Digital Health Industry Regulatory Case Study

Click Therapeutics

Defining robust drug-like evidence: Bringing novel software products to the US market

About Click Therapeutics

Click Therapeutics develops, validates, and commercializes software as prescription medical treatments for people with unmet medical needs. Click Therapeutics products available for market include: Clickotine for smoking cessation and Rejoyn for major depressive disorder.

The opportunity

- Amid a **shortage of mental health providers**, 21M US adults had at least 1 major depressive episode, yet **few evidence-based solutions** without side effects exist.
- Click was keen to **create a novel digital therapeutic (DTx)** for the treatment of major depressive disorder (MDD) symptoms as an adjunct to clinician-managed outpatient care.

The challenge

- Effectively gathering strong evidence for market readiness and validating the efficacy of the combined cognitive-emotional training exercises and therapeutic lessons is challenging.
- Certain payers perceive DTx products as inferior to standard care (e.g. drugs), largely due to their shorter development timelines, quicker regulatory authorization processes, and different requirements for safety and efficacy testing. This often results in skepticism about the quality of evidence and as a result, US payers are increasingly insisting on a higher DTx standard of evidence, akin to that required for pharmaceuticals.

The approach

As Click developed evidence for **Rejoyn**, they **engaged with the FDA** to understand the evidence requirements necessary for its safety and clinical performance. For Click, meeting **pharmaceutical-level evidence requirements was crucial** to combat market skepticism, gain credibility, and secure acceptance in healthcare. Their approach mirrored a drug perspective, demonstrating the **FDA's nimbleness in regulating innovative treatments**. Utilizing **pre-submission meetings**, Click identified the requirements and specifications tailored to their product's distinctive capabilities in MDD for the **510(k) regulatory pathway**.

The success

- ✔ In a business deal reminiscent of a drug company's style, Click took a **non-traditional approach** in developing this product, especially with new regulatory developments in prescription drug use-related software.
- ✔ Click navigated the FDA process through a methodology akin to that used for drug approval, **demonstrating both evidence rigor and market innovation**. They utilized a **novel commercial model** to pair the product with no treatment-related adverse events reported alongside a leading antidepressant medication.
- ✔ 96% of psychiatrists polled said adding exclusive brain training to the DTx could improve outcomes to a different extent than CBT alone.

> "At Click, we believe oversight by regulatory agencies is crucial for companies developing novel treatments for diseases. Our therapeutics are designed to achieve clinically meaningful results by altering brain circuitry through targeted digital interventions, so we validate these results with rigorous clinical studies and prioritize involvement of prescribing clinicians to ensure patients receive high-quality care. This approach provides the credibility that payers, providers, and patients need to trust and integrate new treatments."
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> **— Rich DeNunzio**
> *Chief Commercial Officer, Click Therapeutics*