DIGITAL THERAPEUTICS AS A NEW WAY OF HEALING FOR THE 21ST CENTURY

FROM PLANTS TO DATA – A NEW CLASS OF THERAPEUTICS ENTERS THE MEDICINAL ARSENAL

Historically mankind has prepared its medicines from plants. As science and technology have evolved, so has the isolation and identification of medicinally active chemical compounds for the preparation of standard drugs. While the COVID-19 crisis drew attention to a class of therapeutics called biologics, with the advent of mRNA vaccines developed by Pfizer/BioNTech and Moderna, biology-based inactivated virus and protein-recombinant vaccine technologies were also being developed during the 20th century. These biology-based technologies are now applied in oncology and orphan diseases to cure patients at the genomic level, thus enabling the rise of a 'biologics' class of therapeutics. While this class of therapeutics is based on natural science, a new class of therapeutics based on data science has garnered more and more interest in recent years: Digital Therapeutics (DTx). This class of therapeutics (seen below) is regulated, unlike Connected Health/Medicine:
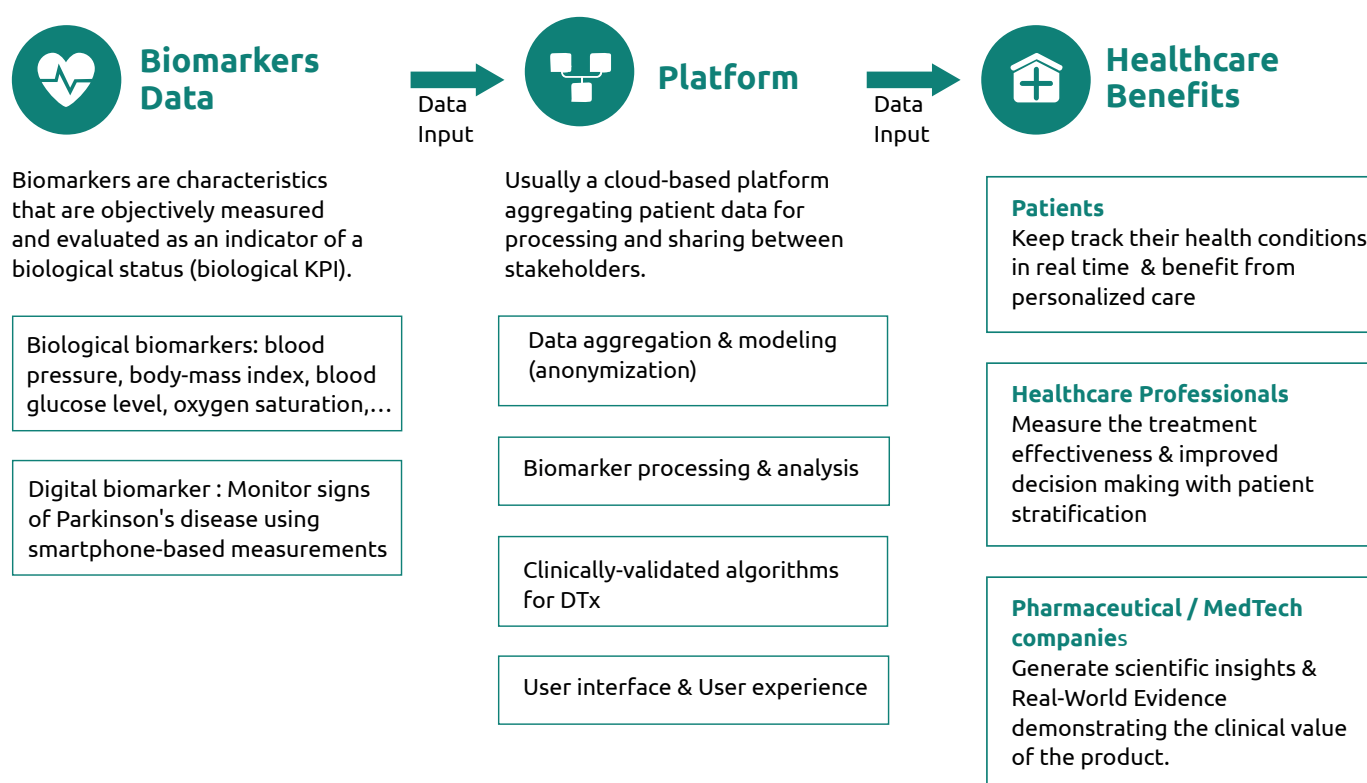
Scheme 1: Connected Health / Medicine / Therapeutics classification

Consumer Digital	Value Based Digital Health	Outcomes Based Digital Health	
Digital Wellness	**Digital Companions**	**Digital Therapeutics**	**Combination Digital Therapeutics**
Technologies, platforms and systems that engage consumers for lifestyle, wellness and health-related purposes, including administrative.	Low Risk, evidence-based software and/or hardware products that work in conjunction with traditional products and measure and/or intervene in the service of human health.	Clinically validated, and regulated software (SaMD) that delivers evidence-based therapeutic interventions and measurable health outcomes for the prevention, management, or treatment of a medical condition.	Clinically validated, and regulated combination of software, drug and/or device, that delivers evidence-based therapeutic interventions and measurable health outcomes for the prevention, mgmt, or treatment of a medical condition.

DIGITAL THERAPEUTICS – HARNESSING DATA TO PERSONALIZE TREATMENT

As defined by the DTx alliance,[1] Digital Therapeutics (DTx) deliver evidence-based therapeutic interventions that are driven by high quality software programs to prevent, manage, or treat a medical disorder or disease. Digital Therapies are therefore based on the analysis of biomarkers, either generated in a traditional way (imaging, medical analyses) or digitally (cognitive score on a telephone game), to generate a patient profile and thus determine the optimal intervention to provide the best possible outcome for this patient profile, thus opening the way to personalized healthcare (Scheme 2).

Scheme 2: Operating model of Digital Therapeutics

Biomarkers Data

Data Input →

Platform

Data Input →

Healthcare Benefits

Biomarkers are characteristics that are objectively measured and evaluated as an indicator of a biological status (biological KPI).

Biological biomarkers: blood pressure, body-mass index, blood glucose level, oxygen saturation,…

Digital biomarker : Monitor signs of Parkinson's disease using smartphone-based measurements

Usually a cloud-based platform aggregating patient data for processing and sharing between stakeholders.

Data aggregation & modeling (anonymization)

Biomarker processing & analysis

Clinically-validated algorithms for DTx

User interface & User experience

Patients
Keep track their health conditions in real time & benefit from personalized care

Healthcare Professionals
Measure the treatment effectiveness & improved decision making with patient stratification

Pharmaceutical / MedTech companies
Generate scientific insights & Real-World Evidence demonstrating the clinical value of the product.

Patient profiling and analysis can then be performed by well-defined algorithms that have proven their clinical value in dedicated trials or by using artificial intelligence and/or machine learning to identify new biomarkers or treatments for research purposes. The value of Digital Therapeutics is delivered throughout the patient journey and benefits can be demonstrated for multiple stakeholders, including:

– **Patients**: personalized treatments whose effectiveness is continuously measured, possibility of sharing medical information with all health professionals throughout the process, insights on current condition

– **Healthcare professionals**: evaluation of the effectiveness of treatments, possibility of being assisted in decision-making by artificial intelligence, real-time monitoring of patients through continuous availability of data and AI/ML-driven alerts for patients at risks

– **Pharmaceutical / MedTech companies**: generating real-world evidence to gain scientific and business insights while demonstrating the clinical value of their products to payers.

Behind the concept – evidence by numbers

As an example, Propeller Health successfully developed an FDA-approved, connected device for inhalers to help people living with chronic obstructive pulmonary disease (COPD) and asthma better manage their disease. Propeller uses a combination of inhaler sensors, apps, analytics, personal feedback, and education to enable patients in the management of their disease in daily life and to provide caregivers with a clear view of the patient's condition over time. Clinical studies demonstrated that Propeller users experienced a 78% reduction in rescue inhaler use over 12 months and hospitalizations were reduced by 57%.[2]

Data concerns apply to medicine too

The Digital Therapeutics market size is expected to reach USD 13.80 Billion by 2027 at a CAGR of 20.5%[4]. This is driven by the current unmet need to effectively manage chronic conditions such as cardio-vascular diseases and diabetes while benefiting from the ongoing development of patient-centric strategies by pharmaceutical and medical technology companies. However, this projected growth is counter-balanced by 4 major hurdles to overcome for healthcare companies as shown below.[5]

Scheme 3: Current challenges faced by DTx development

Regulatory Considerations

A Regulatory framework must be implemented throughout the platform lifecycle to identify required approvals and enforce compliance. Some DTx may even undergo clinical trials depending on their nature and expected outcomes.

Security & Data Governance

The ever-increasing cybersecurity threats associated to the high value of personal healthcare data make DTx a target of choice and a robust security & data governance framework (incl. patient consent) is required to secure such digital platforms.

Organization & Skills

Enabling DTx strategies requires a deep understanding of the therapeutical area while leveraging digital & data science capabilities. The articulation of both skillsets must be supported by an organization empowering DTx as a product, not as a product's complement.

Reimbursement

While the current business model of pharmaceutical & MedTech companies heavily rely on reimbursement schemes (public & private payers), DTx reimbursement suffers from lack of clear guidelines and established acceptance as a therapy of value.

Appropriate regulatory and cybersecurity frameworks must be implemented from the design of the platform and throughout its lifecycle to protect all stakeholders, not least the patients, due to the highly sensitive nature of their data and potentially fatal outcomes in cases of security breaches and wrongful manipulation. Healthcare companies whose organizations have been traditionally centered around products and/or therapeutic areas, must now integrate digital capabilities. This will enable them to offer innovative services that is provided by such DTx platforms while reinventing their business model to circumvent traditional reimbursement-based strategies. Ultimately, the organizational articulation of therapeutical area knowledge, patient and HCP expectations, digital innovation, and business model definition will become a key success factor for the design, launch and maintenance of such Digital Therapeutics throughout their lifecycle.

The potential of Digital Therapeutics as a new way of healing in the 21st century is only just emerging and remains to be further established through the demonstration of clinical value. However, there is no doubt that this type of digital service will become increasingly prevalent in the management of chronic diseases and associated ecosystems. After all, if digital technologies enable personalized marketing & advertising online, why can't we leverage this power to personalize our medical treatments and associated outcomes as well?

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5. Characteristics and challenges of the clinical pipeline of digital therapeutics | npj Digital Medicine (nature.com)

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