

5 innovative ways to bring DHTs to market successfully

Digital health technologies (DHT) offer enormous promise to address pressing and persistent healthcare access, equity, affordability, and patient outcome challenges. A critical step for DHTs that qualify as a medical device toward patient access is demonstrating safety and effectiveness through achieving the appropriate level of regulatory authorization from the Food and Drug Administration (FDA). Read the full guest column [here](#).

In 2023, the [FDA authorized the highest number](#) of novel medical devices in the Center for Devices and Radiological Health's (CDRH) 40+ year history. However, regulatory authorization is only the first step on a medical device's journey to reaching patients, caregivers, and clinicians. Once devices receive authorization, it takes an average of [5.7 years to establish nominal coverage](#). Long timelines delay patient access to novel DHTs, stifle the development of innovative technologies, and negatively impact DHT developers' ability to survive in a competitive market. While a large number of companies have successfully received FDA market authorization for their innovative products, unfortunately to date, many still face obstacles to broad patient access. Despite promising [advancements in reimbursement](#), [M&As](#), and [changing business models](#), [many struggle](#) to survive in today's marketplace.

Strategies and success stories

[Real-world examples](#) demonstrate how developers embarking on their path to market must balance navigating the regulatory pathway with optimizing opportunities for downstream patient access and commercial success. Key strategies behind the successful market entry of these products include:

- ✓ [Diversify commercialization pathways for product market entry](#)
- ✓ [Consider unique aspects related to AI/ML-enabled medical devices](#)
- ✓ [Move from a product to an integrated platform approach](#)
- ✓ [Innovate in markets that solve for underserved, high-patient needs](#)
- ✓ [Pursue drug-alike evidence for digital health where necessary](#)

Diversify commercialization pathways for product market entry

Given [slow congressional action on digital health reimbursement](#), they have not yet become mainstream for public and private payers in the U.S. With limited pathways to commercialization, companies like [AppliedVR](#) and [JOGO](#) are finding creative ways to deliver products to patients.

Following FDA authorization, AppliedVR worked with Centers for Medicare & Medicaid Services (CMS) to include RelieVRx in the existing Medicare part B benefit category for durable medical equipment (DME). In March 2023, CMS established [HCPCS Level II code E1905](#), expanding access to the therapy. Similarly, JOGO-related provider services are reimbursed by Medicare and payers under 4 CPT codes.

Both of these companies engaged in frequent conversations with FDA about pathways and ways to navigate the evolving payment and coding landscape.

Consider new models for AI/ML-enabled medical devices

The prolific growth of innovative AI-products can pose unique regulatory challenges when balancing product safety and effectiveness with the iterative nature of AI-based software. [Caption Health](#) received the first FDA-authorized cardiac ultrasound AI software clearance under the FDA's breakthrough program with a [Predetermined Change Control Plan \(PCCP\)](#). This program allows developers to make certain changes to an iterative product without new regulatory submissions, thus saving time and money.

“ FDA was prompt in responding to our queries and has an open-door policy, whereas payers can be a black box for start-ups like us.”

— **Siva Nadarajah**

Co-founder and President, JOGO

“ It is important to do as many pre-submission meetings with the FDA as you can, even if it is with an ‘out-of-the box’ idea. They want to work with manufacturers to ensure that we develop products that meet patient needs and address critical public health issues.”

— **Michael Chibbaro**

VP Regulatory Affairs & Quality Assurance, AppliedVR

“ We are incredibly proud of the technology we have built, and together with GE HealthCare, we look forward to bringing this technology to more patients across the globe. Combining our [AI applications with GE HealthCare's ultrasound](#) devices will help accelerate our mission to detect disease earlier when an easily obtained diagnostic image can be a great equalizer to health quality and outcomes to ultimately help us reduce costs and enhance care.”

— **Steve Cashman**

Former CEO, Caption Health

Move from an individual product to an integrated platform approach

Following the FDA clearance of multiple condition-specific product solutions, [Empatica](#) developed a full-stack integrated condition-agnostic platform that could be deployed for both research or clinical care and would support integration with third-party algorithms. Conversations with FDA helped them evaluate their strategy to combine regulatory and business needs and pursue the best regulatory path to support patient care. In 2024, the U.S. market is trending toward [connected care](#), and as companies develop regulatory and business strategies, adopting a platform approach can enable greater DHT use and integration.

Innovate in markets that solve for underserved, high-patient needs

It is hard to innovate in the pediatric market due to high development costs and limited commercial market size. Developing DHTs for children comes with anatomical and physiological differences from those of adults, requiring specialized design and testing for products to ensure compatibility and effectiveness. Despite these challenges, [Gabi Smartcare](#) received priority market authorization with a [waived application fee](#) for introducing a product for pediatric use in the U.S. This allowed them to collaborate with 30+ children's hospitals across the U.S.

“ We learned a lot from engaging with multiple FDA divisions over several years to obtain clearance of the Empatica Health Monitoring Platform, and we look forward to ongoing interaction with the Agency to continue streamlining the regulatory submission process for condition-agnostic platforms.”

— **Dr. Marisa Cruz**

Chief Medical Officer, Empatica

“ FDA’s 510(k) clearance of our solution opens the gateway to a key medical sector. It gives us access to our first high-value-added market – the ‘hospital at home’ – where we have strong traction. We are the only digital pediatric solution that enables home monitoring with remote follow-up.”

— **Jonathan Baut**

CEO, Gabi SmartCare

Pursue drug-like evidence for digital health where necessary

[Click Therapeutics](#) successfully navigated the FDA process through a methodology akin to that used for drug approval, demonstrating high evidence rigor and market innovation in their approach. This allowed them to [use a novel commercial model](#) to pair its digital therapeutic for patients with major depressive disorder with no reported treatment-related adverse events in the trial alongside a leading antidepressant medication.

“ 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.”

— Rich DeNunzio

Chief Commercial Officer, Click Therapeutics