The time is now for digital therapeutics

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1 In brief

- With ageing populations, changes in lifestyle and heightened health awareness, there is a need for more comprehensive disease management to improve patient outcomes and address gaps in health care delivery
- Mental health issues and burgeoning chronic conditions are becoming an increasing concern post-COVID-19 pandemic with shared unmet needs, and a need to provide a more comprehensive disease management solution to help both patients, physicians and alleviate burden on the healthcare system
- Several companies are active in this space as the market continues to grow with significant regulatory changes and country level plans accelerating the use of Digital Therapeutics
- A concerted collaborative effort across all key stakeholders in the healthcare ecosystem needs to be upheld effectively to ensure appropriate adoption
- Pharmaceutical companies need to act now to take advantage of more favourable market conditions and reimbursement routes for digital therapeutics which may complement drug therapies and provide product differentiation
- AI will have an important role in next-generation DTx solutions as care models move towards prevention

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Introduction

1. Overview of digital health and digital medicine

Healthcare has continuously evolved due to advances in digital technology and has transformed patient care delivery. Through leveraging digital tools, healthcare delivery has enhanced significantly with improved patient outcomes and with more focus on health and wellness as patients demand more control over their health. At its core, the main aim for digital health is to digitise standard healthcare practices, which includes technologies, platforms and systems that engage consumers for lifestyle, wellness and health-related purposes. Digital health broadly covers four key areas:

1. **Health IT**
2. **Virtual clinical trials**
3. **Digital marketing**
4. **Digital medicine**

Digital medicine comprises technologies that are used to measure or intervene in healthcare and may or may not be regulated e.g., condition management and wellness apps. Several key areas within digital medicine include:

1. Wearables/ durable medical equipment (dme)
2. Virtual care
3. Condition management & wellness
4. Remote patient monitoring
5. Digital diagnostics/ biomarkers
6. Digital therapeutics

Digital therapeutics (DTx) is an emerging field and is rapidly gaining traction in the market as a new way to potentially improve therapies.

This article aims to explore why now is right time to explore digital therapeutics and what key changes are currently occurring that make market conditions more favourable that will help with DTx adoption.

2. What are digital therapeutics (DTx) and why we may need them now

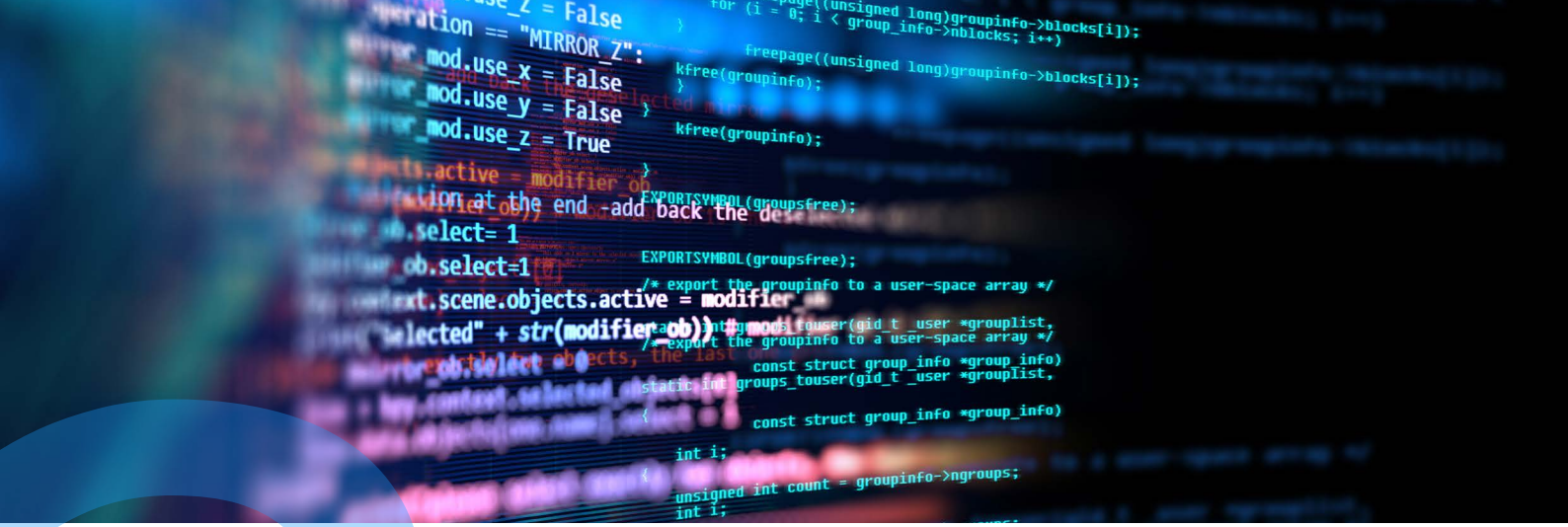
DTx solutions are evidence-based software products used to prevent, treat or manage disease. They are regulated, are clinically backed by clinical trials to validate meaningful benefit to patients and can be used independently or in concert with drug treatments to optimise patient care and health outcomes. DTx solutions also include software as a medical device (SaMD) which are software products intended to be used for one or more medical purposes without being part of a hardware medical device.

With ageing populations, changes in lifestyle and heightened health awareness with more digitally sophisticated patients seeking to better manage their own health, there is more of a pressing unmet need for DTx solutions to combat health issues. Moreover, there has been a burgeoning increase in more chronic conditions globally (e.g., cancer, diabetes, obesity and hypertension), which are largely irreversible and poorly addressed by healthcare systems. More of these patients struggle to manage these diseases and find it difficult to adhere to prescribed medications. Physicians have little control and ability to help monitor patients on these treatments and to ensure patient adherence. In addition, chronic conditions are largely associated with mental health issues such as depression, anxiety and PTSD, where patients are increasingly requiring interventions that help provide support in behaviour modification, cognitive support and better management of their treatment alongside drug therapies. These challenges require a more comprehensive, end-to-end disease management solution where a DTx intervention could help both patients and physicians. In addition, DTx solutions have the potential to also improve adverse events experienced by patients when on treatment regimens, having a significant impact on patient outcomes in the disease management journey as well as economic benefits on health care systems.

In addition to these benefits, a DTx solution could provide other key benefits that have the potential to further transform patient care and alleviate pressure on health care systems. These include:

- ## Remote monitoring
  Patients can be informed in a timely manner as DTx solutions can collect real-time data and provide early detection
- ## Accessibility
  DTx solutions can be accessed anytime and anywhere with a mobile phone or other technological devices
- ## Health equity
  Several patient populations globally, particularly in developing countries and more rural areas, still struggle to gain access to appropriate health care; a DTx solution could help bridge the gap between health care professionals (HCPs) and underserved patient populations
- ## Cost-effective treatments
  For patients that have challenges in accessing treatments due to high cost, a DTx solution can potentially reduce health care costs due to the reduction of in person visits to HCPs

As populations increase globally, digital therapeutics will be essential to provide accessible, evidence-based interventions, and will bridge the gap between traditional health care and innovative technologies.



3 The global digital therapeutics landscape and key regulations

1. Overall market

In 2024, the global revenue for digital therapeutics was estimated to be US$4.7 billion, and in 2025 it is projected to be US$6.8 billion[1]. Between 2025 and 2029, the global revenue from DTx is expected to grow at CAGR of c.10% and will reach US$10.1 billion by 2029[1]. This growth is attributed to the pandemic accelerating the adoption of digital health technologies, emerging reimbursement models and a favourable regulatory landscape towards DTx solutions to combat rising prevalence of chronic diseases.

2. Regulations are changing in the US for digital therapeutics

The regulatory environment in the US for digital therapeutics is mature with a well-defined regulatory framework for digital therapeutics and SaMDs, where defined regulatory pathways vary based on the DTx solution intended use and level of risk; each product is subject to varying degrees of oversight, e.g., full 510(k) certification is required to demonstrate substantial equivalence to a marketed device in US.

The regulatory landscape in the US has made further strides in the last few years, with policy changes becoming more favourable for the use and reimbursement of digital solutions alongside drug therapies.

The Medicare Physician Fee Schedule (PFS) governs how Medicare pays physicians and other clinicians for professional services. In 2019, a prescription digital therapeutic (PDTx) bill was introduced following proposed rules for PDTx in 2024, A year later, the Centers for Medicare & Medicaid Services (CMS) adopted the rule by proposing three new codes in the PFS in early 2025[2] to cover and reimburse PDTx for psychiatric disorders. This marked a significant shift in enabling direct reimbursement for behavioural and mental health treatments as these did not have a defined Medicare benefit category previously, except for those that met the definition of a Durable Medical Equipment (DME).

In parallel in 2023, the FDA proposed a prescription drug-use related software (PDURS) framework[3] which would enable drug labels to be changed through the addition of a digital solution that provides meaningful clinical benefit to a prescription drug. The PDURS framework differs from wellness apps where these do not have clinical benefit claims; on the other hand, PDURS differs from drug-device combinations such as companion diagnostics where there is greater regulatory burden; these must also be prescribed with the drug and is essential for drug use. This optionality with PDURS provides greater flexibility for organisations to consider and gives patients the option to use a digital solution alongside their drug therapies that has the potential to increase drug effectiveness. As per FDA guidance, clinical validation of the software with existing approved drugs under the PDURS framework would be reviewed by the FDA as any label change i.e., via NDA supplement. FDA guidance also suggests clinical evidence is required to demonstrate meaningful clinical benefit that could be achieved via real-world Phase 4 studies for intended use.

Further policy changes in the US have expanded the pathway for reimbursement of innovative digital technologies to help improve patient outcomes. This includes the H.R.8816 American Medical Innovation & Investment Act, 2024[4] that was passed in June 2024 which enabled rule modification of innovative technologies to be covered in certain Medicare payments and benefits.

Overall, there is positive momentum in the US for digital therapeutics, including those that are prescribed, which will see a lot of activity in the coming years as the market develops and will be advantageous for companies to enter the market and maintain growth.

3. Overview of regulatory developments in the EU

For the development of DTx solutions specifically, countries across Europe adopt similar approaches, however there is a lack of alignment across the bloc. As a result, the regulatory and reimbursement landscape for DTx solutions varies significantly. However, the regulatory bodies such as the European Medicines Agency (EMA) and the European Commission are beginning to explore regulations focused on digital therapeutics.

4. EU and UK Country Level Regulations and Approach to Digital Therapeutics

At a country-level, key markets active in policy changes and spearheading regulations in Europe for digital therapeutics include Germany, France, Belgium and the UK. This article focuses on the top 4 EU markets that are leading the way in DTx regulations and what companies need to be aware of when considering entering these markets now.

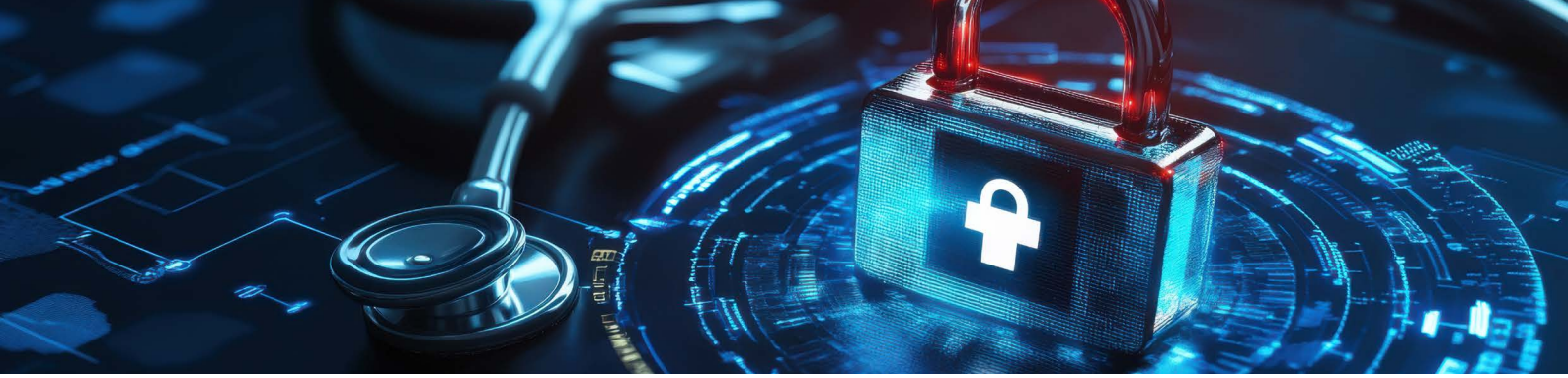
Germany is the front leader globally and is the pioneer for DTx legislation. In December 2019, Germany introduced the Digital Care Act (Digitale-Versorgung-Gesetz [DVG])[5], which marked the introduction of applications being prescriptible for patients. As a result, patients covered by statutory health insurance are entitled to use the digital health application (DiGA) prescribed by an HCP and can be reimbursed. DiGA implementation allowed the German DTx market to grow exponentially, where the market doubled within four years of introduction from US$5 billion to US$10 billion (2019–23) at 21% CAGR; prior to DiGA implementation the market modestly grew from US$3.3 billion to US$47 billion (2016–19) at 13% CAGR. This clearly demonstrates the unlock power of DiGA implementation for DTx reimbursement, where other countries are following closely behind. While the market may be high in competition, leveraging the clear regulatory pathways can offer companies a stable market to enter the EU and gain traction, while strategically positioning themselves for market entry across the bloc.

In France, a similar reimbursement model to Germany's DiGA has been introduced and implemented in the form of Prise en Charge Anticipée (PECAN)[6]. This also offers fast-tracked reimbursement, enabling quicker patient access to DTx solutions. PECAN covers two categories of digital solutions: DTx and remote health monitoring systems.

For these digital solutions to be reimbursed they must adhere to the European CE mark, regardless of the digital solution's risk class, demonstrate innovativeness based on their potential clinical benefits, and meet interoperability and data security requirements set by the French Digital Health Agency (Agence du Numérique en Santé). Unlike DiGA, PECAN is stricter on developers, as they have a 6–9 month window to submit evidence for a permanent listing, while DiGA enforces a 12–24 month timeline.

In January 2021, the National Institute for Health and Disability Insurance (INAMI-RIZIV) in Belgium announced a reimbursement scheme for DTx solutions. Through its mHealthBelgium pyramid platform[7], created in 2018, DTx solutions can now reach a level ('M3' level – socio-economic value substantiated and have appropriate funding), which enables reimbursement. However, DTx solutions still need to pass two subsequent levels ('M1' – certified CE medical device, and 'M2' – company applied for reimbursement in which the device is eligible) before reaching M3 level. To reach the M1 level, the DTx solution must meet basic requirements such as recognition as a medical device (e.g., CE marking), compliance with European data protection laws, and product notification in the Federal Agency for Medicines and Health Products (FAMHP) database. To meet the M2 level, the DTx solution needs to ensure identification and authentication of a user, verification of the treatment relationship, informed consent, interoperability and data protection. However, currently, no DTx solutions have reached the M3 level to date, which may be an opportunity for companies to consider market entry while competition is minimal.

In the UK, DTx solutions are regulated as medical devices and require either a CE mark or a UKCA mark[8]. Further evaluation is conducted by NHSx and NICE to ensure their economic viability, reimbursement potential and accessibility for patients. The NHSx has unveiled its Digital Health Technology Standard in the form of Digital Technology Assessment Criteria (DTAC)[9], which assesses DTx solutions against five criteria: clinical safety, data protection, technical security, interoperability and usability & accessibility. For the reimbursement of digital-wide solutions, NICE has developed a framework that evaluates 21 different areas through the Evidence Standards Framework (ESF). The technology is then placed in either Tier A (tech aimed at cost saving or alleviating staff time without direct patient health outcomes), Tier B (tech assists individuals at managing health and wellbeing) or Tier C (tech to be used for diagnosing, treating medical conditions or guide care choices) categories which determine evidence requirements; should the assessments present a benefit for both patients and the NHS, it becomes eligible for a reimbursement programme at



an individual level. Reimbursement of DTx solutions (Tier C) are largely decentralised and are evaluated at the local level by Integrated Care Systems (ICS) where decisions are made based on ICS clinical budget and DTx solution cost effectiveness. However, there is huge potential now for DTx solutions in the UK given the NHS has a renewed focus to move from treatment to prevention, and analogue to digital in its 10 year Health Plan[10], therefore companies can leverage this opportunity to help alleviate substantial healthcare system burden and improve health outcomes for patients.

By understanding the regulations that exist in key markets where there is a high interest and need for DTx solutions, with clearer regulatory and reimbursement pathways and alignment with market priorities, companies can better position themselves given the time is right, to allow for timely market entry and fuel growth opportunities.

5. Active companies in digital therapeutics

Several therapeutic areas are seeing an increase of digital therapeutics use, which are playing a major role in CNS, mental health and chronic conditions, accelerated by the pandemic. Cognitive behavioural therapy (CBT) solutions, health and nutritional education, and tracking or monitoring of treatment progress are being widely employed to circumvent chronic health conditions as a cost-effective way to help improve patient outcomes. Other areas of focus for digital therapeutics include women's health, oncology, metabolism, Inflammation & Immunology and metabolism. Several DTx solutions are now available in certain therapeutic areas, with many more companies becoming active in this space as the field develops.

The landscape continues to evolve with mergers and acquisitions of many companies, while several have liquidated due to lack of funding opportunities. Click Therapeutics has had some success in a recent FDA breakthrough device designation for its Metabolic Associated Steatohepatitis (MASH) product, acquired through the dissolution of Better Therapeutics. Further acquisitions from Better's portfolio also included AspyreRx, which received a de novo clearance from the FDA in 2023 as the first digital therapeutic for Type 2 diabetes. Click Therapeutics also acquired other assets from Better in conditions such as obesity, diabetes and chronic cardiometabolic disease, in which the former disease areas are a rapidly growing sector dominated by GLP-1 medications.

Click Therapeutics have had several collaborations ongoing with many pharma companies; in 2019 Click Therapeutics collaborated with Otsuka, which committed to fully fund research behind the app Rejoyn, a digital therapeutic solution for adults with major depressive disorder (MDD). In 2024, Click Therapeutics and Otsuka secured FDA clearance for the first prescription digital therapeutic solution for MDD to be used alongside antidepressants. The Digital Therapeutic is designed to act like physical therapy for the brain by delivering personalised, consistent brain-training exercises designed to improve connections in the brain regions affected by depression, therefore improving emotional regulation to help improve symptoms of depression.

These examples demonstrate the active landscape in Digital Therapeutics, with tech startups leading the way, however notwithstanding several risks without funding and scale. Several of the top global pharma companies have also realised the value digital therapeutics can provide and are rapidly making inroads in this space through developing alone, co-developing, licensing and M&A, e.g., Novo Nordisk partnering with DTx companies for GLP-1 adherence tools, Roche's acquisition of mySugr for diabetes management.

4 Health equity and access via digital therapeutics

As mentioned earlier in the paper, digital therapeutics can help address the current and growing health equity divide across the globe by expanding access to remote areas, where healthcare facilities are scarce by reducing barriers to care delivery. Many DTx solutions have been developed with multilingual support and culturally relevant interventions to serve diverse populations, i.e., Omada Health, through its tailored diabetes prevention and chronic disease management programme, and free digital coaching, remote monitoring, and culturally relevant education, increased diabetes management success in Black and Hispanic communities.

The evolving DTx landscape has the capability to adapt treatments based on patient demographics, behaviours and social determinants of health. FDA approved DTx solutions help opioid and substance use disorders, designed for Medicaid populations, previously incarcerated individuals and rural communities where addiction treatment is scarce, has managed to increase treatment adherence by 40% in low-income patients and helped individuals access therapy post-incarceration, reducing relapse rates.

Though the space is still challenged by the digital divide and access to digital resources, digital literacy and usability together with the continued artificial intelligence (AI) improvements, insurer support and equity-focused design suggest DTx solutions may play an even bigger role in closing healthcare gaps for underserved populations.

5 Ecosystem and role of different stakeholders in digital therapeutics

For digital therapeutics to be successful, a large ecosystem of several different stakeholders centred around the patient need to come together to be aware, lobby for, approve and prescribe digital therapeutics to be used alongside treatment options. This will not only help empower patients but also help alleviate challenges faced by clinicians and health care systems.

Health care providers (physicians, nurses, psychiatrists) are key stakeholders that diagnose, prescribe and are involved in monitoring a patient's progress with the DTx. Physicians can also integrate digital therapeutics in broader care plans and may offer guidance to patients, alongside healthcare providers, on how to use the technology more effectively. This may also be carried out in conjunction with digital therapeutic developers or companies to lessen the burden on healthcare providers on technology utilisation, teaching and training to patients. Health care provider support is crucial for validating the efficacy of DTx solutions and ensuring its clinical adoption.

Payers play a key role in ensuring patients have access to digital therapeutics and that these are reimbursed appropriately, which can significantly impact DTx adoption. Their willingness to cover DTx as part of healthcare benefits is essential for broadening access to these treatments.

Technology developers, or those companies responsible for designing and developing DTx solutions, need to ensure they create scientifically validated, user-friendly and secure digital solutions. Most technology developers are working closely with regulators to ensure their DTx solutions meet approval requirements and comply with legal and ethical standards. Technology developers are also increasing lobbying efforts for DTx solutions, advocate for policy changes with policymakers to increase awareness of digital therapeutics and how they can improve patient outcomes and address gaps in health care e.g., Akili Interactive, Big Health and Omada Health.

Technology and data partners, e.g., cloud providers and data analytics companies, offer infrastructure, data storage and analytical tools to enable DTx solutions to function effectively. Data privacy and security are critical concerns in healthcare and call for compliance particularly around GDPR which will need to be considered carefully by these partners.

Advocacy groups and patient organisations, e.g., American Cancer Society, seems to play an essential role in raising awareness of DTx solutions, advocating for policy changes and ensuring patient needs are considered in DTx development. Their involvement can also help drive DTx demand.

For many DTx startups, investors will continue to play a critical role in providing the necessary capital to fund development, clinical trials and commercialisation. Several startups, however, may face challenges with the ability to scale their DTx solutions to reach, and be accessible to, large patient groups.

Pharmaceutical companies may form strategic collaborations and partnerships with DTx companies or begin to develop their own DTx solutions to integrate with their drug therapies, creating a more comprehensive solution for patients, particularly for chronic conditions to help differentiate their products as competition becomes fiercer. More pharmaceutical companies are considering DTx solutions as part of their portfolio which is likely to see further growth in the near future given regulations are more favourable with recent reimbursement changes.

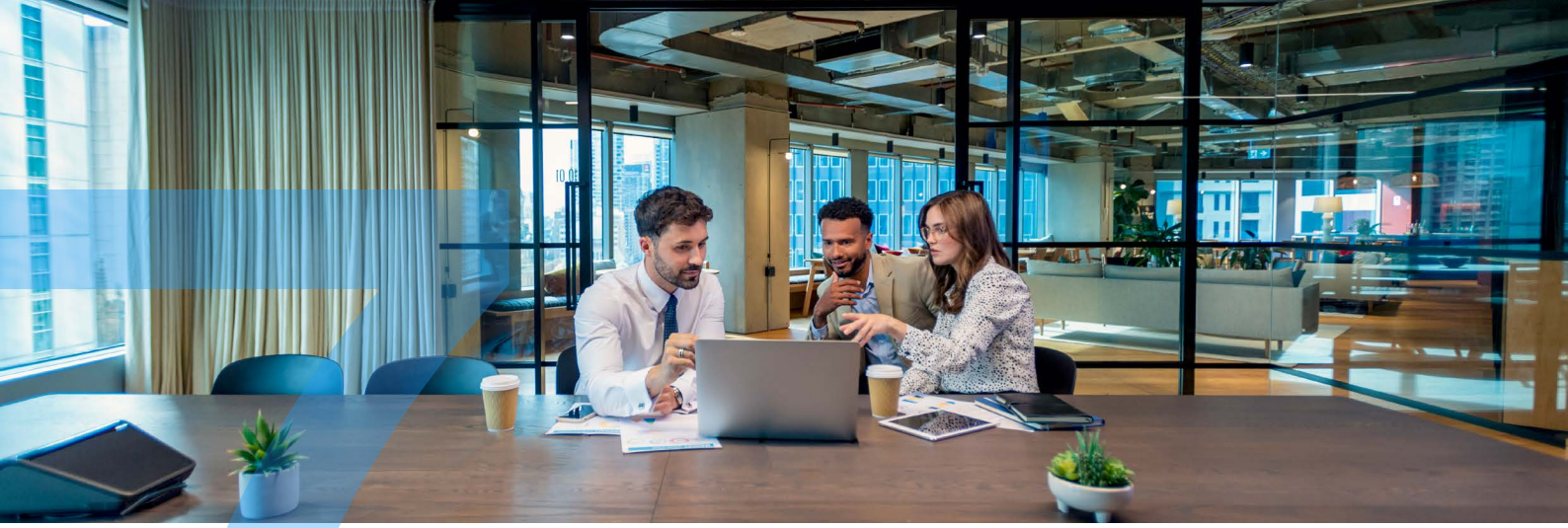
Each stakeholder group is essential in the development, approval, adoption and sustainability of DTx solutions, making timely collaboration essential in the health care ecosystem. Collaboration will be critical to overcome barriers to adoption such as clinician buy-in and patient engagement.

Future outlook of digital therapeutics

Though the global widespread integration of digital therapeutics is yet to be realised, the paradigm shift created by technological advancements, increasing adoption and reforms in regulatory approvals, there is potential to transform patient care, improve patient health outcomes and offer innovative DTx solutions for longstanding healthcare challenges.

With increased attention by investors, technology leaders, providers and payers in this arena, as well as addressing patient unmet needs, the global digital therapeutics market is projected to grow rapidly by 2030. We will see a surmountable accumulation of efficacy data for Digital Therapeutics, health agencies becoming more inclined to formalise regulatory pathways for DTx solutions, regulatory approvals becoming more smoother owed to more structured regulatory frameworks, and reimbursement policies being improved across borders. These factors will together enable better adoption of digital therapeutics for more comprehensive care delivery.

AI will probably play an ever-increasing role in next-generation DTx solutions as care models move towards prevention. Integration of AI may include fully autonomous chronic disease management, e.g., AI adjusting insulin doses in real time, predicting and preventing mental health issues and delivering personalised CBT algorithms, and AI helping to predict side effects of drug therapies to enable pre-emptive symptom management.



What should businesses do now?

Businesses should consider acting quickly as the field grows to commission digital therapeutics as a way to engage with patients and improve health outcomes more comprehensively in their disease management journey. Digital therapeutics may offer more innovative ways to differentiate drug therapies for pharmaceutical companies, delivering value 'beyond the pill' as an opportunity for growth in particular therapy areas. Businesses will need to prioritise real-world evidence to validate DTx clinical impact.

EY teams can help your business assess your growth opportunities, differentiate your product portfolio enhanced by digital therapeutics and leverage regulatory changes that make this opportunity more optimal than before.

Sources

1. **Digital Therapeutics – Worldwide Market Forecast**
2. **Physician Fee Schedule 2025**
3. **Prescription-related Drug Software 2023 FDA regulations**
4. **H.R.8816 American Medical Innovation & Investment Act, 2024**
5. **Digital Care Act (Digitale-Versorgung-Gesetz [DVG])**
6. **Prise en Charge Anticipée (PECAN)**
7. **mHealthBelgium pyramid platform**
8. **UKCA markings**
9. **NHSx Digital Technology Assessment Criteria**
10. **'Road to Recovery' 10 year Health Plan**

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