



Digital Therapeutics

The new healthcare frontier

white  space

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Introduction

The healthcare landscape is on the cusp of a revolution.

Imagine a future where healthcare extends beyond the doctor's office, empowering patients to take an active role in managing their health. This future is closer than you think, driven by the emergence of Digital Therapeutics (DTx). This whitepaper will delve into the transformative potential of DTx, exploring how they can empower patients, enable clinicians, and benefit healthcare systems as a whole.

The core strength of DTx lies in their ability to provide personalized and holistic care. Unlike traditional interventions confined by time and location, DTx can continuously guide and support patients throughout their healthcare journeys. DTx offer patients unique advantages, including increased autonomy, improved self-management skills, and the ability to make informed healthcare decisions.

Clinicians are poised to benefit significantly from the adoption of DTx. These digital tools can streamline workflows, optimize data collection and analysis, and ultimately allow for more focused and cost-effective patient care. We'll examine how DTx can empower clinicians to deliver superior care while navigating the evolving healthcare landscape.

The whitepaper doesn't shy away from the challenges facing DTx. The nascent DTx industry requires skilled business, design, and development teams, and the lack of established benchmarks can make navigating the market complex. These hurdles are explored in this whitepaper, with solutions proposed to ensure DTx can reach their full potential.

To maximize their impact, DTx must not only be clinically sound but also user-friendly and engaging. Thus we also offer design strategies that entice users, fostering sustained motivation and aligning with individual values. We'll cover the science of behavior change and how it can be harnessed to promote long-term DTx use.

Finally, this whitepaper examines various DTx business models, paving the way for successful commercialization. We'll explore how DTx companies can reach patients directly, forge partnerships with healthcare systems, and leverage innovative strategies like data monetization (with robust privacy safeguards in place) to ensure long-term financial viability.

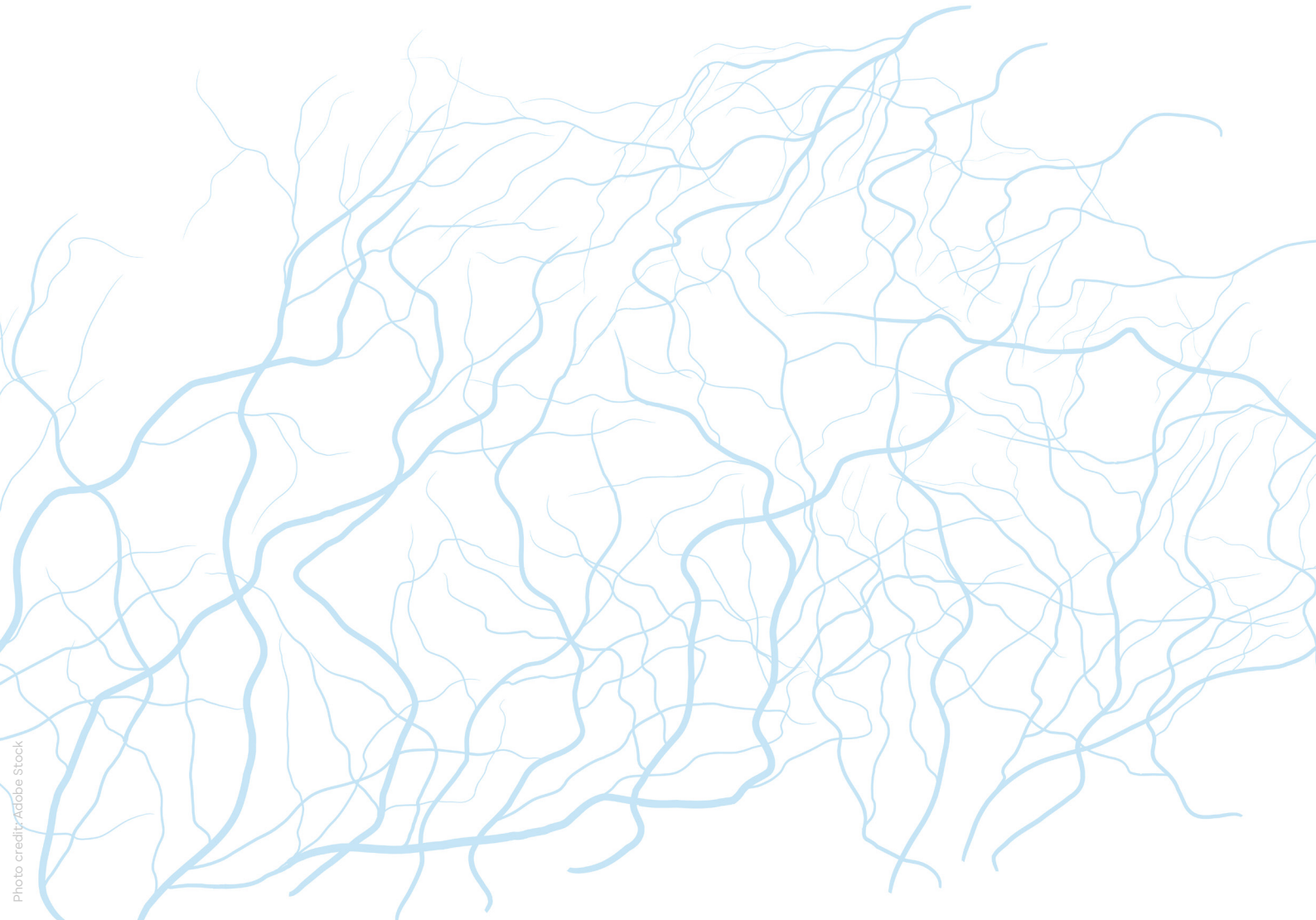
DTx offer a glimpse into a future where patients are empowered, clinicians are enabled, and healthcare systems become more efficient. We hope that by the time you have finished reading this whitepaper, you will be equipped with the knowledge to understand, navigate, and potentially contribute to this exciting healthcare revolution.



Jesse Anton
Founder & CEO
of Whitespace

1

The DTx value proposition



The DTx value proposition

Digital Therapeutics (DTx) are digital products, often working in conjunction with wearable devices and medicines, that prevent, manage and treat disease, with evidence to prove they can improve health outcomes.

As defined by the Digital Therapeutics Alliance, DTx deliver evidence-based therapeutic interventions that are driven by high quality software programs to prevent, manage, or treat a medical disorder or disease. They are used independently or in concert with medications, devices, or other therapies to optimize patient care and health outcomes.

Utilising digital and physical technology in new ways, DTx support people to reduce risk of disease, or progression of existing disease, with less reliance on clinicians. This is achieved through enhanced assessment of health through the use of data collected from patient-completed health questionnaires, wearable technology and even looking at a patient's historical health data.

There are various benefits of DTx for **patients, providers and payers**.



PATIENT



PROVIDER



PAYER



Optimised Patient Journeys - Patients spend less time traveling to point of care locations in order to get a diagnosis or treatment. Data is collected and analysed more commonly wherever the patient is. This reduces the number of in person contact with providers. Thus a dramatic reduction in delayed presentation of disease to providers and missed appointments.

Lower burden of care - clinicians can focus on patients who really need them, when they need them, even remotely. By improving patient data collection and analysis, clinicians spend less time collecting data from patients and more time on the human and physical aspects of healthcare. This can also lead to improved health outcomes due to the reduced occurrence of patient harm caused by the overburden of clinicians.

Personalised and Holistic Care - preventative and therapeutic interventions tailored to an individual. Healthcare is optimised, responding to the unique needs of patients beyond the common categorising of patients for specific diseases or risk factors. For example, cultural beliefs and practices become inherently considered at the start of a healthcare episode rather than an afterthought.

Optimised Clinical Workflows - clinicians can significantly improve in person and remote care by working in unison with digital therapeutics and other digital health solutions. More varied healthcare professionals, including specialist nurses and physician associates can be incorporated into clinical pathways and workflows, gaining new responsibilities. This in turn provides new career prospects for the clinical workforce.

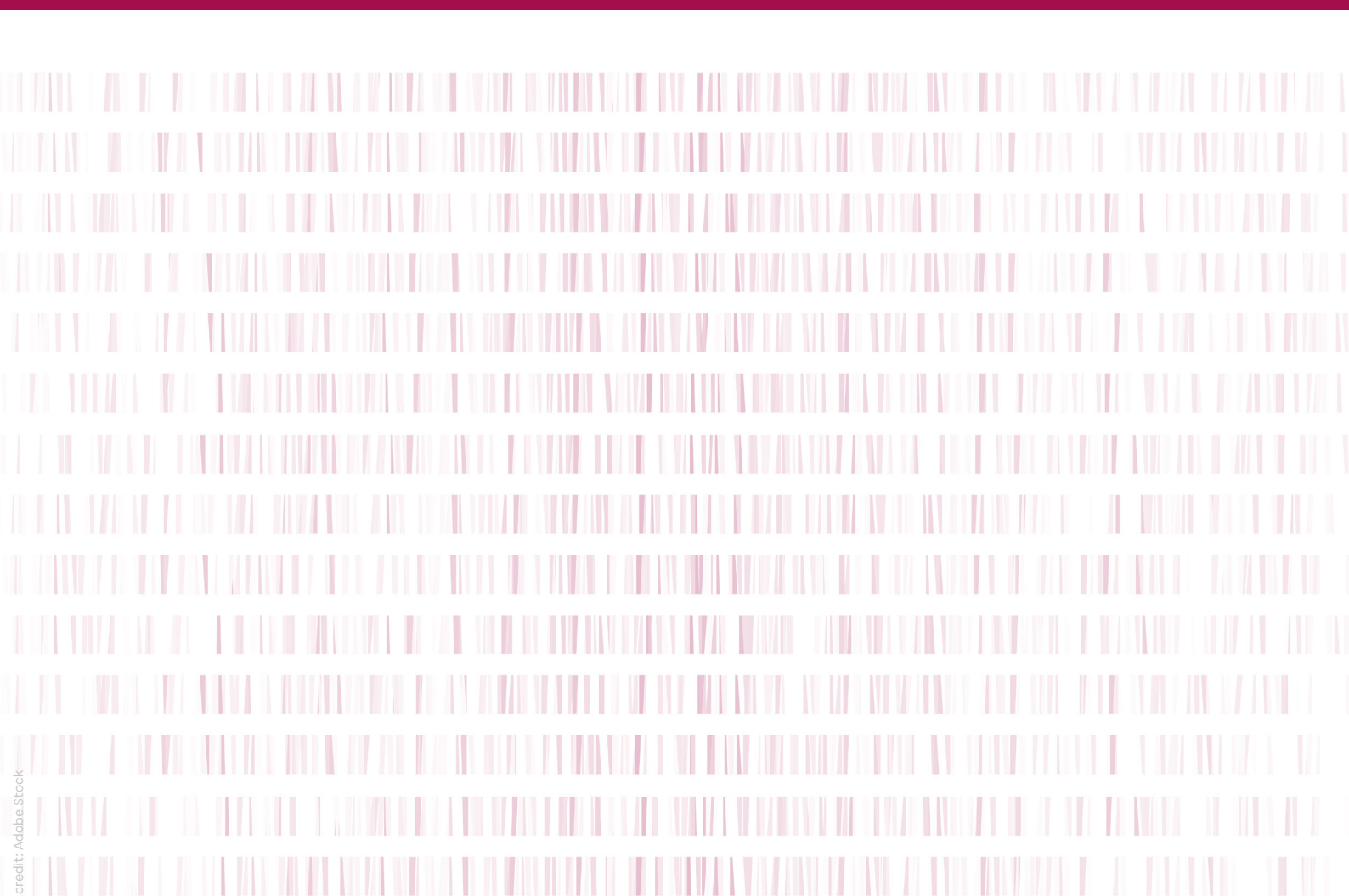
Supports Value-Based Healthcare

- the new standard in healthcare reimbursement which now drives healthcare service delivery in most parts of the world. By using solutions that are known to encourage if not guarantee improved healthcare outcomes, payers stand to both save and earn more money. This is particularly true when using digital therapeutics which can support both short and long term healthcare outcomes.

Reduced costs - expenses are lowered by providing lower cost healthcare services for immediate healthcare needs, but also by limiting and removing the need for advanced treatment. This is achieved through earlier assessment, diagnosis and treatment. This can also reduce the lifetime spend on healthcare care for potentially all users, which can lead to significant savings for insurance companies that can be passed on to patients, lowering healthcare costs for many people.

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Regulation of DTx



Regulation of DTx

The regulation of DTx is complicated, with no single, worldwide regulatory body. However, there are shared standards and similar definitions that help bring consistency in DTx regulation worldwide. Many questions could be asked to classify and in turn, regulate a DTx. But the following three are particularly useful:

What is the intended purpose of the DTx?

If the answer involves anything that supports clinical decision-making, with or without the input of a clinician, then the DTx will be considered a Software as a Medical Device (SaMD). There will also be a requirement for real-world evidence of effectiveness.

Is there a risk of harm to a patient through the use, including improper use, of the DTx?

If yes, then the DTx must be clear on what it can do to mitigate this risk. If a healthcare technology touchpoint is required, will this be provided by the same provider of the DTx, or will the patient user be signposted to appropriate services? If the former is true, there will be a need to adhere to regulation requirements for providing healthcare services.



Will the DTx require any special quality or maintenance procedures?

If yes, then these will need to be outlined clearly for review by a medical device regulator, and indeed the procedures will need to be fully followed once the product is released.

DTx are virtually all considered SaMD, which are software solutions that either work as, in, or with a medical device. Thus DTx have to be regulated to the same standards as medical devices. These standards are dependent on the intended use and mode of action, which together determine the classification of a given SaMD. The classification of a DTx is not completely straightforward, and thus specialist advice must be used to be certain of the regulatory requirements that must be met. With that said, a DTx will have a low classification when the risk of harm is low. Conversely, a DTx will often be given the highest classification when it supports clinical decision-making, provides treatment, and/or works in conjunction with an implantable medical device. This is due to the high level of risk of serious adverse events if the SaMD fails to work as expected.

Regulators and classifications

As alluded to earlier, there are various regulators for medical devices, SaMD, and thus DTx. This is partially due to the evolving state of the technology and the diverse regulatory frameworks governing medical products worldwide. With that said, the two most influential regulators are the European Union's Medical Devices Regulation (EU - MDR) 2017/745 and the Food and Drug Administration (FDA) in the United States. It is these two regulatory bodies that tend to inspire and inform, even informally, other regulators around the world.

EU MDR and FDA

The EU MDR has four classifications over three classes based on their potential risk to patients and operators of the device; Class I, IIa, IIb, and III. The FDA also has four classifications, Classes I, II, III, and IV, with the first three classes being comparable with the EU MDR classes. However, its fourth classification is unique amongst medical device regulators. Below are more details about each class for both regulators.



EU-MDR classifications

Class I	Low risk
Class Is	Sterile devices
Class Im	Measuring devices
Class Ir	Reusable, surgical device
Class IIa	Medium risk
Class IIb	Medium to high risk
Class III	High risk

FDA classifications

Class I	Low risk
Class II	Medium risk
Class III	High risk
Class IV	Very high risk

Class I

Generally used when there is low risk, but unless otherwise stated, also means a non-sterile and non-measuring device, such as a bandage, tongue depressor, or disposable bedpans. However, for the EU MDR, there are three further classifications, considered low to medium risk, which are defined by one of three additional features of the devices: sterility, measurability, and surgical use.

Class Is - Sterile devices with a measuring function, such as sterile gauze used for wound dressings.

Class Im - Non-sterile devices with a measuring function such as a blood pressure cuff.

Class Ir - A reusable, surgical device, such as the handle used to hold a scalpel.

Class II

Used by the FDA, devices under this classification are considered medium risk and are often invasive. This is irrespective of whether the device is temporary or permanent, or is simply more likely to harm through improper use or failure. All these devices generally need some level of real-world evidence to prove they can work as intended. This may not always include the need for a clinical trial, however.

Class IIa - The first of two EU MDR Class II classifications, these are moderate-risk devices that generally have a temporary use but are invasive. This includes infusion pumps, surgical sutures, or disposable contact lenses.

Class IIb - This second EU MDR Class II classification is for devices considered higher risk than Class IIa as these devices are more permanent or are otherwise higher risk due to their functionality. Devices in this classification include implantable heart valves, coronary stents, or automated external defibrillators.

Class III

These devices are rated as high risk since they are permanent devices that provide life-saving or maintaining functionality or can cause serious harm if not death if the device fails or becomes damaged. Examples of such devices include artificial hearts, pacemakers, or breast implants. Clinical trials are always necessary for Class III medical devices to prove they can function as expected and marketed.

For the EU MDR, this is the highest risk classification.

Class IV

The FDA has created a fourth classification used for critical treatment or diagnosis situations. They are deemed critical as treatment and diagnosis must be made within minutes or even seconds, otherwise, a patient could rapidly decline if not die. An example of this would be the need for prompt treatment for a stroke, but there needs to be a distinction between a stroke caused by a blockage or a bleed in the brain since the wrong treatment can be fatal for the patient. An SaMD involved with such an investigation in this context would be considered class IV.

In addition to providing a classification framework, medical device regulators also provide resources and services to support companies making or procuring a DTx, or any other SaMD or medical device. For example, the FDA's Center for Devices and Radiological Health (CDRH) has established a regulatory framework for SaMDs, which includes pathways for clinical evaluation, premarket approval, and postmarket surveillance. The FDA has also created a Digital Health Center of Excellence to facilitate innovation and collaboration in the digital health industry.

BfArM and MHRA

Other regulatory bodies of note include Germany's Federal Institute for Drugs and Medical Device (BfArM) and the UK's Medicines and Healthcare Products Regulatory Agency (MHRA).

BfArM has been an exemplar in the regulation of DTx. The Digital Health Applications Act (DiGA) 2020 provides a streamlined regulatory process for DTx with a proven clinical benefit. This also provides a means for DTx to be reimbursed as long as they are either a Class I or IIa medical device and are primarily a digital solution.

As of early 2024, the MHRA is still establishing a formal, standardized medical regulation process post-Brexit. The UK government intends to have its own DTx and medical device regulatory framework by 2027. In the meantime, the Medical Devices Regulations 2002 (MDR 2002) still applies in Great Britain (England, Wales, and Scotland), whilst North Ireland follows the EU MDR and In Vitro Diagnostic Medical Device Regulation (IVDR). This is significant for companies that intend to serve both Northern Ireland and Great Britain as there will be two regulatory processes to follow.



The situation in France

The situation is even more complicated in France compared with the UK, as there is no single, definitive regulator of medical devices in France. There are three main regulatory bodies involved:

The Agence nationale de sécurité du médicament et des produits de santé (ANSM): This agency focuses on approving and monitoring medical devices and some DTx with a direct therapeutic intent and/or significant risk.

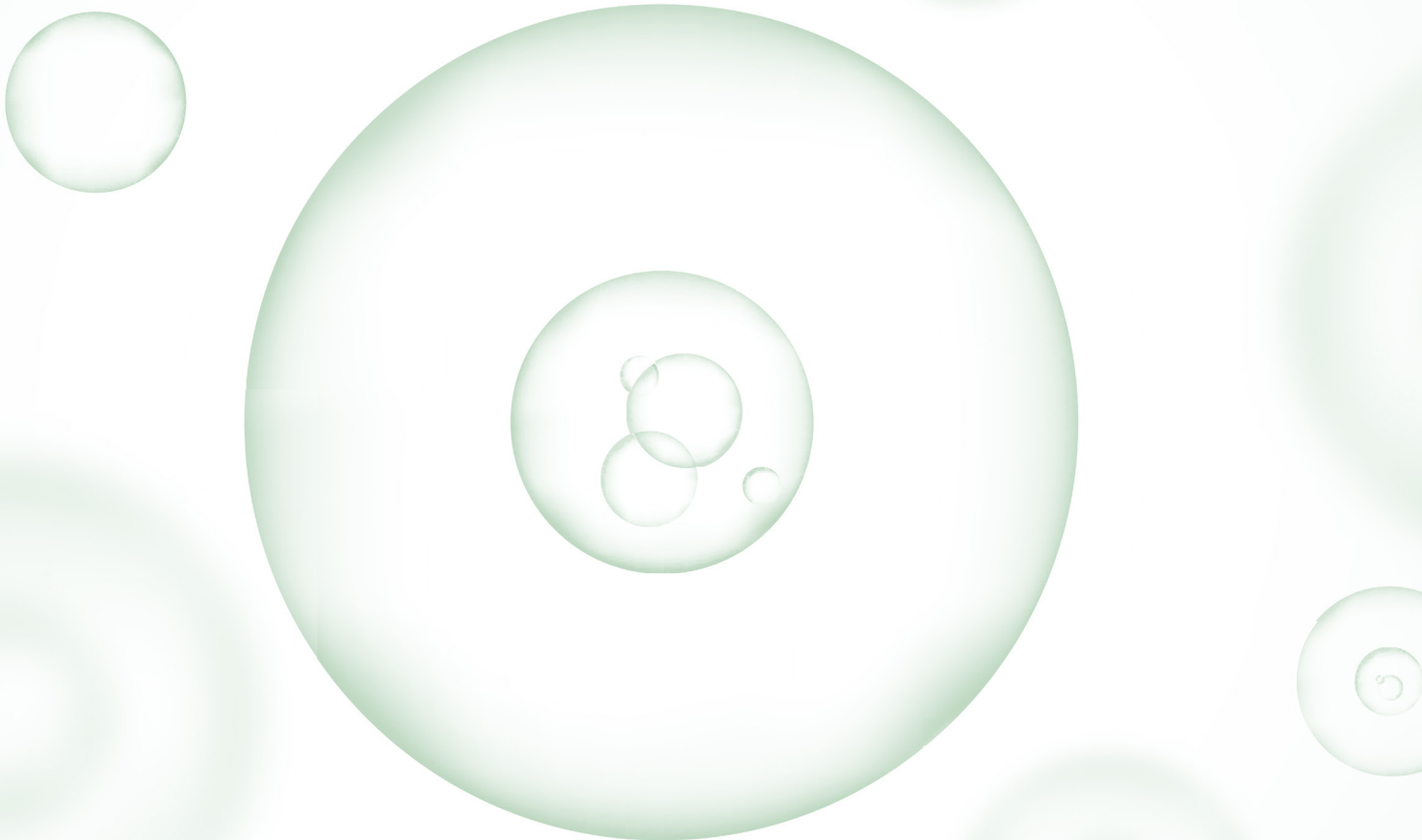
The Commission Nationale de l'Informatique et des Libertés (CNI): This body regulates data privacy, ensuring compliance with GDPR for any DTx that collects or processes personal data from users.

Haute Autorité de Santé (HAS): Offers technical expertise and recommendations on healthcare products and services, including DTx, to inform public health policies and decisions.

Other authorities include the Ministry of Health which oversees France's overall healthcare system and the French National Digital Agency (ANdSN) which supports the development and implementation of innovative digital healthcare solutions in healthcare, such as DTx.

3

The challenges with DTx



The challenges with DTx

Digital Therapeutics (DTx) is an emerging field within digital health, meaning it is still relatively new and still has a long way to go to achieve its full potential. This not only impacts how well a DTx is made but also its adoption and success in improving health outcomes. There are a few specific reasons for this as detailed below.

1/ Limited DTx specialists

By virtue of DTx being an emerging technology, there are still a limited number of people with significant experience creating them. This in itself is not a problem, as this has been the case for all technologies that eventually dominate the marketplace. However, it does mean that progress in the industry can be slow. With that said, by excelling during the early stage of the DTx industry, one can gain a significant market share.

2/ Limited exemplar DTx products

Despite ever-increasing investment in the DTx industry, there is still a lack of standout DTx on the market. An issue compounded by the fact that there have been high-profile failures in the DTx market as well. This has hindered the industry's ability to set standards for good design, development, and deployment of DTx. In turn, this means that the promise of DTx is not being realized as often as it could, and investment can be wasted.

3/ Reliance on early adopters

DTx generally demands significant behavior change from its users, particularly patient users, which hinders fast, large-scale adoption. Both clinicians and patients are used to tried and tested ways of delivering and engaging with healthcare services which DTx disrupt. Therefore, we should not rely solely on the excitement and engagement of early adopters who may already be eager and ready to use the new technology compared with the later majority and laggards. This is a particularly important point as early adopters of cutting-edge technology tend to be amongst the wealthiest and healthiest members of society. Hence early adopters may often have less of a need for digital health solutions including DTx to ensure they stay healthy.

4/ Limited consumer expectations

Since there are so few consumer DTx on the market, the general public has limited experiences, knowledge, and consequently expectations of DTx. Consumer expectations normally drive product development and marketing strategies, which the DTx industry is lacking at the moment. The only significant expectation is based on experiences the general public has with consumer mobile apps, which normally involve an easy-to-navigate interface that is self-explanatory. Such an expectation should be achieved by DTx and seen as part of the success criteria for an approved DTx. But as demonstrated by numerous digital health products on the market, great user experience is not guaranteed.

Pear Therapeutics case study

In 2018, it became the first company to get FDA approval for a DTx in the world, making it an exemplar that other DTx companies aspired to be. Starting with Somryst, a DTx for chronic insomnia, Pear Therapeutics quickly became the company other DTx companies aspired to be. Two more FDA-approved DTx were produced, reSET which supports patients with substance use disorder, and reSET-O for those specifically dealing with opioid use disorder. These products are prescribed as an adjunct to outpatient therapy. They provide cognitive behavioral therapy, behavioral fluency training, and contingency management to prevent relapse or delayed behavior change.

A Special Purpose Acquisition Company (SPAC) merger took place in 2021 with \$400 million in funding raised. This led to Pear Therapeutics with a valuation of \$1.6 billion. But in a dramatic turn of events, Pear Therapeutics announced its intention to file for Chapter 11 bankruptcy protection in December 2022

There are numerous reasons why Pear Therapeutics got to this point. These reasons are all related to the general failure to generate sufficient revenue that outweighed the investment needed to create a regulated, pioneering, emerging technology.

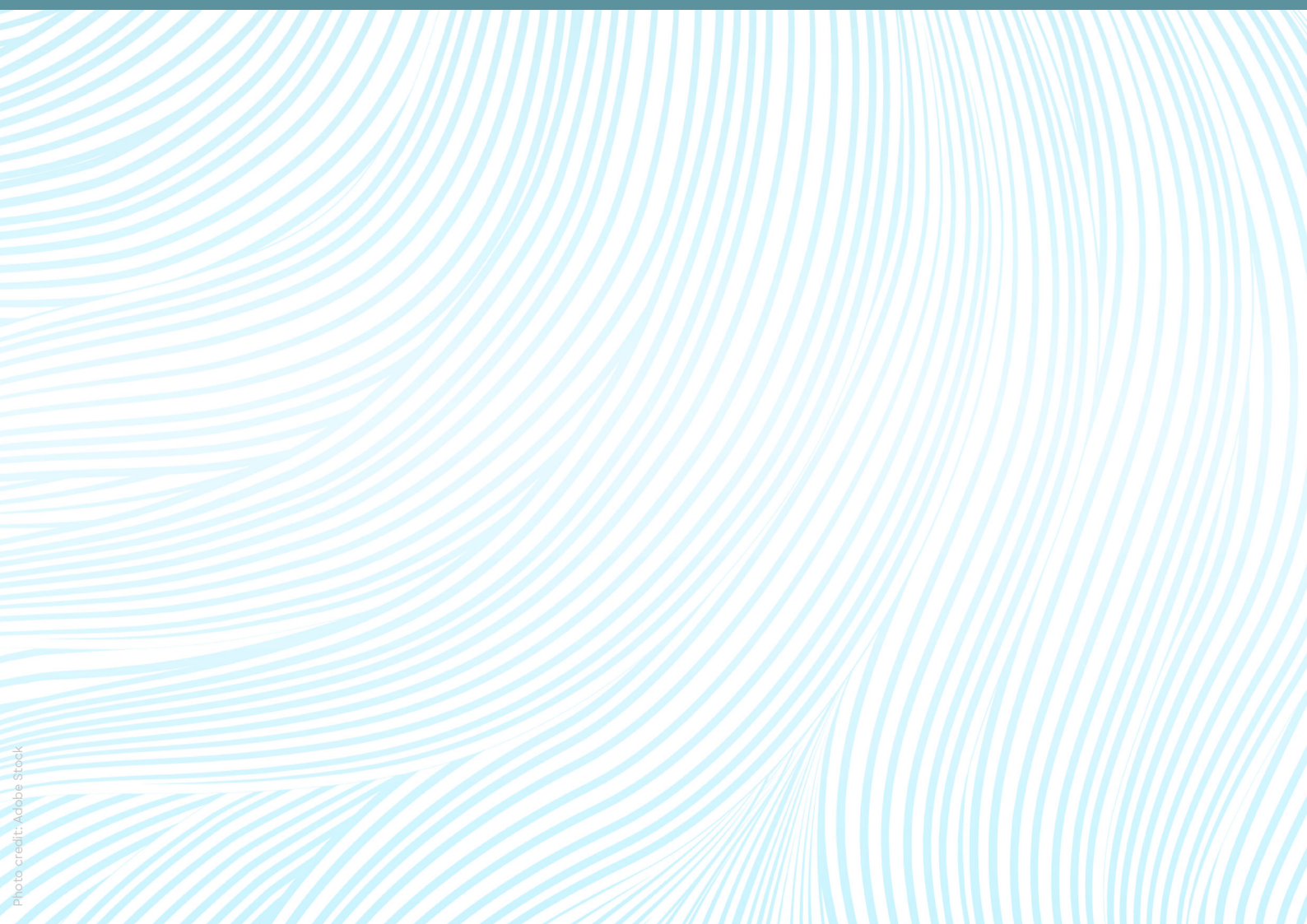
- **High operating costs:** The company's ambitions led to a large expense for research, development, marketing, and sales. This expense grows when it includes the resource-intensive regulatory process and associated clinical trials.
- **High burn rate:** Pear Therapeutics spent its investment in a very short time as a means to be a first mover and ride its own wave of success. However, this spending was too fast to sustain in the long term due to a lack of steady revenue growth.
- **Reimbursement Issues:** DTx require buy-in from a significant majority of, if not all, health payers. Only ten states in the US agreed to reimbursement.

- **High prescription cost:** reSET had a 90-day prescription cost of over \$1000. Due to the reimbursement issues, this was therefore an often out-of-pocket expense that too few patients were willing to pay.
- **Slow adoptions:** As a prescription-only DTx, there was total reliance on clinicians seeing the digital products as a necessary component of successful treatment. It can take a long time to build in clinicians to prescribe a new treatment, even if said treatment has extensive evidence of efficacy.
- **Premature Public Listing:** The public listing of Pear Therapeutics exposed it to further scrutiny and pressure to deliver results before it was capable of establishing a sustainable business model.

Pear Therapeutics proceeded with the Chapter 11 filing in 2023. It would later sell all its assets for \$6.05 million, not even 0.5% of its peak valuation.

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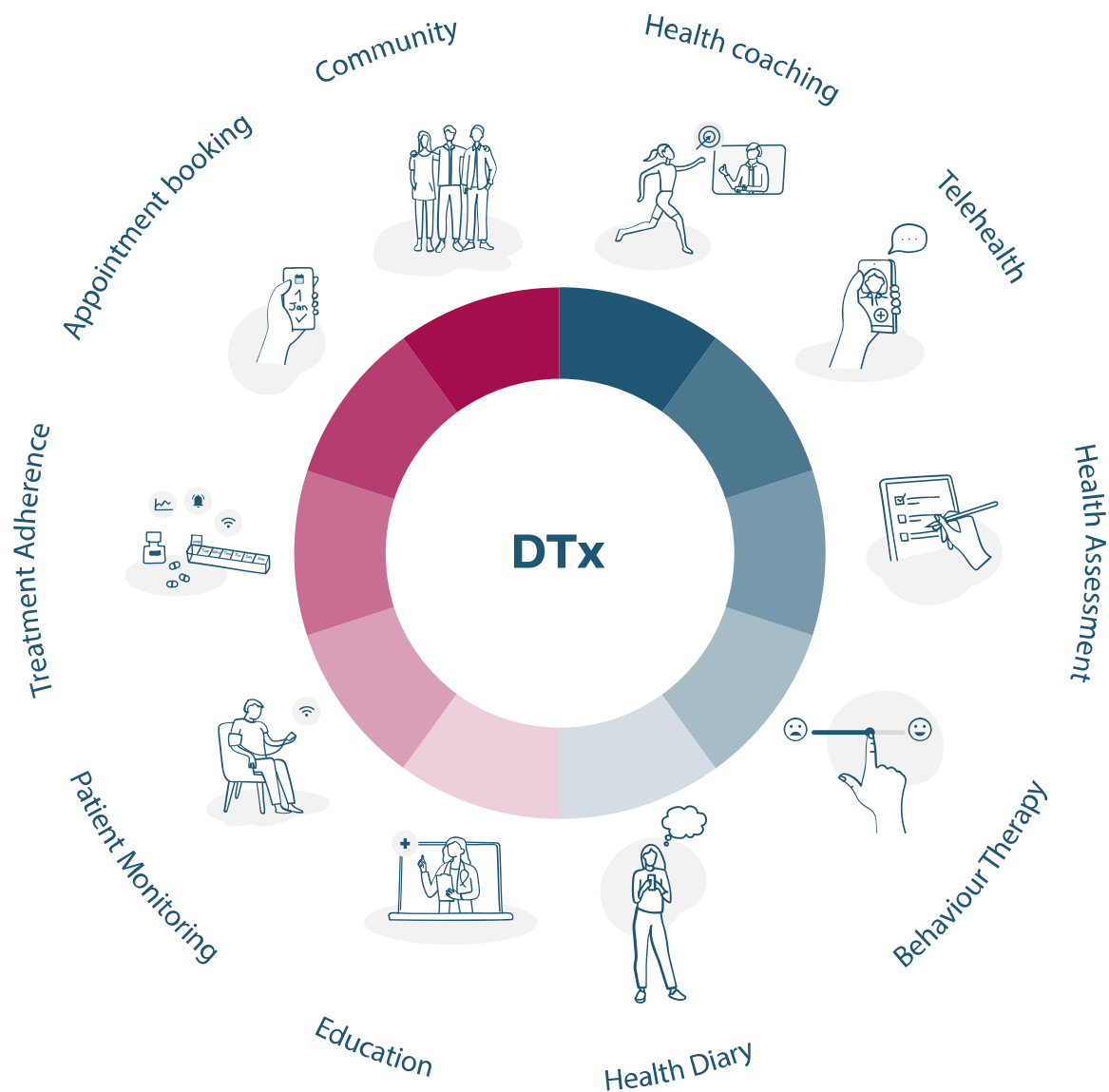
Designing DTx



Designing DTx

Features and functionality of DTx

Most DTx share several features. These features provide a variety of functionality that support specific goals and objectives for both patients and clinicians, often both of them at the same time. What follows is a comprehensive list of these features, explaining their purpose and how they can support patients and clinicians throughout the patient journey.



Patient health record

One of the most common, and almost essential features of a DTx, the Patient Health Record holds details of the patient user's health history. A key distinction from all other types of Electronic Health Records is that a Patient Health Record is created and maintained by the patient themselves. This would include but is not limited to, their current diagnosis, medications, and details of up-to-date symptoms and health issues. But it can also include details such as allergies, family history of disease, and recent investigation results such as blood tests and radiographic imaging. At times these can be updated by a centralized Electronic Health Record controlled by providers. However, this often has complex privacy and security considerations, because giving multiple external users, including patients themselves, access to a health record can lead to data breaches. Thus a Patient Health Record held by patients can be easier to create but is not always as easy to maintain or be accessed by providers.



Health coaching

The provision of a professional health coach, or the use of prompts and instructions, can support patient users to adopt new behaviors. These behaviors could be almost anything but usually include committing to a new diet, exercise regime, or even new positive thinking. Behaviors are tied to goals, which ideally should be SMART, meaning they should be Specific, Measurable, Achievable, Relevant, and Time-bound. The use of professional health coaches is more labor intensive and thus expensive compared with a digital tool. However, health coaches have a superior ability compared with a conventional DTx to understand the nuances of the needs of patients, which leads to more realistic and achievable goals and plans. With that said, an AI-powered DTx could one day bridge the gap and achieve what a human health coach could do.

Health coaching works particularly well with DTx which combines it with health assessments and a community.





Telehealth

Telehealth is an umbrella term that is defined as healthcare services supplied through the use of telecommunications rather than face-to-face interactions. Telehealth could be any service, be it for the first-time presentation of a disease, an outpatient review, providing treatment, or even conducting surgery.

DTx with telehealth functionality can support both live and asynchronous communication. Although telehealth is often associated with video calls, which smartphone-based DTx can easily facilitate, text and audio-only communication are valid and appropriate alternatives. Not all users can use live video or audio tools due to disability. Additionally, some users may not feel comfortable communicating live for various reasons, such as when they are not in a private environment, or when they don't have time to respond instantly. This flexibility for communication allows DTx to provide convenient healthcare professional input when a patient user needs it most.



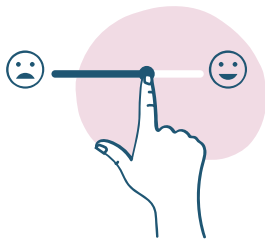
Health assessment

To predict or detect any change in a patient's health there must be a systematic review of multiple health data points. DTx commonly do this by asking patient users very specific health questions that provide insight as to what is going on with their health at the current time or recent past. The most effective way to conduct a health assessment without a clinician is to use a Patient Recorded Outcome Measure (Prom). PROMs are evidence-based health questionnaires, which can often be completed by patients on their own, that offer a conclusion of a patient's health status. Some PROMs go as far as providing recommendations for the next steps depending on the outcome of the completed health questionnaire. An individual PROM becomes particularly powerful if used in combination with other PROMs, data from wearable technology, and investigation findings such as lab and imaging results. DTx that use regular health assessments can provide personalized care that is proactive rather than reactive to the health needs of the patient.

Health and Behaviour Tracking

The tracking of health metrics and behaviors can provide invaluable insight. This could be of how well a patient is responding to treatment, or as a means to measure the risk of disease or deterioration. By providing easy-to-comprehend data visualizations based on tracked data, DTx can inform and inspire patients. This in turn can support behavior change as the patient can see where they have been and where they could go.

There is a strong secondary benefit of data analysis of big data gathered from all patients, as long as consent is taken from patient users. Various trends and patterns can be identified once a rich data set is collected and analyzed. This in turn can provide profound insights on the effectiveness of the service the DTx provides and the wider healthcare system it supports.



Health diary

There are a variety of positive outcomes for patients who log their experiences in a health diary. Firstly, it increases the awareness patients have of their health more objectively and reflectively. This can lead to a patient having a better appreciation of, or new perspective on, their health. For example, it can lead to patients committing to a new, healthy behavior, which in turn is reinforced by regular reflection on the improvement to health outcomes. Alternatively, it can help a patient recognize that a current health behavior is destructive, and support them in deciding to change said behavior.

Additionally, health diaries can offer a significantly more accurate account of a patient's journey which can be discussed with a clinician during a telehealth or in-person consultation. Subsequent treatment plans can be tailored more appropriately as a result of more accurate information being used.





Photo credit: Shutterstock

Education

Patients and clinicians alike can always learn something new. The internet is filled with all the information anyone could ever need, but that does not mean we are learning as efficiently as we can. By providing educational material through a DTx, we are utilizing a channel that patient users should already be using. This provides a learning experience that is deeply connected to the context of the DTx itself which can improve the learning experience and make it more long lasting. Furthermore, the educational material can be offered through a variety of mediums, such as text, imagery, video, and even through an interactive eLearning experience. The most effective learning experiences capitalize on using multiple learning mediums to cater to a variety of learning styles, but also to reinforce the learning that takes place. Educational material can be personalized to adapt to the needs of the patient user as well, further enhancing its effectiveness.



Remote patient monitoring

The use of wearables, PROMs, and telehealth allows patients to be successfully monitored by clinicians at a distance. Remote patient monitoring will never completely remove the need for hospitals, especially for the care of surgical patients or those undergoing extensive rehabilitation. Nevertheless, the response to the COVID-19 pandemic has provided extensive evidence that we can effectively monitor and manage the health of patients whilst they heal in the comfort of their normal place of residence. This not only dramatically reduces healthcare delivery costs, and reduces the risk of infection from fellow patients, but also reduces the effort of patients to go to a healthcare professional when sick. This has the added benefit of empowering patients to take more ownership of their own health needs, without forcing them to make all the decisions on their own. Furthermore, remote monitoring can provide peace of mind for patients, their loved ones, and the healthcare professionals who serve them once patients are discharged from inpatient care.

Medicine and treatment adherence

It is quite obvious that when patients commit to taking their medication as prescribed, they are significantly more likely to improve their health outcomes. With that said, medicine non-adherence is a major contributor to morbidity and mortality. Various studies have looked into this issue with just as various findings. But medicine non-adherence is costing the global healthcare system USD \$100s of billions. The common reasons for medicine non-adherence include intolerable side effects, inconvenience, and simply forgetfulness. DTx can overcome these issues through a combination of improved education to prepare the patient, and to provide personalized prompts to trigger medicine use.



Appointment booking & calendar

Difficulties with booking an appointment with a healthcare professional are a common problem faced around the world. All patients can struggle to get an appointment if there are insufficient clinicians to see, or administrators to confirm appointments. However, the other aspect of appointment booking that is often overlooked is that patients may avoid making appointments due to previous unsuccessful or otherwise negative experiences with appointment booking, or healthcare services in general. DTx can provide streamlined appointment bookings that encourage patients to see a clinician at the right time. Furthermore, DTx can significantly impact the problem, and consequential cost, of patients missing appointments. These costs are quite significant; missed appointments cost the NHS approximately £288 million during the Covid-19 pandemic.



Community

Peer support is a very simple and cost-effective way to inspire and encourage patients throughout their healthcare journey. This phenomenon becomes even more powerful when patients are trained, providing them with techniques and knowledge to maximize the impact of peer support interactions. Such interactions can be done in person for both inpatient and outpatient care. But through the use of DTx, peer support can also be done anywhere with a mobile device, including from the comfort of home. This flexibility offers more opportunities for positive reinforcement of both a patient's plans to improve their health, as well as any existing behaviors they have adopted. Additionally, and as discussed later in this white paper, communities can provide insights to their members on what is realistic regarding getting healthy, and the actions required to achieve health goals. This can be done through the use of leaderboards and other comparative data presentations. But also through the use of storytelling by community members, of both successes and failures, which others can learn from. This then can lead to social proof where members of the community emulate each other to achieve the same, or at least similar, outcomes.



Welldoc case study

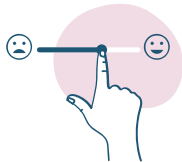
Welldoc provides a sophisticated chronic disease management platform that successfully combines a suite of features and functionality for both clinicians and patients. The platform is composed of an FDA-cleared prescribable DTX, BlueStar, and non-FDA-cleared tools that work in conjunction with BlueStar.

Illustration of a DTx for Diabetes patients



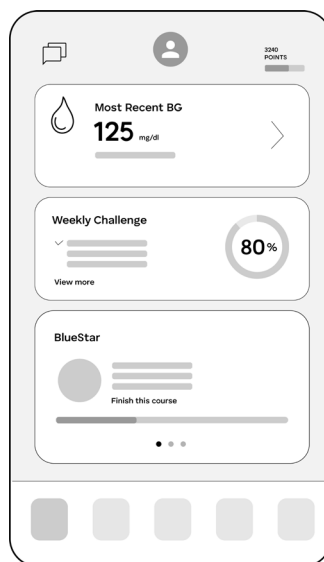
Health coaching

Patient users are supported by health coaches to achieve SMART health goals



Health and behaviour tracking

Blood glucose and other biomarkers are monitored through synchronized medical devices



Telehealth

Clinical teams can communicate directly with their patients through the app



Medicine and treatment adherence

Reminders to take medication and to engage with any other prescribed treatment

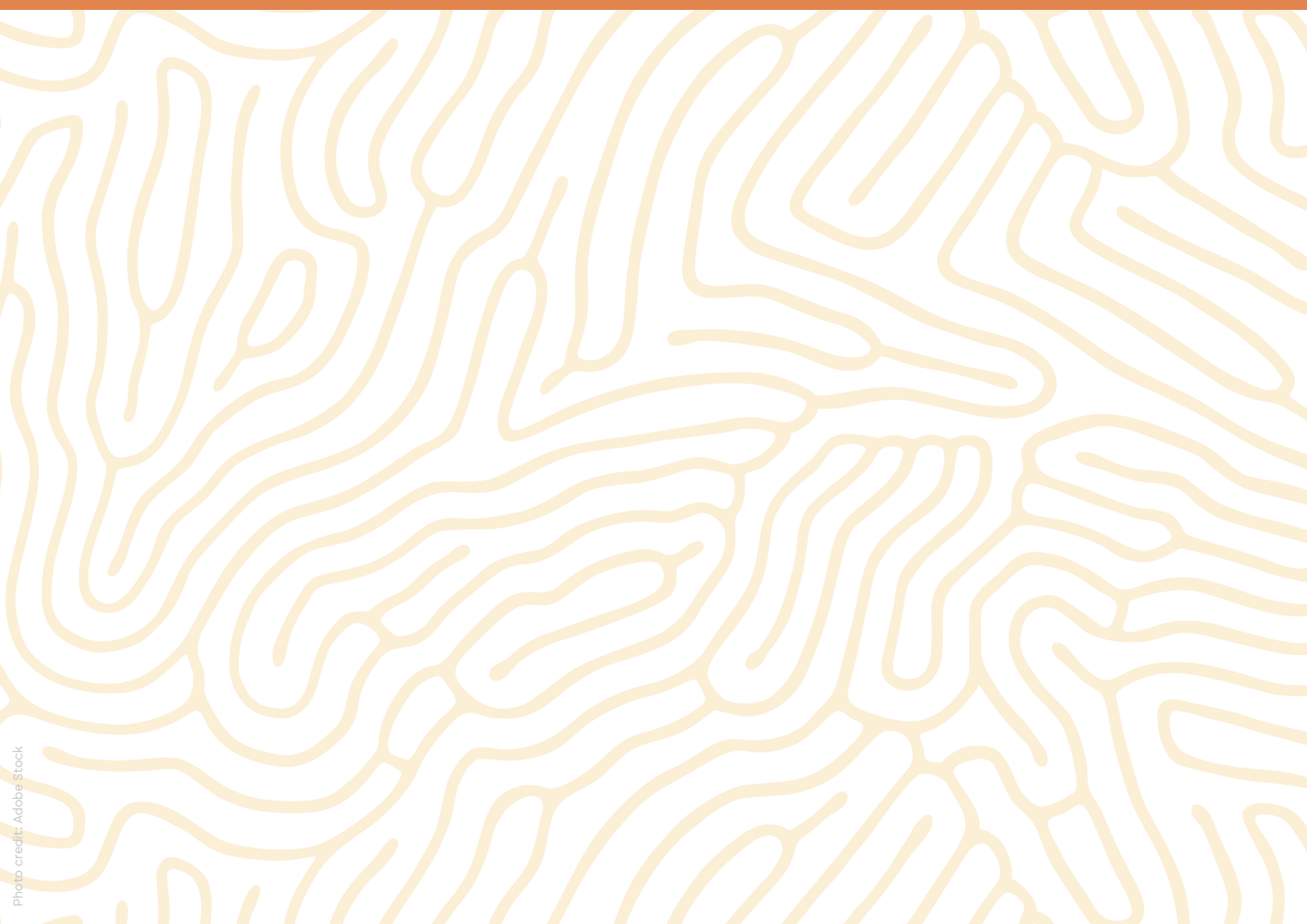


Remote patient monitoring

Dashboards populated with real-time data with analytics and reports highlight the most at-risk patients

5

Empowering DTx users



Empowering DTx Users

When any user – clinicians and patients alike – feels empowered, they are much more likely to change or adopt a new behavior. Empowering people involves giving someone the authority or power to pursue a specific objective. It also means to make someone feel more in control and thus more capable of bringing (positive) change to their life. Empowerment generally can be achieved by correctly applying behavior change theory to a given situation. But we should also be aware of specific techniques that can entice users to engage with a DTx. This is particularly important when using a DTx is a dramatic change for the user or an activity that they otherwise would not commit to.

Enticement techniques

When we entice users, we are drawing their attention and tempting them to interact with something positive if not stimulating and joyful. This is a necessary step to engage people if they don't already have the motivation to engage with a particular activity or thought. Once enticed, we engage people, holding their attention. There are three specific reactions one can have in response to a stimulus designed to entice them. These reactions are tied to the three levels of processing of stimuli that take place when someone has an experience. These three reactions are as follows:



Visceral reaction

the instant reaction one has to a stimulus

Behavioral reaction

the reaction experienced during an experience, based on one's ability to complete a task



Reflective reaction

the activity makes the user reflect on their experience and how this relates to them on a deeper level

For a visceral reaction to lead to engagement, the proceeding activity in itself is pleasurable or at least satisfying. Examples include enjoying the smell of freshly brewed coffee or looking at a cute baby animal.

For a DTx, this would mean looking at and interacting with the mobile app, and seeing notifications that delight the user.

Behavioral reactions require the activity to have a useful outcome for it to encourage engagement. For example, using a microwave can be more engaging if it becomes more useful to use than a stove to reheat or cook food. When a user recognizes their health is improving because of a specific behavior, they are more likely to repeat said behavior. A DTx can instigate and facilitate this positive behavior and become a valued tool to a patient user.

Finally, reflective reactions encourage engagement as a result of the thoughts and reflections one has of a given activity. An example would be how someone feels about eating a vegan meal if they are used to eating meat, especially if they are aware of how harmful cattle farming is to the environment. Reflective reactions place less importance on the level of pleasure or satisfaction one gets from performing an activity, or on whether it successfully helps with completing a task.

Rather, the focus is on rationalization and coming to a logical conclusion. Reflective reactions are particularly useful, because if the user can find value in a DTx that is deeply connected to their personal beliefs, they are more likely to engage, even if they face setbacks. This is of significant value, as patients often have failures on their journeys, and such failures do not have to hold them back from achieving their health goals.

Furthermore, specific enticement techniques can trigger any or all of the three levels of processing. These include customization, personalization, delightful design, and data presentation.

Customization

Customization is the ability for users to select from two or more options for a specific feature or aesthetic of a product or service based on their likes and dislikes. It's closely related to personalization, which also provides a user choice. However, whereas customization may not be specific to an individual, personalization is. With personalization, the options available can be unique on an individual level, such as the inclusion of a user's first name on a welcome screen, or the use of their health history in a DTx. Both customization and personalization can entice users as they will have an experience that is more unique and likely memorable to them. The visceral reaction can draw in the user, with behavioral reactions continuing to empower the user.

Delightful design

Delightful design is the concept that the use of products and services should lead to enjoyment, if not delight, of the user. This is not always appropriate, such as when making a complaint or dealing with bad news, as this can ignore the sentiment of the user and cause offense. However, when a user is delighted on first use or impression of a product or service, the visceral reaction can encourage further inquiry. DTx that find ways to delight the user can encourage users to begin using it. Subsequent experiences with the DTx can then trigger persistent engagement.

Data presentation

Data presentation is the sharing of data in an easy-to-digest format. The most obvious examples are simple graphs, charts, diagrams, and maps. This fits with the definition of data visualization where data is only presented visually. But data presentation can also include the use of text. For example, a statistic shown in a visually striking way, or simply a text description. Interactive elements can help users to manipulate the data and make more sense of it. When a DTx presents data in a simple-to-understand way, it can make it easier for the user to comprehend said data. It may even allow users to find new understanding of data that they regularly see. This could include presenting a patient's diagnosis in a new way.

Engagement techniques

To engage a user is to hold their interest or attention. This may begin by first enticing a user. But it could also start when a user already has the motivation to engage with a product or service. If this motivation is already strong, users can be very committed to using a product or service. However, it is often the case that patients may not have the motivation to change their health or the belief that they are capable of bringing a change to their health. Therefore for a DTx to be most widely used, engagement should not rely on the motivation of the user alone.

There are a variety of engagement techniques that can be used which fall within the two categories of gameful experiences and gamification.

Gameful experience

A gameful experience is when an experience is that of a game. A game requires a user to pursue a specific goal for entertainment purposes, with appropriate resources and rules, and the ability to win or lose. Some games can be extremely short and simple, such as the jumping dinosaur game found on the Chrome browser when a page fails to load. Other games can be far more elaborate, as is the case with so-called triple-A games played on consoles or PCs.

There are a variety of hallmark components of games. The two that are essential include game rules and the chance of failure. Other important, but not essential components are storytelling, power-ups, and leveling up.



Game rules

Rules in games dictate the constraints a player has when playing the game. These constraints can make the game easier or more challenging, but should always be fair. If the rules make it impossible to complete the game, a player will eventually lose interest as the objective of the game cannot be accomplished. Game rules should ideally be explicitly implied, or quick to learn, otherwise players may be confused or give up trying to complete the game. In a DTx, the rules used in a game should be mindful of the abilities, limitations, and resources a user has. A lack of such understanding can make DTx either too easy or challenging, resulting in the user more likely to become disinterested.

Chance of failure

The chance of failure is vitally important in a game as it ensures the game player is stimulated enough during the gameful experience. Without the chance of failure, the game player will only be pursuing a goal. The chance of failure offers motivation. To fail means there is an opportunity to improve and win next time. Furthermore, games that lack a lose state can become boring because skill, knowledge, and experience are not required. With a DTx, and indeed with achieving health goals in general, the chance of failure can motivate people to do all that they can to prevent failure and instead achieve success.



Storytelling

Sharing stories is a practice that transcends all cultures. This is unsurprising as it is a primary means to share information across generations and cultures. This is easily demonstrated by how lucrative the entertainment business is. Interesting stories encourage people to discover the end of the story. Activities that involve an interesting story can thus encourage people to continue the activity if it means they continue engaging with the story. This is why DTx which incorporates storytelling can be so effective. Both fictional and non-fictional stories have their roles and benefits in DTx. Fictional stories can be entertaining and part of escapism. Non-fictional stories however, particularly testimonials and other personal stories, are more likely to inspire hope by showing what is possible or warn users of experiences they may want to avoid.



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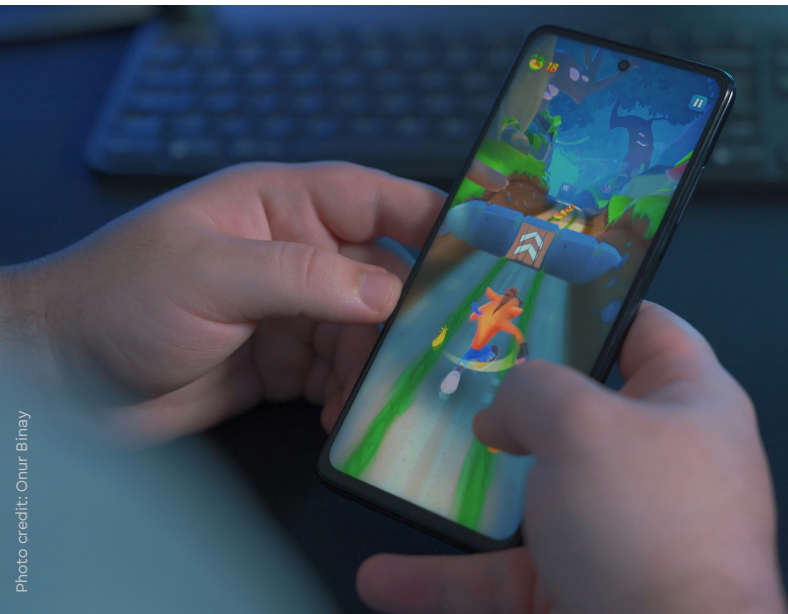


Photo credit: Onur Binay

Powerups and difficulty modifiers

There are instances in games when a player can gain a temporary or permanent adjustment to the rules which makes the game easier or more difficult. A memorable example is when the character Mario touches a red mushroom in Super Mario Bros. becomes taller, but touching a blue mushroom makes him smaller. These size changes are persistent until Mario touches another mushroom, takes damage from an enemy, or either completes or fails the level. However, if Mario touches a flashing yellow Super Star, he temporarily becomes invulnerable to damage from enemies whom he can also instantly vanquish. Incorporating powerups in a DTx can be difficult due to the nature of what they are unless the user is engaging with a powerup in an actual game featured in the DTx. Furthermore, the addition of a handicap can be very demotivating and should normally be avoided in healthcare. However, the concept of a powerup can be altered to instead mean any activity that can make the user more effective. For example, light exercise first thing in the morning, or a good night's sleep, can energize someone later on in the day.



Gamification

Gamification is when features of a game are used in a non-game experience. This specifically means that gamification does not require there to be a win or lose state nor is it specifically designed to entertain. The purpose of gamification is to encourage users to regularly engage with a product or service. The timing of how regular engagement takes place will be specific to the product or service and does not need to be consistent. Common examples of gamification features include leaderboards, achievements, progression data, and in-app currency.

Leaderboards

This is a scoreboard of the names and relevant data of product or service use. In a DTx this data could be the number of steps walked, the amount of weight lost, or the number of days without smoking. It could also show data such as achievements, which is discussed further below.

Leaderboards can be complicated to implement as the use of real names may be unlawful, or at least not information users are willing to share. The use of usernames can overcome this issue, however. Comparing users can demotivate users in certain circumstances, leading to reduced engagement. This is normally a result of comparing users in an unfair way, such as when it would be impossible for a user to ever take the lead. However, a leaderboard in a DTx can motivate users who may be comparing and indeed competing with people they know or need inspiration of what is possible.



Achievements

Recognition of reaching a specific goal or milestone. Achievements can be celebrated in different ways. This can range from the use of badges that represent the achievements, points aligned to the value of the achievement, or a reward of some kind. Achievements could have bonuses to them, which can manifest as an additional achievement that can only be accomplished once the first achievement has been achieved. An example would be achieving a walking distance, but then exceeding it by 10%. Achievements are a great way to motivate users in a DTx as it provides opportunities to celebrate successes and encourage more success in the future. Achievements should be frequent enough to ensure users are appropriately stimulated, but not so frequent that engagement becomes meaningless.





Progression data

Similar to the use of data presentation, progression data shows a user how far they have progressed with a specific task or journey to reach a goal. Milestones and achievements may be presented, and crucially, further details of what is required to reach subsequent goals. How this information is presented can support decision-making. When used in a DTx, progression data can encourage a user to have an emotional response, be it celebratory, mournful, or anything in between. This response, when nurtured appropriately, can support continued success, or trigger a change in behavior to achieve goals.

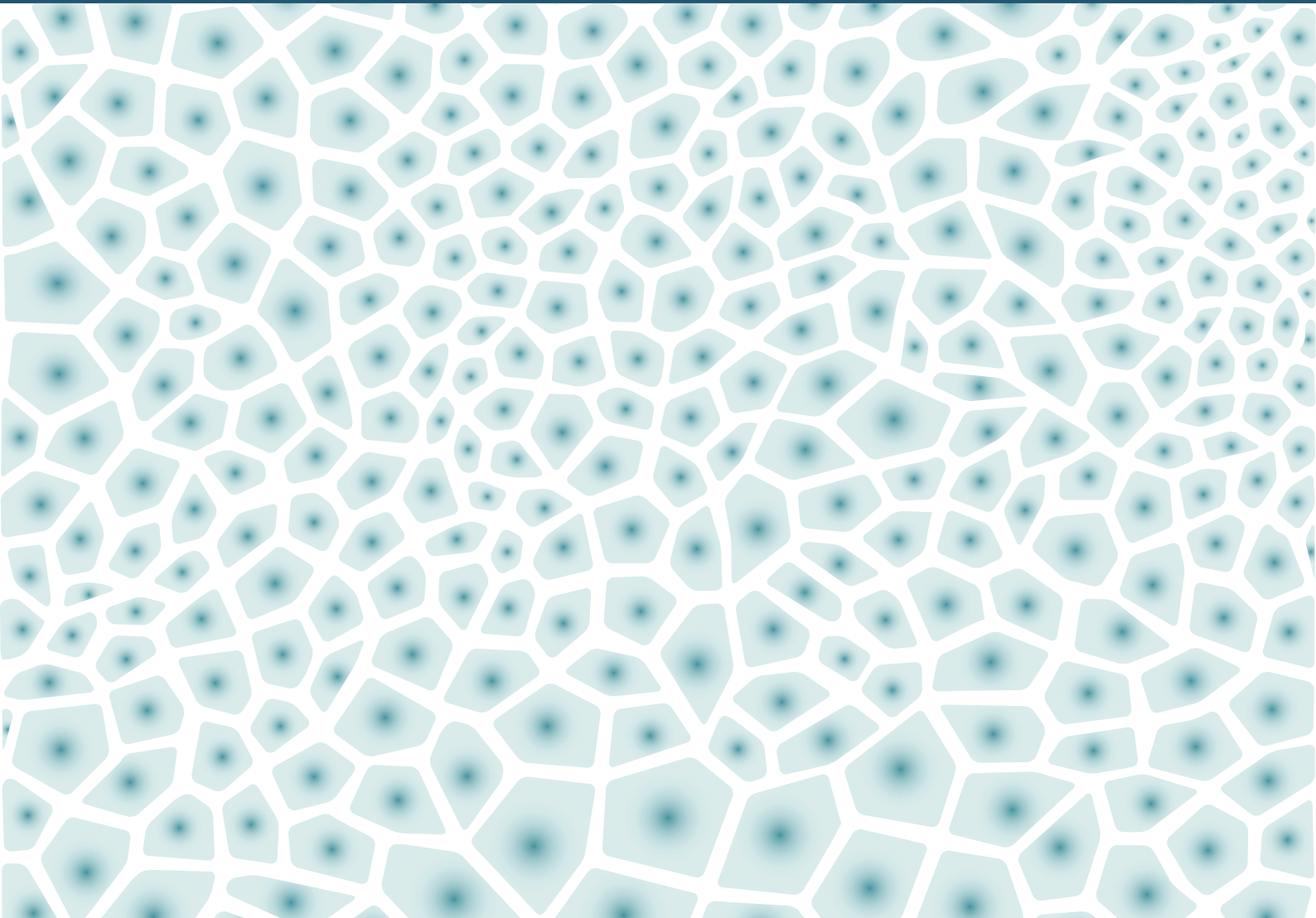


In-app currency

In-app currency refers to a virtual currency used to make purchases within a digital product. This is a popular feature within games, where the in-app currency can be earned through performing specific tasks in the game or maybe purchasable with real money. The latter can be lucrative, but this income stream can backfire. Purchasing in-app currency with real money can be a serious problem for those susceptible to gambling, leading users to go into debt if the game is used inappropriately. Furthermore, many people will prefer to earn in-app currency for free through play rather than spending real money when the option is available. In a DTx, in-app currency can be most effective in encouraging engagement when it is relatively easy to acquire and considered very valuable based on what can be purchased with it.

6

Encouraging Behaviour Change



Encouraging Behaviour Change

Virtually no behavior can be guaranteed to occur.

People can react in several ways, enacting behaviors that are not always predictable. However, a thorough understanding of behavior change can significantly influence how a product or service encourages users to adopt, maintain, or stop specific behaviors. This understanding can support the design of products and services that accommodate the variety of ways users can behave. With healthcare behavior change, influencing and instigating specific behaviors is particularly important as they can directly prevent, manage, or treat disease.

Behavior change is the process of adopting a new habit or pattern of behavior, usually to achieve a specific goal. The use of behavior change models and theories during the design process of a DTx can maximize its ability to encourage specific behavior change within its users.

Models of behavior change are used to understand specific behaviors and the various factors that influence them. There are several models of note including:

BJ Fogg's Behavior Model - proposes that behavior occurs when the sum of ability (A) and prompts (P) is exceeded by motivation (B)

The Transtheoretical Model - also known as the Stages of Change Model, it recognizes six stages people move through for behavior change, from precontemplation to maintenance and termination.

COM-B Model - observe the capabilities, opportunities, and motivations required for behavior change within a specific context.

Theories of behavior change can be used to predict and explain how behavior changes over time. The example models can all do this, but a few others of note include Maslow's Hierarchy of Needs, heuristics, biases, and the Theory of Reasoned Action.

There are many healthcare-specific models and theories of behavior change. A particularly famous one is the Health Belief Model which assesses perceived susceptibility, severity, and benefits of a behavior change that can impact the perceived threat and action. It is particularly useful for public health initiatives, but less so for individual behavior change interventions. In contrast, the theory of reasoned action is a comprehensive way to assess the many variables that determine health. Specifically, it focuses on intentions to perform a behavior, which it proposes are influenced by one's views of the world around them (attitudes), their belief of what is normal or otherwise expected in a given situation (subjective norms), and their belief of what they can (perceived behavioral control). However, it recognizes that attitudes, subjective norms, and perceived behavioral control are complex, and are influenced by various factors such as past experiences, socioeconomic status, and macro-economic forces.

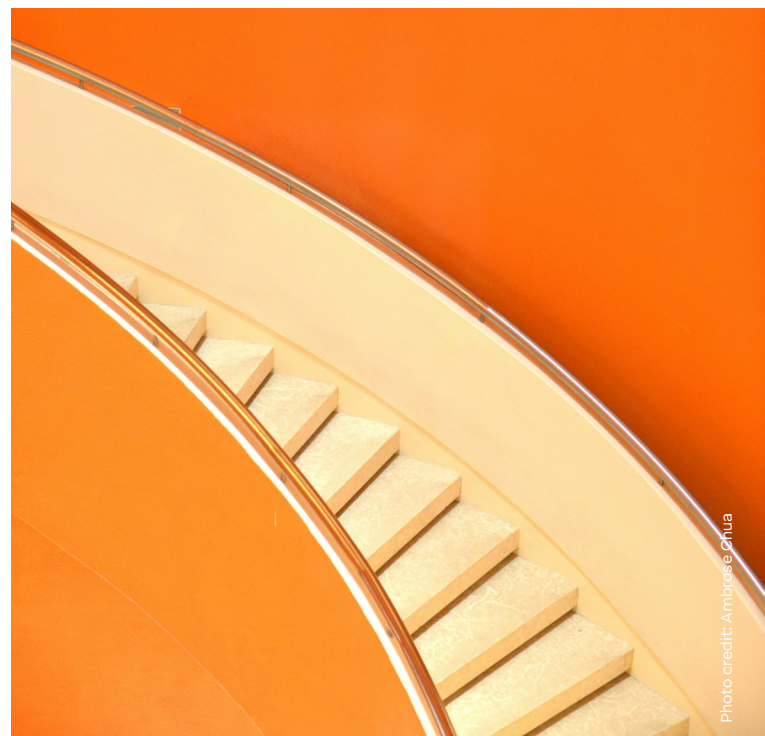
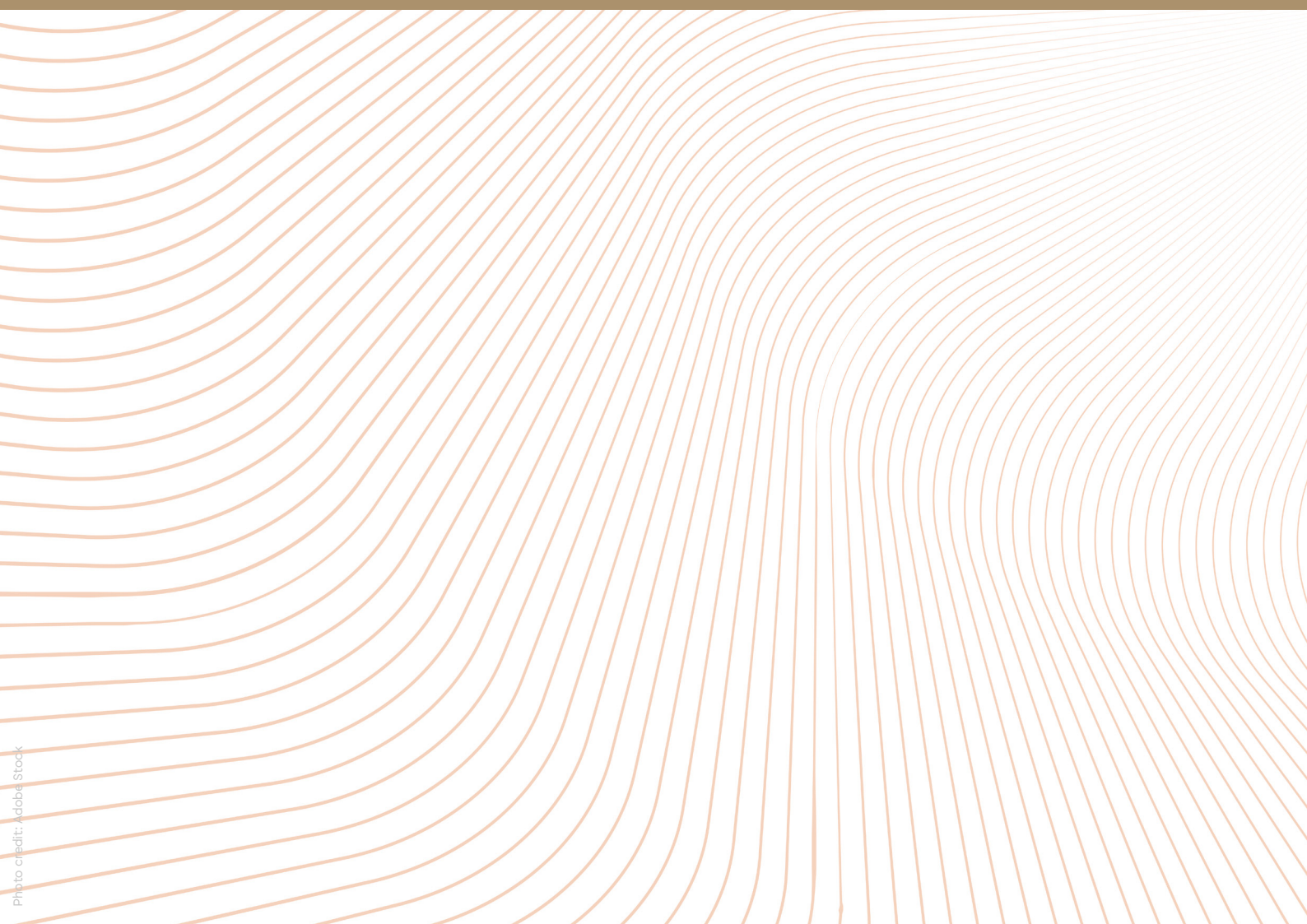


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7

Business models for DTx



Business models for DTx

With limited DTx on the market, there are equally limited examples of successful DTx business models. However, various business models have proven to work, especially in healthcare. These business models fall within the categories of Business-to-Consumers, Business-to-Business and Partnerships:

Business to Consumer (B2C)

Selling a DTx directly to consumers can be rather challenging depending on the price point and whether the product is easy enough for them to decide to commit to. Yet, in an ever-increasing consumerism of healthcare, selling directly to consumers may be one of the most powerful business models. This is particularly true in markets where consumers pay for healthcare directly.

Subscription models - Users are charged a recurring fee for access to the DTx. This might involve a freemium model that has additional functionality users can access for a fee, or be a premium service from the beginning. Both models can support recurring income, but profit is reliant on a balance between subscription fees and the total number of subscriptions.

One-time purchase - Access to some or all of the DTx features and functionality is granted once a one-time fee is paid. This one-time purchase could be a far greater fee than an annual subscription, but cheaper in the long run for users. Providing users with the choice can enhance the sales process as those who can afford a larger one-off purchase would welcome the money saved from the purchase.

In-app purchases - In addition to offering premium features or content within the DTx, users could also purchase physical products or services.

Business to Business (B2B):

A common business model, known for being very time-consuming to finalize, but also very lucrative. DTx sold this way have the opportunity to be used by a large number of users, be they the employees of any company, or the patients served by a healthcare company. Such large contracts can support trial activity due to the large number of users.

White labeled licensing - As mentioned in the chapter The Challenges with DTx, there are limited DTx experts. Thus many companies, especially pharmaceutical and health insurance companies, may prefer to outsource the development of a DTx to reduce their risks and increase chances of profitability.

Enterprise sales - Bulking sales of subscriptions or access to the DTx directly to employers to be used as an employee benefit or as part of an employee wellness initiative. The DTx is then used by either some or all employees based on the goal of the DTx. For example, the DTx may be designed to reduce cardiovascular risk in people with a high risk of heart disease or stroke. Alternatively, a DTx that addresses general mental health and wellness support could be used by everyone. In either case, supporting the health of employees can dramatically reduce the operational and financial costs associated with employee sickness.

Aggregate and anonymized data sales - An effective way to leverage a large data set, which can be sold to other companies, or the same company who have an enterprise license. Can be a controversial option for users not happy to share their data. However, transparent and honest communication, along with a great experience and impact for users can instill the necessary trust required to get permission to sell their data. Legal documentation and both privacy and security processes require significantly more attention, however. Failure to adhere to laws and regulations can lead to heavy fines and reputational damage.

Training and certification programs - This can involve offering training programs or certifications for staff on the effective use of the DTx. This can pair well with either white-labeled licensing or enterprise sales as an add-on service to enhance the onboarding experience of clinical or technical users. For example, training can involve setting up custom reports on data collected from patient users.

Partnerships

Similar to B2B, partnerships rely on contracts that can take a while to complete. However, the terms of such contracts are not based solely on a product or service in exchange for monetary compensation, if at all. The partnership may be a means to achieve a subsequent business objective that is beneficial to all parties in the partnership. The partnership business model can be a useful, if not, essential component of a successful business strategy.

Integration with healthcare systems - Work with healthcare providers, integrating the DTx into their existing systems for patient care. This can be a successful business arrangement for a free-to-use DTx that relies on a large number of users to turn a profit. It can also provide very low-cost marketing of the DTx.

Prescription-based model - Work with healthcare professionals to prescribe or recommend the digital therapeutic as part of a treatment plan, potentially reimbursed by insurance. This can be a challenging business model, as healthcare professionals need

to prescribe what is best for the patient. There are strict laws and regulations requiring transparent communication about such a business arrangement and very clear and comprehensive guidance on how to ensure patients are not exploited.

Clinical trials and research partnerships - An extremely convenient arrangement, where a company collaborates with research institutions, universities, or pharmaceutical companies to conduct clinical trials or research studies using the DTx. Revenue can be generated through the sale or license of research findings, and from grants. This partnership can speed up, and potentially lower the overall cost of clinical trials needed to prove the efficacy of a DTx.

Co-marketing agreements - A company's DTx can be co-marketed with a pharmaceutical agent or other healthcare technology or service, improving the sales of all products and services involved in the agreement. This can be a very lucrative arrangement if there is compelling evidence that the co-marketed products and/or services are more effective than any individual product or service.

Ultimately, the best business model to use will depend on many factors that must be carefully considered to ensure that the DTx can achieve its full potential in the market. As suggested above, multiple business models used in combination are often the most effective and can support both short and long-term goals that are not just tied to revenue.

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Dr Gyles Morrison is a Clinical UX Strategist with a history in healthcare from 2011. He earned his medical degree at Bart's & The London School of Medicine and Dentistry, and a MSc in Human-Computer Interaction with Ergonomics at University College London. His unique background gives him deep insights into healthcare, clinical needs, and the creation of effective, user-centered digital health solutions.

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Illustrations

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With over a decade of experience in the health and life sciences sector – and with a team of senior design and technology professionals collaborating across Europe, North America, and the Asia-Pacific regions – Whitespace is uniquely positioned to service the needs of all Pharma, Biotech, & Medtech stakeholders and help shape the future of healthcare.

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