

Digital Therapeutics

Report

What Opportunities for Pharma Companies?

October 2022

Digital therapeutics are evidence-based software-driven interventions addressing a wide range of conditions – independently or in combination with existing treatments

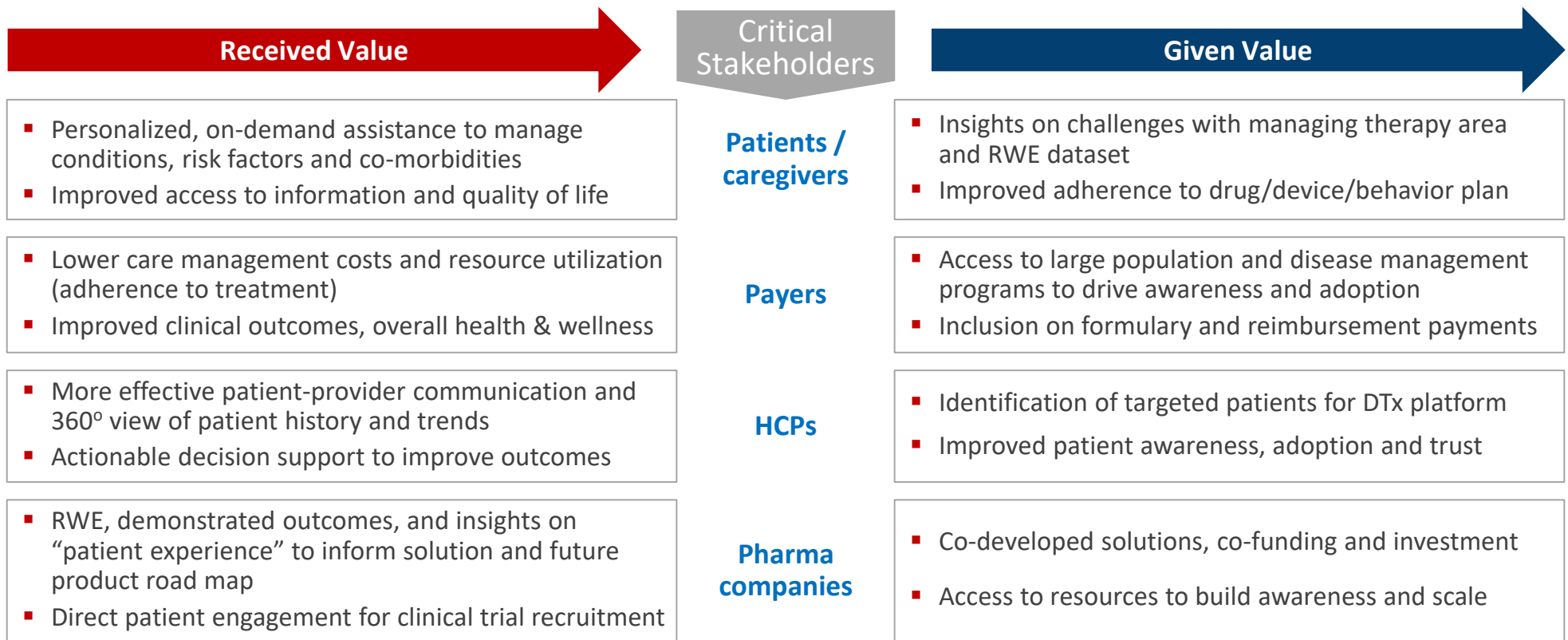
Definition

- Digital therapeutics (DTx) are **evidence-based, software-driven** interventions which can:
 - **Prevent** by improving **lifestyle management** and **nutrition**,
 - **Manage** by encouraging patients' **adherence** by adding **services**,
 - **Treat** by collecting and analyzing patients' data to **personalize** their treatments or by replacing traditional treatments (e.g., cognitive behavioral therapy)...

... a medical disorder or a disease
- DTx are used **independently** or **combined** with drugs, medical devices, or other therapies to **optimize patient care** and **health outcomes** and...
- ... can be subject to a **reimbursement**
- Digital therapeutics empower **patients, HCPs, and payers** with intelligent and accessible tools for addressing a **wide range of conditions** through **high quality, safe, and effective** data-driven interventions

In the DTx ecosystem, critical stakeholders provide products and services, information and emotional value exchanges that improve clinical outcomes

DTx ecosystem: value exchanges



Sources: Realizing the potential value of DTx (EY 2021) – Smart Pharma Consulting

DTx solutions have a multitude of uses and wide-ranging implications for both individuals and society, allowing to move closer from a model treating diseases to a model treating patients

Potential value of DTx

DTx added-value <i>(Provided proposed solutions are acceptable to and accepted by end-users)</i>	Direct beneficiaries		
	Patients	HCPs	HC ¹ System
▪ Empower patients to monitor and self-manage their health	X		
▪ Improve medication management and treatment adherence	X		
▪ Provide predictive, preventive, personalized and participatory care	X		
▪ Support collection and analysis of health data		X	X
▪ Lower the burden of care		X	X
▪ Reduce health inequalities (e.g., for homeless, underserved populations)	X		X
▪ Complement other forms of therapy	X		
▪ Support collection and analysis of health data			X
▪ Reduce costs to healthcare system			X

Sources: After Graphite Digital website (Sep. 2021) – Smart Pharma Consulting

¹ Health Care

DTx can be used for a wide variety of applications leveraging different kinds of technologies and digital capabilities

Typical DTx applications

Patient monitoring and self-management

- Tracking and monitoring of patients' symptoms that are analyzed and sent to HCPs who can ensure the follow-up (e.g., Voluntis' Theraxium to monitor cancer patients' symptoms to better manage side effects)

Digital behavioral intervention

- Apps providing digital cognitive behavioral therapy (CBT) for mental health conditions or personal habits to change to prevent / delay the development of chronic diseases (e.g., GAIA's vorvida program – based on CBT – aimed at reducing alcohol consumption)

Artificial intelligence and machine learning

- Apps using AI and machine learning algorithms to enable real-time interventions or early diagnosis of certain diseases (e.g., Cognoa's Canvas Dx has been granted MA by the FDA for early diagnosis of autism in children)

Apps connected to sensors and wearables

- Apps connected to a sensor or a wearable device to monitor or track specific biomarkers (e.g., Propeller Health system for asthma and COPD¹ tracking when and how patients use their inhaled medications)

Gaming and virtual reality

- These DTx work by providing patients with a video game or a virtual reality-based experience (e.g., Akili's EndeavorRx prescribed for children with attention deficit hyperactivity disorder (ADHD) based on video gaming)

Ultimately, as DTx aimed at changing patients' behavior to improve their health, they should be designed – with the collaboration of users – so that to influence their behaviors over time

What makes a good DTx?

PREMs¹

- PREMs measure the experience (the whole or individual interactions) of patients when engaging with healthcare services
- Patients heal quicker when their experience is positive

PROMs²

- PROMs are evidence-based healthcare questionnaires which identify change in health status
- They help understanding patient's perspective and gauge their health status and should be a feature of DTx

Clinical Best Practice

- Clinical Best Practice combines:
 - Clinical pathways (management tool detailing the way to treat patients)
 - Care plans (specific instructions on how to care for a patient)

Behavioral elements

- Applying knowledge of factors that determine human behavior (e.g., COM-B³) ensures that...
- ... DTx designers can engage users according to their motivational needs and situational contexts to alter target behaviors over time and improve health status

User-Experience (UX)

- The most appropriate methods to understand the contexts and lived experiences of users should be utilized
- Performance indicators and objectives should be set
- It is also essential to test and evaluate the solution with real users over multiple design iterations

Sources: After Graphite Digital website (Sep. 2021) – Smart Pharma Consulting

¹ Patient Recorded Experience Measures – ² Patient Recorded Outcome Measures – ³ The COM-B model considers that for behavior change to occur three factors are requested: capability, opportunity and motivation

Attractiveness of DTx for pharma companies – at national level – is driven by local regulations, competitive intensity, opportunities to partner and position of different key customers

Market determinants driving DTx attractiveness

Health authorities

- Market access and regulatory processes should be adapted to properly evaluate DTx benefits
(Germany which is the most advanced country may pave the road to a pan-European DTx approval and reimbursement process)

Competitors

- Limited number of players (pure players or pharma companies having signed partnerships with digital companies)
- High-quality and pro-active players contributing to shape and develop the DTx market



Customers

- Payers¹: willingness to pay for DTx that prevent, manage or treat diseases
- HCPs: convinced by the medical value of DTx, engaged to prescribe them and to use them to monitor their patients
- Patients: accept to pay² for DTx and show a high degree of adherence and persistence

Partners

- Presence of digital companies inclined to partner with pharma companies which are familiar with market access requirements and have access to HCPs to promote DTx

Sources: Smart Pharma Consulting

¹ Could be public or private health insurance organizations, and patients – ² If not reimbursed

Germany is the most advanced country re. the registration process for DTx market authorization, ahead of the USA where a specific pilot program is on-going, and of other European countries

DTx registration conditions

US regulations

- Several pathways can be used to register DTx:
 - 510(k): one must demonstrate that the DTx is as safe and effective as a legally marketed device
 - De Novo: used to evaluate novel devices of low to moderate risk, having no comparator and requiring stronger clinical evidence evaluation (e.g., Pear’s reSET)
 - Premarket approval (PMA): this is the most stringent FDA process to evaluate Class III devices
 - Precertification (Pre-Cert) program: as SaMDs¹ continuously change, FDA is exploring a faster and iterative release of digital health products model
- Pre-Cert program focuses on patient safety, product quality, clinical and cybersecurity responsibility, proactive culture
- The Pre-Cert program is a pilot program which will require legislation from Congress to be fully implemented

EU regulations

- The new MDR (Medical Device Regulation) which entered into force in May 2021 applies to all medical devices – including software – to be introduced on the EU market
- However, no specific legal regulation exists on DTx
- The European Medicines Agency and the European Commission are starting exploring DTx solutions and will work on application and evidence generation processes²
- On national level, the new German Digital Healthcare Act (DiGA) regulates specific requirements for the use of DTx:
 - A list of requirements defines which features any DTx application must have
 - Factors such as quality, security and data protection must be proven with scientific evaluation
- Several other countries (e.g., Belgium, France, Italy, the UK) are moving forward to implement a DiGA-like process

Sources: DiGA website July 2022 – EU website on DTx – Digital Therapeutics 101: Blue matter (2021) – Smart Pharma Consulting

¹ Software as a Medical Devices – ² Clinical validation of studies either comparing DTx to a control drug or where the submitted indication for a DTx is comparable to that of a drug

DTx can generate direct revenue and indirect non-revenue benefits, but the overall value of the latter is speculative and require to build a compelling business case

DTx monetization strategies

Revenues

- DTx with proven clinical efficacy should produce revenues
- Monetization can come from health insurance companies, consumers or even employers
- DTx companion (e.g., digital pen for insulin with its app) can boost revenues through higher rate of prescription by physicians and/or better adherence rate of diabetic patients

Data

- The patient's digital exhaust from using DTx (via ePRO¹ or utilization patterns) could provide real customer insights that can help improve the product, expand the label and/or the product design and development
- This value could be monetized directly while keeping to all necessary privacy rules and regulations
- Indirect value could also come from the intelligence alone

Competencies

- DTx can also provide indirect value through its use of cutting-edge technology and techniques
- Learnings from AI / ML² to data analytics to patient-centricity – which are central techniques in DTx – could disseminate across the organization as valuable skills and best practices for use in R&D, digital marketing, customer support, etc.
- These products may even provide compelling recruitment for highly coveted data and tech talent

Engagement of pharma companies in DTx should be, firstly, consistent with their corporate vision and ambition, and then, be part of their corresponding strategy and capabilities required, to do so

Pharma companies’ determinants driving DTx attractiveness

Corporate vision & ambition

- DTx are seen as a “beyond-the-pill” and/or “around-the-pill” differentiator to enhance their current value proposition
- Thus, DTx are seen as an opportunity to raise de value of drugs rather than to compete against them, by:
 - Improving the appropriateness of prescribed drugs by personalizing treatments based on patients’ monitoring
 - Enhancing the patient adherence and persistence with the help of special coaching programs powered by AI

Corporate strategy

- Pharma Companies should focus on TAs where they are active, and where...
- ... DTx are clearly a valuable complement to drugs – addressing unmet needs, undeserved populations – and not a potential competitor¹
- To win the “battle”, in this fast-moving market, it is essential to co-develop and co-market DTx with digital companies



Corporate capabilities

- In-house capabilities:
 - Management of regulatory and Price & Reimbursement hurdles
 - Interactions with and communication to HCPs and PAGs
- External capabilities:
 - Software development including AI
 - “Start-up” culture²
- Ability to partner with digital companies

Sources: Smart Pharma Consulting

¹ In Central Nervous System related diseases (e.g., depression, anxiety, insomnia, pain, etc. DTx can compete directly with existing drugs) – ² A high degree of agility and urgency is required because DTx life-cycles are much shorter than drugs’

DTx represent an opportunity for pharmaceutical companies to improve their value proposition, provided they develop their skills and adapt their processes

DTx: Opportunities & Challenges for Pharma Companies

Opportunities

- Combining a digital solution with a conventional therapeutic product can improve the **value proposition** to patients / HCPs...
- ... and allow to **claim a better price level and reimbursement condition** (e.g., through real-word data monitoring, improved outcomes)
- DTx also have the potential to **address unmet needs** (e.g., poor adherence of patients) that conventional treatments and therapies have been unable to provide...
- ... allowing companies able to address this field to gain a **significant competitive edge**

Challenges

- **Cross-industry connections** and robust **alliance management competencies with digital start-ups** and **incubators** need to be developed
- It is essential to establish **new trial designs** and **operational processes** to demonstrate **DTx value** for patients, HCPs, health authorities and payers
- **Pricing & reimbursement models** may need to differ from traditional ones
- Current authorities and payers' **methods for evaluating** these solutions, are ill-suited and...
- ... **data privacy** remains a **main concern**

Around-the-pill DTx contribute to enhance the value of conventional associated products, while beyond-the-pill DTx, more difficult to develop, avoid traditional costs and side effects concerns

Strategic options for Pharma Companies

Around-the-pill DTx

DTx delivering their impact in combination with another treatment, typically a drug (e.g., reSET-O¹ used as an adjunct to buprenorphine)

- May **boost the performance** of conventional products by a more **complete approach**
- **Real-world data collection** can improve product value by allowing a **more personalized treatment strategy**

- For certain patients, DTx are perceived as a **burden** on top of their existing treatments
- Being often seen by patients as an optional add-on, **acceptance, adherence** and **persistency** of DTx are **low**



Beyond-the-pill DTx

Standalone DTx that are designed to work independently of traditional drugs (e.g., Mika² used to reduce distress of cancer patients)

- Unlike the great majority of chemical or biological **drugs**, DTx avoid **side effects** and...
- ... significantly **lower costs** for patients, payers and the healthcare system

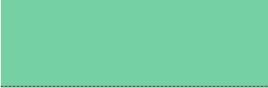

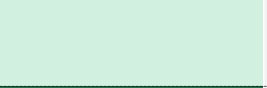





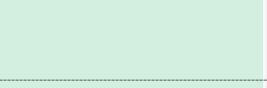






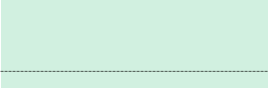

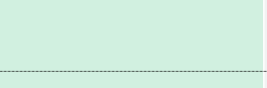






- More **costly** and **time-consuming** to develop and market than around-the pill DTx
- Reimbursement models being still unclear, **risks related to ROI** are higher


Sources: DTx at eyeforpharma 2020: Successful pilots, but a need for new partnership models – ZS: Barriers to broad DTx adoption and ways to overcome (2022) – MIT Technology review: can DTx be as good as drugs (2017) – Smart Pharma Consulting

¹ From Pear Therapeutics – ² From Fosanis

Metabolic Diseases, Mental health and Respiratory Diseases are the 3 most relevant therapeutics areas for DTx, especially for disease management purpose

Main therapeutic areas

Therapeutic area	Prevention	Management	Treatment	Example applications
Metabolic Diseases				<ul style="list-style-type: none"> App to help prevent type 2 diabetes App to help manage insulin
Mental health				<ul style="list-style-type: none"> Digital Cognitive Behavioral Therapy (CBT) Game training improving attention for ADHD¹
Cardiovascular				<ul style="list-style-type: none"> Digital program for acute coronary syndrome Patch to detect early symptoms of worsening heart failure
Respiratory				<ul style="list-style-type: none"> Self-management app to relieve COPD² symptoms at home Recording and monitoring of inhaled medications
Oncology				<ul style="list-style-type: none"> App for follow-up of breast and ovarian cancer patients Symptom-capturing adherence app for follow-up
Immunology				<ul style="list-style-type: none"> Self-assessment app to monitor rheumatoid arthritis Personalized recommendations to manage side effects
Gastrointestinal				<ul style="list-style-type: none"> Integrative approach to manage irritable bowel syndrome
Other ³				<ul style="list-style-type: none"> Acceptance and Commitment Therapy for chronic pain Analysis of fertility level through basal body temperature

Least pertinent  Most pertinent (based on number of players)

Sources: Deloitte: Digital Therapeutics Catalyzing the future of health (2021) – Smart Pharma Consulting

¹ Attention deficit / hyperactivity disorders – ² Chronic obstructive pulmonary disease – ³ Chronic pain, women’s health

Omada is a DTx developed by Omada Health to provide personalized programs to help manage chronic condition to reduce the risks of complications

Examples of DTx (1/3)



Omada Health

- Since 2011, **Omada Health** has been a US-based industry leader in virtual care
- The company offers evidence-based solutions that help people manage **chronic conditions**, such as diabetes, hypertension and musculoskeletal diseases and live healthier lives
- Omada Health works with over **1,600 companies** and counts **half a million members**
- The company has partnerships with **major US employers** and **leading health plans**, such as Cigna and Kaiser

Omada for prevention

- Omada’s product is geared towards employers with large populations of at-risk employees
- The program provides **personalized coaching** and **trainings to lose weight and prevent users at risk of type 2 diabetes**
- The solution leads to a **30% reduction of risks** for type 2 diabetes, **16%** for stroke and **13%** for heart disease
- Omada led to **medical cost savings** of \$1,169 per member in the first year and the solution is paid only if members enroll (Success-Based Pricing model)

Sources: Capgemini Engineering: Getting Digital Therapeutics Right (2021) – Omada health website – Smart Pharma Consulting

Mika is a management DTx developed by the German company Fosanis, providing personalized support to cancer patients in their emotional condition, allowing to reduce distress and fatigue

Examples of DTx (2/3)



Fosanis

- **Fosanis** is a German-based digital health company founded by Dr. Finke and Dr. Raue in **2017**
- The company's goal is to accompany individuals with cancer through quality of life and outcomes of therapy improvement
- Mika has been developed in collaboration with **public actors** (e.g., University hospitals) and **industrial actors** (e.g., Amgen, BMS, Pfizer)
- Debiopharm Innovation Fund invested in May 2022, **€10M to broaden patient access** to the DTx Mika

Mika

- Mika is a personalized DTx that supports **cancer** patients in their **emotional distress**
- Mika consists of **AI-powered monitoring** and **coaching tools** allowing continuous tracking of patient distress and symptoms
- **Daily check-ups** are done through **e-PROs¹**
- A **coaching section** is available with hundreds of **articles, videos** and **courses** to provide people with the information and emotional support they need, **completely tailored**
- The solution allows a **42% distress reduction** and a **23% fatigue reduction**

Somryst is a treatment DTx based on CBT intended to treat chronic insomnia, developed by Pear Therapeutics, a US-based leading company specializing in DTx development and commercialization

Examples of DTx (3/3)



Pear Therapeutics

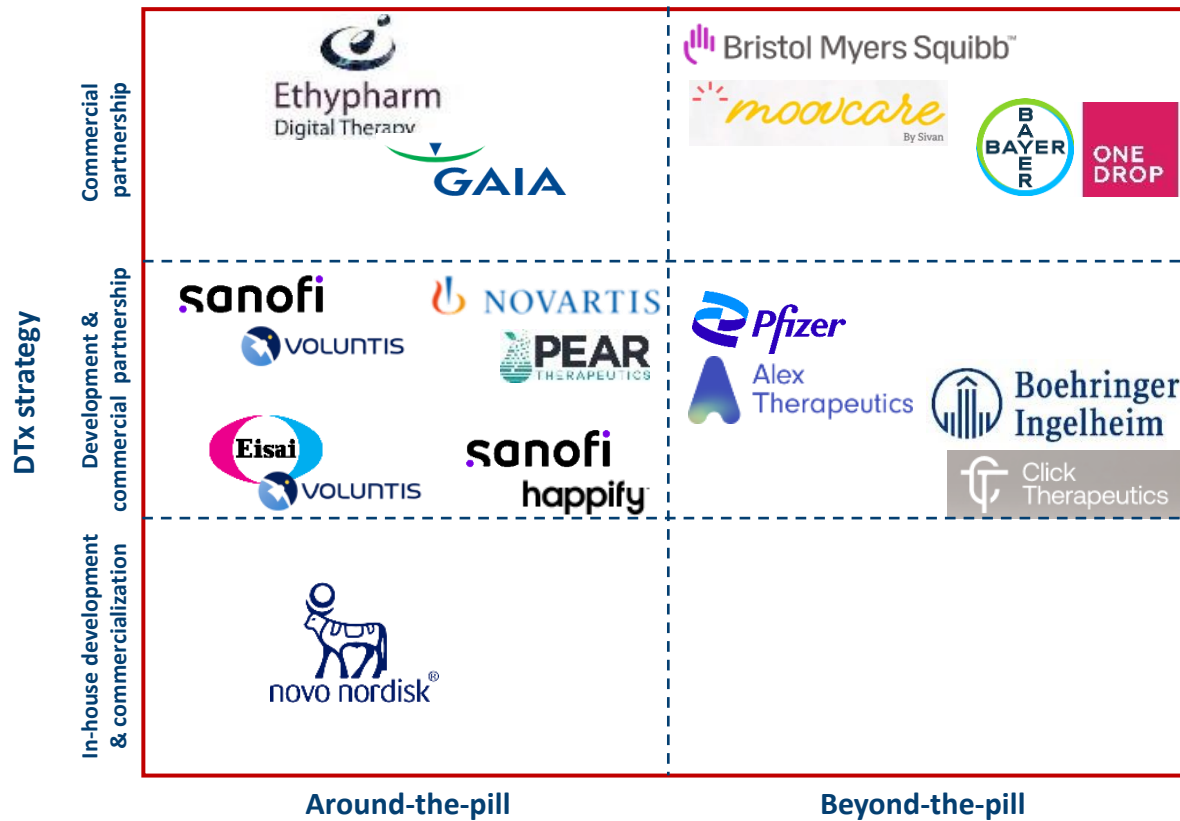
- **Pear Therapeutics** is a **US-based** leading company in developing and commercializing DTx
- Pear's DTx, **reSET**, for the treatment of substance use disorder, was the **first to receive marketing authorization** from the FDA to treat the disease
- The company also commercializes **reSET-O**, for opioid use disorder, and **Somryst** for chronic insomnia
- A **partnership agreement** has been signed with **Novartis' Sandoz unit** to expand sales and Marketing for the DTx reSET and reSET-O...
- ...and to **develop novel prescription DTx** for schizophrenia and multiple sclerosis

Somryst

- Somryst is a **treatment DTx**, FDA-authorized, intended for use in **chronic insomnia** and available on **digital devices**
- The 6- to 9-week program provides **digital cognitive behavioral therapy (CBT)** to improve the sleep through a 45 to 60 minutes use per week...
- ... while providing clinicians with **real-time data** on patient progress through a dashboard
- The solution has proven **persistent benefits** at **6- and 12-months follow-up** and is recommended by the **American Academy of Sleep Medicine** and the **American College of Physicians**

Currently, pharma companies mainly opt for co-development of their DTx with expert players, for their around-the-pill and beyond-the-pill solutions

Pharma Companies DTx strategies



- Ethypharm, BMS and Bayer have opted for the licensing of a solution already developed by a DTx player to strengthen their value proposition
- Other pharma companies (e.g., Sanofi, Novartis) have opted for co-development of DTx with expert partners
- Development and commercial partnerships are currently the preferred entry strategy for pharma companies
- The 2 categories of DTx, "around-the-pill" and "beyond-the-pill" are of interest to pharma companies

Sources: Digital Therapeutics and Pharma: How Novartis, Sanofi and al. embrace DTx (2021) – Smart Pharma Consulting

Pfizer signed a commercial partnership with Alex Therapeutics, with an initial focus on Germany to develop a DTx for nicotine addiction

Examples of strategies implemented by Pharma Companies (1/3)



Alex Therapeutics

- **Alex Therapeutics** is a **Swedish platform** providing an operating system enabling a quick and effective development of DTx
- The company utilizes the **most well-established** and **evidence-based form of psychotherapy** to create treatments for psychiatric and somatic disorders
- Patients are supported through **exercises**, development of **coping skills¹** and **educational content**
- Alex therapeutics develops DTx in partnership with **Pfizer** and **Vicore Pharma** in **nicotine addiction** and **depression** respectively



Pfizer partnership

- In 2022, Pfizer signed a **commercial partnership** with Alex Therapeutics, with an **initial focus on Germany**
- The joint effort consists in an AI-based platform integrating **Cognitive Behavioral Therapy (CBT)** and **Acceptance and Commitment Therapy (ACT)** to provide personalized standalone treatments
- The solution is a DTx, named Eila, treating nicotine addiction
- Pfizer is conducting a clinical trial to further validate the medical benefits of the solution and be available as a **reimbursable prescription DiGA**

Sources: Alex Therapeutics (2022 press release) – Smart Pharma Consulting

¹ Coping skills help people tolerate, minimize, and deal with stressful situations in life

BMS signed a partnership with Sivan, a DTx expert to deploy the Moovcare app, indicated to monitor patients with lung cancer

Examples of strategies implemented by Pharma Companies (2/3)



Sivan

- Founded in 2014, **Sivan Innovation** co-creates and develops solutions for early disease detection and improved management
- The company is a pioneer in **e-PROs** (Patient-Reported Outcomes)
- Sivan Innovation ambition is to become a leader in digital health solutions for patients with chronic diseases
- The company currently offers 2 digital applications, **Moovcare** for lung cancer and **Smokecheck**, to help smokers monitor their health and alert them to problems



Bristol-Myers Squibb partnership

- BMS, which is a leading oncology player, signed in 2020 a partnership with Sivan to **deploy the use of Moovcare amongst HCPs**
- Moovcare, which is a reimbursed **application** in France, provides a weekly questionnaire to **detect recurrences or complications** of lung cancer patients
- **Data** are **analyzed by the algorithm** and transmitted to HCPs in case of detected anomaly
- Improvement in **overall survival of +7.6 months** was observed (resulting from earlier detection and optimized treatment of patients) with a reduction of the care costs

Ethypharm has signed a license agreement to market in four European countries a DTx indicated for depression and developed by the German DTx expert Gaia

Examples of strategies implemented by Pharma Companies (3/3)



Gaia

- Gaia is a **German company** focusing on evidence-based, safe and accessible DTx that help patients restore and maintain their mental and physical health
- Gaia focuses on neuroscience, depression, anxiety and immunology
- The company has:
 - Over **20 years** of experience
 - More than **70 products**
 - Clinically proven effectiveness in more than **19 RCTs¹** and **2 meta-analyses**



Ethypharm partnership

- Deprexis is a DTx developed by Gaia, and **licensed to Ethypharm**, indicated for the treatment of depression
- Ethypharm commercializes Deprexis in France, Spain, Italy and the UK
- The solution offers **personalized techniques and exercises** based on **CBT²** in **addition to the usual care**
- The 90-day program is **reimbursed in Germany³**, but not yet in France, where it is currently available at the patient's expense
- Deprexis showed to effectively reduce symptoms of depression in 13 RCTs as well as in real-life

Sources: Deprexis website – Ethypharm 2022 Deprexis press release – Smart Pharma Consulting

¹ Randomized Controlled Trials – ² Cognitive Behavioral Therapy – ³ In Germany, the license has been granted by Gaia to the pharma company Servier

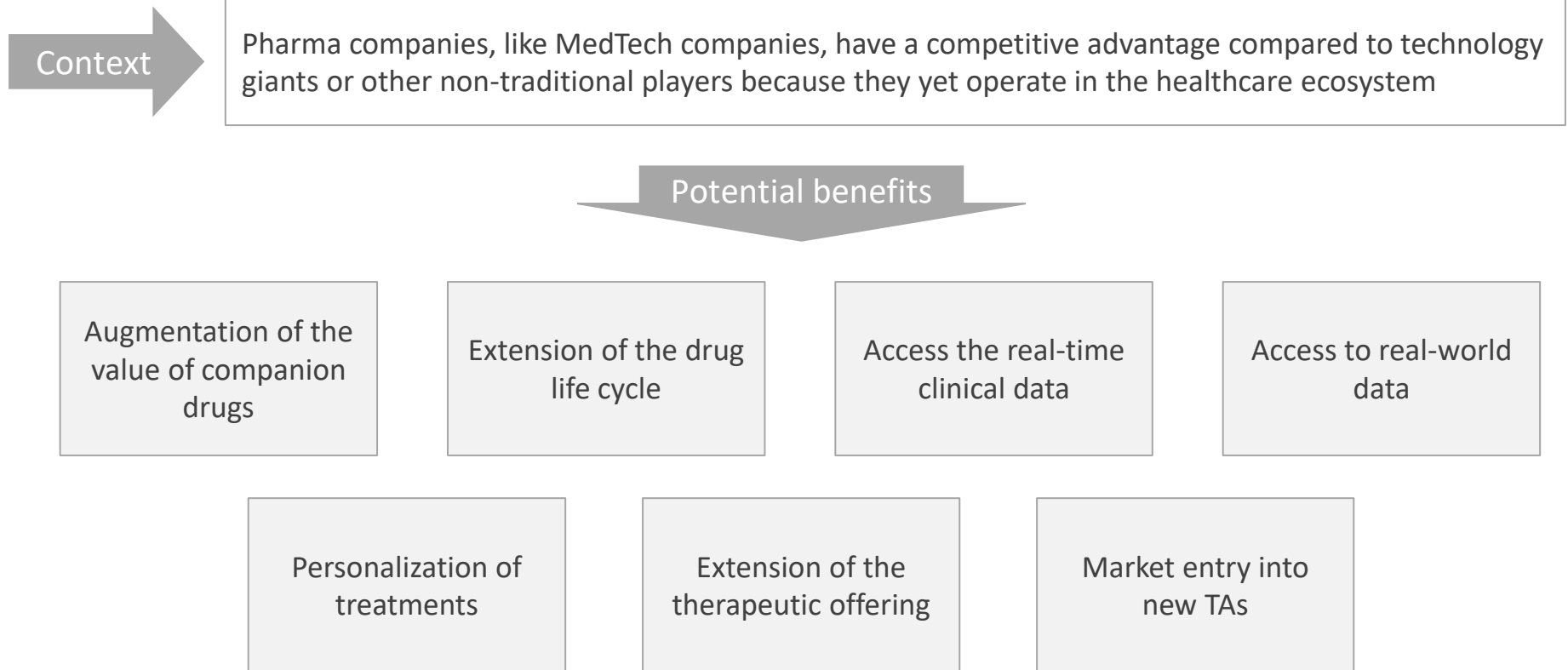
Advanced SWOT analysis (2022 – 2025)

DTx market Opportunities	Rate	DTX market Threats	Rate
<p style="text-align: center; color: red;">Authorities</p> <ul style="list-style-type: none"> ▪ Governments are willing to accelerate digitalization of the healthcare system and thus facilitate the development of DTx <p style="text-align: center; color: red;">Customers</p> <ul style="list-style-type: none"> ▪ Unmet medical needs (e.g., access to healthcare, patients' adherence, treatments' monitoring, healthcare efficiency) ▪ Fast-growing development (e.g., AI¹, ML²) and access (e.g., smartphone, internet) to digital technologies <p style="text-align: center; color: red;">Competitors / Partners</p> <ul style="list-style-type: none"> ▪ Willingness of / need for digital companies to partner 	<p>3</p> <p>4</p> <p>4</p> <p>4</p>	<p style="text-align: center; color: red;">Authorities</p> <ul style="list-style-type: none"> ▪ Regulatory frameworks and market access processes are not yet clearly defined in most countries, slowing down the development of the DTx market <p style="text-align: center; color: red;">Customers</p> <ul style="list-style-type: none"> ▪ Low HCPs and patients' adoption and engagement <p style="text-align: center; color: red;">Competitors / Partners</p> <ul style="list-style-type: none"> ▪ Most of the leading pharma companies entering in the market ▪ Coexistence of free DTx solutions 	<p>4</p> <p>4</p> <p>4</p> <p>3</p>
Pharma companies Strengths	Rate	Pharma companies Weaknesses	Rate
<p style="text-align: center; color: red;">Products</p> <ul style="list-style-type: none"> ▪ Opportunities to leverage synergies between the product portfolio and DTx in certain TAs to enhance the global value ▪ Know-how and expertise in clinical development process, regulatory environment and market access hurdles <p style="text-align: center; color: red;">Services & Reputation</p> <ul style="list-style-type: none"> ▪ Large access to HCPs ▪ Marketing skills to promote healthcare products ▪ Culture of risk-taking through major investments 	<p>4</p> <p>3</p> <p>4</p> <p>3</p> <p>2</p>	<p style="text-align: center; color: red;">Products</p> <ul style="list-style-type: none"> ▪ Not all the products in all TAs may benefit equally from DTx added-value (e.g., acute treatments like anti-infectives) <p style="text-align: center; color: red;">Services & Reputation</p> <ul style="list-style-type: none"> ▪ Insufficient knowledge, expertise and culture in IT and digital technologies across the value chain ▪ Unclear vision and strategy re. the DTx opportunity ▪ Lack of agility and sense of urgency from pharma companies 	<p>2</p> <p>4</p> <p>4</p> <p>3</p>

Rate from 1 to 5 according to the importance of the criteria

Pharma companies should evaluate the opportunity to enter DTx market considering the potential synergies with their existing business and their favorable position in the healthcare ecosystem

The potential added-value of DTx for pharma companies



Sources: Deloitte: Digital Therapeutics Catalyzing the future of health (2021) – Smart Pharma Consulting

If there is no doubt about the development of the DTx market, pharma companies should carefully evaluate the real value of taking part in it and the most successful and least risky model to adopt

Key takeaways

DTx Market

- Despite the exponential affluence of DTx solutions developed by e-health start-ups...
- ... **few** have yet **demonstrated** robust **clinical evidence** and **real-world outcomes**
- So far, DTx innovations address **mainly cardio-metabolism, CNS** and **oncology diseases**

Key barriers

- Current medico-economic **evaluation** processes are **not well-adapted** to DTx
- The number of **DTx reimbursed** by public and/or private health insurers is still **very limited**
- Most of **HCPs** do **not** consider DTx as **serious** therapeutic **options**
- In real-world conditions, **patients** are **not very compliant**, nor **persistent**, while using DTx

Business strategy

- Pharma companies have the choice to develop “**around-the-pill**” digital companions, to complete and improve the value of (their) existing products or...
- ... “**beyond-the-pill**” solutions offering an alternative to existing treatments

Recommendations

- Pharma companies must keep in mind that **DTx is a tough market** with **no easy money**
- Thus, before deciding to enter this new business, they must **develop** a **robust business case**
- At this stage of the market maturity, **partnerships with start-ups** seem to be the **best option**

Consulting firm dedicated to the pharmaceutical sector operating in the complementary domains of strategy, management and organization

Market Insights Series

- The Market Insights Series has in common to:
 - Be well-documented with recent facts and figures
 - Highlight key points to better understand the situations
 - Determine implications for key stakeholders
- Each issue is designed to be read in 15 to 20 minutes and not to exceed 25 pages

Digital Therapeutics

What Opportunities for Pharma Companies?

The key issue for pharma companies regarding Digital Therapeutics (DTx) is to assess their potential value and the possible synergies with their existing activities

This position paper provides pharma companies with information, analyses and recommendations structured as follows:

- Market attractiveness assessment
- Strategic opportunities for pharma companies
- Advanced SWOT analysis (2022 – 2025)
- Key takeaways

Smart Pharma Consulting Editions



- Besides our consulting activities which take 85% of our time, we are strongly engaged in sharing our knowledge and thoughts through:
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- Our publications can be downloaded from our website:
 - 41 articles
 - 62 position papers covering the following topics:
 1. Market Insights
 2. Strategy
 3. Market Access
 4. Medical Affairs
 5. Marketing
 6. Sales Force Effectiveness
 7. Management & Trainings
- Our research activities in pharma business management and our consulting activities have shown to be highly synergistic
- We remain at your disposal to carry out consulting projects or training seminars to help you improve your operations

Best regards

Jean-Michel Peny