Exploring Digital Therapeutics: Case Study Series

Digital therapeutics publish trial results inclusive of clinically-meaningful outcomes in peer-reviewed journals

Why do digital therapeutics companies do **clinical trials?**

Recognized on par with medications and other clinically-validated therapies by demonstrating their power to improve patient outcomes through peer-reviewed research, all DTx products must adhere to industry-adopted core principles, including undergoing adequate and well-controlled clinical investigations that establish the product as safe and effective.

In health care, every product that claims to produce a specific outcome, is required to complete a randomized control trial to identify the outcomes correlated to the use of that product that impact patient needs and disease state. Clinical outcomes demonstrated through peer-reviewed research includes increasing symptom-free days, reducing unnecessary medication use, and lowering the use of the emergency room.

What does this look like **for industry?**

Digital therapeutics have the power to reveal insights through research that analog medicines cannot access. Prior to digital therapeutics, studies were largely reliant on hospitalization or mortality data to assess how patients respond to environmental factors. Exacerbations that did not involve hospitalization or fatalities were often overlooked because the data did not necessarily exist.

With digital therapeutics data, we can pinpoint the exact time, date and location of a patient's medication use and compare that with environmental data to understand how external factors impact disease. Digital therapeutics research represents a huge area of opportunity to better understand how patients use medication and experience chronic disease. Clinicians are able to know exactly how their patients on a certain medication or protocol are doing and intervene, if needed, between appointments. Patients and their caregivers are able to see their real-time recordings of medication use or symptoms to more fully engage in their care and care planning conversations.

Unlike traditional medications, digital therapeutics products can be iterated and improved. Peer-reviewed research enables digital therapeutics companies to continue iterating enhancements and new features that best serve patients.

Pharmaceutical companies, payers, and healthcare organizations invest in digital therapeutics, and we expect to see that investment increase as consumers grow to expect a digital component to their medication regimen. We hope to continue to see more partnerships, investment and interest in research that uses digital medicines to better understand patient outcomes.

***Digital therapeutics** have the power, through research, to reveal insights that analog medicines can't access.*

DIGITAL THERAPEUTICS ALLIANCE

The Digital Therapeutics Alliance (DTA) is a non-profit trade association of industry leaders and stakeholders working to expand access to high quality, evidence-based digital therapeutics for patients, healthcare providers, and payers in order to improve clinical and health economic outcomes.

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The process to achieve validation of the outcomes of a digital therapeutic product include gathering evidence to demonstrate the clinical validation of a digital therapeutic is complex, with multiple considerations across a range of domains, including regulatory, scientific, and operational needs for product launch and ability to go to market. This process is not unique to digital therapeutics, evidence generation for a therapy to receive regulatory approval to make a claim has been well established for decades.

Duke Clinical Research Institute

What does a **DTx clinical trial look like?**

A clinical trial for a digital therapeutic is the same as any drug or therapy clinical trial!

The DCRI, which has a long history of managing large clinical trials for drugs and non-digital devices, was engaged to conduct a registration study for a digital therapeutic product with the ultimate goal of supporting an FDA filing for device clearance. From the beginning, there were important distinctions between the process for designing and conducting a multi-site efficacy trial for a digital therapeutic and a more traditional product.

The process involved all of the following important steps:

- Coordination between the company and DCRI to meet with and gather feedback from the regulatory agency (FDA), which also included interfacing with agency representatives from their digital products group.
- Consideration of novel trial design elements (eg. outcome measure selection, blinding/control conditions)
- Consideration of novel trial execution elements (product supply and management, maintaining blinding, messaging to clinical sites and trial participants)

The paradigm for establishing clinical validation for a digital therapeutic has important differences from the traditional process. These include but are not limited to:

- Differences in the way a SaMD is evaluated leading to regulatory approval
- Differences in trial design, analysis, and interpretation
- Differences in trial execution

To the extent that there are design features in the digital therapeutic product that are distinct from traditional drug/device trials, there are considerations for how results can be interpreted and shared. Regulators, health care providers, and even patients/end-users are accustomed to assessing clinical validation in a certain way and the process for establishing this with digital therapeutics may be different and needs to be considered.

*In order to maintain credibility as an industry and maximally benefit patients/end-users, it is critical to **use standard, rigorous and accepted processes for evidence-generation.***

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