market access

This vague regulation hampers the uptake of high-quality digital health solutions, often carefully created in cooperation with health providers. But it could change since recently, EHIF announced a national reimbursement scheme that is currently under development. According to the first draft, digital health developers must specify their business model by answering three key questions:

- Does the solution exchange data with the national healthcare database?
- Is the solution a medical device following the MDR?
- Should the solutions be reimbursable by EHIF?

For EHIF, the critical will be the evidence for the DTx. Besides, in 2019, EHIF established the so-called Innovation Fund to accelerate the development of novel digital health solutions. Furthermore, EHIF wants to provide funding for impact assessment studies for digital health developers. All these initiatives demonstrate that the regulatory framework for the DTx is in the process of being slowly established. The change is also expected by society, which already can benefit from many other e-government services. One of the advantages of DTx for the Estonian healthcare system would be the improvements in the continuity of care and the possibility of measuring the outcomes of digitally-enabled therapies.

## Recommendations for DTx use in the Estonian healthcare system

- Creating a pan-European health technology assessment (HTA) scheme to avoid re-evaluation of DTx in the EU Member States with two separate paths: economic impact and clinical evidence;
- Establishing a regulatory framework based on a consensus between health payers and digital health developers;

- Strengthening the governance of digital health innovations, so they enable the policy-makers to meet health-related priorities;
- Enabling citizens to have full control over their data to boost trust towards DTx;
- Educating societies on digital-related issues to improve digital (health) literacy;
- Introducing a digital health action plan so the digital health developers can create a business model that is aligned with the healthcare system's future evolution;
- Creating pathways for generating clinical and economic evidence of their digital health solutions. In addition, the new model should be affordable for DTx start-ups;
- Introducing a European/national CE-mark for digital health for trusted and safe DTx;
- Accelerating the development of the pathway initiated by EHIF.

**References:**

Outcomes of the EIT Health InnoStars DTx roundtable with stakeholders from Estonia
https://www.haigekassa.ee/en/partner/medical-institutions/telemedicine-pilot-projects
https://e-estonia.com/
https://www.bertelsmann-stiftung.de/de/unsere-projekte/der-digitale-patient/projektthemen/smarthealthsystems/estland

# ROMANIA

**It is very encouraging for all healthcare innovation stakeholders in our event to witness the opening of the authorities and the ability of Romanian start-ups to access advanced European markets, like Germany. These examples can become benchmarks that will encourage future innovators to build connections and augment their aspirations.**

*Ion-Gheorghe Petrovai, Co-Founder and Director of Innovation at FreshBlood HealthTech, EIT RIS Network Member*

## Digital health landscape

To understand the complex background of implementing digital health innovations in Romania, it is necessary to analyse the current state of Romanian healthcare. For years, it has been facing significant challenges, including underfunding, shortages of medical staff and corruption, among others. Public healthcare spending remains at one of the lowest levels in Europe (less than 5% of GDP).

Although the salaries of healthcare professionals have increased recently, the country is a major supplier of medical workers in European countries. Unfortunately, the healthcare infrastructure also remains underdeveloped. Many hospitals need urgent renovation and experience a chronic shortage of medical equipment. This is due not only to low health expenditures but also to the relatively low level of absorption of EU funds.

Also, the information and communication infrastructure is at a low level which is a roadblock to implementing digital health solutions. In the medical community, there is low awareness of the benefits of digitisation and even resistance, which stems from concerns about an inspection of work through access to electronic records.

Despite all the hurdles, Romanian healthcare is undergoing digital transformation. The rollout of the Health Electronic Record *(Dosarul Electronic de Sanatate)* started in 2013 and was initiated by the National Health Insurance House *(Casa Nationala de Asigurari de Sanatate, CNAS)*. CNAS manages the Health Insurance Information Platform, which consists of the integrated health information system, the national system of the social health insurance card, the national system of electronic prescription and the system of the patient's electronic health record. The adoption of the EHR is relatively high since it's necessary for health providers for reimbursement purposes. Digital health innovations, such as telemedicine, are being adopted faster in private healthcare facilities (out-of-pocket expenses). Health data

processing is subject to the data protection law (*Noul Regulament General de Protecția Datelor*) in line with the GDPR.

---

## DTx market access

Considering the abovementioned challenges for Romanian healthcare, the broader implementation of digital health innovations, including reimbursement of digital health solutions, is not a priority. This is also due to – as highlighted by local interviewees – the constant staff fluctuation at the Ministry of Health and the lack of a national e-health strategy (every new team has new plans that don't support the continuity of policies). Regulations regarding health technology assessment exist and are executed by The National Agency of Medicines and Medical Devices. However, they refer only to market access for new medicines. Such an unfavourable ecosystem causes digital health solution developers to base their business model on operating in foreign markets. During the COVID-19 pandemic, the National Health Insurance House introduced reimbursement for remote teleconsultations, which are still covered for patients with chronic diseases. The Recovery and Resilience Plan for Romania (RRP) is expected to boost digitalisation. Out of €14.24BN in grants, 20.5% will support the digital transition (ca. €100M for telemedicine and €300-400M for the digitalisation of hospitals). Even the business-to-patient model is unpopular – although widespread internet access and smartphone adoption are high, digital health literacy and awareness of digital health benefits and tools in the community are very low

## Recommendations for DTx use in the Romanian healthcare system

- Supporting strategical absorption of the RRP grants to remove the gaps in essential digital health infrastructure and improve digital health literacy among health professionals;
- Leveraging know-how exchange between the national authorities – like the National Agency of Medicines and Medical Devices and National Health Insurance House – and corresponding institutions from countries with more experience in digital health innovations rollout in the public health system;
- Investing in digital skills among healthcare professionals. EIT Health RIS programme Hello AI could be an example;
- Demonstrating how broader use of DTx supporting the health professionals in their work could serve to tackle their shortages and improve access to healthcare;
- Launching a pilot project for the reimbursement of telemedicine services and DTx in the national health system;
- Setting up an EU-wide base of recommendations for the validation of digital health solutions;
- Prioritising digitisation as part of achieving national health goals in EU funding projects.

**References:**

Outcomes of the EIT Health InnoStars DTx roundtable with stakeholders from Romania
http://country.eiu.com/article.aspx?articleid=1020997485
https://www.dataprotection.ro/
https://health.ec.europa.eu/system/files/2016-11/laws_romania_en_0.pdf
https://ec.europa.eu/info/business-economy-euro/recovery-coronavirus/recovery-and-resilience-facility/recovery-and-resilience-plan-romania_en
https://www.oecd-ilibrary.org/sites/305423b6-en/index.html?itemId=/content/component/305423b6-en
https://www.anm.ro/en/

# GREECE

**"We are very glad to see important steps towards the digital transformation of healthcare in the country, even if digital solutions cannot still be prescribed and reimbursed in Greece. EIT Health contributes to this direction, providing us with tools that can be adapted to the local context and can help to build the capacities of the Greek ecosystem. Through our Greek hub's activities, key stakeholders are aware of best practices, new trends and models in digital health, such as DiGA, while our ambitious initiative SymbIASIS wants to help hospitals embrace innovation and start-ups to create products that add real value to healthcare.**

*Varvara Vasilaki, Innovation Consultant and Project Manager, EIT RIS Network Member*

## Digital health landscape

The 2010 economic crisis was both a shock for many companies and a boost for innovation, including healthcare. Greece was one of the first countries to introduce e-prescribing. In recent years, there has been significant progress in implementing an electronic patient record (EHR). However, according to a recent study by the Foundation for Economic and Industrial Research (IOBE), Greece falls behind in the implementation of the EHR, ranked 26th among the EU 27.

One of the strongest pillars of digital health is telemedicine. Remote consultations are widely applied, among others, to provide services on the Greek islands. Besides, digital health plays a vital role in the start-up ecosystem. Up to 80% of life science start-ups in Greece focus on digital health and medtech, including artificial intelligence (AI), data analytics, web or mobile applications, cloud computing, software, the Internet of Things, and 3D printing. In the latest European Innovation Scoreboard 2022 published by the European Commission, Greece ranks among moderate innovators with a performance at 80.2% of the EU average. With the new National Framework Programme Greece 2.0 and Health 2.0 Programme, with a budget of €2.5BN, it is expected that the digital transformation of healthcare in Greece will gain momentum. Topics like digital literacy are covered by The Digital Transformation Strategy 2020-2025 – strategic document, which sets priorities for the country's digitalisation. However, there are many concerns if the investments will help to build a favourable digital ecosystem in healthcare.

## DTx market access

Despite such advances in the digital transformation of healthcare, driven by the Ministry of Health and the Hellenic Ministry of Digital Governance, digital health solutions are still not reimbursed in Greece. The exception is teleconsultations, which uptake accelerated during the COVID-19 pandemic.

EIT Health recently initiated a dialogue on reimbursable digital therapeutics following the model implemented in Germany (DiGA). One of

the initiatives is SymbIASIS – the Capacity Building Programme established by EKT. It aims to connect hospitals and start-ups and could eventually lead to pre-pilot testing and market validation of innovative solutions.

To harness the potential of DTx in the Greek healthcare system, there is a need for more engagement from the Hellenic Ministry of Digital Governance, the Ministry of Health, the National eHealth Governance Council (responsible for the elaboration of the e-health strategy and the overall functioning, financing and monitoring of e-health projects) and Greek National Organization for the Healthcare Provision (the national payer).

In 2018, the Committee on Health Technology Assessment and Reimbursement of Medicinal Products for Human Use, established within the National Organization for Medicines, introduced a new health technology assessment in Greece. However, it doesn't address digital health innovations. Regarding medical devices, the accreditation system provides only the evaluation for the CE marking aligned with the MDR.

In 2022, the Hellenic Ministry of Digital Governance and the Ministry of Health established a dedicated Committee that – among many issues – also aims to explore digital health applications that could pave the way for the development of the regulatory landscape. Stakeholders welcome this move since digitalisation and telemedicine services could improve healthcare delivery, especially in remote areas (Greece has 168 inhabited islands).

## Recommendations for DTx use in the Greek healthcare system

- Establishing centres of excellence to promote research and innovation in the health sector through the collection and utilisation of real-world data;
- Identifying best practices for fast-track evaluation of DTx and initiating a multistakeholder dialogue regarding the national approach;
- Developing European Digital Innovation Hubs that focus on Health and AI, Big Data, and digital skills among healthcare professionals;
- Bridging the operational and regulatory gaps in real-world data processing and utilisation
- Creating the capacity and framework for data exchange between national research organisations, universities, healthcare professionals and other stakeholders;
- Creating a framework for the collaboration between public research and academic organisations with private healthcare organisations to exploit, utilise and give value to the collected health data;
- Setting rules for the protection and anonymisation of the patient's data and the provision of health and financial benefits back to the data owner;
- Speeding up digitalisation – including scaling DTx – to address healthcare inequalities
and improve health delivery in remote areas.

**References:**

Outcomes of the EIT Health InnoStars DTx roundtable with stakeholders from Greece

https://www.ekathimerini.com/news/1179739/greece-still-ranks-low-in-digital-health/

https://eithealth.eu/news-article/flourishing-of-the-greek-start-up-ecosystem/

https://ec.europa.eu/regional_policy/en/newsroom/news/2020/12/12-03-2020-telemedicine-services-extended-to-new-islands-in-greece

http://iobe.gr/

https://research-and-innovation.ec.europa.eu/statistics/performance-indicators/european-innovation-scoreboard_en

http://iobe.gr/docs/research/RES_05_A_10032022_REP_GR.pdf

https://www.ekt.gr/en/events/27610

https://www.mednet.gr/archives/2019-4/pdf/444.pdf

https://digital-skills-jobs.europa.eu/en/actions/national-initiatives/national-strategies/greece-digital-transformation-strategy-2020-2025

Digital Transformation & COVID-19: the Case of Greece, European Scientific Institute

# HUNGARY

**There are several prerequisites of digital health solution usage in a country – at first, we have to focus on education and attitude fine-tuning of patients and physicians. After such establishment and development of our social capital regarding digital health, we can start creating structures, processes and tools. When we have these factors, money and funding will be smart by definition and we will see digital health as a high-tech industry that supports economic growth and success.**

*Zsolt Bubori, Ecosystem Lead for Hungary, EIT Health InnoStars*

**Unmet medical needs in themselves will not justify raising public expenses. Before developing financing schemes for digital health solutions, we need to be sure of what we are paying for because the marginal utility of having better health is infinite.**

*Gergely Merész, Head of the Technology Assessment Department of the National Institute of Pharmacy and Nutrition*

## Digital health landscape

There was a big step in the Hungarian digital transformation, that the National eHealth Infrastructure (EESZT) launched in 2017. It serves as a central e-health system facilitating data exchange between healthcare stakeholders: health providers, healthcare professionals, pharmacies and patients. EESZT is a backbone for sharing documents like e-prescriptions or electronic health records. EESZT has several other important digital health projects ongoing.

The digitalisation of the health sector, which has been underway for years, made it possible to guarantee the continuity of medical services for patients during the pandemic. As a result, among European countries, Hungary saw one of the most significant increases (by more than 50%) in the share of remote consultations with general practitioners between June/July 2020 and February/March 2021 – according to the State of Health in the EU Report: Companion Report 2021. Besides, the national payer – Health Insurance Fund – can reimburse telecare services if they meet specific requirements.

During the pandemic, the Hungarian government and healthcare stakeholders have set up a Data Team which has had significant results in easing the bad consequences of the pandemic. The Data Team has used connected databases, AI and Big Data-based algorithms to predict and support decisions.

HTA methodologies were partially implemented in 2004, including cost-effectiveness analysis to support pricing and reimbursement decisions regarding new medicines. In Hungary, devices are regulated by the National Institute of Pharmacy and Nutrition *(Országos Gyógyszerészeti és Élelmezés-egészségügyi Intézet).*

To date, it hasn't been extended or updated to include digital health solutions. There are no special provisions for coverage for the use of mobile apps. It means that health apps classified as medical devices – due to the European Medical Devices Regulation – and have a CE mark can't be reimbursed in the national health.

Thus, digital therapeutics remain unregulated and there is no division between digital health solutions compliant with MDR (and/or with demonstrated clinical benefits for the patients) and the broad group of wellness apps. What is missing is a mind shift, political will and leadership that could boost digitalisation in healthcare, including the introduction of DTx.

## DTx market access

Digital health solutions developers can indirectly enter the reimbursement system with telemedicine solutions that support the doctors in providing care (diagnosis, therapy advice), including issuing e-prescriptions. In all other cases, start-ups focus on business models around out-of-pocket payments or cooperation with private healthcare providers. Several start-ups target directly foreign markets before they establish a Hungarian market presence. This significantly undermines Hungary's digital health innovation ecosystem, which consists of around 160 medtech start-ups. Besides, it

creates a gap in accessibility to digital health innovations for all patients to benefit those who can afford private health services. Given the non-effective public spending on healthcare, it is unlikely to see much change in this area.

Examples of other operating models include public-private partnerships. One of these is a joint project of the University of Pécs and the E-Group, research examining the prediction of migraine attacks. However, these are only single initiatives that won't change the status quo.

Due to the increasing economic crisis, interest rates and lack of cheap financing sources for Hungarian public spending there is not a high chance to focus regulatory activities and budgets towards digital health development in the next couple of years. Although, there will be a new governmental umbrella institution established called the National Capital Fund on 1 January 2023. This fund will manage all governmental Venture Capital Funds, so there is an opportunity to dedicate budget and governance structure for Digital Health in a more effective way than in the past.

## Recommendations for DTx use in the Hungarian healthcare system

- Introducing a certification system for "trusted apps" could be the first step towards such needed awareness-raising of DTx;
- Developing – as the second step – a new framework for market access for DTx jointly with the National Institute of Pharmacy and Nutrition and the State Department of Health;
- Establishing a dedicated mixed (EU and national) fund for digital health innovations acceleration;
- Establishing hubs in the national healthcare systems where medtech companies could cooperate with healthcare providers and academic centres on solutions with scientifically demonstrated benefits;
- Creating a network/accelerator for close dialogue between innovators, academia, healthcare providers and public institutions responsible for health policy, including the State Department of Health;
- Enabling the secondary use of data so start-ups can gain access to data lakes required for digital health innovation development;
- Harmonisation of the national and EU legislation in terms of medical devices and data protection;
- Launching an EU-wide set of recommendations for DTx that should be based on leaders' experience in this area, e.g. Germany and Belgium.

**References:**

Outcomes of the EIT Health InnoStars DTx roundtable with stakeholders from Hungary
https://e-egeszsegugy.gov.hu/web/eeszt-information-portal/the-role-of-the-eeszt-in-hungarian-healthcare
https://health.ec.europa.eu/system/files/2022-02/2021_companion_en.pdf
https://link.springer.com/article/10.1007/s40258-021-00710-z
https://www.egroup.hu/data-driven-migraine-research/
https://www.statista.com/statistics/1254772/hungary-most-funded-health-care-companies/
https://ogyei.gov.hu/medical_devices/
https://egeszsegvonal.gov.hu/en/health-care-system/national-healthcare-service-center-okfo.html
https://cms.law/en/int/expert-guides/cms-expert-guide-to-digital-health-apps-and-telemedicine/hungary
https://www.euro.who.int/__data/assets/pdf_file/0007/419461/Country-Health-Profile-2019-Hungary.pdf

# PORTUGAL

**❝ This roundtable provided a comprehensive discussion on how to lay the foundations of a DiGA model adapted to the reality of the national health system. It also helped to place this topic on the national agenda and strengthen cooperation between some of the main stakeholders involved in its implementation.**

*Marta Passadouro, Ecosystem Lead for Portugal, EIT Health InnoStars*

**❝ At the Health Cluster Portugal, we recognise the importance of this topic for the Portuguese health sector and for the digital health segment in particular. As such, understanding the expectations and hearing the suggestions from stakeholders might drive and guide the necessary change in Portugal, making it a very relevant and promising initiative.**

*Patrícia Patrício, Knowledge and Intel Manager at Health Cluster Portugal*

## Digital health landscape

Portugal started digitisation very early – in 2009, the Digital Health Agency *(Serviços Partilhados do Ministério da Saúde)* was created to drive the development of digital health services. Already in 2012, a national health information platform and a summary document containing clinical data, or clinical patient summary, were ready.

To further develop e-health services, the Commission for Monitoring Clinical Information Technology *(Comissão de Acompanhamento da Informatização Clinica)* established the think tank "eHealth in Portugal: Vision 2020" which issued a paper "eHealth in Portugal – Vision 2020". It called for the development of mobile health services and interoperability.

The heart of the eHealth system is the National Health Data Platform (PDS), which includes sub-portals for healthcare professionals and citizens. The uptake of Electronic Patient Records by physicians is relatively high. Patients can use several e-services: registering for appointments, controlling access to data, recording the results of their own measurements of health parameters, and accessing laboratory results. As of 2016, electronic prescriptions can only be issued and exchanged electronically – Portugal is one of a few countries in the EU with obligatory e-prescriptions.

Portugal was also among the first group of countries to enable the exchange of Patient Summaries and e-prescriptions with other EU countries under the eHealth Digital Service Infrastructure (eHDSI) – an infrastructure ensuring the continuity of care for European citizens while they are travelling abroad in the EU. Telemedicine and remote patient monitoring is also widespread. For example, 84% of healthcare organisations have implemented at least one project regarding telehealth.

Among the latest projects to boost digital innovations in Portugal are:

- The national network of Test Beds "AI Test and Experimentation Facilities (TEFs)" – testing and experimentation facilities for Artificial Intelligence in Healthcare, co-funded by the Recovery and Resilience Plan;
- DigiHealth Portugal – Digital Innovation Hubs (DIHs), a national collaborative network interconnected with the European networks, that include specific digital competence centres, aiming at the dissemination and adoption of advanced digital technologies by companies, especially SMEs and start-ups, through the development, testing and experimentation of these technologies, thus function as a one-stop-shop, while acting as a gateway and strengthening the innovation ecosystem.

## DTx market access

Although digitalisation in healthcare is progressing in Portugal, a strategic approach to digital therapeutics is still missing. Furthermore, there is no structured mechanism or legal framework for evaluating digital health solutions for patients.

All medical devices – including software-as-a-service solutions – must obtain the CE mark under the MDR regulation, similarly to the other EU Member States. However, after the introduction of the Regulation in Portugal, the certification process has become more complex, demanding, and time-consuming for start-ups. Therefore, there is an urgent need to develop a national approach to the evaluation of digital health solutions to enable start-ups to build a sustainable business model, thrive in the national market and support healthcare, health professionals and patients. Keeping the status quo can lead to a brain drain – many SMEs are already emigrating with their innovative ideas and solutions outside the domestic market.

Among other barriers to digital health innovations are low digital literacy among

healthcare professionals, patients, and caregivers; insufficient number of specialised human resources (for example, data scientists); low institutional digital maturity; missing solutions regarding data privacy, security and liability, which is not favourable for building trust; lack of interoperability and technological infrastructure. The stakeholders also point out that digital health is not on the top of the political agenda (for example, new plans and strategies are missing).

## Recommendations for DTx use in the Portuguese healthcare system

- Investing in human resources in institutions that could be responsible for the process of evaluation of digital health solutions. For example, the leading Portuguese regulator, Infarmed – due to a shortage of workers – can't deal with new challenges, including the implementation of the Portuguese DiGA model;
- Creating innovation hubs within, for example, university hospitals to enable start-ups testing their digital solutions in terms of performance, safety, clinical benefits and outcomes, thus providing scientific evidence on the usefulness of the DTx (high-value care). Such hubs already exist in some EU countries. An example is the Smart Health Tech Center at the Erasmus Medical Center (the Netherlands);
- Creating an infrastructure for introducing DTx. For example, in Germany, the health innovation hub was established to help implement the new legislative framework;
- Updating an existing national (health) digitalisation strategy that will focus on leveraging DTx;
- Taking into account that the legislative framework should be harmonised with other solutions implemented in the EU countries to create so that a DTx approved in one EU Member State does not have to be re-evaluated when entering another market (DTx single market);
- Initiating a dialogue between the policy-makers and the developers of DTx to work jointly on a solution that will guarantee the quality and safety of digital health solutions while addressing the existing market barriers, like the high costs of clinical trials. In addition, a well-designed evaluation process is crucial since it gives the doctors confidence that the solutions they prescribe are safe and beneficial for the patients;
- Including DTx in the debates on the future of health systems that harness the power of prevention, personalisation and patient engagement.

**References:**

Outcomes of the EIT Health InnoStars DTx roundtable with Partners and stakeholders from Portugal
Barómetro da Saúde Digital: da adoção Telessaúde e Intenligência Artificial. Relatório Intercalar – Focado na Liderança. 2022. Glintt & APAH.
https://www.iapmei.pt/PRODUTOS-E-SERVICOS/Incentivos-Financiamento/Documentos-Incentivos/AvisoRNTestBeds_06042022.aspx
https://www.iapmei.pt/PRODUTOS-E-SERVICOS/Empreendedorismo-Inovacao/Inovacao-e-Competitividade/Programas-e-iniciativas/Rede-de-Polos-de-Inovacao-Digital.aspx
Smart Health Systems, International comparison of digital strategies, Bertelsmann Foundation

# CONCLUSIONS AND RECOMMENDATIONS

The study by EIT Health InnoStars in selected Central, Eastern and Southern Europe countries aimed to map the landscape of the national digital health ecosystems and identify current capabilities for introducing a shared European approach to digital therapies (DTx).

It includes a deep dive into the current state of digitisation and DTx readiness, measured by the development of digital infrastructure, the implementation of essential e-health solutions, the degree of digital literacy, acceptance of digital health tools among healthcare professionals and citizens, and regulatory framework.

Each country has its own specific needs related to the implementation of DTx determined by several factors: (digital) health literacy, technical infrastructure, openness to innovation, available budget resources, health priorities, culture, etc. Despite these differences in the national recommendations and a clear conclusion that "there will be no

one-stop-shop for DTx in Europe," some steps must be taken on the EU level.

During the study by EIT Health InnoStars and conducted interviews, many stakeholders highlighted that the introduction of DTx needs strong cooperation between the EU Members States and – what could be the most essential – leadership on the EU level. The challenge is to create an approach allowing start-ups and companies to develop DTx and operate in all EU countries without re-validating their systems. There is great potential – in terms of boosting the digital health innovation market and accelerating digital transformation in healthcare – in the European DTx single market.

To harness this promise DTx can deliver, there is a need for initiatives at the EU level and dialogue among regulatory bodies in member countries. We should also ensure that recommended in this report actions are taken as soon as possible to avoid fragmentation of digital therapy validation processes in the EU.

**The strategic recommendations for the acceleration of DTx in the EU are:**

- **MDR and CE mark are insufficient as a framework for developing reliable digital health innovations. Therefore, more focus on DTx in the Health Technology Assessment guidelines is expected.**

The current framework in the EU does not support the development of the DTx. While health policies are the responsibility of the EU Member States, the European Commission can create specific health-related documents, non-binding frameworks, and advisory documents but also binding acts that address DTx.

- **There is an urgent need to clearly define what DTx is and standardise requirements for DTx in the EU to create a single digital therapeutics market.**

There are wide discrepancies in the interpretation of the term digital therapeutics. Unfortunately, this leads to confusion among healthcare stakeholders, causing the topic to be neglected in the public debate. EU needs a vision for a common DTx single market and must take steps toward harmonising national approaches in this field.

- **Digitalisation in healthcare must be accelerated with a focus on interoperability, data safety and trustworthy data processing.**
  **This is the foundation for the development of DTx.**

Digital health deployment may be limited by a lack of coercive regulative frameworks, which has also been highlighted in the recent [Study on Digital Health Implementation in the EU](). Interoperability standards will allow the DTx developers to integrate their solution with the existing digital health infrastructure (e.g., electronic health records) to harness the potential of data exchange.

- **EU should advocate or DTx, so there is a common understanding in all Member States of the need for strengthening the governance of DTx.**

While some countries (Estonia) are already thinking about harnessing the potential of DTx, the topic is off the political agenda for others (Romania). There needs to be coordination so that the development of DTx in Europe is stimulated in all EU Member States, if possible.

- **Some EU funds should be directed to develop working groups or hubs in the EU Member States that will initiate dialogue between stakeholders. EIT Health could be instrumental in this.**

EIT Health has the competencies and network to lead the dialogue on DTx between different EU countries and stimulate the exchange of know-how in order to develop the best models adjusted to national healthcare landscapes.

- **More EU-funded projects should cover the area of evidence generation for digital health apps and platforms developed by consortia of start-ups, science and academia.**

A significant obstacle to the development of DTx is the financial limitations of start-ups in generating evidence, such as in the process of randomised clinical trials using real-world data. However, special funding programmes in this area could spur DTx development in Europe.

- **Digital health solutions/data processing for health-related purposes should be more embedded in the EU-wide health-related strategies.**

For example, Europe's Beating Cancer Plan refers to digital health as a facilitator of research and prevention. Such an approach of embedding digital technologies in health-related strategies should be a common practice to actively shape the future of health, which will be digital.

- **The forthcoming creation of the European Health Data Space (EHDS) should enable start-ups to access high-quality data that could allow them to evidence generations.**

One of the obstacles to the development of AI-based solutions – and DTx is one of those – is the lack of access to data on which European start-ups could train algorithms.

- **National bodies should support coordinated actions regarding DTx frameworks on a national level to avoid the migration of start-ups to countries with DTx-friendly ecosystems (innovation gap).**

Unless a pan-European approach to DTx is established, there is a risk of creating innovation centres in countries with favourable regulatory frameworks and marginalising countries that are lagging behind. The result is a migration of start-ups, as is now happening in countries with low rates of innovation. It also includes putting more focus on digitalisation in the EU Member States that fall behind in digital infrastructure, (digital) health literacy and skills in order to avoid digital gaps in the EU. EIT Health can be instrumental in supporting the EU Member States in this.

- **EU should develop a new approach to the health data economy, including core values of privacy, transparency and full control over data.**

Only if the public trusts digital tools based on data acquisition and analysis, digital health (including DTx) can thrive.

- **There is a visible need to create a network of innovation centres in the leading university hospitals that support co-developing, consulting, testing and validating digital health innovations.**

Similarly to European Reference Networks, the network of innovation hubs could foster the exchange of knowledge and experience regarding DTx. Start-ups could apply to test their solutions in real-life settings in one of the hubs. A shared database on tested/developed innovations and their effectiveness could help to boost research regarding digital health innovation. It could also become a part of the EHDS. EIT Health and its Partners could be a basis for creating such a network.

# INNOSTARS AND MORNING HEALTH TALKS

EIT Health InnoStars is a regional chapter of EIT Health, an international network developing healthcare innovations, supported by the European Institute of Innovation and Technology (EIT), a body of the European Union. InnoStars is focused on promoting entrepreneurship, innovation, and education in the domain of healthcare, healthy living and active ageing within European countries where the overall pace of innovation is still moderate, according to the European Innovation Scoreboard. We support the development of four main regions – Hungary, Italy, Poland and Portugal in close collaboration with partners and key stakeholders. Additionally, we support development of local ecosystems in 13 regions in collaboration with EIT RIS Network Members.

On yearly basis, we support and include in the pan-European innovation loop over 70 innovative solutions. We also train more than 1,000 healthcare professionals in Artificial Intelligence, business development, technology transfer, IP and more.

Since 2019, EIT Health has inclusively stimulated communities to undertake local discussions about the acceleration of healthcare innovations. The EIT Health Morning Health Talks (MHT) — regional forums in 13 countries in Central, Eastern and Southern Europe were dedicated to convening national- regional- and local leaders to help map best practices and common challenges of innovative health solutions. All regions are facing an increasing demand to provide health services to patients, both by quality and volume, and there are many innovations, which help address that need. Often, national and regional ecosystems must understand and gain confidence in what works.

The local Morning Health Talks bring an outlook on the development of the health ecosystems in the regions that are considered moderate and modest innovators in Europe. Regional key opinion leaders, policymakers, public institutions, top managers of healthcare providers, medical and technical universities, start-up leaders and founders, investors, doctors and other healthcare professionals discuss some of the most urgent healthcare challenges faced in European systems. In the 2022 edition, they have been digital therapeutics and hospital engagement in innovation.

Aiming at improving the local ecosystems within the EIT Regional Innovation Scheme (RIS), the Morning Health Talks has become a safe environment for leaders to discuss what works, what does not, and where there is room for improvement and to learn from each other, not only for the benefit of particular organisations but for local communities as well. The discussions help formulate recommendations for public administration and/or strengthen partnerships on the regional, national, and pan-European levels.

# APPENDIX: speakers and panellists

## ITALY

| Name | Organisation |
| --- | --- |
| **Public administration, regulatory authorities** | |
| Fidelia Cascini | Digital Expert, Ministry of Health (Italy) |
| **Research and academia** | |
| Gennaro Piccialli | Director, CESTEV, University of Naples Federico II |
| **Entrepreneurs & innovators** | |
| | IRCCS SYNLAB SDN |
| Giuseppe Recchia | CEO – Vice-president, daVi Digital Medicine – Fondazione Smith Kline |
| Alberta Spreafico | Global Head of Digital Health & Innovation Strategy, Healthware Group |
| **EIT Health staff and collaborators** | |
| Marco Aiello | Supervisory Board Member, EIT Health InnoStars |
| Ilaria Leggeri | Head of Public Affairs and Stakeholder Relations, EIT Health |
| Chiara Maiorino | Ecosystem Lead for Italy, EIT Health InnoStars |
| Ferenc Pongracz | Regional Director, EIT Health InnoStars |

## ESTONIA

| Name | Organisation |
| --- | --- |
| **Government agencies, regulatory authorities** | |
| Claus Duedal Pedersen | Director of the Sentinel Unit, Sundhed.dk (Denmark) |
| Silja Elunurm | Head of project, Ministry of Social Affairs (Estonia) |
| Jukka Lähesmaa | Senior Adviser, Ministry of Social Affairs and Health (Finland) |
| **Research and academia** | |
| Raivo Kolde | Associate Professor, University of Tartu |
| Jaanus Pikani | Chairman, ScanBalt BioRegion |
| **Entrepreneurs & innovators** | |
| Katrina Laks | CEO and co-founder, Migrevention |

| EIT Health staff and collaborators | |
|---|---|
| Sven Parkel | General Manager of Tartu Biotechnology Park, EIT Health Hub in Estonia |

## ROMANIA

| Name | Organisation |
|---|---|
| **Public administration, regulatory authorities** | |
| Ann Gustafsson Granqvist | Program officer, Swedish eHealth Agency |
| **Research and academia** | |
| Rozalina Lapadatu | Vicepresident, Institute for Development in Health and Education |
| **Healthcare providers** | |
| Stefan Busnatu | Cardiologist, Bagdasar-Arseni Emergency Clinical Hospital |
| **Entrepreneurs & innovators** | |
| Laura Broek | Digital Health Fellow, Allied for Start-ups |
| Camil Moldoveanu | CEO and Co-founder, Re.flex |
| **EIT Health staff and collaborators** | |
| Dr Ion-Gheorghe Petrovai | Co-Founder and Director of Innovation at FreshBlood HealthTech, EIT Health Hub in Romania |

## GREECE

| Name | Organisation |
|---|---|
| **Government agencies, regulatory authorities** | |
| Spyridon Arsenis | Coordinator NBG Seeds Accelerator, National Bank of Greece |
| Michalis Dritsas | Ministry of Development and Investments (Greece) |
| Louisa Stüwe | Head, DIGA TaskForce - Project lead, Ministry of Health (France) |
| Dimitrios Vlachakis | Assistance Professor, Genetics, Agricultural University of Athens, Vice President of Health Technology Assessment – National Organisation of Medicine (EOF) |
| **Research and academia** | |
| Yanis Dimitrakopoulos | TTO Manager, National and Kapodistrian University of Athens |

| | |
|---|---|
| Athanasios Kakarountas | Associate Professor, Univ. of Thessaly, Director of Smart Systems Lab, Vice President, GRNET |
| Charalampos Karanikas | General Secretary, Hellenic Society of eHealth Services and Education (ΕΕΜΕΠΥ), Associate Professor, University of Thessaly |
| Panagiotis Vlamos | Professor, Department of Informatics, Ionian University |
| **Healthcare providers** | |
| Maria Bigaki | Head, Project Management Office Manager, Papageorgiou Hospital |
| Georgios Korres | Attikon Hospital, University of Athens |
| **Entrepreneurs & innovators** | |
| Pantelis Angelidis | Professor University of Western Macedonia & CEO President VIDAVO A.E. |
| Alexander Berler | Strategic Business Development Director at IHE Catalyst AISBL, Consulting services Director at Gnomon Informatics, Vice-Chair at HL7 HELLAS |
| Georgios Dafoulas | Doctor, Scientific Partner University of Thessaly, GiSeMi Innovation Hub etrikala SA |
| Giorgos Dimitriou | Cluster Manager, Hellenic Digital Health Cluster (HDHC) |
| Mary Papa | HTA and Market Access Manager, Bayer Hellas AG |
| Lefteris Papadopoulos | Portfolio Manager, Athroa Innovations |
| Kostas Saridakis | Founder and CEO, Collaborate Healthcare |
| Evi Tsaliki | Scientific Manager, Hellenic BioCluster (HBio) |
| Tasos Vasileiadis | President iED, Founder and CEO, Joist Innovation Park |
| Konstantinos Votis | Director of Visual Analytics Lab, CERTH/ITI & MindMed |
| **EIT Health staff and collaborators** | |
| Beata Kurucz | RIS Collaboration Lead, EIT Health InnoStars |
| Georgios Megas | Coordinator, EKT, EIT Health Hub in Greece |
| Varvara Vasilaki | Project Manager, EKT, EIT Health Hub in Greece |

# HUNGARY

| Name | Organisation |
|------|-------------|
| **Public administration, regulatory authorities** | |
| Martin Curley | Professor, Director of Digital Transformation and Open Innovation, Health Service Executive (HSE), Ireland |
| Anikó Kuczkó | Startup Coordinator, Neumann Nonprofit Ltd. |
| Gergő Merész | Head of Department, National Institute of Pharmacy and Nutrition (OGYÉI) |
| **Research and academia** | |
| Péter Ács | Director, Soctira Kutatóközpont np. Kft. |
| Tímea Csákvári | Teaching Assistant, University of Pécs |
| Sándor Kovács | Data Analyst, University of Pécs |
| Noemi Liber | Doctor, Vice-director of the Institute of Transdisciplinary Discoveries, University of Pécs |
| Ádám Schiffer | Director of Institute, Faculty of Engineering and Information Technology, University of Pécs |
| Attila Sík | Professor, Director of Institute of Transdisciplinary Discoveries, University of Pécs |
| **Entrepreneurs & innovators** | |
| Attila Haág | Head of Development, Avinty Hungary Kft. |
| Milán Hatházi | Entrepreneur |
| **EIT Health staff and collaborators** | |
| Beata Kurucz | RIS Collaboration Lead, EIT Health InnoStars |


# PORTUGAL

| Name | Organisation |
|------|-------------|
| **Government agencies, regulatory authorities** | |
| Luis Goes Pinheiro | Chairman of the Board of Directors of Serviços Partilhados do Ministério da Saúde (SPMS), EPE |
| **Healthcare providers** | |
| Alexandre Lourenço | Hospital Administrator, Centro Hospitalar e Universitário de Coimbra, EPE (CHU Coimbra) |
| **Entrepreneurs & innovators** | |
| Pedro Cid Ferreira | Co-founder, Digital Health Portugal |

| | |
|---|---|
| António Lindo da Cunha | Senior Executive Director of Automatics Lab, Instituto Pedro Nunes |
| Cristiano Marques | Head of Product Development, Glinnt |
| Ricardo Moura | Co-Founder and CEO, Gripwise |
| Patricia Patrício | Knowledge and Intel Manager, Health Cluster Portugal |
| Luis Pereira | Country Manager, Medtronic |
| **EIT Health staff and collaborators** | |
| Filip Domański | Stakeholder Relations Lead, EIT Health InnoStars |
| Marta Passadouro | Ecosystem Lead for Portugal, EIT Health InnoStars |

# Acknowledgements