



Why a Digital Therapeutic Launch is Radically Different than a Pharmaceutical Launch

The rise of digital therapeutics in recent years has been an area for innovation in often 'stale' pharmaceutical therapeutic areas (e.g., diabetes, substance use disorders, incontinence, depression). This has driven the investment, venture funding, and large pharma partnerships in the space (e.g., pioneer Click Therapeutics has publicly disclosed partnerships with large pharma organizations including Otsuka and Boehringer Ingelheim). However, the commercial model to launch these digital therapeutics has yet to be crystallized and has repeatedly resulted in underwhelming launches and provided limited value to patients, providers, and manufacturers. That's because the model needs to be radically different than a pharmaceutical launch in a few key areas. We have identified four areas of focus where manufacturers pursuing digital therapeutics should be exceptionally creative and innovative to successfully bring these assets to market in a commercially viable manner.

1) Establish Clear Provider and Patient Segmentation:

Digital therapeutics are not likely to be applicable to all patients and providers within a specific disease state given the degree of innovation and change in workflow required to prescribe and use. To avoid this pitfall, developing clear market maps and segmentation will be critical to drive appropriate targeting and utilization.

2) Ensure a Comprehensive Evidence Package to Drive Market Access:

Potentially the greatest barrier to the utilization of digital therapeutics has historically been the lack of coverage by payer organizations resulting in poor patient access and high out-of-pocket costs (particularly in the immediate post-launch period). Strong evidence packages paired with unique strategies, partnerships, and contracting will be necessary to break down the market access barriers that currently limit adoption.

3) Design an Appropriately Sized Field Force and Selling Model(s):

Digital therapeutics are in a unique market position that requires significant education to prime the market to integrate these technologies into the treatment paradigm while balancing appropriate reach to target the identified provider segments. A phased approach balancing non-branded disease education alongside general DTx awareness (pre-launch) with a conservative, digitally enhanced sales model can drive a successful launch without the investment typically pursued by traditional therapeutics.

4) Draft a Cohesive Implementation Plan to Limit Provider Burden:

Providers often manage significant workloads and are also unfamiliar with the requirements to prescribe and administer a digital therapeutic. Ensuring products and eRX services are integrated into EMRs to enable easy prescribing will be paramount to successful commercialization of DTx. Furthermore, limiting the requirements for providers to monitor or review data from the application will likely be a driver of use whereas significant provider burden will be highly limiting.

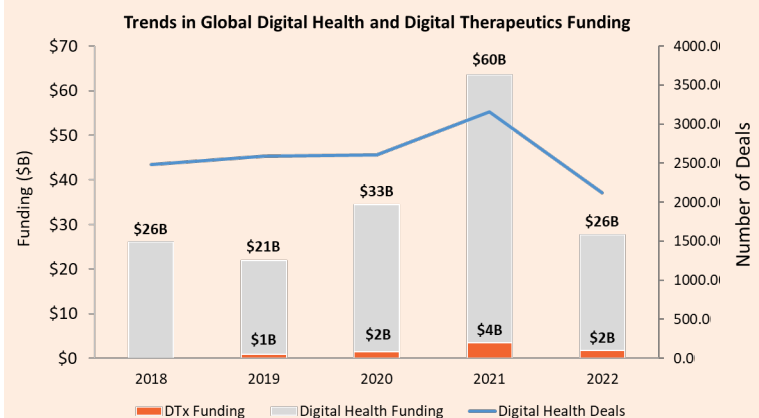
Triangle Insights will publish a series of four insights pieces focused on these key differences in launching a digital therapeutic (DTx) relative to a pharmaceutical product, so that manufacturers entering this space can optimize these important tools and avoid previously experienced commercialization hurdles.

This first piece establishes foundational principles and market trends and then focuses on unique considerations for "Establishing a Clear Provider and Patient Segmentation."

Background: What are digital therapeutics and how do they differentiate themselves from digital health?

Digital health, which broadly encompasses technological solutions that enhance healthcare delivery, has become increasingly popular in recent years. Digital therapeutics (DTx) are evidence-based digital health interventions used to prevent, manage, or treat disease (with or without prescription requirements).

Market Trends: What are the key trends in the digital health and digital therapeutics space?





- *Prior to 2022, DTx funding increased significantly YoY, signaling the promise of the industry.*
- *In 2022, digital health funding, following the trend of the biotech industry overall, dropped to below 2020 funding levels (more than 50% YoY).*
- *Consolidation of the digital health sector increased in 2021 with a record number of M&A deals (~570 total deals), but has since declined by 33% YoY (2021 – 2022).*
- *Example of the impact of shifting market dynamics: Despite Pear Therapeutics' significant venture capital funding, the company filed for bankruptcy and auctioned assets for \$6M in the first half of 2023.*
- *Given the evolution of the marketplace for DTx, smart commercialization strategies will be crucial to the overall corporate health and long-term success for digital therapeutic manufacturers.*

Provider and Patient Segmentation: Identifying relevant providers and patients is critical to commercialization success

Because digital therapeutics are making product or marketing claims like that of traditional pharmaceuticals, they are being held to the same clinical efficacy standards. However, DTx face a unique challenge compared to their pharmaceutical counterparts in that physicians exhibit added skepticism of their efficacy because the concept of a DTx is much less mature. Specifically, providers may be concerned about the added complexity of incorporating a digital therapeutic adjunctively or in place of pharmaceutical intervention. Furthermore, there are logistical hurdles (e.g., access to technology and Wi-Fi) that influence provider willingness to prescribe.

Added skepticism may limit prescribing to the most “trustworthy” or “eligible” patient subpopulations (e.g., prescribing to individuals most comfortable with technology or more familiar with smartphone applications, prescribing to younger patients or those with the most incentive to comply [depending on the therapeutic area]). Given these

preconceived notions regarding DTx, it will be crucial to establish a market map and associated customer profiles early in the development process.

This segmentation exercise should be performed for both patients and prescribers and incorporate beliefs and behaviors that may influence product utilization. Manufacturers should maximize the strength of the value proposition by targeting clinical evidence generation towards the appropriate segment of patients within the market map. Identifying patients where clinicians have a higher willingness to prescribe, and where there is greater likelihood of clinical success, will enable an appropriate targeting strategy and early wins for DTx manufacturers.

Several digital therapeutic companies have targeted specific patient subsets with positive outcomes to-date. For example, SparkRx created a digital therapeutic specifically for adolescent depression. Adolescent patients are a key demographic that prescribers highlight as having a high likelihood for success with DTx (given their generation's comfortability with technology). In addition, for its Medicare study, Propeller Health required eligible COPD patients to have had at least one emergency department visit or hospitalization, further focusing their efforts to the segment with the greatest motivation to follow-through with therapy. Additionally, in the case of Propeller Health, one could argue that the targeted patient segment is more severe and therefore could demonstrate better outcomes and cost savings (which may, in turn, enable a clearer economic story and better market access).

In summary, early in the development process, digital manufacturers should be sure to establish a clear market map and associated customer profiles for both patients and providers, leveraging underlying behavioral and ethnographic drivers to identify the most likely and appropriate targets. Avoid the trap of “being everything for every patient” to establish a preliminary beachhead into the market and expand appropriately from that point.

Reach out to Triangle Insights Group to learn more about our approach to market segmentation and patient identification and tune in for our next installment in the series focused on strategies to optimize market access for DTx.