



DTx Commercialization Launch Playbook Case Study

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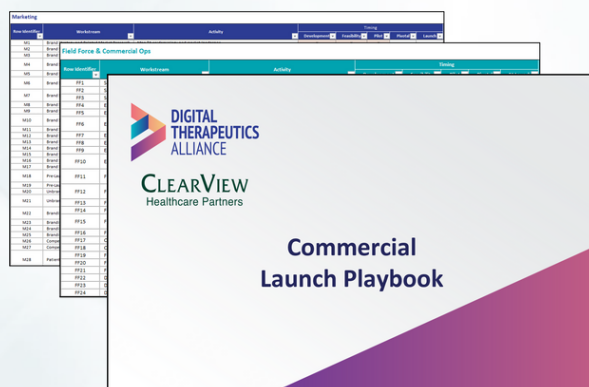


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Introduction

In recent years, the digital health space has continued to expand and evolve, leveraging technological advances to address unmet needs across the healthcare system. Innovations range from streamlining analysis of patient data to improving accessibility to care via telehealth. Digital therapeutics have emerged as a novel approach to harnessing technology as a direct treatment for some of the most widespread public health issues facing Americans today including mental health disorders, obesity, diabetes, and neurorehabilitation. To effectively commercialize in the evolving digital health space, digital therapeutics companies need to consider the many nuances that differentiate DTx from a traditional pharmaceutical drug. Considerations include more specific product-level differences, such as point of utilization, as well as broader regulatory and market access dynamics that have yet to catch up to the rapid innovation we are seeing in digital health today.

Freemira, a start-up company with an FDA-approved digital therapeutic for treatment of panic disorders and PTSD, provides a valuable example of strategic launch optimization within the digital therapeutics landscape. Learnings from Freemira's launch, along with ClearView's broader experience in supporting DTx companies, illuminate the importance of patient journey mapping, defining the end customer, and market shaping for a successful launch. These learnings are valuable to a wide range of stakeholders, from digital health developers to potential biopharmaceutical partners. Through this whitepaper, we will explore several critical success factors for digital therapeutics launch, gathered through over a decade of ClearView's advisory services to digital health organizations, and illustrated directly by the unique experiences of Freemira.





Lesson 1 – Understand Your Patient Journey Early

To effectively deliver a differentiated product, understanding the patient experience (i.e., patient interactions with the health care system and their perception of the quality and value of care) as well as the entire patient journey (i.e., the full sequence of care events that a patient follows from first symptoms to treatment completion) is crucial. Given digital tools' emerging role as a therapeutic approach, the point at which a digital therapeutic should be introduced to the patient often varies depending on the therapeutic area being pursued, and perspectives may differ across stakeholders. In the mental health space, for example, the patient journey is often nonlinear – PTSD patients may experience symptom onset immediately after an incident or years later, while also delaying seeking treatment due to avoidance and feelings of shame. Therefore, a successful launch approach should account for adoption at multiple points in the patient journey, while zeroing in on the point at which patients are most likely to benefit from a new, innovative intervention. For example, a high-impact entry point may be with post-diagnosis patients who have sought treatment, but struggle with compliance or accessibility, and are looking for a more convenient approach to their care. While physicians may not be reaching for DTx as a first line of therapy quite yet, there is a valuable use case for patients after initial treatment who could benefit from an improved patient experience.

Across product launch engagements, ClearView has identified that depth of understanding is particularly crucial during the feasibility and pilot stages. However, integrating patient perspectives in the development phase helps to ensure a product that is tailored to persistent unmet needs in the space. Patient advocacy groups, forums, and caregiver networks are key resources to leverage to understand how and when a digital therapeutic may be most impactful to its target user.

In its early development phases, mapping the patient journey became a key priority for Freespira. The nuances of the patient journey in panic disorder and PTSD emphasized the importance of understanding the real-world challenges associated with maintaining and prioritizing treatment (e.g., varying time points for seeking care). Throughout this process, Freespira recognized that patient groups are likely to evolve over time and, as result, evaluating and incorporating the patient journey should be an ongoing process.

"It was crucial for the internal team to truly understand the patient journey from onset to prescription and fulfillment to allow us to continually ensure that our product is best adapted to meet our patient's needs."

Freespira Team Member



Lesson 2 – Define Your End Customer (Yes, there should only be one.)

In the process of mapping the patient journey, another critical decision for digital therapeutic development involves defining the end customer. As with any therapeutic product, there are multiple customer stakeholders for DTx including patients, payers, and healthcare providers. However, a nascent space, the payment guidelines for digital therapeutics are not well defined; as a result, companies often struggle to determine which key stakeholder will ultimately pay for their products, and what is required to ensure a high conversion rate. Patients with mental health disorders are typically heavily involved in treatment decisions, ultimately being the key decision-maker regarding the pursuit of a psychotherapy, pharmacotherapy, or a combination. However, while strong patient buy-in is required, companies typically struggle with the question around whether these patients should ultimately be the end buyers given limited willingness to pay compared to other ecosystem stakeholders.

Aside from patients, insurers may represent an alternative end customer with potential for substantially higher willingness-to-pay, though this has proven difficult to translate into reality thus far. As such, the choice between patients or payers as the end-customer sets up a unique dichotomy: payers are most difficult to convert, but if converted effectively they offer significantly higher spend. In contrast, patients are easier to convert though estimated potential spend is notably smaller. Physicians and institutional stakeholders, on the other hand, represent a third critical end customer type. Physicians can serve as the bridge between the payer and patient end customers; strong clinician buy-in can not only increase patient uptake but also be a key driver of payer coverage due to demonstrated clinical benefit. However, health care providers present their own unique set of challenges for digital therapeutics, such as the need to integrate into their institutional workflows, that should be considered when being pursued as the end customer.

Throughout their launch journey, Freespira considered multiple end customers. For each stakeholder type, the team had to consider the specific expectations and access considerations. Thus, each pivot required additional time for Freespira to adjust the business model and develop the appropriate evidence package. Their experience highlights that investing time early in the launch process to build confidence in a clear end-customer strategy is crucial and will support the ability to effectively pivot down the road. Moreover, the choice of end customer should be supported by market research to confirm the validity of the products' value proposition and to ensure that specific stakeholder needs are addressed.

"It is important to ask yourself the strategic question of which end customer you plan to target early on based on whether their model of distribution and data requirements are best aligned with your product."

Freespira Team Member



Lesson 3 – Prioritize Market Shaping

Once patient journey and end customer has been identified and characterized, digital health companies must determine how to best communicate their product's value to key stakeholders. Digital therapeutics are still emerging as a key treatment option for patients and, as a result, the current levels of acceptance represent only a fraction of their potential. Thus, market shaping is a critical component for any digital therapeutic launch, regardless of disease area. Based on the therapeutic area and existing market, strategies may range from unbranded messaging and education to more targeted stakeholder education to support brand awareness. By utilizing these tactics, companies will continue to increase disease awareness while driving acceptance of digital therapeutics and the underlying mechanisms by which these products work to treat disease. This will allow physicians to clearly understand how DTx can complement and enhance existing treatment approaches rather than further complicate them.

In the case of Freespira, the team recognized that many market stakeholders felt well-versed in their understanding of panic disorders which was potentially limiting to DTx adoption over widely utilized medications. However, Freespira's core value is its ability to target the hypersensitivity to carbon dioxide associated with panic symptoms, which was not well understood by consumers. Freespira's therapeutic strategy of regulating breathing patterns requires measurement, tracking and coaching capabilities which a digital therapeutic is uniquely positioned to support. Given that pharmaceutical-based interventions are deeply entrenched in the panic-disorder treatment paradigm and DTx options are not yet widely adopted, the team has considered unbranded education activities to prime the market with the necessary tools to understand the differentiated value of Freespira's therapeutic.

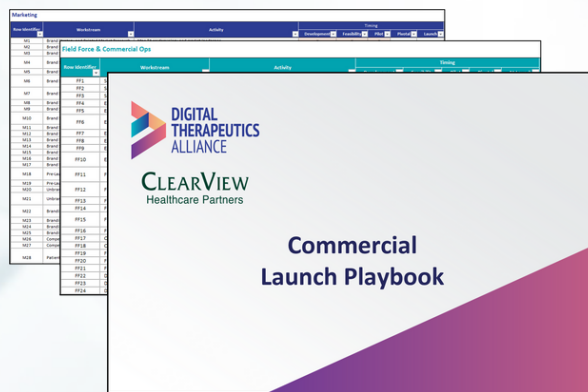
"Market shaping is a continuous effort, so while unbranded education was not used during our initial launch it may serve to further educate stakeholders on the physiological mechanism that underlies panic disorders and is being increasingly considered as a core tactic supporting best practice launch strategy for digital therapeutics."

Freespira Team Member

Conclusion

While digital therapeutics have increasingly new territory to conquer to enter the market, a thoughtful launch strategy is a foundational component of successful commercialization that requires DTx-specific considerations. To effectively lead these products to market, it's crucial that DTx companies have a clear understanding of not only their end user, but the key points of conversion that balance between the patient, physician, and insurers. Additionally, given DTx's evolving regulatory landscape, significant market shaping may be required to ensure that physicians understand the value-add of digital therapeutics and can envision seamless integration into existing treatment paradigms. Freespira is just one example of how innovative biotech companies as well as pharma players of all sizes can proactively engage with the market to ensure launch readiness and successful commercialization of their digital products.

Our launch playbook, in collaboration with the Digital Therapeutics Alliance, captures these insights and more. For more information, please contact the Digital Therapeutics Alliance at lani@dtxalliance.org. To learn more about ClearView's Digital Health and Launch practices and how our team can help unlock a high-impact DTx launch strategy, please contact us at digitalhealth@clearviewhcp.com.



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