

Promise of Digital Health

An opportunity for BioPharma to transform
healthcare delivery

Sep 2022



Executive summary



A range of digital solutions like wearable, sensors, remote monitoring tools and smartphone-based apps are transforming the healthcare systems and enabling personalized patient-centric care



Digital Health space is witnessing numerous diverse players aiming to prevent, manage or treat diseases using smartphone-based interventions and cognitive behavioral therapy with already several told approved by the FDA



Chronic disease and CNS are the key areas targeted by digital health interventions, owing to the key focus on lifestyle management



Digital health is already demonstrating significant benefits to all key stakeholders - holistic care for patients, workload management for providers, decreased costs for payers and new modalities for treatments for pharma companies



Financial Investors and corporate pharma strategic partners are bullish alike on the digital health space with \$7B+ invested since 2018 including several IPOs, 400+ deals and 100+ M&As in the recent past



Clinically proven digital tools or digital therapeutics (DTx) provide offers a unique opportunity to biopharma to transform business models, while enhancing patient engagement; 2021 saw 50+ deals between pharma and digital health cos, including 8 M&A and 25+ venture investments



Several considerations are critical to identify the right digital health tools/partners - Defining the specific business problem, defining responsibilities for go-to-market, insights generation, life-cycle support updates, regulatory compliance, legal manufacturing etc. are amongst a few to mention

MP Team, with over 3 decades of diverse and global biopharma experience and deep understanding of the Digital Health space, is ideally positioned to catalyze your Digital Health initiatives

Digital solutions are driving transformation of health systems

Digital interventions are driving personalization with around/beyond-the-pill solutions for a holistic patient-centric care

Traditionally, diseases are treated in a single target format such as the use of drugs/devices to treat individual symptoms. However, there is an increasing shift towards more integrated disease care, and digital technologies are driving this change.

Education and information support to patients

- Personalized content delivery
- Pharma sponsored access to patient communities for support
- Gamification of content for retention

Empowered patient



Informed care



Improved cross-talk between all stakeholders

- HCPs and care member informed with continuous data for improved care
- Pharma and Payors informed with real world evidence

Several at-home solutions

- Easy scheduling of visits through apps
- Teleconsultation or telemedicine
- Guided medication adherence, lifestyle management tools



Convenient access



Continuous monitoring

Wearables and smart-devices

- Monitor and document health data continuously
- Stick-on sensors to measure physical parameters such as ECG, blood sugar or respiratory rate

Digital Health broadly encompasses Digital Medicine, which in turn includes Digital Therapeutics

Level of clinical evidence and regulatory oversight required varies according to purpose/function of the digital product

	Definitions	Example applications	Typical business models
Digital Health	Technologies or platforms that do not require clinical evidence . These apps engage consumers for <i>lifestyle, wellness, and health-related purposes; capture, store or transmit health data; and/or support clinical operations</i>	Telehealth / telemedicine Wellness and lifestyle education apps Medication reminder apps EHR/EMRs	Largely addresses general health as opposed to specific indications and hence do not need Rx. These apps are mostly direct-to-consumer or provided by employers
Digital Medicine	Digital medicine includes clinical evidence-based software and/or hardware products that measure and/or intervene in the service of human health.	Digital biomarkers Digital diagnostics Remote patient monitoring Clinical outcome assessment	While an Rx is not required (not FDA approved), these apps often provided by health plans & systems, employers or directly to patients
Digital Tx	Digital therapeutics (DTx) are clinical evidence and real-world evidence-based therapeutic interventions to prevent, manage, or treat a medical disorder or disease.	Can be standalone or in combination with a pharmacological agent or medical device. Eg: reSET-O™ is prescribed in combination with buprenorphine for the treatment of opioid-use disorders	Typically requires FDA approval and Rx prescriptions are needed by health systems for these apps

A range of diverse players have emerged in the Digital Health space

DTx can be used to prevent, manage or treat diverse disorders and diseases through evidence-based methods delivered via softwares

The majority of current and pipeline solutions are targeting chronic diseases and neurological/psychiatric disorders

Diabetes	Obesity	Cardiovascular	Digestive
  	  	  	  

Companion apps to **manage or prevent** chronic diseases. 60% of all DTx companies have offerings in chronic diseases, making it the most populated segment

Neurological	Anxiety/Depression	Insomnia	Addiction
  	  	  	  

Mono or Combination apps using CBT, music therapy, and virtual reality to **treat and manage** psychiatric conditions. About 25% of all DTx trials are for CNS conditions.

Pain & MSK





Companion apps with guided video physical therapy and camera-based mobility assessment scoring capabilities to **manage pain**.

Women's health





Companion and combination apps to **treat** digital pelvic floor health (approved) or **manage** contraception, fertility, PCOS, gynaec cancer etc.

Respiratory






Mono- or combination apps to **diagnose and manage** respiratory diseases using sound-based diagnosis on smartphones or smart inhalers.

Oncology

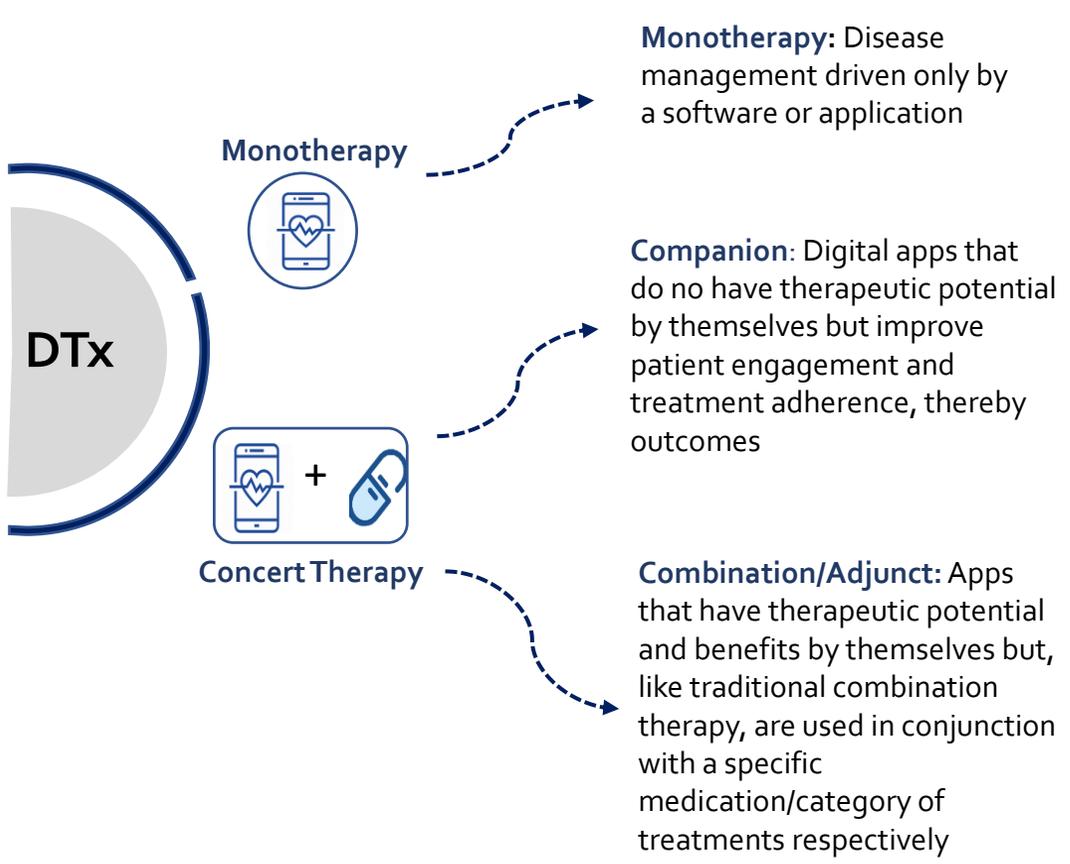





Companion DTx products to **manage** side effects such as fatigue, anxiety, depression, opioid abuse, etc.

Digital Therapeutics: evidence-backed, tightly regulated solutions

~80% of pharma-digital health partnerships involve either a digital therapeutic or a prescription-based digital therapeutic. DTx can be a standalone software or a combination of software & pharmacological interventions



Big Health

Clinically proven applications- Sleepio™ for insomnia and Daylight for anxiety- delivered through digital cognitive behavioral therapy (dCBT).

welldoc

FDA-approved BlueStar® to analyze glucose and provide coaching to self-manage Type 2 Diabetes with healthcare team connected

Temedica

A companion app in development for Bristol Myers Squibb's drugs for psoriasis to increase patient adherence and improve long-term patient outcomes.

HUMA

Developed companion app solutions catering to orthopedic, diabetes, and heart health on its disease-agnostic platform.

PEAR THERAPEUTICS

FDA-approved PDTx reSET-O used in combination with buprenorphine for opioid use disorder increased abstinence by ~90%.

BrightInsight

Developed a combination DTx on its disease-agnostic platform for Roche's Hemlibra® used to treat Hemophilia A.

AKILI

EndeavorRx is a mono- and adjunct PDTx, delivered as a video-game-based device for ADHD treatment in kids aged 8-12 to improve cognitive function.

deprexis

Indicated for the adjunctive treatment of chronic or recurrent depressive disorders as a primary or secondary diagnosis

Digital health provides significant benefits to all key stakeholders

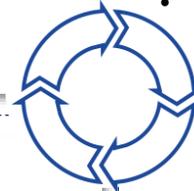
Digital health can make healthcare more transparent, inclusive, and patient-centered

Patients benefits

- On-demand or easy access to treatment and care, even in remote and rural areas
- Personalized treatment programs that use machine learning and AI to continuously update and tailor software to meet the needs of the patient based on real-time data analytics
- Increased access to evidence-based interventions

Pharma benefits

- More favorable risk/reward product development with higher probability of technical and regulatory success, and shorter timeframe for product development
- Potential for increased patient compliance to pharmacological interventions
- Increased direct and earlier patient engagement



Payers' benefits

- Improved clinical and health economic outcomes and reduction in overall medical costs, including decreased HCP visits and reduction in pharmacological intervention
- Increase sales by improving patient experience and personalized plans
- Bring down the volume of claims generated per patient by improving health outcomes

Provider benefits

- Reduce the need for frequent intervention of physician in managing people with chronic conditions with monitoring of patients in real time
- Identify the gap in care and provide timely interventions
- Improve efficiency of care delivery through evidence-based care therapies
- Empowers them to provide effective and reliable care options

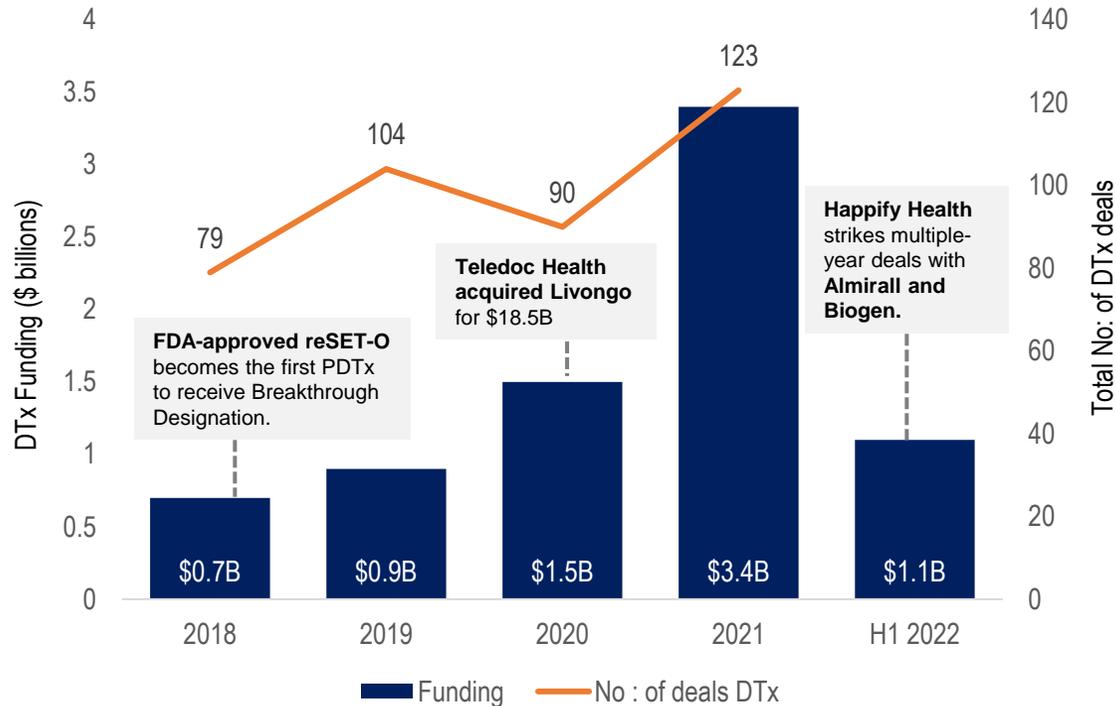
Investments and deal activity is steadily increasing over past 5 years

After an unusual surge in 2021 due to pandemic and increased need of remote management solutions, investments are reaching back to pre-pandemic levels



US leads the way in overall DTx funding followed by Europe and Asia

Chronic diseases & CNS disorders continue to remain the top investment area



\$7B+ raised in funding since 2018

100+ M&A deals for 7 consecutive quarters

6 unicorns formed so far

400+ DTx deals observed since 2018



Bigger healthcare companies are acquiring smaller companies to expand and unify their offerings

- *Invitae, a public genetic testing company, made a total of 14 acquisitions in digital health since 2016*



Companies are solidifying their presence as key investors

- *Corporate VCs primarily investing in mid-stages (B+) and later; more than 60% of VCs were repeat investors in 2020/21*

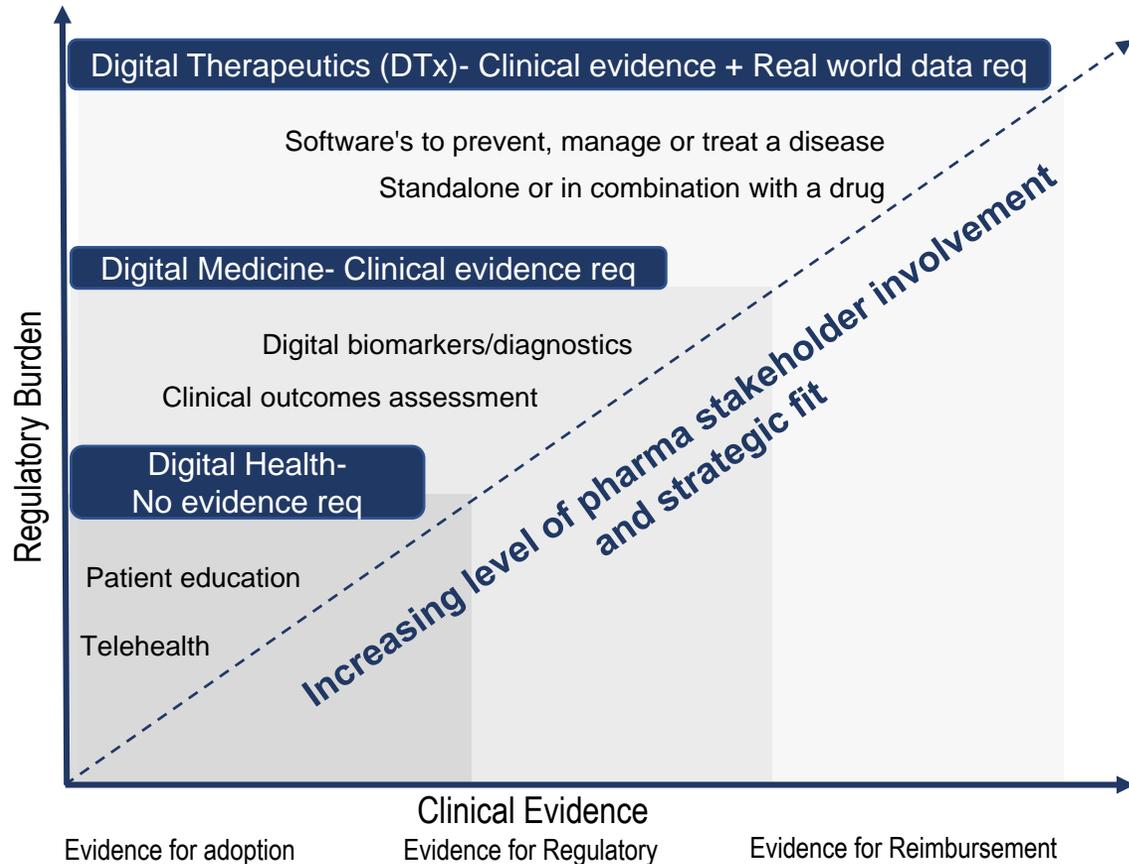


Top tech companies like Apple, Google also ventured in this space

- *Apple acquired asthma monitoring company, Tuelo Health, to collect relevant data, alert users of changes in condition and set up a live consultation should the need arise*

Digital therapeutics & BioPharma are a natural fit

Among the Digital Health, DTx provides the highest strategic fit for pharma offering new modalities of intervention and augment the current portfolio



Digital technologies will impact diagnosis, prognosis and treatment of diseases, adding new revenue streams while generating new insights across the care continuum



Diagnosis/Clinical Trials

- Digital biomarkers for stratification and clinical trial enrollment
- Improved adherence, progression scoring and decision support
- Continuous and remote monitoring with decentralized clinical trials



Treatment and patient support

- Improved brand performance with patient education, engagement and support
- Extension of the drug/medical device life cycle
- Increased revenue potential with medication/regimen adherence apps



New value and sources of revenue

- Better RWE and generation of data driven insights for disease
- New modalities of care and revenue and entry to new TAs
- More favorable risk/reward product development with higher PTRS and shorter timeframe for product development

Biopharma cos are experimenting with many different approaches

2021 witnessed 50+ deals and alliances between pharma and digital health companies, including 8 acquisitions and 25+ corporate venture deals. The trend is continuing in 2022, albeit a bit slowly.



July 22: Merck is collaborating with Evidation for the **identification of digital endpoints for Alzheimer's** that can be collected during remote monitoring in order to accelerate drug development.



June 22: Eli Lilly is collaborating with Sidekick Health for an integrated **digital therapeutic for breast cancer** for behavior modifications (adherence, side effect management, etc) using the **companion app with Lilly's drugs**



April 22: Sanofi announced a \$30 million, 5-year agreement with DarioHealth to integrate Sanofi's products onto its platform including an app to **manage diabetes, correct posture, monitor PT exercises at home, and provide digital cognitive behavioral therapy exercises**

Partnerships



Mar 22: AstraZeneca bought a **stake worth \$33M** in Huma Therapeutics, a company with a platform to launch **companion apps**. Two will together launch SaMDs for various diseases, including asthma, chronic obstructive pulmonary disease (COPD), and heart failure



Mar 22: Bayer **invested \$9.5M** in Woebot Health, builder of an **AI bot to provide mental health advice and solutions** to users via an app. They are also collaborating to assess joint opportunities for delivering integrated care solutions in mental health.



Apr 20: Novartis **acquired Amblyotech**, a startup that combines **3D glasses and video game software to treat amblyopia**, more commonly known as "lazy eye" to add to its ophthalmology portfolio

M&A/Equity

Evolving business models for the digital health companies

With the aim to eventually integrate reimbursement, digital health companies are exploring multiple revenue models to expand market accessibility

Business Model

Examples

Advantages

Considerations



Direct-to-customer/
Employer as customer



- Powerful model to test a new product, acquire new customers and demonstrate traction
- Faster sale cycles
- Early revenue opportunities

- High marketing and sales costs
- Consumers hesitation as the plan is not covered by the insurance



Healthcare providers
and Payors



- Fee for service
- Clinically proven, physician-prescribed solutions increase credibility
- Value/device like reimbursement models
- Dedicated CPT or HCPCS codes will facilitate reimbursement

- Fee for service
- Potentially a long contracting process
 - May require a pilot or testing period
- Value/device like reimbursement models
- Difficult to allocate costs savings to a product
 - Requires FDA approval



Pharma:
Co-development /
Commercialization



- Large revenue potential with a one-time deal
- Support for commercialization and increased credibility with the patients
- Combination therapeutics is the most likely proposition for digital health companies

- Long partnership and negotiations discussions due to bureaucracy, long diligence cycles and competitive opportunities
- Requires FDA approval and path from there to reimbursement still unclear

Key considerations for partnering with Digital Health companies

Steps after a careful identification of a digital health partner to work with..

Who brings the **expertise for disease areas** and clinical pathways? Who is responsible for designing/ analyzing clinical trials?

Who is responsible to develop **know-how of digital solutions** to address the unmet needs of patients and clinicians?

Who is responsible for data usage, management, and **insights generation** from collect data?

Who is responsible for the updates, **life-cycle support**, and service evolution?

Who is responsible for **go-to-market**, marketing, sales, distribution, and reimbursement?

Who is the **legal manufacturer and will be accountable** for any future disputes or issues in data security?

Who is responsible for **compliance with any future regulatory changes** that may be required?

In case of **failure/bankruptcy of digital health partners**, who will be responsible for providing support for existing patients on the platform and maintaining the platform for the future?



Digital
health co



Pharma
internal
teams

MP Group can catalyze your digital health journey

With over 3 decades of diverse experience and integrated perspective in domestic and global BioPharma, and a deep understanding of Pharma-Tech and Digital health space, MP Group has the capabilities to help establish your initiatives

MP Team will be happy to be an extension of your management team and help with one or more of the below initiatives:

- Asses the internal capabilities and identify the key business segments for potential augmentation by digital health platforms
- Market analysis and competitive landscaping to identify partnering or investment opportunities unique to your requirements
- Technical due diligence to investigate the platforms best suited for the need

We invite you to write to us -

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