

Digital Therapeutics

————— Keynote —————

Challenges for Pharma Companies

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Digital therapeutics are evidence-based software-driven interventions to prevent, manage or treat a medical disorder or a disease, independently or in combination with existing treatments

Introduction

Definition	Typology of DTx		
	Prevention DTx	Management DTx	Treatment DTx
<ul style="list-style-type: none"> ▪ Digital therapeutics (DTx) are evidence-based, software-driven interventions which: <ul style="list-style-type: none"> – Prevent – Manage or – Treat 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 	<ul style="list-style-type: none"> ▪ DTx can be designed to prevent a condition or its progression... ▪ ... by empowering patients to take an active role even while they are still healthy 	<ul style="list-style-type: none"> ▪ DTx can help encouraging patients' adherence to better manage their conditions... ▪ ... and to collect and analyze patients' data to personalize their treatments 	<ul style="list-style-type: none"> ▪ Treatment DTx intend to have a direct therapeutic action on patients... ▪ ... or aim to improve a treatment by adding services

Omada Health, Mika and Somryst are examples of DTx marketed in diabetes, oncology and sleep disorders, respectively

Examples of DTx



Prevention DTx

- Omada Health launched a DTx that **prevents** people at risk of **type 2 diabetes**
- The program provides **personalized coaching** and **trainings** to **lose weight**
- The solution leads to a **30% reduction of risks** for type 2 diabetes, **16%** for stroke and **13%** for heart disease

Management DTx

- Mika¹ 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-PROs**²
- The solution allows a **42% distress reduction**

Treatment DTx

- Somryst³ is a DTx, developed by Pear Therapeutics, intended for use in **chronic insomnia**
- The 6- to 9-week program provides **digital cognitive behavioral therapy** to improve the sleep...
- ... while providing clinicians with **real-time data** on patient progress through a dashboard

Sources: Capgemini Engineering: Getting Digital Therapeutics Right (2021) – Pear therapeutics website (press release Somryst) – Mika website – Smart Pharma Consulting

¹By the German health company Fosanis – ²Digital electronic patient-reported outcomes – ³ By Pear Therapeutics

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

- 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 **persistence** of DTx are **low**



Beyond-the-pill DTx

Standalone DTx that are designed to work independently of traditional drugs

- 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

Pfizer and BMS have signed partnerships with DTx players to improve their leading position in their therapeutic areas

Examples of strategies implemented by Pharma Companies



Pfizer

- In 2022, Pfizer signed a **commercial partnership** with the Swedish startup Alex Therapeutics
- 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 initial focus is a DTx **treating nicotine addiction**, adapted to the German market requirements, one of the leading countries in DTx
- Pfizer is conducting a **clinical trial** to further **validate the medical benefits** of the solution



Bristol-Myers Squibb

- BMS, which is a leading oncology player, signed a partnership with Sivan to deploy the use of Moovcare amongst HCPs
- Moovcare is an **application**, providing a questionnaire to **detect recurrences or complications** of lung cancer patients
- **Data are analyzed by AI** and transmitted to HCPs
- An improvement in **overall survival of +7.6 months** was observed (resulting from an earlier detection and an optimized treatment of patients)

Sanofi and Ethypharm both have signed agreements with DTx players, to launch digital solutions related to their field of activity

Examples of strategies implemented by Pharma Companies



Sanofi

- Sanofi and Voluntis, a DTx company, have signed a partnership to develop digital **solutions** for **diabetes**
- **Diabeo** is a **digital logbook**, reimbursed since 2017, for type 1 diabetic patients
- The application **automatically calculates the insulin doses** to be injected according to the blood glucose measurements
- The data are **automatically shared with the HCP team**



Ethypharm

- Deprexis is a DTx developed by the German company 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 **cognitive behavioral therapies** in **addition to the usual care**
- The 90-day program is **reimbursed in Germany**, but not yet in France

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

Conclusions

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**



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