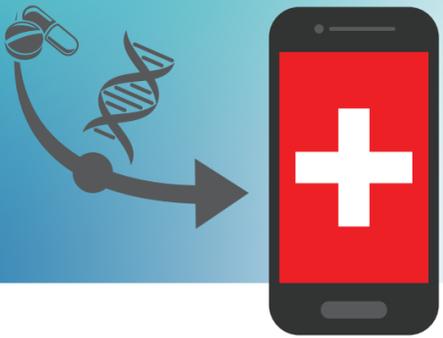


DTx Digital Therapeutics



What are DTx?

DTx, or Digital Therapeutics, are a new category in the health and life sciences industry described as any digital platform that promotes a claim to treat, cure or prevent a specific medical disorder or disease.

Therapy Types



Majority of analyzed DTx platforms leverage traditional **Cognitive Behavioral Therapy (CBT)** via new delivery mechanisms to treat the targeted disease.



Therapy Targets

Depression

Depression was the most common therapy area target, followed by addiction and anxiety. Other interesting applications included autism and Parkinson's and multiple sclerosis.

Delivery Methods

88% of current DTx products are **mobile application-based** (23), with other mediums including virtual reality and video games.



Academia Wins

12%
commercial



Commercial vs. Academia

12% of registered DTx clinical trials are funded by commercial pharma (2), while the other **88% are funded by academia** (15).



FDA Approval

20% of companies have **FDA approved products** or are seeking approval.



FDA Approved

20%



Big Funding

31%



Funding Size

31% of companies are backed by a **medium or large funder** (8, CrunchBase rating).



Establishing Medical & Clinical Affairs Leadership

DTx Success = FDA Approval

As the FDA's guidance around DTx product health claims continues to evolve, PDT and NPDT companies that invest in Medical and Clinical Leadership and FDA approval strategies will be in a superior position to succeed in the market post-launch for the following reasons:

PDT/NPDT **WITH** Medical/Clinical Leadership and FDA Strategy

Legal promotion of a claim to treat, cure or prevent a disorder or disease

- ✔ Doctor and Patient Education
- ✔ Outcomes Communication
- ✔ Trial/Study Design
- ✔ Data Security and Use Strategy

vs.

DTC **WITHOUT** Medical/Clinical Leadership and FDA Strategy

Illegal promotion of a claim to treat, cure or prevent disorder or disease

- ✔ Potential of Being Outpriced
- ✔ Potential Public Safety Threat
- ✔ Potential FDA Fines
- ✔ Potential Criminal Liability

Methodology

SSI performed an analysis of over 50 digital health organizations in the US, from December 2018 to March 2019, through funding announcements, the Apple app store and 17 registered DTx clinical trials (clinicaltrials.gov) to develop baseline research on the current state of the DTx landscape. This research resulted in the identification of what SSI qualified as 26 Digital Therapeutics (DTx) companies that informed the insights above.

These companies were broken into 3 categories for consideration: 1) FDA approved, prescription based (PDTs), 2) FDA approved, non-prescription based (NPDTs) and 3) non-FDA evaluated, direct to customer (DTC) products. While PDT and NPDT products have undergone rigorous FDA evaluation in order to achieve approval status for their claims, DTCs have not.