EIT Health Ireland-UK

Digital health on prescription: Is Ireland ready?

eit Health

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Introduction

Digital health is a broad concept that includes solutions for telemedicine and teleconsultation, remote monitoring, connected medical devices, digital health platforms, and health apps. At their best, digital health technologies have the power to ensure equitable access to health education and literacy by bringing knowledge contained in clinical guidelines into the daily lives of patients and personalising it to their needs. They can enable people to take an active role in their own health, prevention of illness, and care. They also have the potential to increase the efficiency, sustainability, and resilience of health systems by reducing demands on medical staff and resources. Furthermore, a new class of therapeutic, digital therapeutics (DTx) which are software solutions with evidence-based therapeutic capabilities, could complement or even replace existing treatments and care, helping patients achieve the health outcomes that matter most to them.

There are over 350,000 mobile health applications available in the main app stores today, with 5 million downloads recorded daily (IQVIA, 2021) . Yet the majority of these are unregulated, untested, potentially low-quality or unsafe technologies being put into the hands of citizens. So, how can patients and healthcare professionals recognise the solutions that really make an impact? A first answer to this question came in 2019. Germany passed its Digital Healthcare Act (DGV) and established a dedicated regulatory approval and reimbursement pathway for digital health applications (DiGA) under the responsibility of its national medicines agency, the Federal Institute for Drugs and Medical Devices (BfArM). Digital applications that successfully complete the review process become eligible for prescription by doctors and psychotherapists and, importantly, for reimbursement by all of Germany's statutory health insurance funds. This covers 73 million citizens.

The initial experience with the so-called DiGA Fast-Track has sparked much interest from other European countries. France became the first Member State to introduce its own reimbursement pathway modelled on the DiGA framework in 2022, Belgium implemented an equally standardised process in 2020 and other countries such as Austria and Finland are considering a similar approach. To crystallise thought on whether the DiGA model could inspire a digital health framework for Ireland, and how that would be implemented, EIT Health Ireland-UK staged an expert panel discussion at the Smart Health Summit in Dublin on September 28th 2022. One-on-one interviews were also conducted with key stakeholders from Irish and European healthcare, academia, and the medtech industry. The following report offers insights from these conversations.

About EIT Health

EIT Health is one of nine Knowledge and Innovation Communities (KICs) of the European Institute of Innovation and Technology (EIT), a body of the European Union. EIT Health facilitates collaborative opportunities across industry, universities, and governments, leading to the acceleration of new healthcare products and services to reach market for the benefit of European patients.

In addition to providing pan-European training, public and private financing, mentorship programs, and consortium building, EIT Health hosts a Think Tank thought leadership forum. Subject matter experts collaborate across disciplines and borders to explore the most pressing topics impacting health and the adoption of innovation. To facilitate this dialogue, 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.

The DiGA Fast-Track

Before DiGA was introduced in Germany, the only alternative to direct-to-consumer reimbursement for developers of patient-facing health apps was to negotiate coverage with individual insurance providers, of which there are 110 in the German statutory system and 41 in its private health sector. According to Anne-Sophie Geier, Managing Director of Germany's industry association for e-health, SVDGV, making reimbursement from the statutory health insurance system automatic upon regulatory approval removed what used to be a major barrier to the scaling of solutions.

Today, patients can activate a DiGA at no out-of-pocket expense, either with a prescription or directly through their health insurance with proof of a diagnosis that falls under the app's indications. Physicians receive an additional reimbursement when medical services are needed as part of the treatment with the DiGA.

What is a DiGA?

To be listed in the BfArM's DiGA directory, technologies must be CE marked medical devices of the (low) risk class I or IIa according to the European Medical Device Regulation (MDR), whose main function is based on digital technologies, achieving objectives through their digital function. A DiGA must meet requirements relating to safety and suitability for use, data protection and information security, quality, and interoperability.
DiGAs are either used by the patient alone or by patient and healthcare provider together, to support the diagnosis, monitoring, treatment or alleviation of diseases or the recognition, treatment, alleviation or compensation of injuries or disabilities.

If manufacturers do not yet have the clinical data necessary to prove their solution's efficacy and directly obtain permanent listing but fulfil all other requirements, they can apply for provisional listing and become reimbursed for a 12-month trial phase. During this period, they must conduct a comparative clinical study to demonstrate their solution's "positive healthcare effect." From the time a complete application is filed for either provisional or permanent listing, the BfArM has three months to assess the DiGA and make an approval decision.

As of January 2023, 40 listed DiGAs covered about 12 disease areas including several mental health indications, from stress and burnout to eating disorders or depression (BfArM, 2023). Fifteen apps had achieved permanent approval by demonstrating their positive healthcare effects through large randomised controlled trials (RCTs).

"In each of these, we have seen profound reductions in symptom burden and improvements in quality of life," said Geier.

"The long-term health economic effects will take more time to measure, but for some apps there is already data[3] to suggest that these solutions are cost-effective."

The European Landscape

Across Europe, what is defined as a transformative digital technology can vary from one national health system to another. In 2021 and 2022 respectively, Belgium and France implemented their own national reimbursement frameworks for patient-facing digital health applications and devices. In many respects, the French process is modelled on Germany's DiGA Fast-Track, however unlike Germany's, theirs also covers telemonitoring solutions. Innovative CE-marked digital medical devices, that are gathering data, can be granted early reimbursement at the recommendation of the national Health Technology Assessment (HTA) body.

In certain countries, digital medical devices for patients can be eligible for reimbursement, but only through decentralised frameworks. In the UK, 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.

"NICE has specifically recommended the use of digital health technologies to manage mental illness in children because most drugs cannot be prescribed to the paediatric population—but we need to clearly define which technologies should be prescribed to whom and how they should be used, based on clinical evidence, and return on investment. Otherwise doctors simply will not adopt them," said Liz Ashall-Payne, CEO of UK-based compliance organisation ORCHA.

No dedicated reimbursement provisions for digital health technologies exist in the Nordic countries, however a particular framework ORCHA has been involved in the development of is NordDEC. This is the first cross-border framework with the aim of establishing a system for healthcare providers to evaluate and identify trusted digital health technologies within healthcare and preventive care. By drawing from international best practice, it establishes a common benchmark of criteria across Denmark, Finland, Iceland, Norway, and Sweden, offering the ability to simply layer on local requirements.

Health Technology Assessment (HTA)

HTA is an evidence-based process that assesses the added value of a given health technology and compares it with the current standard of care. Current practice in the EU is for HTA to be conducted at a national level. In 2018 the European Commission proposed a new regulation to 'promote convergence in tools, procedures, and methodologies and to facilitate a more efficient use of resources and strengthen the quality of HTA across the EU and to improve business predictability.' However, as the development of HTA methodologies has been led by the pharmaceutical industry, this proposal would not support HTA best practice for the medtech or digital health industries due to their unique characteristics spanning evidence factors, industry factors, user factors, and market factors (Irish Medtech Association, 2021).

Digital health in Ireland: poised for change

Ireland is Europe's third-largest exporter of medical devices and, as of 2021, was leading the continent with a trade surplus of €10 billion in this sector (MedTech Europe, 2022). It is also the largest medtech 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).

The Irish government's Department of Enterprise, Trade and Employment has also created opportunities for start-ups and scale-ups in health technology through mechanisms such as the Disruptive Technologies Innovation Fund (DTIF)[8]. This €500M challenge-based fund invests in the development and deployment of disruptive innovative technologies, on a commercial basis, targeted at tackling national and global challenges. The fund drives collaboration between Ireland's top-quality research base and industry, along with facilitating enterprises to compete directly for funding and seeding a new wave of start-ups. EIT Health-supported start-ups such as Novus Diagnostics, ProVerum, and Symphysis Medical, among others, have previously been awarded DTIF funding.

Investment and breakthroughs made in health innovation, research, and development stand in contrast to the uneven progress made in the digitalisation of the public health system. Despite a €21 billion budget (gov.ie 2021), the Irish government's biggest ever investment in health and social care, there remains a need to reduce costs and increase efficiencies. Up to 85 percent of hospital records are still paper based (Irish Times, 2022) and digital infrastructures remain fragmented.

Digital health applications fall outside the categories covered by the Health Service Executive's (HSE) current reimbursement scheme for medical devices, and the HTA system isn't structurally set up to support this. "The Health Information and Quality Authority (HIQA) performs HTAs at the request of the HSE or the Department of Health, but only in small numbers, and the HSE's internal capabilities have fallen away for lack of funding," explained Tom Melvin, Associate Professor of Medical Device Regulatory Affairs at Trinity College Dublin. As a result, patients' access to digital health remains limited to the disparate offerings of individual healthcare institutions and solutions purchased by patients from mainstream app stores.

Faster change could come in the wake of the COVID-19 pandemic, which in Ireland as in other countries saw a surge in implementation of telemedicine and teletherapy solutions to connect practitioners with patients for remote consultations, physiotherapy, speech and language therapy as well as remote monitoring. "Companies like Salaso and patientMpower were tested and used in the healthcare system during COVID-19. Isaac Care and Connected Health are being piloted now. These companies were able to enter the Irish market quickly and were readily accepted by the health system because they were addressing a critical need," said Steven Griffin, Manager, Health Innovation Hub Ireland (HIHI) at the University of Galway.
A public-private partnership funded by the HSE and Enterprise Ireland, HIHI connects companies that are developing solutions to unmet needs in healthcare with healthcare professionals to inform the development, validate the use, or run pilots of their products.

Examples of solutions being developed in Ireland

- Bluedrop Medical's at-home monitoring device for the prevention and early detection of foot ulcers in diabetes patients.
- Feeltect's pressure sensor to optimise compression therapy and accelerate healing of veinous leg ulcers
- Amara Therapeutic's platform to deliver bladder training and pelvic floor physiotherapy interventions directly to patients.

Does Ireland need its own DiGA framework?

Overall, participants agreed that a path to reimbursement for digital health technologies similar to the DiGA Fast-Track would be desirable for many of the same reasons that motivated the creation of the German framework. Reasons include:

1. To ensure equitable access to healthcare for patients
2. To prevent further disparity in levels of digital literacy and income among citizens
3. To create a standardised and structured process for those developing digital solutions
4. To enable healthcare professionals and payors to channel resources towards the most clinically beneficial among the many technologies already available and in use
5. Tying reimbursement to quality is key to driving adoption of digital solutions in areas of critical unmet need.

→ An opportunity to revitalise national healthcare provision

Focusing on the Irish landscape, participants believed that in a system ranking 80th out of 89 countries globally in the 2021 edition of CEOWORLD magazine's Health Care Index, digital health technologies could enable a rapid and cost-effective transformation of public healthcare provision. Waiting times in Ireland routinely exceed 12 months (Irish Times 2022), including for up to one in three children with speech or learning disorders who may miss the windows of time within which interventions are effective. Access to physical therapy and mental healthcare is another challenge which has been accentuated by the pandemic, with over 200,000 people on therapy waiting lists by the end of March 2022. In addition to improving patients' outcomes by providing support and symptom relief while they await in-person care, digital therapeutics could effectively replace certain physical consultations and give medical personnel more time to manage the most critical or complex cases.

Further improvements to the patient journey could include:

1. Giving people more autonomy to manage and group their medical appointments
2. Better coordination of care between hospital and community settings with connected patient records
3. Enabling patients to self-monitor their recovery and complete their rehabilitation therapies at home.

"This would be especially relevant for outpatients in rural regions like Donegal, where Galway is the nearest hospital providing the required service, treatment, or speciality but a hospital visit may entail a four-hour drive," Griffin emphasised.

Centralised procurement and insurance coverage for digital medical devices was seen by several stakeholders as key to increasing the number and quality of solutions available to patients in Ireland. As Neil O'Hare, Professor of Health Informatics at University College Dublin and Group Chief Information Officer for the Ireland East Hospital Group, explained, these are currently limited by the financial and

organisational incentives of individual hospitals, which typically do not have an innovation budget. Funding should be obtained from the actors who stand to benefit the most: in the case of preventive and self-care solutions that reduce the need for hospital visits or medications, the HSE.

A national reimbursement scheme would also attract more developers to sell into the Irish market, according to Brendan Staunton, CEO of Galway-based DTx manufacturer Amara Therapeutics: "Right now, even Irish-based companies tend to commercialise their products in the USA and Germany first."

What are the challenges?

In the DiGA Fast-Track's first two years of operation, several difficulties and unintended effects were observed, which participants believed would also emerge in Ireland and should be anticipated by policymakers.

→ Inconsistencies across Member States

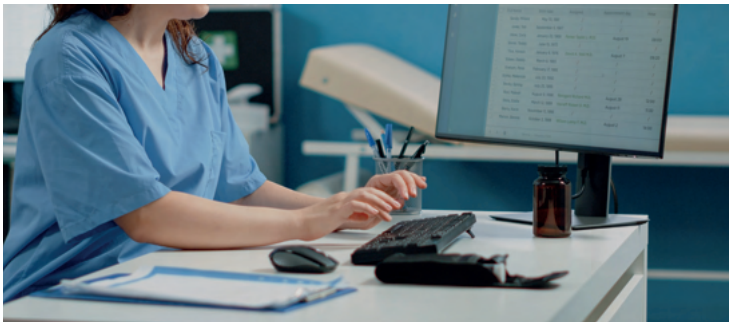
From the outset, most EU Member States taking steps to define assessment frameworks for digital health technologies are doing so separately. Even the types of technologies that fall under these frameworks differ from one country to another, and terms such as "digital therapeutic", "digital health", "digital medicine" are inconsistently defined. Furthermore, there is a lack of consensus on technical quality and interoperability standards, and on requirements for clinical evidence. Developers seeking to expand into other European markets may need to modify their solutions or invest in further clinical evidence generation.

→ Long time-to-approval is incompatible with software life cycles

Despite being named a fast-track, experience has shown that the DiGA process takes significantly longer than three months to complete. This is due to the time and effort needed to prepare an application in line with the BfArM's requirements spanning interoperability, quality, user centricity, cybersecurity and data privacy—and that is after having obtained CE certification as a medical device, another lengthy process which can take up to two years under the new Medical Device Regulation.

This problem has been compounded by the enactment of the European Medical Device Regulation (MDR) in May 2021. The MDR has made the process of CE certification itself much lengthier: many software products that have been moved from risk class I to classes IIA, IIB or III now require assessment by a notified body and potentially clinical trial data to support their application for regulatory approval. The resulting surge in submissions for digital products has also led to significant delays as notified bodies have lacked the manpower and experience required to process these.

"Recent research by our association shows that new companies trying to enter the European market with a medical device today would be waiting up to two or three years to find a notified body and complete the regulatory review process," Geier reported. By that time, the product in the form initially submitted for approval would likely be obsolete due to the inherently evolving nature of software, which could be updated several times a year.



The impact of Medical Device Regulation

Since the entry into force of the MDR in May 2021, developers across Europe are reporting that obtaining CE-marking as a digital medical device has become a significant challenge. From risk class I, many software products have been moved to classes IIa, IIb or III, now requiring 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, as notified bodies have lacked the manpower to process the resulting surge in submissions for digital products. Due to the unpredictability of regulatory requirements coupled with the unavailability of scientific advice on clinical trial design, more manufacturers are turning to the USA or choosing to commercialise their technologies with limited functionality in the unregulated market for wellness apps.

→ Lack of transparent criteria and guidance for developers

In the transition from a system that was self-certifying for most products to one where third-party assessment is needed, several participants warned that the lack of predictability of requirements combined with the inability to get advice on clinical study design was making the European market impracticable for developers. "Although the possibility for advice is written into the new regulation, it is not available yet and it remains to be seen whether the work of the EU Medical Device Coordination Group will achieve the necessary standardisation and transparency," said Melvin. Some predicted that the impact on Europe's competitiveness could be felt for years, with more manufacturers considering the US market first, or choosing to commercialise their technologies with limited functionality in the unregulated market for wellness apps.

Similar concerns were raised about DiGA applicants' difficulties planning and meeting the BfArM's criteria for clinical evidence. Almost two thirds (98) of the 155 applications submitted in Germany as of XX November 2022 were rejected or withdrawn by manufacturers, most commonly for failing to define the positive healthcare effect in the scientific evaluation concept and suitably proving it. This will likely be a persisting challenge for an industry in which small and medium-sized companies are often the drivers of innovation but lack the experience and resources necessary to navigate regulatory processes and clinical evidence generation.

→ Insufficient health system maturity could hinder implementation

The introduction of DiGA also revealed the importance of considering and planning its integration into the existing health system. Infrastructure is required to allow electronic prescription, procurement and interoperability with healthcare provider systems. Acceptance needs to be garnered from stakeholders. These are potential challenges for Ireland. "The HSE is used to obtaining apps for free to support products they already pay for—though of course the cost of those apps is built into the products—so it will take some effort to convince payors of the clinical and health economic benefits of digital therapeutics in their own right," predicted Colin Kavanagh, Partner and Head of the Life Sciences Group at Arthur Cox LLP.

Close collaboration with the HSE would also be needed to understand what implementation would look like in practice, for instance considering the strategy and timeline for the rollout of electronic health records. O'Hare highlighted a need for legal

clarity on data governance issues in this context: "Where is the data being generated in apps going? Do healthcare providers also need to store it? We are legally obliged to hold the data on our patients for almost a lifetime, so we have to be cautious about adopting new technologies considering that only a fraction of those currently being developed will still be there in five years' time."

How could an Irish reimbursement system be implemented in Ireland?

Although participants were generally in favour of creating a new reimbursement scheme for digital health solutions under the responsibility of a dedicated entity, some advocated an incremental approach to updating the current model. "In today's financial climate I don't see health budgets increasing, so businesses will need to work within the existing framework to encourage payers to evaluate and reimburse solutions that improve patient outcomes and save the system money," said Kavanagh. With the basic regulatory systems, processes and required legal structure considered to be in place with the Health Products Regulatory Authority (HPRA) and notified body, and the HSE and HIQA expected to remain the key bodies on the payer side, three main recommendations emerged:

→ **Share the assessment responsibilities**

Clearly attributing responsibilities will be important to allow the development of capabilities and specific expertise for assessing digital medical devices, said Sebastian Eckl, Founder and CEO of German DiGA manufacturer ProCarement: "If the equivalent to Germany's BfArM - the HPRA - is to take the lead, it will need to prepare for this role early because that is a key factor for success." As Melvin highlighted, the HPRA's current medical device software team of around three people will not have capacity for this purpose. Evaluation tasks could be shared with HIQA and the HSE, which would equally need to build capacity well beyond current levels.

Arguing that as a small country, Ireland will be limited in the HTA infrastructure it can build, Melvin proposed an agile strategy that could include leveraging positive assessments from other EU countries. It should then be decided whether this will be done in compliance with the EU HTA Regulation. A view shared by Ashall-Payne who advocated for building on international standards whilst considering what is different for Ireland.

With new technologies continuously emerging and product personalisation potentially enabling a wide range of use cases, Ashall-Payne also reported growing interest from governments in sharing the assessment work with third-party organisations like ORCHA. "In England, we work with the National Institute for Health and Care Excellence (NICE), which only has capacity to evaluate the clinical evidence for about six technologies annually. Having reviewed thousands of solutions to a certain level, ORCHA can advise on which ones are worth looking at as a priority," she said. The organisation has also recently begun a collaboration with the United States' Food and Drug Administration (FDA).

→ **Define the quality framework**

The next step would be to define clear quality standards and build the criteria for assessment. The International Organisation for Standardisation's (ISO) benchmarks for medical software development and information security were considered a good basis for the technical evaluation of solutions. In showing clinical efficacy, according to Staunton, unofficial standards have already emerged as many companies opt for RCTs not just to maximise their chances of regulatory approval, but also to convince payors to

invest in their solutions. Among the methodological aspects that would benefit from formal criteria being set, he cited the question of what should be used as controls for digital devices in comparator trials.

Nonetheless, Staunton and others called for a broader framework for evidence generation that would incorporate more patient-centred outcomes. Improved autonomy or reduced burden of disease could be considered alongside traditional study endpoints like mortality, symptom burden or avoided complications. Alternative trial designs more suited to the complexity of care settings and to the nature of the solutions themselves would need to be agreed on. These are explicitly allowed under the DiGA framework, but no approvals have been based on this kind of evidence so far: a sign that detailed guidance is needed. Ideally, the requirements for future solutions with advanced diagnostic and clinical decision-making functions and clinician involvement should also be anticipated. One panellist recommended establishing a mechanism for reviewing and amending the criteria, as well as a process for repeat evaluations as technologies and quality standards evolve.

Some considered the possibility of applying for provisional listing and providing proof of efficacy during the one-year trial phase as an important part of the German concept, allowing companies to finance their clinical trial at least in part with the flow of reimbursement from DiGA prescriptions. However, others saw this as one of the reasons why uptake was initially slow, with only 50,000 app activations in the first year.

"As a prescriber, I want clinical evidence and I wouldn't recommend anything to a patient without it," Ashall-Payne emphasised.

She went on to emphasize the need for infrastructure in place to enable the safe deployment of these technologies. Becoming a distributor of medical devices in Ireland requires various HPRA obligations to be met.

The Irish Medtech Association made similar recommendations in its Budget 2022 Submission (p. 20) to ensure any Health Technology Assessment is 'fit-for-purpose': "Predictable joint clinical assessments for selected medical technologies (with transparent selection criteria, a predictable timeframe, use Real World Evidence, use fit-for-purpose methodologies, and involve technology developers in final assessment)."

→ Engage with stakeholders

In addition to allocating resources to DTx within the national institutions and investing in procurement and prescription infrastructure to support their implementation, specific measures to drive adoption will need to be planned and funded. These should convince both the public and the Irish clinical community unaccustomed to prescribing medical devices of the safety, quality, and benefits of these solutions. Key tools could be a national repository of proven, trustworthy technologies and a mechanism for compensating healthcare professionals for the associated medical services.

To foster change in a conservative environment like the healthcare system, several participants proposed a process for integrating and testing digital healthcare solutions by moving forward first with an alliance of the willing: regions, networks, or individual institutions where, following approval, technologies could be piloted to produce reference data showing their efficacy in a live environment. Another possible starting point for implementation is exploring synergies with the HSE's "Stay Left, Shift Left" campaign or Sláintecare policy[14] to reduce the number of hospital inpatient bed days through preventive medicine techniques or telemedicine.

Suggestions for implementation

- Share the assessment responsibilities
- Define the quality framework
- Engage with stakeholders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How can Europe support its Member States?

EU-level action could help individual Member States improve access to digital health technologies faster, some argued.

"The US benefits from having a defined regulatory framework and a large, consolidated market. Germany is more advanced in terms of tying the regulatory pathway to the infrastructure and reimbursement, but it's just one country. If Europe were to move towards greater harmonisation in these areas, it could become the leader in digital therapeutics in a very short time," said Staunton.

→ Make better use of EU regulations

Participants called for better integration between the MDR and the HTA Regulation, and for more resourcing of scientific advice processes on the model of the European Medicines Agency. "There will always be the national competence for reimbursement, but tying together market access and the HTA basis for reimbursement with as much transparency as possible would start to reverse the predictability challenge which currently puts Europe at a disadvantage compared to the US," said Melvin. Joint HTAs in Europe would also help smaller Member States like Ireland to implement reimbursement of digital medical devices without having to build an entire framework from scratch locally. However, another legal specialist cautioned that the HTA Regulation will apply only to the most innovative solutions that have EU-wide public health impacts.

→ Agree on common standards

In the absence of a pan-European approval and HTA pathway for digital health technologies, participants agreed that the way forward would be to define common technical standards for critical aspects like interoperability and data security, and to develop a pan-European consensus on assessment criteria and evidence standards. The first would allow manufacturers to enter national markets and integrate their solutions with local digital systems more easily, the second should enable companies to conduct multi-centre studies across different EU Member States or use study results obtained in one country to apply for reimbursement in others.

A call for European action

- Define a regulatory framework
- Create joint HTAs
- Set common standards and assessment criteria

A mission for EIT Health

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. "With initiatives to implement digital medical devices underway in several EU countries, we are already seeing differences in what Member States are choosing to include in this category. DiGAs so far are mostly low-risk health apps and web-based platforms, whereas other countries like France and

Finland are also integrating telemedicine, AI solutions, and robotics in their frameworks," said panellist and coordinator for the taskforce at EIT Health Fruzsina Mezei, emphasising the importance of laying down common foundations now to avoid increasing fragmentation in the future.

The taskforce is made up of 20 members representing the academic sector, policy makers and national competent authorities and HTA agencies from Austria, Belgium, Finland, France, Germany, Italy, Luxembourg, and Spain, among others. Its goal is to develop a proposal for harmonising the taxonomy and nomenclature of digital medical devices, as well as recommendations for standardising the clinical requirements to assess these technologies. Following feedback from an External Advisory Board regarding real-world feasibility, the results will be presented in 2023 and published as a consensus article.

Conclusion

This report has taken stock of the initial experience with, and lessons learnt from the DiGA Fast-Track in Germany and identified challenges, but also opportunities to improve patient care that could come with the broader introduction and reimbursement of digital medical devices in Ireland. Contributing experts outlined possible approaches to evaluating, funding, and deploying evidence-based digital health technologies, considering the financial and structural constraints of the national health system.

As a small country, Ireland will not replicate Germany's DiGA exactly – but it may not need to, as the emergence of alternative quality frameworks and pan-European collaboration in this field could allow it to share the assessment work with other EU Member States. Nationally, areas of great unmet need such as mental healthcare and other forms of therapy could become flagships for the implementation of digital technologies which measurably improve population health and individual, patient-relevant outcomes, while potentially reducing use of and expenditure on medications or acute care, all for a comparatively modest investment. The necessary political effort to make this a reality should not underestimate the cultural shift that will need to take place throughout the Irish healthcare system. However, it will be able to look to Ireland's flourishing digital medical device industry to provide effective, home-grown solutions to one of the pressing challenges of our time: making high-quality, sustainable healthcare accessible to all.

Participants

→ **Smart Health Summit Panellists**

Liz Ashall-Payne – Founder and CEO, ORCHA
Sebastian Eckl – Founder and CEO, ProCarement
Colin Kavanagh – Partner and Head of Life Sciences Group, LLP Arthur Cox
Fruzsina Mezei – Health economist and DMD taskforce coordinator, EIT Health
Neil O'Hare – Professor of Health Informatics, University College Dublin and CIO, Ireland East Hospital Group

→ **Interviewees**

Anne-Sophie Geier – Managing Director, Spitzenverband Digitale Gesundheitsversorgung
Steven Griffin – Manager, Health Innovation Hub Ireland, University of Galway
Tom Melvin – Associate Professor of Medical Device Regulatory Affairs, Trinity College Dublin
Brendan Staunton – Founder and CEO, Amara Therapeutics

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