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GAIA

Digital therapeutics

Catalysing the future of health

Contents

Digital therapeutics: A primer

Digital therapeutics are a novel category of medical interventions that have the potential to disrupt the future of healthcare models

What are digital therapeutics?

Digital therapeutics (DTx) are software-based products for the prevention, management and treatment of health conditions. They are defined by the Digital Therapeutic Alliance as evidence-based therapeutic interventions that are driven by high-quality software programs to prevent, manage or treat a medical disorder or disease.[1] Digital therapeutics are a subcategory of digital medicine products, which in turn are a subset of digital health (see Figure 1 for definitions). A feature of DTx is that they require both clinical evidence and evidence from real-world outcomes. As such, they need to be reviewed and approved by regulatory bodies for claims of safety, risk and efficacy.

DTx products may be used as a standalone alternative to pharmacological interventions (monotherapy). Alternatively they may be used to augment or complement medication, devices or other treatments for improving health outcomes.

Digital therapeutics are developed for a variety of indications, particularly chronic diseases like diabetes, respiratory diseases and mental health disorders, where traditional pharmacological therapies cannot fill the gap in unmet needs and behavioural change is required for end-to-end disease management.

According to a recent Deloitte report, digital therapeutics are one of five forces[i] that will have a disruptive impact on the future of biopharmaceutical companies and the patients they serve.[2] They are increasingly effective and scalable non-pharmaceutical (digital) interventions – including those focused on behaviour modifications – that might also reduce or even eliminate the demand for medications. According to our 2025 predictions for the future of the healthcare and life sciences sector, medicine will undergo a paradigm shift from healthcare to holistic health, and clinicians will base their diagnoses and treatment decisions on predictive, preventative, personalised and participatory care (4Ps). This shift, towards prevention and well-being replacing or complementing traditional care in healthcare facilities, will be driven by technological and scientific advancements which include digital therapeutics, epigenetics and artificial intelligence (AI).[3]

"A lot of people have doubts that software can have such an impact, but it is astonishing to see the results of digital therapeutic interventions in randomised controlled clinical trials"

Vice President Commercialisation
Digital Therapeutics company

[i] The five forces of potential disruption to the biopharma industry are: prevention and early detection, customised treatments, curative therapies, precision intervention and digital therapeutics

All in all, digital therapeutics have the potential to accelerate the shift from healthcare to holistic health, as per Deloitte's Future of Health™ vision: these interventions are likely to move the needle toward prevention and well-being, replacing or complementing traditional care in healthcare facilities.

Figure 1. Differences between digital health, digital medicine and digital therapeutics

Digital Health

Digital health includes technologies, platforms, and systems that engage consumers for lifestyle, wellness, and health-related purposes; capture, store or transmit health data; and/or support life science & clinical operations.

Data & information capture, storage, and display

- User-facing technologies
- Health Information Technology (HIT)
- Consumer health information

Data & information transmission

- Telehealth
- Decision support software
- Enterprise support
- Clinical care administration & management tools

Digital Medicine

Digital medicine includes evidence-based software and/or hardware products that measure and/or intervene in the service of human health.

Measurement products

- Digital diagnostics
- Digital biomarkers
- Electronic clinical outcome assessments
- Remote patient monitoring
- Decision support software

Measurement & intervention products

- Digital companions
- Digital products that measure and intervene, and do not require human intervention to serve primary purpose

Digital Therapeutics

Digital therapeutic (DTx) products deliver evidence-based therapeutic interventions to prevent, manage, or treat a medical disorder or disease.

Monotherapy

- Designed to treat a disease by delivering therapeutic intervention digitally
- Mostly used in mental health as Cognitive Behavioural Therapies (CBT) that can be digitally delivered to patients to treat several conditions

Adjunctive

- Designed to improve the effectiveness, management or treatment of a prescribed pharmacological intervention
- Usually prevalent in complex indications such as diabetes, obesity and hypertension

No clinical evidence → **Clinical evidence required** → **Clinical evidence and real-world outcomes required**

Source: Digital Therapeutic Alliance, Digital Medicine Society, Deloitte analysis

The evolution of digital therapeutics

Although the term 'digital therapeutics' has emerged only since 2012,[5] the idea of applying technology to deliver care is not new. In mental health, for example, the first applications of artificial intelligence (AI) to model interactions with a therapist date back to the 1970s.[6]

In recent years developments in DTx have been accelerated by technological advances, and also by changes among individuals towards a more personalised and participatory attitude to their health. This change in attitude is evidenced by the widespread adoption of wearables and other wellness devices to monitor and track vital parameters of physical and health conditions.

Some of the major milestones in the history of digital therapeutics include:

- Clearance by the US Food and Drug Administration (FDA) in 2010 of WellDoc's prescription version of its BlueStar diabetes management system platform, making it the first prescription digital therapeutic to be approved in the US[7]
- GAIA AG, having proved in several randomised control trials (RCTs) in the United States and Europe with over 4,000 patients the effectiveness of its fully automated multi-language depression treatment deprexis®, received market authorisation from the FDA in 2015
- Clearance in 2017 by the FDA for Pear Therapeutics'reSET®, the first prescription digital therapeutic for substance use disorder (SUD), demonstrating improved treatment retention[8]
- Approval from the FDA in 2017 for the first 'smart pill' system Abilify MyCite® which combines drug tablets with an ingestible sensor to measure the effectiveness of medication treatment and help physicians improve clinical outcomes for schizophrenia, bipolar disorder and depression[9]
- The foundation of the Digital Therapeutics Alliance in 2017 as a non-profit trade association of industry leaders and stakeholders engaged in the evidence-driven advancement of digital therapeutics[10]
- In 2019, the German Parliament passed the Digital Healthcare Act (*Digitale-Versorgung-Gesetz*, DVG) allowing all doctors in Germany to prescribe digital therapeutics (*Digitale Gesundheitsanwendungen*, or DiGA) to publicly-insured individuals in Germany.

Despite being a relatively recent development in the spectrum of available medical interventions, digital therapeutics have the potential to address patient needs that traditional treatments and therapies have been unable to meet – and development timelines for DTx products are much faster.[11]

Why are DTx generating so much interest?

A growing market landscape, finance from venture capitalists and digital acceleration in response to the COVID-19 pandemic make digital therapeutics a promising area for investment.

Market size and growth

The global digital therapeutics market currently generates annual revenue of $3.4 billion and this is projected to reach $13.1 billion by 2026, increasing at a compound annual growth rate (CAGR) of 31.4% during this period.[12]

Key drivers of market growth include:

- The increasing incidence and growing prevalence of preventable chronic diseases
- The need for safe and accessible solutions for the treatment of chronic and mental health diseases
- A pressing need to control healthcare costs
- The growing focus on predictive, preventative, personalised and participatory healthcare
- A surge in investments in digital therapeutics.

Venture capital financing

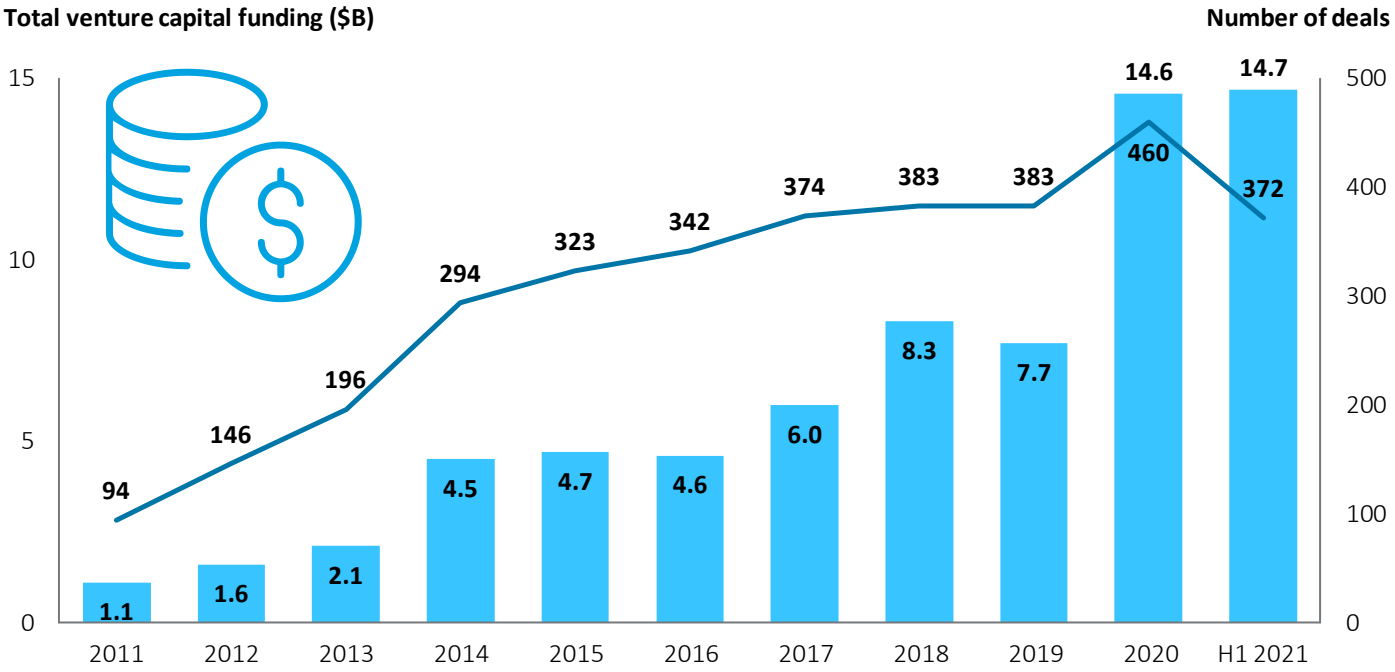
Digital therapeutics have the potential to become a convenient and cost-effective treatment for diseases and disorders that affect many people. Thanks to their lower development costs, ease of distribution and possibility to scale up their application, DTx software products have attracted a large number of investors.

Based on Deloitte's analysis of data from Rock Health's Digital Health Funding database (see Figure 2 below), venture capital funding in the US for health tech innovators almost doubled in 2020 compared to 2019, and its growth has continued in 2021, with the level of investments in the first half of the year already surpassing the total for 2020.

"The COVID-19 pandemic has done something quite unique in the digital therapeutics space, as it has propelled us forward a decade in terms of cultural change, acceptance and adoption of remote and digital-first approaches"

Vice President Commercialisation
Digital Therapeutics company

Figure 2. US digital health funding



Source: Deloitte analysis of Rock Health's Digital Health Funding Database

A recent study by Deloitte found that the rate of increase in health tech initial public offerings (IPOs) and large merger and acquisition (M&A) deals is likely to accelerate. In 2020, 33 innovators raised more than US$100 million in late series funding (C+).[13] Some IPOs have been arranged through special purpose acquisition companies (SPACs), which are shell companies that acquire a private company (such as a digital health company) and take it public. Recent examples of digital therapeutics companies using a SPAC to obtain a listing are Better Therapeutics, a developer of prescription DTx designed to address the root causes of cardiometabolic diseases such as Type 2 diabetes,[14] and Pear Therapeutics, which develops prescription DTx products for substance use disorder and chronic insomnia.[15]

There have also been large-scale traditional mergers and acquisitions (M&A) involving digital therapeutics companies:

- **Digital health innovators' consolidation through sales partnerships and/or vertical integration:** An example is the US$18.5 billion merger of virtual care solution provider Teladoc and chronic health management solutions provider Livongo in 2020, allowing them to offer more comprehensive insights into preventative care and help manage 'whole person care', starting with diabetes care[16]
- Large life sciences players and tech companies acquiring digital health innovators: Examples in digital therapeutics include Roche's 2017 acquisition of diabetes management app mySugr and Resmed's 2019 acquisition of digital respiratory health company Propeller Health.

Impact of COVID-19 as an accelerator for DTx

An industry survey in Q1 2021 found that more than one-third of respondents believed that COVID-19 had accelerated digital transformation in the pharma industry by more than five years,[17] making what was once regarded as a 'nice-to-have' an absolute 'must-have' for business survival.

In particular, the pandemic significantly accelerated the rate of change in digital therapeutics, thanks to an increase in patient demand and regulatory flexibility that has expanded access to digital health products.

Increase in patient demand

Virtual access is becoming increasingly instrumental in providing healthcare to patients. This is particularly important for patients affected by co-morbidities, where services like digital therapeutics and telehealth enable continuity of care. Furthermore, DTx offers chronic patients the opportunity not only to have their healthcare needs fulfilled, but also to avoid the risk of exposure to COVID-19 from in-person hospital visits.

Regulatory flexibility expanding access to digital health

In the United States, the Federal government issued a new regulation in 2020, allowing all medical professionals to practice across state lines, thus opening up access to care and creating a larger supply of healthcare providers for digital health companies.[18] This, in combination with higher reimbursement rates for telehealth set by CMS (Centers for Medicare & Medicaid Services), should help solve the problem of insufficient numbers of medical professionals using DTx platforms.[19]

In 2020 the FDA issued new guidance on its "Enforcement policy for digital health devices for treating psychiatric disorders during the COVID-19 public health emergency", waiving regulatory requirements like the need to submit a 510(k) premarket notification during the COVID-19 pandemic. This expanded the availability of digital therapeutics devices, allowing patients to receive mental health treatment while reducing exposure to infection for users and healthcare providers during the COVID-19 emergency.[20] Companies that took advantage of this opportunity include:

- Akili Interactive Labs, which released EndeavorRx, a game-based digital therapeutic to improve the attention span of children with attention deficit hyperactivity disorder (ADHD)[21]
- Orexo's marketing of GAIA AG's RCT-proven digital therapeutics for alcohol misuse (vorvida®) and mild-to-severe depression (deprexis®).[22]

Overview of the DTx landscape

Digital therapeutics can be used to prevent, manage or treat a growing number of disorders and diseases by leveraging a variety of digital capabilities

Different types of DTx

We distinguish between three types of digital therapeutics solutions, depending on their use cases:

- **Prevent:** These digital therapeutics applications in the realm of preventative care include lifestyle management and nutrition (e.g. obesity, mental health), as well as interventions to delay the development of chronic diseases (e.g. prediabetes).
- **Manage:** The vast majority of applications currently available on the market aim at helping patient populations manage their disease effectively, capture symptoms and improve adherence to treatments. As such, these types of digital therapeutics are usually administered in concomitance with other pharmacological interventions (e.g. web portals connected to blood glucose meters, providing real-time basal insulin recommendations and educational coaching messages based on blood glucose values captured in diabetes patients' apps and sensors to record and monitor prescribed inhaled medication in asthma and COPD patients).
- **Treat:** Typically standalone (monotherapy) interventions, these digital therapeutics work independently and can replace pharmacological treatments. The most common application relies on digital cognitive behavioural therapy (CBT) solutions that target mental health and behavioural disorders, such as substance use disorders, depression, attention deficit and hyperactivity disorder (ADHD), stress and anxiety.

There is also a trend towards digital therapeutics which endeavour to treat rather than manage/prevent a disease, especially for indications where there is currently no pharmaceutical solution. For example, GAIA´s elevida® is currently the only DTx that treats fatigue in multiple sclerosis patients.

"The future is incredibly bright for digital therapeutics. We are in an exciting game-changing space"

Vice President Clinical
Digital Therapeutics company

Key therapeutic areas

The range of indications addressed by digital therapeutics is constantly evolving, with the majority of current and pipeline solutions targeting chronic diseases and neurological/psychiatric disorders (see Figure 3). DTx may be developed in any therapeutic areas that are characterised by evidence-based behavioural or psychological aspects and for which digital can be a valuable element in treatment, especially if demand is projected to outgrow treatment capacity. This is especially the case for chronic conditions whose prevalence will increase substantially due to aging populations and for which there will be insufficient numbers of healthcare practitioners.

Figure 3. Digital therapeutics use cases per therapeutic area and example applications

← Digital therapeutics use cases →

Therapeutic areas	Prevent	Manage	Treat	Example applications
Metabolic				• App to help lifestyle modification to prevent type 2 diabetes • App giving insulin recommendations based on blood glucose values
Mental Health, Neuro-logical and behavioural				• Digital Cognitive Behavioural Therapy (CBT) • Game training improving attention for ADHD
Cardiovascular				• Clinically-validated digital program for acute coronary syndrome • Patch to detect early symptoms of worsening heart failure
Respiratory				• Self-management app to relieve COPD symptoms at home • Recording and monitoring of prescribed inhaled medications
Oncology				• App for follow-up of breast and ovarian cancer patients • Symptom-capturing adherence app for follow-up of cancer patients
Immunology				• Self-assessment app to monitor rheumatoid arthritis • Personalised recommendations app to manage side effects
Gastrointestinal				• Integrative approach to manage irritable bowel syndrome, Crohn's disease and colitis symptoms
Other (incl. chronic pain, women's health)				• Acceptance and Commitment Therapy (ACT) for chronic pain • Analysis of basal body temperature showing user's fertility level

Key: Pertinence of application (based on number of players)

Most pertinent — Least pertinent

Source: Deloitte analysis

Typical applications

Digital therapeutics, because of their software nature, can be used for a wide variety of applications that leverage different kinds of technology and digital capabilities. Our analysis of the current landscape of digital therapeutics has identified five main categories of applications and underlying technology. As digital therapeutics become more advanced, some products may fit into more than one of these categories.

Patient monitoring and self-management

Digital therapeutics in this category enable patients to track and capture their symptoms, and analyse and send data to the medical team which can then follow up with patients as needed. An example is Voluntis's Theraxium, an app which enables oncology patients to identify, qualify and report their symptoms in order to better manage the side effects during their cancer treatment and contact their care team when appropriate.[23]

Digital behavioural interventions

This type of digital therapeutics includes apps that provide digital cognitive behavioural therapy (CBT) for mental health conditions or personal habitsto promote modification of lifestyles in order to prevent or delay the development of chronic diseases. Digital therapeutic vorvida®, a program developed by GAIA aimed at reducing alcohol consumption and based on CBT, is just one example of an app that provides evidence-based ways to address behavioural or psychiatric conditions, in this case harmful and hazardous alcohol consumption patterns and alcohol dependence.[24] An example in preventative care is Omada, a digital prevention program to achieve lifestyle changes in order to reduce the risk of type 2 diabetes.[25]

Artificial intelligence and machine learning

Arguably the most advanced from a technological standpoint, this type of interventions includes apps that use artificial intelligence and machine learning algorithms to enable real-time interventions (e.g. treatment recommendations) or even early diagnosis of certain diseases. An example is Cognoa's Canvas Dx, which has been granted marketing authorisation by the FDA for the early diagnosis of autism in children aged 18 to 72 months who are at risk of developmental delay.[26]

Apps connected to sensors and wearables

These mobile health applications are characterised by connection to a sensor or wearable device for monitoring or tracking particular biomarkers. An example is Propeller Health's system for asthma and chronic obstructive pulmonary disease (COPD), which tracks when and how often patients use their inhaled medications.[27] Another application is Voluntis's Insulia diabetes management companion, which provides real-time insulin recommendations based on blood glucose values in type 2 diabetes patients, helping them with dose titration.[28]

Gaming and virtual reality

Usually an extension to digital behavioural interventions, these digital therapeutics work by providing patients with a video game or virtual reality-based experience. Applications include Akili's EndeavorRx, the first FDA-cleared prescription treatment for children with attention deficit hyperactivity disorder (ADHD) based on a video-game,[29] and AppliedVR's EaseVRx product which uses virtual reality for the treatment of treatment-resistant fibromyalgia and chronic intractable lower back pain.[30]

Enablers for the adoption of DTx

Adoption of this novel category of interventions will become more widespread when their value for health system stakeholders has been established. This will then pave the way for reimbursement of DTx products and the generation of much more clinical evidence.

Value of DTx for health system stakeholders

Market data and investor interest indicate that digital therapeutics are a very promising area for healthcare solutions. However, in order to reach their full market potential it will be necessary to persuade patients, providers and health systems, policymakers and payers about ther value.[31]

Value for patients

- Empower patients to monitor and self-manage their health
- Increase access to therapies which are clinically effective and safe, with side effects that are typically less severe than in traditional pharmacological interventions
- Improve medication management and patient adherence
- Help alleviate the limited access to therapy
- Receive updates on outcomes through regular monitoring
- Potential to reduce medication dosages for patients who adopt healthier lifestyle habits as a consequence of using DTx to track their symptoms and health status
- Reduce the number of face-to-face interventions, e.g. through digital cognitive behavioural therapies
- Enhance patient experience and receive care in a more convenient set-up, in the comfort and privacy of patients' homes
- Increase access to interventions for underserved populations (e.g. in rural areas)
- Enable more predictive, preventative, personalised and participatory care.

Value for providers and health systems

- Increase access to new treatment options for patients with unmet needs
- Improve patient adherence and outcomes while freeing up health system capacity, by prescribing clinically-proven therapies that allow self-management
- Enable intelligent data-driven care management and clinical decision support
- Serve a larger number of patients more effectively and at a lower cost
- Integrate data with healthcare delivery systems, including patient engagement and response to therapy.

Value for policymakers and payers

- Improve clinical and health economic outcomes, especially for patient populations with chronic disorders and high unmet needs

"There is commercial value behind DTx programs if you set them up right and have the right patient impact in terms of outcomes"

Vice President Commercialisation
Digital Therapeutics company

- Potential to decrease overall healthcare cost of medical interventions (e.g. reducing the costs associated with emergency, hospital and physician visits through preventative care or self-management)
- Facilitate analysis of population health outcomes through collection and integration of real-world data
- Provide access to treatment options for diseases that are not well treated by traditional therapies
- Enable new models of care such as value-based care and population health management.

Changes in the regulatory framework

A critical enabler for the adoption of digital health solutions (and in particular digital therapeutics, which require clinical and real-world evidence), is the willingness of regulators to adapt and innovate the approval pathways for taking these new medical interventions to market. Digital therapeutics are most frequently regulated as Software as a Medical Device (SaMD), although not all DTx products qualify as SaMD and not all SaMD products qualify as DTx.

There are several instances where regulators have started to evaluate and enable changes that will contribute to speeding up the adoption of digital therapeutics, with the United States, Germany and Belgium paving the way.

United States

In the United States, digital therapeutics companies were faced with regulatory hurdles and by reluctance from payers with regard to reimbursement for their products. Recent developments have eased the situation. The FDA recently launched a digital health pre-certification programme[32] to provide a streamlined path to software product approval. This programme enables the FDA to approve the developer of a digital health product instead of each individual software product, thus speeding up product development and release.

Germany

In Germany, the Digital Healthcare Act 2019 (*Digitale-Versorgung-Gesetz*, DVG) paved the way for reimbursement for digital therapeutics (*Digitale Gesundheitsanwendungen*, or DiGA), enabling doctors to prescribe digital therapeutics to publicly-insured patients and receive payment in the same way as for traditional treatment. The criteria for listing as DiGA are aligned with the European Medical Device Regulation (MDR). The DVG introduced the 'Fast-Track Process', an accelerated regulatory pathway for digital health applications. Digital therapeutics can therefore undergo a streamlined review in order to be included in a central registry of apps that can be prescribed by healthcare practitioners (HCPs), and psychotherapists and reimbursed by Germany's statutory health insurance providers.[33]

Belgium

The National Institute for Health and Disability Insurance (NIHDI) launched a scheme to approve digital therapeutics for reimbursement, provided that they fulfil the criteria for reaching the top level of Belgium's mobile health (mHealth) validation pyramid,[34] i.e.:

- CE marking as a medical device and meeting GDPR requirements
- Interoperability and connectivity tests
- Demonstration of clinical and socio-economic added value.

Early signs of reimbursement

Although at an early stage, examples of reimbursement for specific digital therapeutics are beginning to emerge.

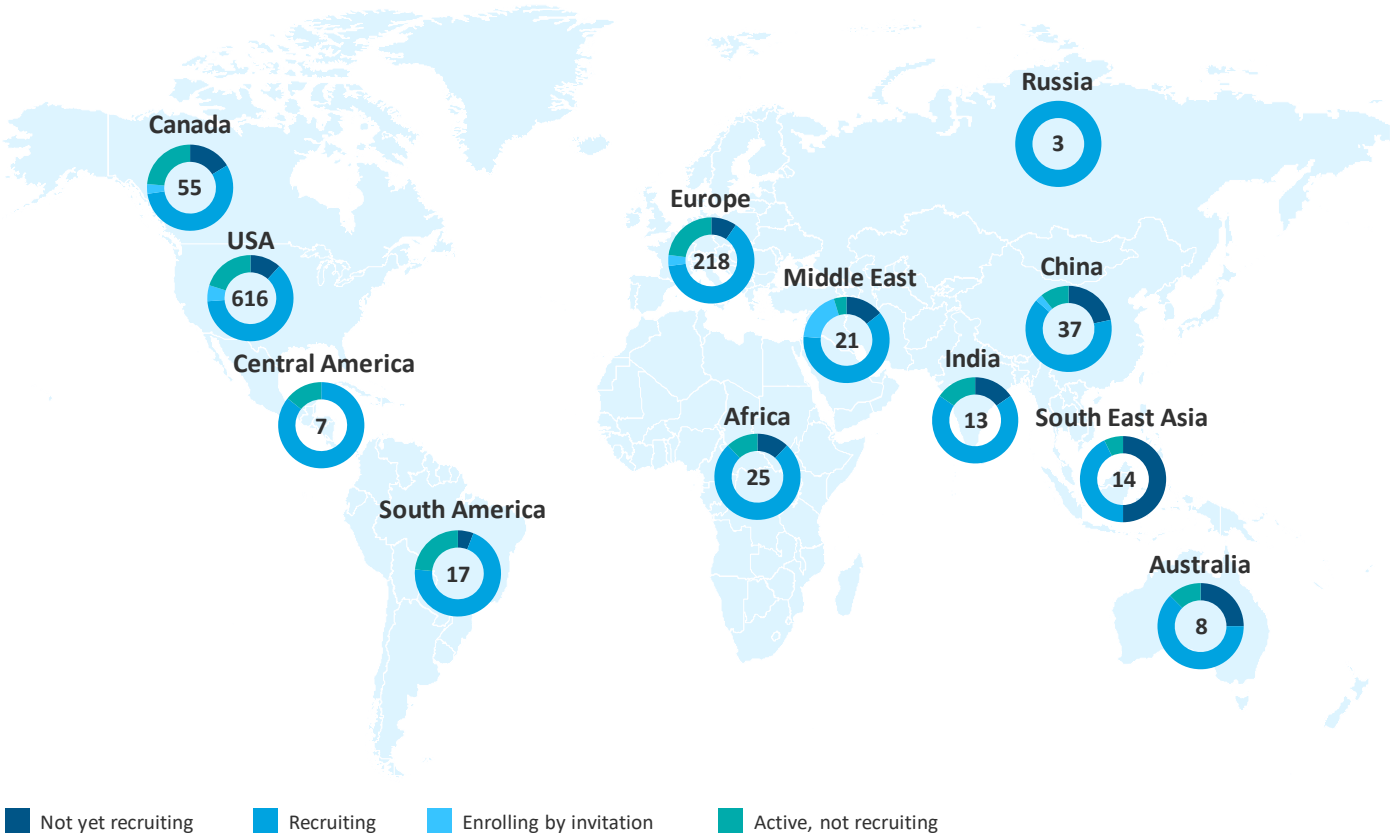
- In 2019, the two largest pharmacy benefit managers (PBMs) in the United States, CVS and ExpressScripts, launched digital health formularies[35]
- Germany's DVG Act paved the way for digital therapeutics reimbursement, and at the time of writing five applications have been made available for reimbursement permanently by statutory health insurers and 14 for a one-year trial period[36]
- In the United Kingdom, the NHS approved reimbursement for digital therapeutics deprexis® for depression,[37] Sleepio for insomnia[38] and Oviva for diabetes and obesity[39]
- In France, the HAS (Haute Authorité Sanitaire) approved the digital therapeutics Moovcare for the follow-up of cancer patients[40]
- In 2020, Japan health authorities granted regulatory authorisation and reimbursement by the public healthcare insurance system to CureApp, a prescription digital therapeutic for nicotine addiction.[41]

Acceleration in development of clinical evidence

Deloitte's analysis of the clinical trials database shows that more than a thousand clinical studies are ongoing in the area of digital therapeutics and mobile health (mHealth). This complements the 1,600 studies already completed in this space (see Figure 4 for an overview of ongoing studies, segmented by patient recruitment status).

In terms of location, ongoing studies in the digital therapeutics space are mostly taking place in North America, followed by Europe and China.

Figure 4. Overview of ongoing clinical trials in digital therapeutics



Note on methodology: Based on search criteria for intervention/treatment digital therapeutic, internet-based, web-based or mHealth. Data as of 21 July 2021

Source: Deloitte analysis of clinicaltrials.gov database

Hurdles to the adoption of DTx

The future of digital therapeutics will depend on the ability of companies to overcome fundamental challenges

A recent Deloitte study[42] has highlighted how the future of digital therapeutics will depend on their ability to demonstrate impact, optimise pricing and reimbursement, and improve user perception.

Ability to demonstrate impact

Digital therapeutics must be able to demonstrate their impact, but this not an easy task. It will be necessary to establish clinical evidence through rigourous clinical trials in order to convince decision-makers to adopt digital therapeutics, and this must be complemented by extensive real-world evidence to demonstrate patient outcomes and economic value[43]. Digital therapeutics manufacturers are still striving to prove that their interventions can provide measurable clinical outcomes, and prescribers are unlikely to endorse their solutions if claims are not justified by rigorous randomised-controlled trials (RCTs) whose results are published in peer-reviewed journals.

Optimisation of pricing and reimbursement

Apart from isolated cases in some countries such as Germany, pathways to market access for digital therapeutics are ill-defined. In many regions of the world reimbursement and coverage issues are difficult to resolve as they are characterised by unclear requirements and lengthy (or even non-existent) processes. Despite this, digital therapeutics can provide an opportunity for manufacturers and payers to experiment with innovative payment models, such as pay-for-performance and outcomes-based contracts, given the wealth of real-world data that DTx solutions are able to generate.

User perception

There is some scepticism around patient adoption of digital therapeutics products. Some interviewees in a recent Deloitte report[41] believe that some patients may try out the technology but lose interest after a few days or weeks. Moreover, the higher socioeconomic classes will be more likely than the lower classes to use these technologies, which could potentially broaden health disparities. There is also a discussion around data privacy concerns, with patients increasingly worried about the use of their personal health data, especially with regard to digital therapeutic devices characterised by real-time monitoring.

When it comes to clinical use, adoption by physicians and healthcare providers is still limited, but this will be key to persuading payers and other influential health system stakeholders about the value of DTx. Several digital therapeutics require changes to provider processes, especially in data gathering and analysis, and this could exacerbate constrained healthcare capacity and require extensive training for staff to learn how to take advantage of the new-found wealth of data.

"The best solution in the world in terms of user engagement and marketing appeal becomes completely irrelevant if it can't prove its effectiveness in an RCT."

Chief Medical Officer
Digital Therapeutics company

How to win in the market: Strategic choices for life sciences companies

Life sciences companies have a unique opportunity to invest in digital therapeutics before other non-traditional players

Will life sciences companies see DTx as an opportunity or a threat?

Traditional life science companies may see digital therapeutics either as a potential threat to their business model or as an opportunity to innovate. On the one hand, digital therapeutics could compete with existing pharmacological treatments for market share. On the other hand, a digital therapeutic offering could play the role of differentiator, as an attractive value proposition for those pharmaceutical companies that have historically been interested in 'beyond the pill' value delivery.

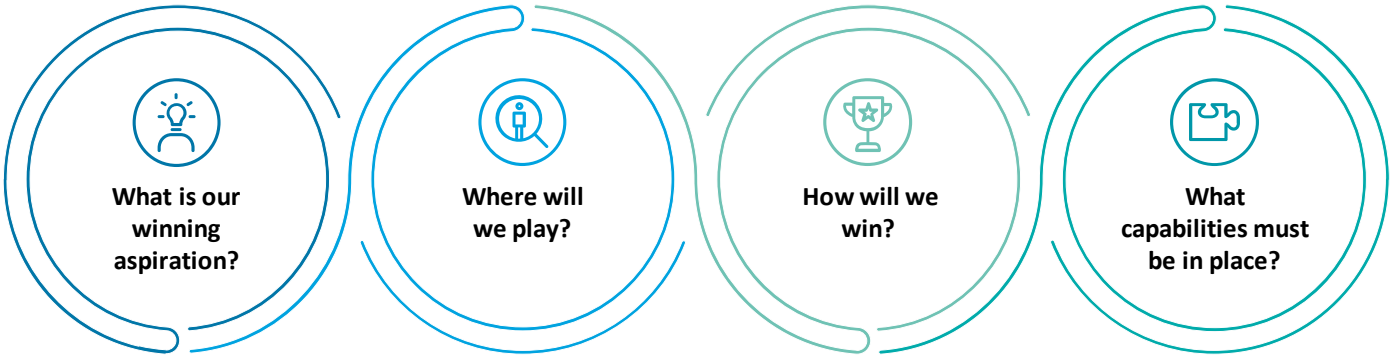
Traditional pharma and medtech companies have a first-mover advantage to capitalise on the opportunity presented by digital therapeutics, before players in other industries, like technology giants, take over. Benefits for life sciences companies from becoming active in the development of novel digital therapeutics are:

- Improvement in patient health outcomes
- Augmentation of the value of companion drugs/medical devices
- Extension of the drug/medical device life cycle
- Access to real-time clinical information and real-world data
- Personalisation of treatment
- Extension of the therapeutic offering
- Market entry into new therapeutic areas
- Potential for innovation in the product pipeline
- Possibility to explore digitisation of commercial model including field sales force

Strategic choices to take

Life sciences companies have a unique opportunity to structure their strategic approach to enter or consolidate their position in the digital therapeutics space. There are some fundamental questions that biopharma and medtech companies will need to answer. We have formulated these questions around a strategic choice cascade framework (see Figure 5).

Figure 5. Strategic choice cascade framework for digital therapeutics



- What is our **vision for digital therapeutics (DTx)**?
- What are the **strategic goals** that support our vision?
- Which **therapeutic areas (TAs)** will we prioritise?
- Which **patient populations** will we target?
- How will we position for **competitive advantage**?
- How will we **expand traditional business models**?
- What **organisational structure** for our digital expertise?
- What **capabilities** will we leverage to scale and deliver our digital interventions?

Source: Deloitte analysis

Winning aspiration

Biopharma and medtech companies should articulate a clear vision for their role within the digital therapeutics ecosystem. Do they see themselves as preferred partners or as leaders in the space? What strategic objectives would be achieved by playing in the innovative digital therapeutics space? What would be their contribution to society? Answering these questions will provide a guide to strategy development.

Where to play

Once life sciences companies have defined their role and vision in the digital therapeutics space, they should consider which patient populations and therapeutic areas (TAs) they will explore in this field. Will they leverage digital therapeutics products in TAs where they are already active? Or will they take the opportunity to explore entirely different areas of therapeutic interventions, possibly addressing unmet needs for untreated or undertreated conditions, or underserved patient populations?

How to win

Arguably the most crucial choice to make, biopharma and medtech companies will need to assess what their key differentiators will be in the development of digital therapeutics offerings. A recent Deloitte study on digital medicine products[44] has highlighted the importance of considering viable partnership models, as life sciences companies explore whether to develop digital therapeutics in-house or whether to partner with technology companies active in the field. Partnership is currently the more common option, with life sciences companies playing to their strengths in regulatory science and market access while leveraging their partner's expertise in software development.

Several partnerships between pharma companies and digital therapeutics players have already been established. For example:

- Boehringer Ingelheim partnered with Click Therapeutics to develop a digital therapeutic for patients with schizophrenia[45]
- Sanofi partnered with Happify Health to build a digital therapeutic to help multiple sclerosis patients manage their mental health[46]
- Servier partnered with GAIA to commercialise the depression treatment deprexis®.

As digital therapeutics products start to proliferate within the portfolios of life science companies and as the experience of life sciences companies in the field grows, we expect a shift from partnerships in favour of insourcing.

Moreover, as digital therapeutics demand the proactive involvement of all stakeholders in the healthcare ecosystem, new business models will likely emerge beyond the traditional commercialisation approaches, especially when it comes to developing a reimbursement model that is 'fit for purpose'.

Building new capabilities

The iterative nature of developing software will require tighter coordination between commercial, medical and product development teams. Moreover life sciences companies will need to decide whether to distribute or whether to centralise their expertise, concentrating digital resources within R&D or the commercial function, or as a separate centre of excellence.

Despite the current preference for partnering and outsourcing, in order to succeed life sciences companies will nevertheless need to develop relevant technical skills in software development, artificial intelligence, virtual reality and cybersecurity.

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GAIA AG is a world leader in the development of digital therapeutics. GAIA's aim is to offer evidence-based, safe and accessible digital therapeutics that help patients restore and maintain their mental and physical health. As a research-based company, GAIA has combined scientific, technological, and therapeutic expertise under one roof for over 20 years. GAIA's product range includes over 70 effective solutions for mental illnesses, as well as other areas of indication, including Oncology, Rheumatism, Multiple Sclerosis and Pain.

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