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Digital Medical Devices: Paths to European Harmonisation

Summary Report



**“THE BEST WAY TO
PREDICT THE FUTURE
IS TO INVENT IT.”**

— ALAN KAY

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Foreword

Europe today finds itself at a crossroads. Healthcare expenditure is on a constant rise, with a 24% increase seen across the European Union (EU) in the last decade alone (European Commission, 2022). In 2021, more than one in three European citizens reported suffering from a longstanding illness or health problem. (European Commission, 2022) As things stand, our health systems are unsustainable, and the COVID-19 pandemic highlighted how quickly their limits are reached. At the same time, the pandemic proved to be a catalyser for a wave of technological innovation in healthcare and, importantly, its rapid adoption by patients and healthcare professionals alike. Digital health and care – a broad concept that includes solutions for telemedicine and teleconsultation, remote monitoring, connected medical devices, digital health platforms, and e-health apps – demonstrated its ability to improve access to health services, enhance their quality, improving patients engagement, and increase the efficiency of healthcare delivery at a time when human and material medical resources were stretched thinner than at any other time in recent history.

Predating the coronavirus outbreak, a national effort in Germany to integrate digital health applications into standard care pathways under universal health coverage, known as the DiGA Fast-Track, has since sparked initiatives in various other European countries to facilitate their widespread adoption. At EU level, a decade of work to accelerate the continent's digital transformation has culminated in 26% of funds from the Recovery and Resilience Facility, Europe's unprecedented post COVID-19 stimulus package, being allocated to digital spending. This rapid pace of change represents an opportunity for Europe to fully realise the potential of digital health and care to improve both population health and patient satisfaction with care. Taken together, our publicly funded health systems could also constitute an unrivalled market for digital health innovation and rapidly propel Europe to global leadership in this field. That, however, will require removing significant regulatory, financial, technical, as well as cultural barriers that innovators face to implement their solutions across Europe's fragmented national healthcare environments. Left unaddressed, asymmetrical and uncoordinated development of digital health and care in the EU could stunt the progress made during the pandemic, hinder rather than help Europe's competitiveness long-term, and deepen rather than attenuate health disparities between its people.

As a European entity, EIT Health supports the development and adoption of innovative health solutions in a transnational context so that they may benefit all citizens. For this reason, EIT Health has over the last year sought to investigate the pioneering German model for introducing digital health apps on prescription, which has been in operation and under close international scrutiny for three years, as a starting point for harmonising the EU landscape for digital health and care. This report presents the consolidated insights from a series of EIT Health regional roundtable discussions on the



lessons learned from the DiGA Fast-Track and how they may be leveraged in the variety of national healthcare contexts, regulatory frameworks and policy environments found in other EU Member States. These form the basis for a wider reflection about how to foster the necessary European integration in a field, the provision of healthcare, that is within the remit of national governments. Europe is at a crossroads in the digitalisation of health and care, and now is the time for countries to choose converging paths.

Jean-Marc Bourez
Chief Executive Officer, EIT Health

About EIT Health and the EIT Health Think Tank

EIT Health is one of nine Knowledge and Innovation Communities (KICs) of the European Institute of Innovation and Technology (EIT), an EU body. EIT Health is an Institutionalised Partnership under Horizon Europe's Pillar III – Innovative Europe. Established in 2015 to tackle the societal challenges of health, demographic change, and well-being within the EU, its mission is to help overcome the well-known EU paradox whereby state-of-the-art education, excellent research, and a dynamic industry seldom turn breakthrough ideas into new transformative products and services.

Within the EIT Health network, ~130 partner organisations and institutions from academia, business, research and healthcare delivery collaborate across disciplines, borders and sectors to reinforce excellence, create knowledge and innovation, and encourage greater investment in innovation that delivers the outcomes that matter to citizens and patients. As a result, EIT Health represents a unique match between a sustainable innovation ecosystem model gathering and leveraging different partners and funding sources, and a change agent with extensive capacity to generate real-world insights for evidence-based policymaking and the transformation of healthcare.

The EIT Health Think Tank is EIT Health's thought leadership forum. It brings healthcare leaders together to prepare the ground for life-changing innovation and to identify the next opportunity for a step-change in how healthcare is delivered. Subject matter experts collaborate across disciplines and borders to explore and assess the most pressing topics impacting health and the adoption of innovation. This allows for continual assessments of the environmental needs of EIT Health's portfolio of projects and programmes. To facilitate this dialogue and its findings, EIT Health drives a range of activities to generate knowledge and insight, including research, expert round tables and interviews, publications, and dissemination of key information.

Previous EIT Health Think Tank topics have focused on determining how to overcome the barriers to and capitalise on the opportunities of the adoption of innovation and new technologies in healthcare. These included the use of Big Data, future-proofing Europe's digital health innovation pathway, the role artificial intelligence (AI) can play in healthcare workforce and organisational transformation, the impact of the Medical Device Regulation (MDR) and leveraging innovation to make European health systems more resilient and sustainable.

Methodology

OBJECTIVES

This EIT Health Think Tank report aims to crystallise discussion about the potential for regulatory frameworks to accelerate the development of and improve citizens' access to health innovations throughout Europe. Taking stock of the lessons learned from the first three years of activity of the German DiGA Fast-Track, and of the current healthcare, regulatory, and policy environments in 14 other European countries, it evaluates the prospects for a harmonised digital health and care regulatory landscape and a Digital Single Market for health technologies in Europe.

ANALYTICAL APPROACH

Between September 2021 and November 2022, EIT Health organised a series of roundtable discussions across Europe, bringing together experts and key stakeholders from the worlds of healthcare, medical device regulatory affairs, academia, and business to discuss the German DiGA model and its potential to inspire digital health regulatory frameworks in different EU countries. Insights from these discussions were published in regional whitepapers. In this EIT Health Think Tank report, we present the consolidated findings to offer a pan-European overview on the state of the digital health and care transformation in individual Member States, and distillate the recommendations that emerged for making the EU an environment that is favourable to its development and implementation.

Roundtable events focusing on the DiGA model were held in Germany, Sweden, France, Spain, Ireland, Italy, Portugal, Estonia, Romania, Greece and Hungary (see Annex). Research was also conducted to identify trends and perspectives for digital health and care development across the EIT Health InnoStars region,¹ covering central, eastern, and southern Europe.

This report additionally builds upon insights generated from previous Think Tank activities, in particular the 2020 and 2022 reports titled, "**Optimising Innovation Pathways: Future Proofing for Success**" and, "**Unlocking Innovation to Build More Resilient and Sustainable Healthcare Systems in Europe**" respectively. The former outlined recommendations on overcoming pathway barriers to innovation and the latter accounted for digitalisation in healthcare as one of three key focus areas for healthcare system adaptation in the post-pandemic era.

The process was conducted by EIT Health. Drafting support was provided by Alison Bouissou.

¹ Croatia, Czechia, Estonia, Greece, Hungary, Italy, Latvia, Lithuania, Poland, Portugal, Romania, Slovakia, and Slovenia



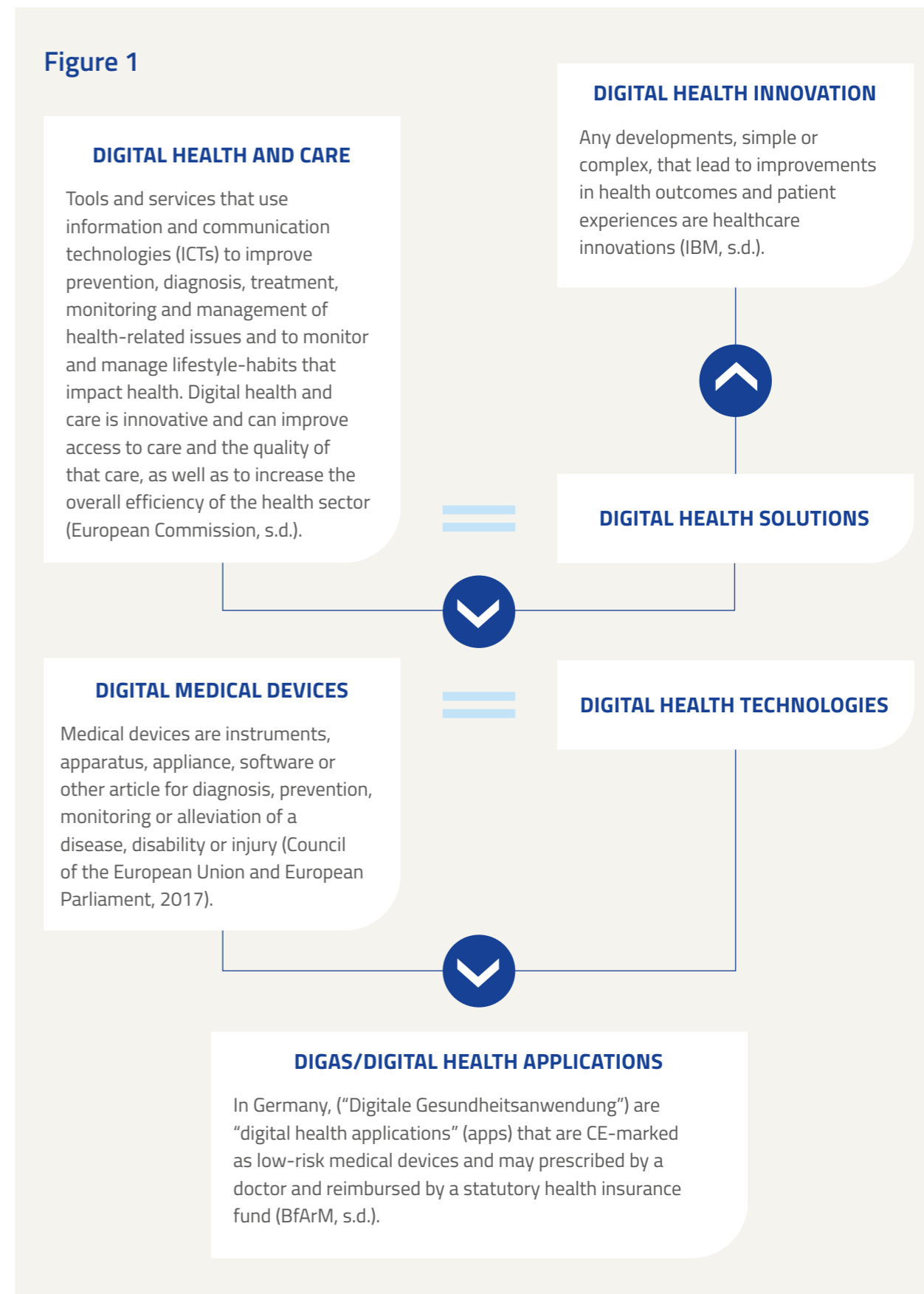
TERMINOLOGY

“Digital health” is a broad and interdisciplinary concept with no agreed upon definition to date. Terms such as “digital therapeutic”, “digital health”, “digital medicine” are largely used interchangeably, possibly reflecting the different perspectives which academia, scientific institutions and industry players have vis-à-vis this domain. Such ambiguity in meaning extends to an inconsistency pertaining to the categorisation of technologies falling within the scope of digital health. In Europe, different terminology and categorisation exist in different countries (EIT Health Ireland-UK, 2023).

For the purpose of this report, based on extant literature and the terminology used by the European Commission, the retained taxonomy is presented in Figure 1.

For insights generated from regional roundtables, this report (namely in Chapters 3 and 4 and the Annex) reflects the language used in the national/regional discussion and accounts thereof.

Figure 1



Introduction

DIGITAL HEALTH TRANSFORMATION: YEARS IN THE MAKING

Citizens throughout Europe today take for granted the digital technologies that allow them to communicate with their peers anytime, anywhere, or to manage bookings for transportation, accommodation and leisure activities with a few simple clicks. This is a development promoted by the European Union over the past decade: EU decisionmakers have made the digital transformation a policy priority and have invested significantly in legislation and funding apt to support the transition.

Digitalisation has been slower in the health sector than elsewhere, a fact often attributed to the strict regulatory environments that underpin healthcare provision in Europe, the nature of the risks incurred when a technology fails, and the sensitivity of handling personal health data (Schuller, 2020; EIT Health, 2020). For all of these reasons, few had suspected the speed at which change could, and did sweep through European health systems during the COVID-19 pandemic.

COVID-19: A NEW IMPETUS FOR DIGITAL HEALTH AND CARE IN EUROPE

COVID-19 forced patients, medical professionals and institutions to reorganise almost all existing care pathways to manage the pandemic. With medical practices and hospitals restricting in-person appointments to essential consultations, teleconsultations and telemedicine became the new standard of care in many European countries, despite constituting the first experience of virtual care for as many as 84% of patients at the time (European Parliamentary Research Service, 2021).

In France, the number of teleconsultations reimbursed by the national insurance fund surpassed 18 million in 2020, up from a mere 140,000 in 2019 (Cour des Comptes, 2021). The governments of countries like Germany, Romania and Poland relaxed existing regulations on who was authorised to offer teleconsultations and how many could be performed, and others including Austria, Greece, Ireland and Italy implemented emergency legislation to open up the use of digital health solutions such as electronic prescriptions (European Observatory on Health Systems and Policies, 2021).

On the international level, unprecedented collaboration, funding and data sharing in favour of the crisis response were made possible by EU Member States' willingness to cut through red tape in the race against time.

The European COVID-19 Data Platform facilitated epidemiological surveillance and research on the virus by allowing the aggregation of data from various national sources. Meanwhile, the European Medicines Agency (EMA) COVID-19 Pandemic Taskforce expedited the development, regulatory review and safety monitoring of the vaccines that would ultimately be administered to billions of people around the world less than two years after the start of the outbreak (European Commission, s.d.; European Medicines Agency, s.d.).

The pandemic also exposed the vulnerabilities of both the health and digital spaces in Europe: dependence on non-European products and technologies led to supply bottlenecks and shortages of medicines and equipment (European Medicines Agency, s.d.), the implementation of contact tracing apps rekindled fears surrounding data privacy, and concerns emerged about the impact of disinformation on the efficacy of public health policies. These are in large part not substantively new challenges, but rather an exacerbation of previously identified issues intensified by the crisis: what is new is the sense of urgency generated by the pandemic (EIT Health, 2022).

Today, this new impetus for digitalisation can play a key role in accelerating the recovery of health systems from the COVID-19 pandemic and strengthen Europe's resilience to avoid future crises. EIT Health (2022) in its report "**Unlocking Innovation to Build More Resilient and Sustainable Healthcare Systems in Europe**", identified digitalisation as a pillar of this recovery and highlighted ways to leverage EU funding, policies, and regulations to remove barriers to innovation in health. Looking beyond the pandemic and its consequences, the current moment may be a historic opportunity to finally make digital technologies an integral part of public health services, which could thereby simultaneously become more equitable and accessible for all European citizens and offer greater personalisation and value to the individual patient.

DIGA: A GERMAN EXPERIMENT

Assessment and reimbursement models for digital medical devices, like the **DiGA (Digital Health Applications) Fast-Track** pioneered by Germany just before the coronavirus outbreak, and having inspired since several European countries – including France (Healthcare IT News, 2021), could contribute to making that a reality.

However, since the first DiGAs were approved in 2020, it has become clear that their implementation poses a number of challenges which national policymakers must anticipate and be ready to address in the future. Allowing this burgeoning sector to become too fragmented across Europe also risks stalling progress through which the EU could aspire to become a global leader in digital health and care. Having mapped the European digital health and care landscape and outlined recommendations for state-level action, this report therefore offers a reflection on aspects of the necessary framework for digital health technologies that EU Member States and relevant stakeholders can and should consider together.

CHAPTER 1

The EU Digital Health and Care Landscape



Through a process that culminated in the rapid and far-reaching adaptation of health systems to the COVID-19 pandemic, the foundations for a pan-European digital health and care transformation have been laid. Building on heightened public awareness and political will, several important levers have been pulled at EU level to usher in this new, digital age in healthcare: these include a supportive policy and regulatory framework, and dedicated funding.

Policy and Regulation

Over the past decade, EU policy has conveyed an ambition to digitalise Europe. Already in 2015, having recognised the potential for growth and improved welfare from the European digital economy early on, the EU adopted its Digital Single Market strategy as one of the European Commission's 10 political priorities to create an environment where digital services and networks can prosper European Union, 2015). Ever since, even the more fundamental aspects of life as a citizen – paying taxes, voting – have been shifting to digital channels across the continent. Consistently, in March 2021, the European Commission stepped up the game by announcing the 2030 Digital Compass, setting out Europe's ambitions to empower citizens and businesses through digitalisation by the end of this decade (European Commission, 2021).

The digitalisation of health and care followed suit, with a clear acceleration in correlation with the COVID-19 pandemic. In 2017, EU Member States and the Commission set out to collaborate in view of enabling the Digital Single Market in health (Council of the European Union, 2017). EU legislation on medical devices, data protection, electronic identification and security of network and information systems ensued to enable a responsible use of digital technologies in healthcare (European Commission, 2018). A most recent, and remarkable example is represented by the Proposal for a Regulation on the European Health Data Space (EHDS) (European Commission, 2022), one of the central building blocks of the European Health Union and a milestone in EU's digital transformation:

it aims to establish a framework that will empower individuals to take control of their own health data, while supporting the use of such data for better healthcare delivery, research and innovation, and policymaking. Interestingly, the 2022 report of the European Parliament's Special Committee on Artificial Intelligence in a Digital Age (AIDA), even identified health as one of six key areas in which a fourth industrial revolution driven by digital technologies could happen (European Parliament, 2022).

Impetus beyond the healthcare spectrum is also noteworthy for the ripple effect on a digital transformation in health and care. In July 2022, the European Commission New European Innovation Agenda laid out five flagships in the areas of research and innovation for positioning Europe at the forefront of a new wave of deep tech innovation to achieve the green and digital transitions (European Commission, 2022). At the annual State of the Union address in September 2022, President of the European Commission Ursula von der Leyen focused on the education and talent gap and announced that 2023 will be the European Year of Skills (Leyen, 2022). The outcomes of such an initiative are set to contribute to reaching the targets for Europe's Digital Decade: these include at least 80% of all adults acquiring basic digital skills and 20 million ICT specialists being employed in the EU by 2030, with more women being encouraged to take up such jobs. (European Commission, 2021).



Funding

EU funding has invested in the digital health and care transformation for many years.

The EU's long-term funding programme, Horizon Europe, dedicated €4.1 billion for the years 2021–2027 to support Cluster 1, Health, which will serve to generate new knowledge and develop innovative solutions in this area. Another €95.5 billion has been allocated to Cluster 4, Digital, Industry, and Space, which alongside Cluster 1 is being implemented through the newly established European Health and Digital Executive Agency (HaDEA).



The EU's pandemic recovery plan and unprecedented stimulus package of €2.018 trillion, NextGenerationEU, was launched with a focus on making Europe greener, more digital and more resilient. In the area of health, the Recovery and Resilience Facility (RRF) was endowed with €723.8 billion to help mitigate the economic and societal impact of the pandemic. The EU Health Programme (EU4Health), the largest of the health programmes ever launched, specifically in response to the pandemic, meanwhile is injecting €5.3 billion towards building a European Health Union and explicitly provides for reinforcing health data, digital tools and services and digital transformation of healthcare as a means of strengthening Europe's health systems.

A RECOVERY SUPPORTED BY EIT

As part of the EU recovery effort, the European Institute of Innovation and Technology (EIT) launched the **EIT Crisis Response Initiative**, which awarded €60 million to 207 innovation projects and ventures from 32 countries. The **EIT Health COVID-19 Rapid Response** contributed €7 million in funding for short-term projects to provide immediate and impactful solutions to help health systems navigate the pandemic.

Aiming to reduce Europe's dependence on systems and solutions coming from other regions of the world, which has become a significant cause for concern since the pandemic, the Digital Europe programme was created with a planned overall budget of €7.5 billion. This is being used to provide strategic funding for projects to build capacity in the key areas of supercomputing, artificial intelligence (AI), cybersecurity, and advanced digital skills, as well as to support the broad uptake of digital technologies across the economy and society. The programme further contributes to the economic recovery and to shaping the digital transformation of Europe's society and economy with a particular focus on supporting small and medium-sized enterprises (SMEs). The Connecting Europe Facility programme supports the construction of infrastructure for cross-border exchange of patient summaries and electronic prescriptions.

SUMMARY

The EU has been stepping up its policy and legislative agenda to reach its objectives for digital sovereignty, including in digital health and care.

EU Funding for post-pandemic recovery comprises levers for a digital transformation of healthcare.

CHAPTER 2

The German DiGA model – a worthwhile investment?

With increasing policy and financial attention towards the digital transformation and an expanding landscape of digital health and care solutions entering the European market, the time is ripe to define the framework conditions that will guarantee equitable access to high-quality, evidence-based digital health and care for patients across Europe. Three years on, an analysis of the mechanisms, initial implementation, and observed effects of the DiGA fast-track regulatory approval introduced in Germany in 2019 informs about the potential to accelerate the digital health and care transformation in Europe.

WHAT IS A DIGA?

The German Federal Institute for Drugs and Medical Devices (BfArM) defines a DiGA (*Digitale Gesundheitsanwendung*) as a “digital health application” (app), which may be prescribed by physicians and psychotherapists and are reimbursed by health insurers. DiGAs are thus also known as “apps on prescription”. Included in this category by German law are CE-marked medical devices of the (low) risk classes I or IIa according to the European Medical Device Regulation (MDR) or its predecessor, the Medical Device Directive (MDD). DiGAs are used either by the patient alone or by patient and healthcare provider together. Apps serving as primary prevention and those that are only used by the healthcare provider to treat the patient are excluded (BfArM, s.d.).

Rationale for the fast-track process

Putting digital healthcare solutions directly in the hands of patients has the potential to empower patients, fill gaps in care, improve or even replace existing therapies and alleviate some of the pressure on healthcare resources and personnel. An expanding industry in recent decades, digital health and care thus unsurprisingly boomed during the pandemic and proved its ability to meet critical patient needs. It is estimated that by the end of 2021, there were 3,000 mobile health apps available on the EU market, more than twice as many as in 2015 (European Parliamentary Research Service, 2021).

European digital health start-ups raised nearly €4.23 billion in 2021, nearly three times the €1.45 billion invested in 2020. Over 600 companies are believed to be active in digital health and care across Europe today, two thirds of which were created in the last five years (Karista, 2022).

This growth cannot be unrelated from a favourable policy and regulatory environment. A case in point, the DiGA framework was designed to link regulatory approval of patient-facing healthcare applications (apps) to reimbursement by the country’s statutory health insurance funds. Before the path to statutory reimbursement was introduced, app developers had to market their products directly to consumers who would pay for them out of pocket, to single healthcare providers who would offer them to their patients or negotiate contracts to obtain coverage with individual health insurers. All of these paths significantly limited companies’ ability to scale their solutions for the benefit of more patients (EIT Health Ireland-UK, 2023)

Applying for listing in the DiGA directory

With the passing of the Digital Healthcare Act (DVG) and the Digital Health Applications Ordinance (DiGAV) in Germany, a fast-track process for the assessment of DiGA was placed under the responsibility of its national medicines agency, the German Federal Institute for Drugs and Medical Devices (BfArM). The essence of this assessment is the examination of the manufacturer’s statements about the product qualities – its safety and suitability for use, data protection and information security standards, as well as quality and interoperability – and the evaluation of the evidence for the DiGA’s positive healthcare effect. From the time a complete application is filed, the BfArM has three months to assess and decide whether to include the DiGA in its directory of reimbursed apps.



If manufacturers cannot immediately demonstrate a positive healthcare effect with evidence from a comparative clinical trial, but already meet all other requirements and submit data on the use of their DiGA that plausibly shows it contributes to improving health outcomes, they can apply for provisional listing for a period of one year, or in exceptions of up to two years. They can then conduct the required study during this trial phase.

According to its legal definition, a positive healthcare effect can be either a medical benefit or a patient-relevant improvement of structure and processes in healthcare. The latter represents a new category for evidence generation and can include better coordination of treatment procedures, alignment of treatment with guidelines and recognised standards, improved adherence, facilitated access to care, enhanced patient safety, health literacy, patient autonomy, as well as reduced burden of disease for patients and their relatives. The workload of medical staff or economic indicators of healthcare are not considered patient-relevant endpoints.

Although manufacturers are free to submit evidence from a prospective randomised controlled trial (RCT), retrospective comparative study designs are also accepted. Use of real-world data (RWD) is explicitly permitted, for example data from disease registries, insurance claims, electronic health records (EHRs), or even patient-generated data from digital health applications and wearables.

Both permanently and provisionally listed applications immediately become eligible for prescription by doctors and psychotherapists, and for ensuing reimbursement by all of the country's statutory health insurance funds covering 73 million citizens in Germany.

Patients also have the possibility to request access to a DiGA directly from their health insurance, provided they can prove a diagnosis in the relevant indication. After the initial 12-month period following provisional or final listing in the directory, during which manufacturers can freely set the

price of their DiGA, the amount of remuneration must be negotiated between the manufacturer and the National Association of Statutory Health Insurance Funds (GKV-SV). Where medical services are necessary as part of the treatment, physicians receive an additional reimbursement.

From policy to practice: two years of DiGA in action

By January 2023, 160 DiGA applications had been submitted to the BfArM, more than three quarters (125) of which were applications for provisional listing. These resulted in 40 positive approval decisions, 16 rejections and, of note, more than half (87) were withdrawn by manufacturers. In 2022, five apps were added to the directory, and five were removed (BfArM, s.d.). Of the 40 DiGAs included in the BfArM's directory, 15 had achieved permanent listing.

Shedding light on the high failure rate of applications, the most commonly cited reasons for rejection and manufacturer retractions were the BfArM's strict requirements for approval, especially with respect to study design and evidence standards, and the investments necessary to meet these (EIT Health Germany, 2021). Many manufacturers significantly underestimated the effort and expense involved in the process, likely for lack of experience with regulatory frameworks, review processes and clinical evidence generation. A major difficulty reported was defining the positive healthcare effect in the scientific evaluation concept and suitably proving it. Failing to plan and expedite both the technological development and the evidence generation processes simultaneously from the start also frequently led manufacturers to retract their requests (EIT Health Germany, 2021).

MANUFACTURER AND DIGA PROFILES

The overwhelming majority of successfully listed DiGA manufacturers are based in Germany, most of them medium-sized businesses or start-ups registered as limited liability companies. However, three developers from Austria, the Czechia, and Romania have also successfully registered their DiGAs.

One of these is **re.flex**, a digital health application for musculoskeletal physical therapy developed by EIT Health-supported start-up Kineto Tech Rehab and enabling the treatment of knee, hip, and lower back pain without the intervention of a physiotherapist.

Among the indications covered, mental health applications are the most common with 40% of listed DiGAs falling into this category, which includes conditions such as depression, phobic disorders, tobacco or alcohol addiction, as well as stress and burnout. Other represented illnesses are bone and joint disease, diabetes, obesity, and breast cancer.

QUALITY AND ADDED VALUE FOR PATIENTS

Some observers had predicted that apps approved via the fast-track process would have low quality standards (EIT Health Germany, 2021) Though long-term healthcare benefits will require follow-up to be confirmed, DiGAs are approved based on meeting uniform quality requirements and all permanently listed technologies have provided the highest level of clinical evidence – data from an RCT – in support

of their positive healthcare effect. Common benefits demonstrated in the comparative efficacy studies include reductions in symptom burden or improvements in psychosocial wellbeing and quality of life. Added value for patients of many of these solutions comes from the support provided in the intervals between appointments with their healthcare providers, or potentially as a substitute for in-person services that are difficult to access, such as psychotherapy or physiotherapy.

More than two years on from the first DiGA listing, however, the German directory of 40 applications in 12 disease categories is still far from covering the spectrum of patient needs and ensuring equitable access to digital healthcare.

While some argue it is legitimate that only the very best solutions should be accepted for reimbursement, others believe that the best return on investment will only be achieved through a large formulary of solutions from which prescribers can choose the most suitable for their patients' specific needs. Expanding this repository of formally reviewed and approved technologies is also necessary to offer citizens an alternative to using unregulated software downloaded from app stores, an estimated 85% of which does not meet basic quality criteria (Organisation for the Review of Care and Health Apps, s.d.).

ADOPTION

Facilitating market access and even reimbursement did not automatically lead to widespread adoption of DiGAs. In the first year after the fast-track was launched, only 50,000 prescriptions were registered, issued by just 7,000 of Germany's 180,000 doctors (4%) (Die Techniker, 2022). Several observers attributed this slow uptake to insufficient communication and stakeholder engagement, arguing that neither clinicians nor patients had been adequately informed about the availability of DiGAs and their benefits. On the prescriber side, further obstacles identified were the lack of an e-prescription infrastructure, unfamiliarity with digital health technologies, fear of increased workloads from having to interpret patients' data, and, importantly, reluctance to recommend provisionally listed solutions without clinical evidence (EIT Health Ireland-UK, 2023). The demographic characteristics of DiGA users, the majority of whom were reportedly between 30 and 60 years of age and more than two thirds (67%) female, have also raised concerns about a digital divide leaving certain patient groups behind (Die Techniker, 2022).

Still, 90% of DiGAs were prescribed and only 10% were obtained directly from patients' health insurance funds, which was considered a good sign because, according to one expert, these solutions should be part of a holistic treatment concept (EIT Health Germany, 2021). A sign that adoption is picking up, 25,000 DiGA activations were expected for the last quarter of 2022 alone (Research 2 Guidance, 2022).

PRICING AND SUSTAINABILITY

Scarcity of incoming prescriptions initially may have contributed to manufacturers' price policies, with several consecutive increases recorded during the trial phase. The possibility for manufacturers to set their prices freely in the first year, coupled with low evidence thresholds for provisional listing in the

DiGA directory, has therefore become a central point of contention (Gensorowsky, et al., 2022). While the GKV-SV has urged for a restriction on free pricing and an increase in evidence standards (GKV-SV, 2021), industry representatives argue that the current system design is key to its success as it helps manufacturers to shoulder the cost of clinical evidence generation (EIT Health Ireland-UK, 2023).

Price negotiations with the GKV-SV at the end of the trial phase have resulted in considerable markdowns, in some cases of more than 50% (BfArM, s.d.). DiGA prices range from €119 for a one-time license to access Mawendo, an app to help patients with knee disorders autonomously complete their physical therapy, to €2,077 to activate levidex, which is provisionally approved to deliver cognitive behavioural therapy aimed at improving the quality of life of individuals with multiple sclerosis.

In terms of overall budget impact, DiGAs still represent only a small fraction of public health expenditure in Germany, which exceeded €430 billion in 2020 (European Commission, 2022).

SUMMARY



A new regulatory framework for digital health and care has emerged in Europe. In 2019, Germany introduced a fast-track procedure for the assessment of health apps (in German, "Digitale Gesundheitsanwendung" or DiGA).



A slow implementation pace. In the first three years, only 15 DiGAs achieved permanent listing. Prescription of DiGAs has also been slow to pick up.

A path to European convergence on digital health and care

In a previous Think Tank Report, EIT Health (2020) warned against fragmentation in the European market for digital health and care. This exposes innovators to vastly different requirements and processes to achieve market access across the EU, and hinders patients' prospects of using new – potentially ground-breaking – solutions no matter their country of residence. While the German DiGA experience promoted discourse surrounding harmonisation of regulatory frameworks applicable to digital medical devices at pan-EU level, today still very few digital health solutions successfully expand beyond their home country. Yet, momentum and concentrated efforts are at hand for achieving a digital single market for health and care.

Following the launch of the DiGA Fast-Track in Germany and the ensuing announcement by President Macron to replicate the model in France (Healthcare IT News, 2021), discourse surrounding harmonisation of digital health and care regulatory landscape in the EU gained momentum. In November 2021, at the Digital Medicine Conference organised by the "hih – health innovation hub"² and attended by EIT Health, several EU Member States expressed keen interest to continue the dialogue about possible harmonisation, as inspired by the German DiGa. (hih, s.d).

Following suit, a "European Taskforce for Harmonised Evaluation of Digital Medical Devices (DMDs)" was established in April 2022 under the French Presidency of the Council of the EU and with the coordination support of EIT Health. The Taskforce brings together pan-EU experts to discuss and make progress on the common goal of harmonising evaluation procedures for Digital Medical Devices (DMDs) in the EU.

² The hih – health innovation hub was set up by the German Federal Ministry of Health as a think tank, sparring partner, and implementation supporter. Since its inception, the hih has been involved in generating support for digital health and care, through online and in-person events, among several national players in the German healthcare system. In addition to the DVG, the hih also supported the conception and implementation of the electronic patient file, electronic medication, the medical research data center and the medical AI strategy.

The European taskforce for harmonising evaluation of digital medical devices (DMDS)

Efforts to build such a framework began in 2022 with the creation of a **European taskforce for harmonising evaluation of digital medical devices (DMDs)**, chaired by the Ministerial Delegation for Digital Health of the French Ministry of Health, co-chaired by the European Network for Health Technology Assessment (EUnetHTA) and coordinated by EIT Health. The taskforce is constituted of 20 members representing the academic sector, policymakers, national competent authorities and health technology assessment (HTA) agencies from Austria, Belgium, Finland, France, Germany, Italy, Luxembourg, and Spain, among others.

The mission of the taskforce is to provide a blueprint for appropriate assessment procedures and methodologies, with the overall goal of enabling a harmonised approach for European assessment supporting national appraisal and reimbursement by statutory health insurance organisations for distinct subclasses of DMDs. The aim of the taskforce is to harmonise the nomenclature and taxonomy of DMDs based on their application purpose, and to reach consensus on evidence requirements in the light of national implementation requirements. The taskforce seeks to advise the HTA Coordination Group (HTAR), national responsible authorities and agencies, innovators and policymakers – in alignment with EU medical device regulators – on the development of a joint DMD assessment procedure, including the definition of DMDs based on their application purpose and evaluation categories.

The common understanding of many European countries regarding the need to develop

a tailored market access for digital health technologies and give patients early access to effective, innovative DMDs offers a unique opportunity for collaboration and convergence of practices, while acknowledging the national competencies of Member States and their access to reimbursement. By developing a joint approach producing concrete outputs that can be used in HTAs in EU Member States, the generation of evidence can be simplified, patient access accelerated, and public health safeguarded. With EUnetHTA as co-chair of the taskforce, a first framework for the HTA procedures should be aligned, where possible, with existing collaboration processes defined by the EU Regulation on Health Technology Assessment (European Parliament and Council of the European Union, 2021).

The concrete goals of the taskforce are:

- To harmonise nomenclature and taxonomy of DMDs
- To issue recommendations for a joint clinical evidence assessment framework of DMDs based on respective national responsible authorities and agencies' mandates
- To propose healthcare system integration aspects and socio-economic requirements

Following feedback from an external advisory group regarding real-world feasibility, the first results will be presented in 2023 and published as a consensus article.



The same impetus prompted the present EIT Health Think Tank project, which brought together relevant stakeholders throughout Europe, to consider opportunities and challenges for a harmonised digital health and care regulatory landscape. Published in six country or regional reports, and summarised throughout this chapter, the insights from these discussions paint a heterogeneous picture characterised by uneven progress in health system digitalisation, variability in the size and diversity of the digital health and care offering, diverging levels of openness or acceptance to digitalisation as well as irregular institutional and regulatory maturity across Member States.

Prevalence, perceptions and forms of digital health and care across Europe

In a survey on trends in digital health and care across 12 countries within the EIT Health InnoStars region³, virtual care and telemedicine emerged as the most frequently implemented adaptations in the course of the COVID-19 pandemic (EIT Health InnoStars, 2022). Observers saw the most significant acceleration in **GREECE**, and almost half of the respondents also reported solutions aimed at the digitalisation of medical records and appointment booking being implemented in their respective countries. Only one in five to one in four observed the implementation of personal health management, prevention and wellness apps, or of remote monitoring devices and wearables. Public perceptions also reportedly evolved and translated to increased willingness among patients to use digital health and care solutions – though not across all social groups, for example the elderly. Medical literacy was generally considered poor in these countries, meaning that patients do not understand medical messages and efforts are needed to ensure they appreciate and adhere to their treatments. However, some expected that more widespread scientific awareness resulting from the pandemic could further increase openness to digital health and care in the future.

³ The EIT Health InnoStars region encompasses EU Member States ranked as moderate or emerging innovators by the European Innovation Scoreboard. It covers half of Europe, including Hungary, Italy, Poland and Portugal, as well as additional regions included in the EIT Regional Innovation Scheme – Croatia, Czechia, Estonia, Greece, Latvia, Lithuania, Slovakia, Slovenia, and Romania.

A similar surge in implementation of telemedicine and teletherapy solutions was seen over the course of the pandemic in **IRELAND**, as local companies like Salaso and patientMpower were able to enter the market quickly with solutions addressing a critical need to connect practitioners and patients for teleconsultations, teletherapy, and remote monitoring (EIT Health Ireland-UK, 2023). As Europe's third-largest exporter of medical devices (MedTech Europe, 2022), Ireland is also the largest medical technology employer per capita in Europe, with 45,000 people working for up to 350 companies in the industry, 200 of which are Irish-owned (Enterprise Ireland, 2021). Solutions currently under development include connected digital medical devices like a scanner for early detection of foot ulcers in diabetes patients and a pressure sensor for bandages to facilitate the healing of venous leg ulcers. Under a recently announced government plan to invest an unprecedented €23.4 billion in health and social care services, which allocates €500 million for a Disruptive Technologies Innovation Fund (DTIF), several EIT Health-supported start-ups (e.g., **feeltect**) have been awarded additional funding (Irish Government News Service, 2022). The biggest international players in this sector are also present in Ireland, including nine of the top 10 med tech companies and all 10 of the world's leading biopharmaceutical groups (Ibec, 2022). The country is home to world-class research centres within the Science Foundation Ireland (Government of Ireland, 2021) and fellowships such as BioInnovate at the University of Galway each year produce several leading med and health tech entrepreneurs (BioInnovate, s.d.). The country's east coast has seen the emergence of a connected health and wellbeing cluster at Dundalk Institute of Technology aiming to boost engagement between businesses and local knowledge providers (Darmody, 2022). Notwithstanding the progress made during the pandemic, however, sizeable public and private investments in Ireland's vibrant health innovation ecosystem have so far been slow to transfer to its healthcare system, where up to 85 percent of hospital records remain paper based (Thompson, 2022) and chronic challenges include hospital overcrowding (Carroll, 2023) and long waiting lists for various medical and therapy interventions (Cullen, 2022).

In the series of roundtable discussions staged by EIT Health InnoStars in Estonia, Greece, Hungary, Italy, Portugal, and Romania to explore the emergence of digital medical devices in these countries, disparities in national digital health and care landscapes became apparent (EIT Health InnoStars, 2023). In **ITALY**, three digital health solutions against chronic insomnia, arterial hypertension, and for neuromotor rehabilitation were in the development phase, but to date no such solution has been marketed or reimbursed. National digital health and care companies were frequently reported to relocate to countries with more favourable environments for their solutions. Similarly, in **ROMANIA**, local developers of digital health applications reportedly focus primarily on entering foreign markets, as digitalisation is met with resistance within the medical community and even direct-to-consumer models are unpopular due to poor digital literacy and low awareness of the benefits of digital health solutions among Romanian citizens. The same was reported for **PORTUGAL**, despite the country being a forerunner in other areas like telehealth, which 84% of healthcare organisations have implemented. In **GREECE**, by contrast, digital health and care plays a vital role in the innovation ecosystem, with up to 80% of life science start-ups focusing on digital technologies such as AI, big data analytics, web or mobile applications, cloud computing, medical software, the Internet of Things (IoT) and 3D printing. Telemedicine is widely available and used, including to provide services to Greece's 168 inhabited islands. (EIT Health InnoStars, 2022)

The Nordic countries, including European Innovation Scoreboard leaders Denmark, Finland and Sweden (Directorate-General for Research and Innovation, 2022), are generally more advanced in terms of digitalisation in health, with electronic health records implemented nationwide, widespread use of e-prescription, and availability of patient health data for research and innovation purposes. In **SWEDEN**, but also **ESTONIA**, select digital medical devices were already used in routine practice in the field of diabetes care. However, awareness of digital health technologies was still considered disparate in **DENMARK**, where recommendations of solutions were reported to occur on a largely random basis, depending on physicians' personal knowledge. (EIT Health Scandinavia, 2021)

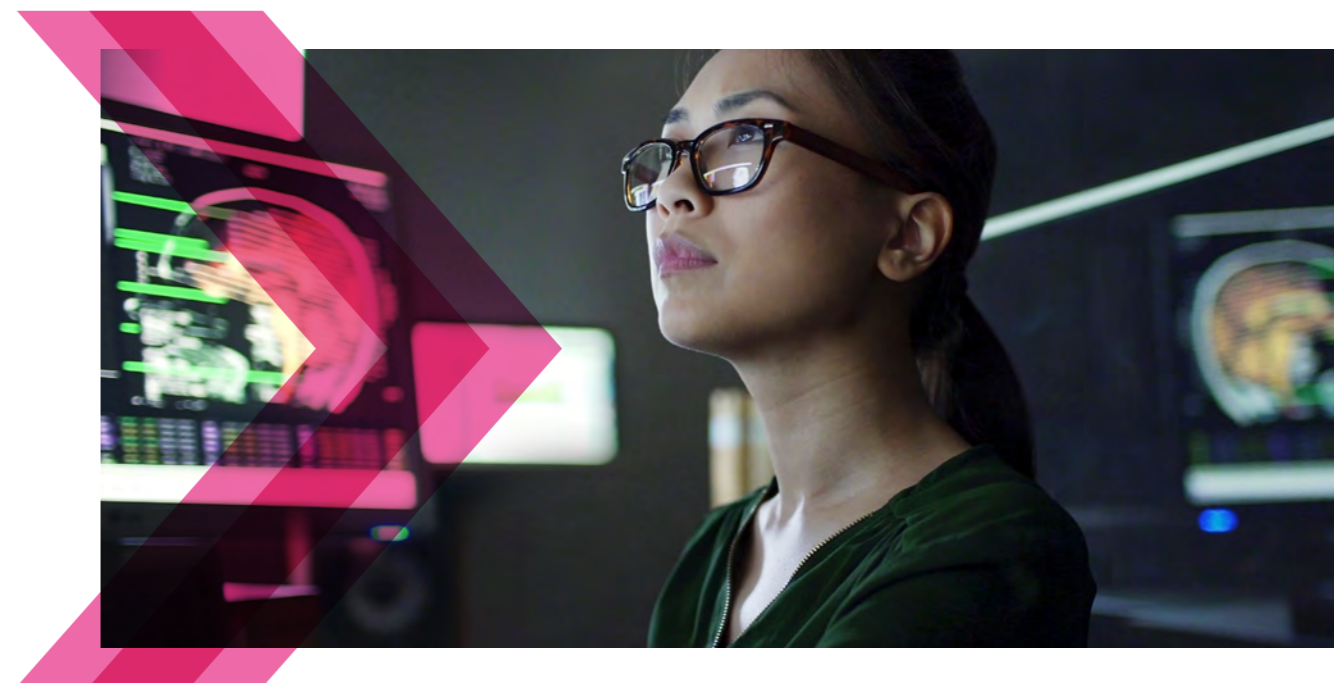
Digital health policy and funding: a growing European patchwork

In an effort to better integrate an expanding offering of digital health and care, a number of countries besides Germany have begun to adapt their national frameworks and policies in recent years. With almost as many approaches to this as there are health systems, significant differences can be observed in the types of technologies countries have included, as well as the methods chosen to assess and make them available to patients.

In 2021 and 2022 respectively, **BELGIUM** and **FRANCE** implemented their own national reimbursement frameworks for patient-facing digital health applications, which, unlike Germany's, also cover telemonitoring solutions. In many other respects, the French process is modelled on the DiGA Fast-Track. Importantly, it creates the possibility for innovative CE-marked digital medical devices to be granted early reimbursement at the recommendation of the national HTA body, the *Haute Autorité de Santé* (HAS), for a 12-month trial period during which manufacturers must generate clinical evidence and submit an application for admission to the list of products and services reimbursable (LPPR) by the national health insurance (Commission des Affaires Sociales – French Senate, 2021). In Belgium, mobile health applications and telemonitoring services must pass three levels of validation by three competent national authorities: medical device certification, technical validation, and approval for reimbursement based on clinical and socio-economic value (MedTech Europe, 2021).

ESTONIA has also shown interest in replicating the German DiGA model, and work has begun to build a framework for the use and reimbursement of digital health solutions. In 2020, the Estonian Health Insurance Fund (EHIF) launched a pilot programme in which four telemedicine solutions were selected for reimbursement after meeting MDR-related technical requirements and completing a validation process based on clinical, economic and usability assessments, and manufacturers were given until the end of 2022 to submit the required clinical evidence to support permanent reimbursement. In 2022, the EHIF announced the development of a national reimbursement scheme for digital health applications based on CE medical device certification and evidence of clinical efficacy (EIT Health InnoStars, 2023).

In certain countries, digital medical devices for patients can be eligible for reimbursement, but only through decentralised frameworks. In the **UK**, for instance, an Evidence Standards Framework for Digital Health Technologies was defined by the National Institute for Health and Care Excellence (NICE) in 2018, but it is left to Clinical Commissioning Groups and regional National Health Service Trusts



to negotiate reimbursement with developers. In the Netherlands, the most common route for digital medical devices is to obtain coverage by individual insurance companies, which assess their benefits according to the needs of their stakeholders, with a focus on improving care processes, patient outcomes and reducing the cost of care. Some health apps linked to hospital-based specialist care can fall under a national reimbursement provision, but not those in the community or home settings (MedTech Europe, 2021).

In **SPAIN**, where the public health system is organised in several regional systems, the adoption and statutory reimbursement of digital health applications is conditioned upon their inclusion in the National Portfolio of Health Services following positive evaluation by regional HTA bodies (EIT Health Spain, 2022). To date, however, no such approval requests have been submitted. An effort to standardise the assessment of digital technologies nationwide is currently being led by the Health Quality and Assessment Agency of Catalonia (AQuAS), which is collaborating with the country's network of HTA bodies, RedETS, but also with NICE in the UK as well as experts and representatives from academia and industry. The final document produced will serve as a template that all RedETS agencies can use for future evaluation reports, in line with stipulations for digital health technology assessment set out in Spain's national digital health strategy (Spanish Ministry of Health, 2021).

No dedicated reimbursement provisions for digital health technologies exist in the **NORDIC COUNTRIES** to date, with single exceptions seen for diabetes applications in Sweden. However, in June 2022, the Nordic Digital Health and Evaluation Criteria (NordDEC) became the first international framework aiming to enable healthcare providers to evaluate and identify trusted digital technologies for healthcare and preventive care. The NordDEC programme was developed by the UK-based Organisation for the Review of Care and Health Apps (ORCHA) for the Nordic Interoperability Project (NIP), which involves Denmark, Finland, Iceland, Norway, and Sweden. A national regulatory framework for digital medical devices could emerge in Greece in the future, as the Hellenic Ministry

of Digital Governance and the Ministry of Health in 2022 established a dedicated committee that will among other things explore the integration of digital health applications (EIT Health InnoStars, 2023).

Conversely, **IRELAND** has recently moved to provide public funding for digital health applications, but to date no formal framework has been developed for their regulatory approval and reimbursement. This will likely be necessary going forward, as digital medical devices fall outside the categories covered by the Health Service Executive's (HSE) current reimbursement scheme for medical devices, and structural as well as resource limitations within the country's HTA system would need to be overcome to allow a more systematic introduction of these technologies in public healthcare services (EIT Health Ireland-UK, 2023).

In many EU Member States, plans for healthcare digitalisation are being executed but stop short of creating a clear framework for digital medical devices, with no provisions for assessment beyond CE certification. **PORTUGAL** was among the forerunners with the creation of its Digital Health Agency in 2009, the implementation of its National Health Data Platform including an EHR system, and the generalisation of electronic prescriptions, which became mandatory in 2016 (EIT Health InnoStars, 2023). It was also among the first countries to enable cross-border exchanges of e-prescriptions and Patient Summaries under the European eHealth Digital Service Infrastructure (eHDSI), but as digital health has receded from the political agenda new strategies have not been developed and digital medical devices remain out of scope. **ITALY**, where the regulatory landscape is characterised by significant gaps and inconsistencies across the country's 20 autonomous regions, has recently introduced a national digital health plan that provides for centralised digital services like a single health record (*Fascicolo Sanitario Unico*) and a single appointment booking centre (*Centro Unico di Prenotazione*). However, this does not include a clear definition of digital medical devices or any information about their use and implementation.

Finally, certain European countries face barriers to digitalisation that make the implementation of digital health solutions at scale unlikely in the short term. In **ROMANIA**, for instance, public healthcare spending represents less than 5% of gross domestic product (GDP), compared to almost 13% in Germany in 2021 (Statista, 2022). Reimbursement of digital health innovations is not a priority in a context where many hospitals require urgent renovation and shortages of medical staff and equipment are common fare. Although national electronic health records has been implemented, the country lacks a digital health strategy, and prospects for one being adopted are poor as political continuity within the Ministry of Health is not assured. **HUNGARY**, which started its digital transformation only recently with the launch of its National eHealth Infrastructure in 2017, saw one of the most significant increases in the share of remote consultations during the pandemic (European Commission, 2022), and telemedicine as well as certain virtual care solutions are reimbursed by the national payer. However, further progress is hampered by low public spending on healthcare and ongoing tensions between the Hungarian government and the European Commission, which have led to €7.2 billion in grants under the Recovery and Resilience Facility being blocked.

SUMMARY



Health digitalisation is progressing at different paces across the EU.

Despite a universal surge in adoption of digital health solutions during the pandemic, disparities in the availability and use of digital health and care persist between and within individual countries.



DiGA-like initiatives are mushrooming across Europe.

A number of countries are introducing their own assessment and funding frameworks for patient-facing digital medical devices (DMDs). Approaches differ in terms of the types of technologies considered, their focus on defining quality standards versus opening paths to reimbursement – or even integrating the two. A first transnational framework for the evaluation of DMDs exists in the Nordic European region.



A digital health and care divide is emerging.

In some countries provisions are yet to be made for a systematic introduction of DMDs. This means that disparities in European citizens' access to healthcare could deepen.

Recommendations for Action



Evidence gathered via EIT Health roundtables indicates that a number of barriers to digital health innovation are shared by various Member States. Recommendations emerged for action to foster more widespread access to safe and effective digital health technologies for citizens. While it is unlikely that one model will be suitable for every country, several areas exist in which convergence between EU Member States will be critical to scaling up digital health and care and realising Europe's potential to become a global leader in this field.

From developing evidence-based solutions and defining effective regulatory frameworks for their assessment, through securing the necessary funding to make digital health technologies accessible to more patients, all the way to ensuring that the digital infrastructure and stakeholders within health systems are ready to support their widespread implementation, common challenges were identified at every stage of the innovation journey. Participants in this EIT Health Think Tank Roundtable Series thus called for action to prevent the deepening of health disparities between EU citizens and within national communities in the future. This chapter presents a summary of their recommendations and suggests recognisable opportunities. Indeed, as exemplified by the [European Taskforce for Harmonised Evaluation of Digital Medical Devices](#) presented in the previous chapter, the joint understanding of many European countries regarding the need to develop a tailored market access combined with a patients' early access to effective innovative DMD presents a unique occasion for collaboration and convergence of practices, while acknowledging the national competencies of Member States and their access to reimbursement.

Funding and Regulation

Countries that do not have clear regulatory frameworks and funding mechanisms to distinguish digital medical devices from the plethora of available wellness apps are seeing nationally based innovators relocate or opt to target foreign markets with their digital health solutions. This was reported from Denmark, Ireland, Italy, Hungary, Portugal, and Romania. However, a universal difficulty in developing accreditation processes for potentially thousands of digital technologies is the need to take into account their evolving nature, which challenges the traditional regulatory timeline and requires repeat assessments to follow the cycle of software updates. This would likely overwhelm the capabilities of most regulatory agencies, especially those of smaller EU Member States.

Meanwhile, a common barrier to securing funding for digital medical devices is that payers are not always the ones benefitting the most from their use. In Ireland, for example, the absence of central procurement in this area leaves public hospitals to allocate funds for digital solutions from their own budgets, limiting the range of technologies that can be implemented. A further obstacle is that digital health technologies, which enable new practices of healthcare delivery anywhere, anytime and allow a focus on prevention and wellbeing, are no easy fit with the traditional pay per-service or per-product models founded on disease response that reimbursement mechanisms of publicly governed healthcare systems rely on (EIT Health, 2020).

In Italy and Germany, strict data privacy regulations going beyond the provisions of the General Data Protection Regulation (GDPR) and limiting access to and secondary use of health data were also highlighted as barriers to digital health innovation, which often relies on AI algorithms that require large amounts of historical data to develop their predictive or diagnostic functions.

Since the entry into force of the MDR in May 2021, obtaining CE marking as a digital medical device has become one of the greatest challenges for developers across Europe. From risk class I, many software products have been moved to classes IIa, IIb, or III and now require assessment by a notified body and potentially clinical trial data to support their application for regulatory approval. This has made the process of certification much lengthier, a problem compounded by significant delays as notified bodies have lacked the manpower and experience required to process the resulting surge in submissions for digital health solutions. Some expected that the unpredictability of regulatory requirements coupled with the unavailability of scientific advice on clinical trial design would negatively impact Europe's competitiveness for years to come, reporting that more and more manufacturers are turning to the USA or choosing to commercialise their technologies with limited functionality in the unregulated market for wellness apps (EIT Health Ireland-UK, 2023).

Recommendations for governments

DEFINE A CLEAR STRATEGY

- Update or develop and fund a national digital health strategy to include a clear taxonomy for digital health technologies and a roadmap for their implementation focusing on interoperability, data security, and the development of supportive digital health and care infrastructure such as electronic prescriptions

ADAPT REGULATORY FRAMEWORKS

- Develop specific legislation for the assessment of digital health technologies based on solid scientific evidence and consensus with industry associations
- Review and update national data privacy regulations to create a framework that facilitates access to and use of health data for research, development and regulatory purposes and gives citizens full control of their data in accordance with the GDPR

OPEN NEW FUNDING PATHS

- Include digital health technologies in existing HTA frameworks
- Tie funding for digital medical devices to clinical evidence and return on investment, considering the costs of the entire model of care associated with different treatment strategies when assessing cost-effectiveness
- Implement value or outcomes-based models of financing healthcare focused on treating individuals rather than illnesses
- Build on legal provisions introduced to address changing reimbursement needs during the pandemic to develop a funding framework for using digital health technologies
- Launch pilot projects for the reimbursement of select telemedicine services and digital solutions
- Consider PPI models to accelerate adoption and funding of innovative digital health technologies in decentralised health systems

Recommendations for regulatory bodies

ACQUIRE NEW COMPETENCIES

- Invest in human resources and competencies for the evaluation of digital health technologies
- Leverage dialogue and exchange of know-how with institutions from countries with more experience in the rollout of digital health innovation in the health system

DEVELOP SPECIFIC PROCESSES

- Establish a process for continuous assessment to reflect the evolving nature of digital health technologies, for example relying on independent certification bodies to perform large numbers of preliminary and repeat evaluations

PROVIDE GUIDANCE

- Make assessment criteria transparent and provide guidance to developers, for example through regular discussion forums engaging the regulatory agency with the scientific community to address methodological issues and other obstacles, on the model of pharmaceutical approvals
- Develop guidance on regulatory requirements and support with clinical trial design for digital health technology manufacturers in the process of CE certification, for example through the EU Medical Device Coordination Group

Innovation ecosystems and digital health infrastructure

As was observed in Germany, the introduction of a dedicated regulatory and reimbursement framework for digital medical devices, though necessary, does not on its own guarantee the market entry and widespread implementation of large numbers of solutions for patients. In the development stages, manufacturers experienced significant difficulties in planning, funding, and executing the necessary steps to generate clinical evidence for their solutions. This was expected to be a recurring problem for a sector made up predominantly of SMEs with cultural roots in the software development community, rather than the pharmaceutical industry. Considered the gold standard of clinical evidence, RCTs have emerged as an unofficial norm for providing proof of benefit of digital medical devices and maximising the chances of achieving broad uptake and reimbursement. These, however, are extremely costly to run, difficult to design, and not always adequate to reflect the complexity of the healthcare settings in which digital health solutions are used, for example in conjunction with interventions by medical professionals. Difficulties in gaining access to RWD and live healthcare environments in which to test and validate their solutions were identified as further barriers to the development of diverse innovations.

In the market entry phase, the successful penetration of digital medical devices relies on healthcare professionals being able to identify and prescribe suitable solutions for their patients' needs, and on patients or health insurance funds being able to procure and activate them. In Germany, for example, it was noted that the absence of an electronic prescription infrastructure at the time of DiGAs' first introduction contributed to making the process of activating solutions lengthy and difficult for both clinicians and patients, thus limiting their uptake. The interoperability of digital health technologies with EHRs, but also with prescriber IT systems, to ensure for example that doctors can view and interpret the data generated by patients using digital solutions, represents another major challenge for their integration into health systems where multiple vendors are present.

Recommendations for governments

ENCOURAGE DATA-DRIVEN INNOVATION

- Leverage EU funding such as the Recovery and Resilience Facility to establish a dedicated fund for the acceleration of digital health innovation, in particular to support evidence generation for solutions developed by consortia of start-ups and academic organisations
- Create a framework for collaboration and data sharing between public research and academic organisations and private healthcare organisations to use and give value to collected health data

DEFINE A TIERED EVIDENCE FRAMEWORK

- Define differentiated evidence standards according to the risk level of the application to keep technologies out of the highly-priced market of solutions with high medical benefit, and to facilitate the market entry of products that enable incremental progress for chronic illnesses

DEVELOP SUPPORTIVE DIGITAL INFRASTRUCTURE

- Develop digital infrastructure and processes for the prescription, procurement, and distribution of digital medical devices
- Accelerate the rollout of a single national EHR system
- Establish standards for EHRs and interoperability of health information systems at EU level

Recommendations for healthcare system actors

INTEGRATE EVIDENCE GENERATION IN PRODUCT DEVELOPMENT

- **Digital health companies:** Plan and expedite evidence generation to provide clinical proof of benefit from the start of the technological development process
- **Engage in public-private partnerships to develop, pilot, and generate evidence for digital health solutions in a process of co-creation with patients and healthcare providers, on the model of national health innovation hubs**

BUILD HEALTH INNOVATION NETWORKS

- **Academic centres:** Develop digital innovation hubs that focus on health and AI, big data, and digital skills among healthcare professionals
- **University hospitals:** Establish a European network of centres of excellence to promote research and innovation in the health sector through the collection and use of RWD, on the model of the European Reference Networks

REVIEW AND UPDATE CARE PATHWAYS

- **Healthcare providers and payers:** Integrate digital health solutions into care pathways, defining the correct stages of the patient journey in which to insert them

Stakeholder engagement

To varying degrees, the digital skills of healthcare professionals as well as their knowledge and perceptions of digital health innovations were considered barriers to implementation in clinical settings in every country.

As some observed, the lack of reliable clinical evidence of the benefits of provisionally reimbursed DiGA in Germany undermined the trust and acceptance of both prescribers and payers in the system. In Ireland, as well as in the Nordic countries, the concern was also raised that both in hospital and community settings, the short time doctors have with patients – approximately seven minutes – would not be sufficient to explain the solutions, obtain informed consent, and subsequently interpret the data generated through the technology.

Conversely, citizens' and patients' digital literacy and attitudes towards digital health technologies were seen to vary significantly along generational, socio-economic, and geographic lines. Groups such as the elderly, who could benefit significantly from digital health innovation allowing them to live autonomously for longer, thus risk being left behind in the transformation of healthcare. In the absence of specific frameworks to govern the collection and processing of health data, concerns over data privacy and misuse will also fuel scepticism towards digital medical devices.

Recommendations

BRING HEALTHCARE PROFESSIONALS ON BOARD

GOVERNMENTS:

- Invest in education on digital health technologies and structured forms of training in digital skills for healthcare professionals
- Create incentives for healthcare professionals to utilise digital medical devices in their treatment approaches, for example through financial compensation of additional medical services associated with their use

MEDICAL PROFESSIONAL ASSOCIATIONS:

- Develop best practice guidelines on when and how digital medical devices should be prescribed and how to discuss them with patients

HEALTHCARE INSURANCE FUNDS:

- Raise awareness of the digital health solutions among physicians and patients, for example through a formulary of trusted technologies including evidence and indications for their use

FOSTER PUBLIC TRUST AND ACCEPTANCE

GOVERNMENTS:

- Invest in educational measures to reduce disparities in citizens' digital literacy
- Define rules for the protection and anonymisation of data and its use for the purpose of providing health and financial benefits to the patient, ensuring that citizens retain full control over their health data

REGULATORY BODIES:

- Engage in dialogue with citizens and patients in the regulatory decision-making process, for example through consultation with patient associations, to build trust in digital health technologies

GENERATE SUCCESS STORIES

GOVERNMENTS:

- Designate model regions or "alliances of the willing" within which to pilot the implementation of digital health technologies to foster stakeholder trust and acceptance for wider rollout

Harmonised Standards

As highlighted by various stakeholders, the only way for Europe to rival the United States in both attracting and producing digital health innovation is to become a single market in this area. While pricing and reimbursement decisions will remain a national competence, there is potential for pan-European harmonisation of quality and market access frameworks to make it easier for impactful solutions to reach more European patients, faster. With national and regional initiatives emerging across the continent, there was broad agreement among roundtable participants that further fragmentation must be urgently prevented through EU-level collaboration. This will have to take into account the varying levels of digitalisation and digital literacy, but also funding capabilities of the EU Member States to avoid creating or worsening a digital health divide. Common standards should be implemented in a way that helps rather than hinders the weakest countries in this area.

QUALITY AND CLINICAL EVIDENCE

At present, most EU Member States taking steps to define assessment frameworks for digital health technologies are doing so separately. Even the types of technologies that fall under these frameworks differ from one country to another, and terminology like "digital therapeutic", "digital health", "digital medicine" is inconsistently defined. In the absence of consensus on technical quality and interoperability standards and on requirements for clinical evidence, developers seeking to expand beyond their national market may find themselves having to modify their solutions or invest in further clinical evidence generation. Conversely, without common assessment criteria public payers will not be prepared to accept solutions that have achieved reimbursement in other EU countries, even though such an approach could allow smaller Member States to leverage foreign assessments in order to develop their digital health solutions. Particularly noteworthy in this respect is a decision made public by France's HAS in February 2022 (Haute Autorité de Santé, 2021), concluding that evidence of significant clinical benefit was insufficient to warrant the temporary reimbursement of **Deprexis**, a virtual psychotherapy indicated for the treatment of light to severe episodes of depression, despite the solution having achieved permanent listing as a DiGA in Germany.

The goal should be for the EU countries to agree on a common quality and evidence framework that can provide developers with the assurance that their applications will be admissible across Europe, and which would allow them to use one multicentre trial as a basis for applying for reimbursement in several jurisdictions. Considering that the cost and complexity of conducting such international studies will exceed the capabilities of many digital health developers, rules must also be clarified for the results of clinical studies done in one country to be considered applicable in other countries.

As has become clear in Germany, simply allowing for new methods of evidence generation and patient-centred outcome measures does not give manufacturers clarity or security about what they must do to provide proof of a positive healthcare effect. Clear consensus is needed regarding alternative study designs to the traditional RCT, and guidance on the model of the US Food and Drug Administration's framework for the rigorous generation of real-world evidence (RWE) using RWD (US Food and Drug Administration, s.d.) is particularly critical for the efficient development of digital

technologies, which are ideally suited for such approaches. Methodological aspects, such as the question of what should be used as controls for digital medical devices in comparator trials, but also relevant study endpoints, which alongside traditional medical outcomes could include non-clinical measures such as patient autonomy or burden of disease, need to be precisely defined and should reflect the specificities of digital technologies.

Recommendations for EU policymakers

- Advocate for digital health technologies to raise awareness and interest in strengthening their governance within Member States
- Develop HTA guidelines with a stronger focus on digital technologies within the Member State Coordination Group on Health Technology Assessment (HTACG) created by the HTA Regulation
- Define European technical quality and interoperability standards for digital health technologies

Recommendation for national HTA bodies

- Support the **European Taskforce for Harmonised Evaluation of Digital Medical Devices** effort to shape consensus on what DMDs are and how their clinical benefits should be assessed

Data

From hypothesis generation, through development, testing, and validation of solutions, all the way to regulatory approval and post-market surveillance, RWD is integral to the implementation of digital health technologies at scale. In turn, the data generated through digital health applications could, if made accessible, power future healthcare research. An ambitious goal in this context would be to develop a European DMD ecosystem where all data produced through digital technologies is incorporated into a structured database to facilitate quality-assured research projects.

Currently, this remains a distant possibility in Europe as national legal frameworks for secondary use of health data differ widely, from the most restrictive in Italy and Germany to the most liberal in Finland, where all health data is made available for research. Roundtable participants recognised that the GDPR is not sufficient as a basis for governing the use of health data. In the shorter term, the European Health Data Space (EHDS) is expected to provide more tailor-made rules for the health sector and to make electronic health data available and usable, both by patients and for research, innovation, policymaking, patient safety, statistics or regulatory purposes. Once adopted, it could narrow national differences in interpretation of European data protection rules, however its implementation will be conditioned by progress on digitalisation in individual Member States over the next few years.

At both national and EU levels, efforts to make health data findable, accessible, interoperable and reusable (FAIR) across national borders must be underpinned by strong data protection, but also clear ethical standards, in order to win the trust and support of citizens (EIT Health, 2022).

Recommendation for EU policymakers

- To accompany health data specific EU regulation, develop common ethical guidelines around its use founded on core values of privacy, transparency and full control over data

Recommendations for governments

- Collaborate at EU level to determine common data security, interoperability and quality standards for health data
- Support the development of and gear national digitalisation efforts and data-sharing structures towards integration into the EHDS
- Provide programmes and financing for digital skills training on data analysis, AI and implementation of real-world data standards into practice, with an emphasis on upskilling healthcare professionals

Market Access

Once digital technologies are CE marked, joint HTAs similar to those already conducted in networks like the EUnetHTA could be an initial way of establishing benefit and provide a basis for reimbursement conditions to be specified in the countries. The HTA Regulation, which entered into force in 2022 and will become applicable in 2025, establishes a framework for joint clinical assessments of new medicines and certain high-risk medical devices. However, this excludes most digital health technologies, which typically fall into lower risk categories. These would need to be the object of voluntary cooperation between Member States.

Going one step further, another possibility would be to establish a testing authority similar to the European Medicines Agency (EMA) to assess applications and issue joint approvals that would make digital medical devices eligible for reimbursement in all EU countries. However, some caution that a three-step process of MDR-compliant CE certification, application to an EU authority and submission to country-specific reimbursement frameworks would not necessarily improve the current situation.

Recommendation for EU Policymakers

- Ensure better integration between the MDR and the HTA Regulation with as much transparency as possible, resourcing scientific advice processes on the model of the EMA

SUMMARY

DMDs call for a new regulatory and financing approach, to avoid a competitive disadvantage for Europe. The traditional pay-per-service or per-product models are ill-suited for digital health technologies. In parallel, better guidance and support are needed to face the growing heterogeneity of rules, standards, and paths to market entry and reimbursement for digital health technologies between European countries.

There is huge potential to unify the EU market for DMDs and facilitate the penetration of solutions across national borders by defining common quality criteria and evidence standards. The work of the EIT Health-coordinated **European Taskforce for Harmonised Evaluation of Digital Medical Devices** is an important first step towards achieving a pan-European understanding.

Data is the foundation of digital health innovation. Digital health technologies require data at every stage of their life cycle. Conditions for the safe use of health data must be harmonised across the EU to facilitate data sharing and allow the implementation of DMDs at scale.

Perspectives for single market access for DMDs. Possibilities for European integration on digital medical devices range from agreement on common quality and evidence standards, through joint health technology assessments that smaller Member States could leverage to accelerate implementation locally, all the way to the creation of a common testing authority like the EMA to issue single marketing authorisations. Whatever the chosen level of harmonisation, common standards should be implemented in a way that helps to ensure a level playing field amongst all countries.

EIT Health – an asset to be utilised



Supported by the European Institute of Innovation and Technology, an EU body dedicated to strengthening Europe's ability to innovate, EIT Health is Europe's largest public-private partnership in the field of innovative healthcare. Bringing together over 130 leading education, research, and technology institutes, but also industry, hospitals, patients, and governmental organisations, it is ideally positioned to foster dialogue between key stakeholders in the EU Member States and accelerate the integration of innovations in digital health and care in a way that benefits all citizens. Today, and in the years ahead, EIT Health aims to deploy its full range of activities both to support innovators in bringing their digital medical devices to market and to help Europe shape its digital transformation to be simultaneously resilient and sustainable.

FUNDING AND SUPPORT FOR INNOVATION

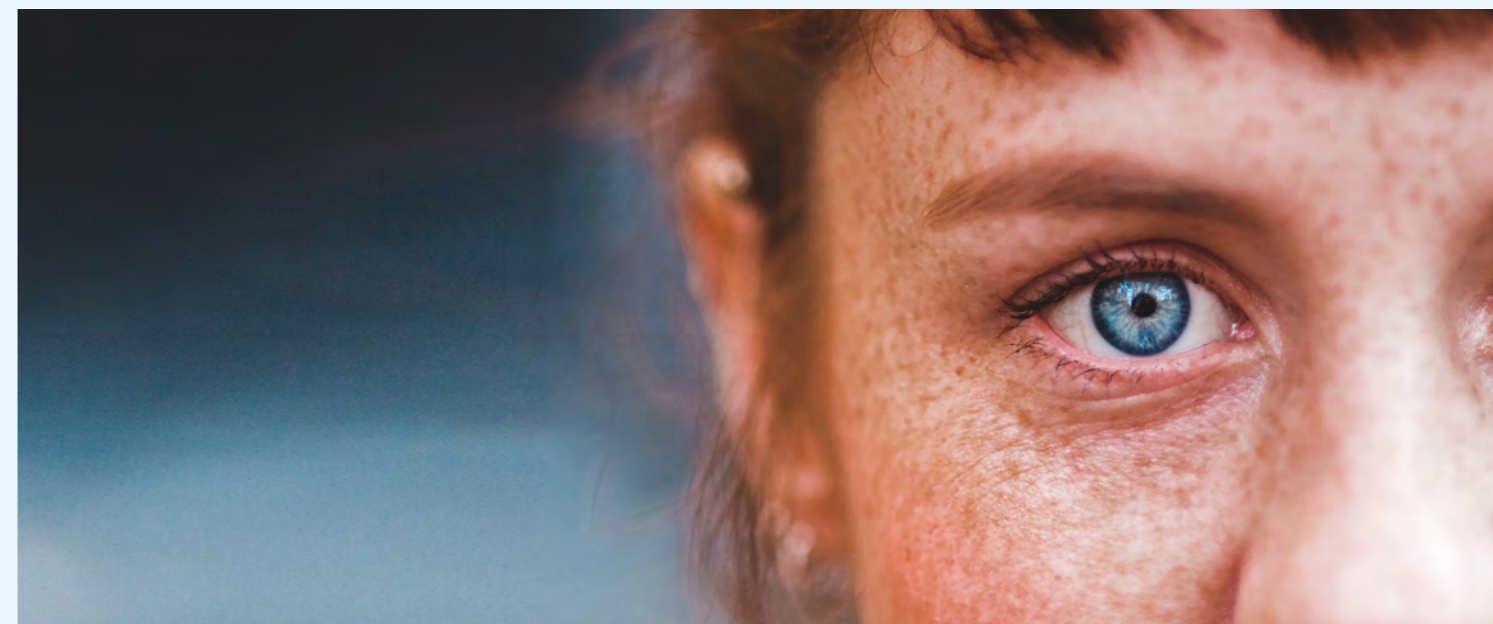
In 2022, EIT Health developed a more focused operational programme that leverages the power of the network to deliver on EU priorities and is geared towards establishing stronger synergies with EU programmes and instruments. "**Facilitating the uptake of digital medical devices in Europe**" is one of four flagships set to shape the EIT Health Business Plan 2023-2025 and is directly inspired by the knowledge and insights gathered by the EIT Health Think Tank and reflected in this report. This operational model will allow for the seamless integration of EIT Health's offering, consisting of educational programmes, business-focused services and innovation projects, within an external environment favourable to digital health and care.

The **DiGinnovation** programme supports the journey to market access of digital health solutions developed by start-ups. As of February 2023, more than ten percent of DiGAs listed on the BfArM's DiGA directory were developed by EIT Health – supported start-ups (see Annex 2). EIT Health **User Validation Labs (ULabs)** connect start-ups with EIT Health partners to conduct validation studies of their innovations.

The **Venture Centre of Excellence (VCOE)**, a public-private co-investment programme jointly operated by EIT Health and the European Investment Fund (EIF) and endowed with €2 billion in investment capabilities, represents a key tool available to DMD developers and digital health investors to empower finance and foster the development of innovative digital health technologies in Europe.

NARROWING THE DIGITAL HEALTH DIVIDE

The digital transformation of health and care has the potential to make Europe more competitive, more sustainable, and even more equitable, if efforts are made to leave no patient groups, and no Member States, behind. EIT Health is durably committed to reducing disparities in health between EU citizens and has previously called for researchers and the medical device industry to collaborate on developing medical devices that are appropriate for low-resource settings (EIT Health, 2022). Through outreach initiatives like the **EIT Regional Innovation Scheme**, Europe's emerging regions benefit from innovation, education, or acceleration projects as well as developing regional competitive advantages and innovation strategies.



Education is particularly key to accelerating uptake, driving innovation, and helping "moderately" innovative countries catch up with the rest of Europe. EIT Health education programmes such as **HelloAI Professional** equip students and healthcare professionals with the AI and machine learning knowledge and skills necessary to increase the adoption and development of new technologies in healthcare. Over 1,750 participants from central, eastern, and southern Europe have already graduated in the last four years.

The digital divide does not just run along national borders, but also along social and generational lines. EIT Health's **WorkInHealth Foundation** therefore supports the acceleration of upskilling and reskilling of talent for Europe's health industry. EIT Health also offers support programmes and educational courses on health innovation for

healthcare professionals through the **Healthcare Transformation Academy**, alongside catalyser initiatives for research scientists, entrepreneurs, and patients throughout the EU. The **Patient Innovation Bootcamp**, for instance, is designed to channel the insights of those with first-hand experience of disease treatment and care into meaningful product innovation. The **EIT Health Ageing PhD School** for academic researchers and the **Healthy and Active Ageing Bootcamp** for entrepreneurs, meanwhile, ensure that the needs of the elderly are not overlooked in the development of innovative healthcare solutions.

Conclusions

The insights gathered through the EIT Health Think Tank Roundtable Series and aggregated in this report provide a snapshot of Europe's digital health transformation: the result is a nuanced picture (see Figure 2) of individual countries at different stages of this journey and following distinct paths towards implementation of digital medical devices in their public healthcare systems.

There is uncertainty surrounding the trajectories that individual countries will take in the coming years, but what this picture unequivocally shows is that digital medical devices have gained recognition as fully-fledged therapies and, as such, are increasingly being regulated and funded in many parts of Europe. Boosted by unprecedented levels of EU investment in digital health, an increasing number of diverse, innovative solutions are reaching the market. This presents health authorities with novel challenges around assessing and implementing technologies that outpace traditional regulatory timelines in their development, overwhelm the capabilities of national institutions with their numbers, and transcend existing reimbursement models in the value they bring to patients. The German experience of the DiGA Fast-Track has shown that requirements for clinical evidence need to be defined collegially with manufacturers, who often require both methodological guidance and financial support to bring forward the necessary proof of efficacy for their products. It has also made clear the importance of evidence for garnering acceptance of and support for digital health applications among healthcare payers and prescribers. As for the implementation of DMDs in routine practice, its success has proven to be dependent on factors other than reimbursement, including the efficiency of prescription and procurement processes and the awareness, understanding, and proficiency of both medical professionals and patients in their use. The solutions being found to this complex equation differ from one country to another and are not easily transposable across different health systems, as shown for example by diverging assessments of the same technology in France and Germany, despite the former having explicitly sought to replicate the DiGA model. Of course, the specificities of national healthcare contexts must be taken into account in decisions to allocate public funds to certain therapies rather than others. Yet allowing the multiplication of different frameworks for market access of DMDs across Europe not only risks leaving behind entire patient populations in countries unable or ill-prepared to implement them, it also threatens to undo the progress achieved so far by making the European market unpracticable for digital health innovators.

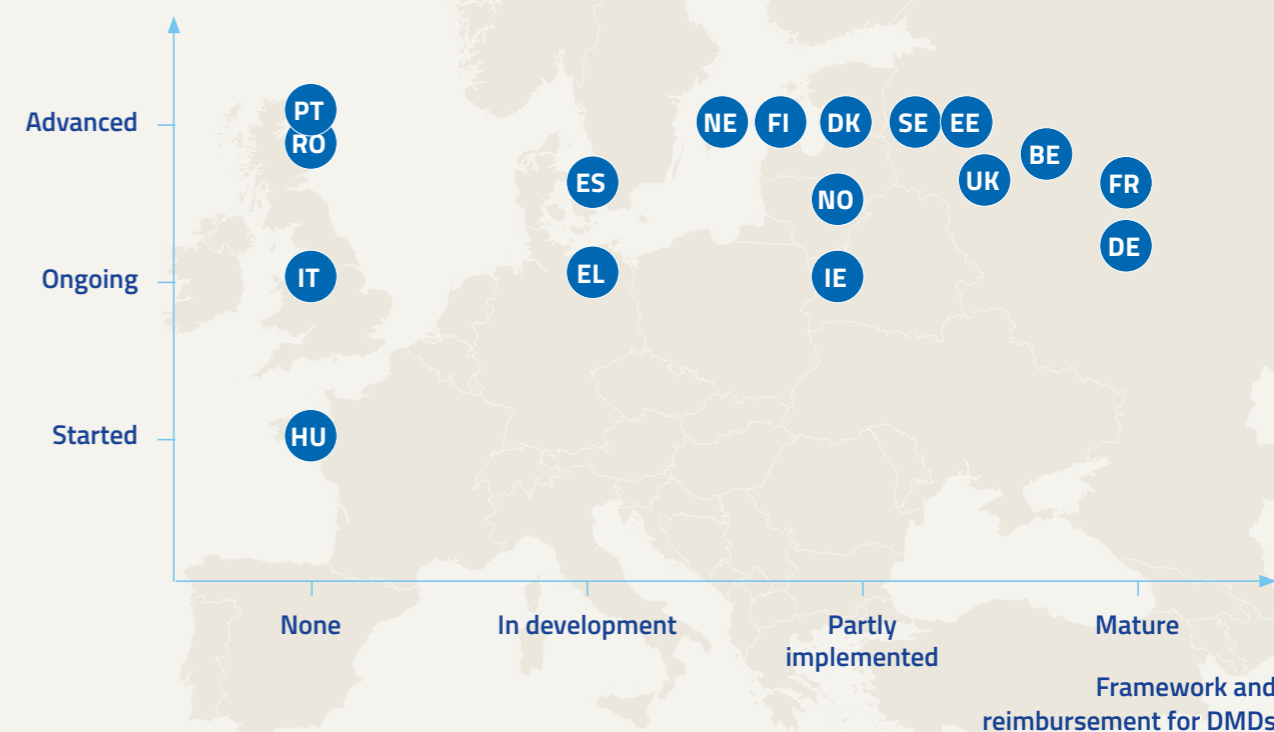
The recommendations that emerged from each of the national and regional roundtables therefore pertain to two broad questions that will need to be addressed simultaneously going forward: how to accelerate the digital transformation of healthcare in individual countries to support the introduction of DMDs in care pathways, and how to drive European convergence in key areas to create a single, globally leading digital health market. Many of the suggested actions, such as increasing political awareness of digital health and enhancing digital skills among healthcare professionals and patients, can and should be led by both national and European actors. Others must be initiated by local policymakers – developing a national digital health infrastructure, making health data available for research, building networks for the validation and piloting of solutions, and defining processes for their implementation – but can leverage the funding streams that the EU has made available for this purpose. Meanwhile,

pan-European collaboration should be prioritised to define the common clinical evidence standards and technical quality criteria that will allow DMD developers to submit valid requests for reimbursement in multiple EU countries without having to invest in new clinical studies or software development for each targeted market. As the secondary use of health data underpins most innovation in this sector, efforts must also be sustained to establish European quality, security, and interoperability standards specific to this peculiar category of data. These should be accompanied by shared ethical guidelines to underpin data sharing and use within the future European Health Data Space.

The possibilities for European integration towards a single market for DMDs span all the way to joint health technology assessments as a common basis for considering reimbursement in the individual Member States, or to the creation of a pan-European scheme for the centralised evaluation and approval of DMDs similar to pharmaceuticals. Whatever the chosen level of harmonisation, common standards should be implemented in a way that supports all countries. EIT Health will be a committed partner in this process, as its role in coordinating the European Taskforce for Harmonising Evaluation of DMDs and its programme offering already testify. Europe is already moving on digital healthcare: the key to success will be to ensure it moves forward together.

Figure 2

Status of digital health and care transformation



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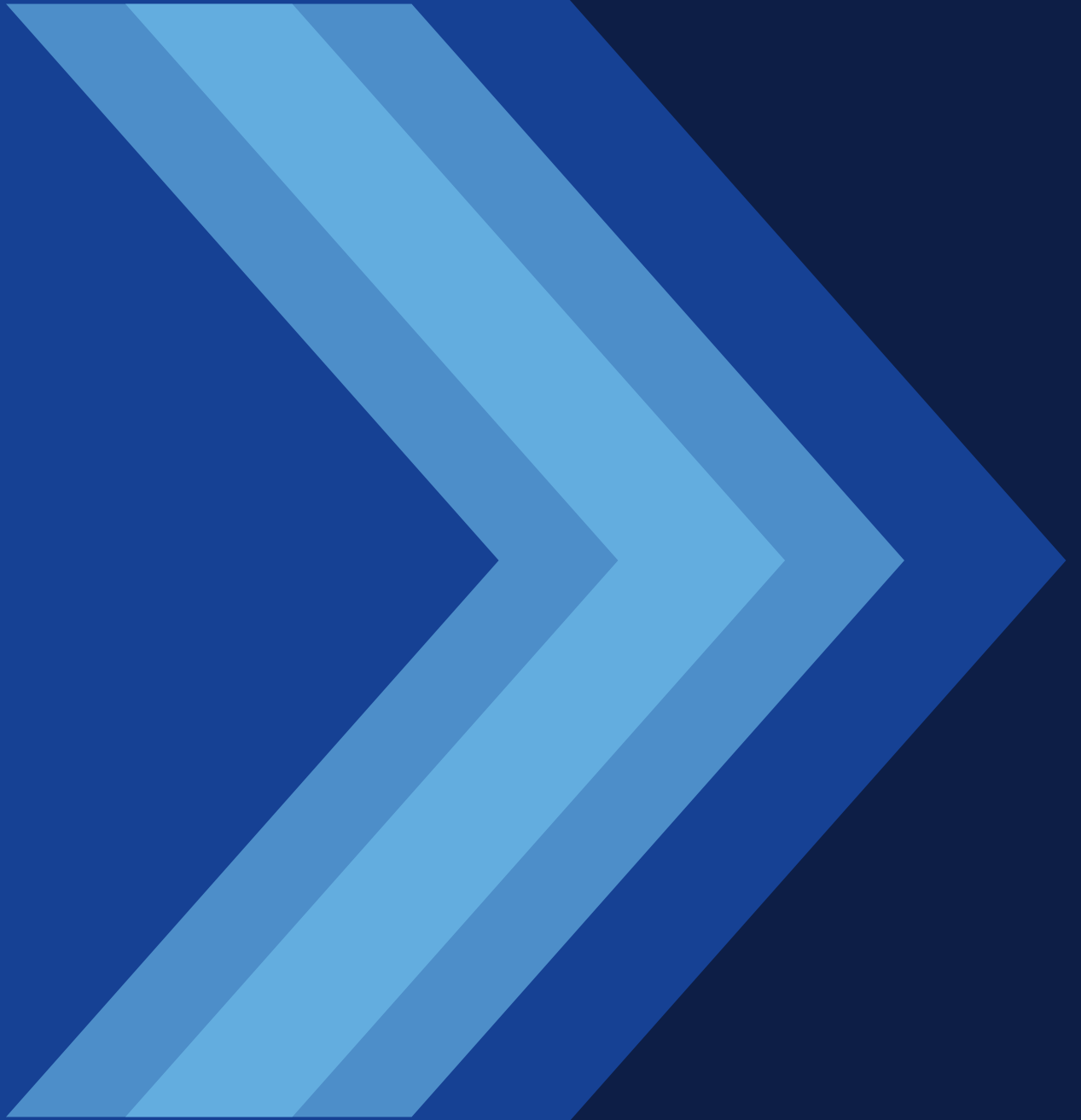
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Annex I: EIT Health Think Tank Roundtable Series

DATE	COUNTRY	TITLE / REPORT
16 September 2021	Germany	DiGAs – a model for Europe? Possible options for achieving a European system
8 November 2021	France	EIT Health France roundtable on transposing the German DiGA system to the French market
24 November 2021	Scandinavia	The DiGAs framework – a model for Europe? Insights from a round table on digital health application frameworks for the Nordics
2 February 2022	Spain	A new era in Europe for health apps. Harmonizing the evaluation, reimbursement and adoption processes
28 September 2022	Ireland-UK	Digital health on prescription: Is Ireland ready?
April 2022	InnoStars	Digital Health: Trends and status of progress in the emerging regions
January 2023	InnoStars	Towards harmonised EU Landscape for Digital Health : Summary of the roundtable discussions in selected EIT Health InnoStars countries

Annex II: EIT Health – Supported DiGAs

EIT HEALTH STARTUP	DiGA	STATUS	HEALTH INDICATION
Endo Health GmbH	Endo-App	Recorded provisionally	Endometriosis
GAIA AG	deprexis	Recorded permanently	Depression
	elevida	Recorded permanently	Multiple Sclerosis
	levidex	Recorded provisionally	Multiple Sclerosis
	optimune	Recorded provisionally	Cancer (Malignant neoplasm of the mammary gland)
	velibra	Recorded permanently	Agoraphobia and Panic disorder
	vorvida	Recorded permanently	Mental and Behavioural disorders from alcohol use
Kineto Tech Rehab SRL	re.flex	Recorded provisionally	Gonarthrosis
Mindable Health GmbH	Mindable: Panikstörung und Agoraphobie	Recorded provisionally	Agoraphobia and Panic disorder
Vitadio s.r.o.	vitadio	Recorded provisionally	Diabetes Mellitus
aidhere GmbH	zanadia	Recorded permanently	Obesity
kaia health software GmbH	Kaia COPD: Meine aktive COPD Therapie	Recorded provisionally	Chronic Obstructive Pulmonary Disease



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