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Floreo CEO Champions FDA Path For Autism VR Therapy

Firm Aims To Establish DTX Legitimacy With Its Immersive Learning Platform That Helps Build Communication And Social Skills

by Hannah Daniel

Vijay Ravindran, founder of autism therapy digital therapeutic firm Floreo, spoke to *Medtech Insight* about working with the FDA, and why the TAP pilot made sense for them.

Medtech Insight is honoring May and June awareness months for mental health, Alzheimer's and brain health by speaking with industry leaders about rising innovations to address neurological diseases and mental health, the regulatory and investment climate, reimbursement, and more.

Vijay Ravindran wants to get his product to market the "right way."

Ravindran is the founder and CEO of Floreo, a virtual reality program that teaches social and behavioral skills to autistic individuals. He told *Medtech Insight* that the company chose to pursue FDA approval for the digital therapeutic (DTX)—and a breakthrough device designation—to be responsible with its investors.

"When we started Floreo, we didn't start ... with a clear sense of exactly how we would commercialize," Ravindran said. "I wasn't necessarily thinking about [the US Food and Drug Administration] at all, or even that Floreo was a digital therapeutic, I was thinking of it probably more in line as an educational tool that could be wielded by parents."

Learners, as they're called by Floreo, use a virtual reality headset to work through *lessons* that teach a variety of skills such as eye contact, conversations and social cues.

AN EXAMPLE OF A LESSON FROM FLOREO PRACTICING GREETINGS: "THE LEARNER WILL INDEPENDENTLY RECOGNIZE AND RESPOND TO A VARIETY OF SOCIAL GREETINGS, USING BOTH VERBAL RESPONSES AND NONVERBAL CUES, ACROSS 6 OPPORTUNITIES." *Source: Floreo*

Ravindran found that the product gained traction with therapists and health care providers, which suggested Floreo might fit the definition of a medical device.

He also learned that without reimbursement, there was a "limited ability to adopt new technology that increased costs for the provider."

"What led us down the regulatory path was really working backwards from reimbursement [that was] needed by healthcare providers and the ecosystem," he said.

The company decided to enter the Total Product Lifecycle Advisory Program (TAP) Pilot and

pursue a breakthrough designation to “be responsible with shareholders and investors.”

Ravindran said that the company first began talking to FDA through its Q-submission program, which allows companies to request early feedback before a premarket submission. (Also see "*Q-Sub Guidance Needs Clarity On Informal Meetings And Timelines, Say Commenters*" - Medtech Insight, 29 May, 2024.)

Since there hasn’t been an approved medical device to treat autism (not including its diagnosis), dialogue with the FDA about what a clinical trial would look like was invaluable, he said.

They ran smaller studies before applying for and receiving breakthrough device status, which validated “that our approach [made] sense to the FDA,” he explained.

“We applied for breakthrough device designation, mainly because we knew it would be an asset to have that badge that our study from last year was done appropriately,” Ravindran said.

To join the TAP pilot, a device must have received a breakthrough designation but should not have started its pivotal trial, which is a clinical trial that measures the safety and efficacy of a device. Ravindran acknowledged that this can be a very narrow window in the development process, but for Floreo, the opportunity came at the perfect time.

TAP is a pilot to test the “feasibility and benefits” of early interactions with the FDA. The TAP pilot was launched in January 2023, and as of 30 April, there are 45 devices enrolled in the program. (Also see "*‘Banner Year’ For FDA’s Device Center Includes Record Number Of Novel Authorizations*" - Medtech Insight, 18 Jan, 2024.)

“The TAP [pilot] seemed to open up a unique opportunity to further tune our pivotal trial with an eye towards payers, and that was definitely in line with our interest and what we wanted to accomplish,” Ravindran said. “We were willing to take a delay of several months to participate in the program and get that feedback.”

Having to slow down the development process can be a large burden on some companies, but Ravindran believed that it was the most responsible pathway for Floreo and its investors.

A pivotal trial can take up a large amount of investor capital, especially for an early-stage company, so Floreo chose to break it into small stages, achieving positive feedback that reassures them that they’re on the right track, instead of steaming ahead without those checks.

“A lot of companies have gone straight to a pivotal trial without even doing a pre-submission in some cases … and so that seemed irresponsible with investor capital, especially in 2023 and 2024,” he said.

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How To Get Paid

Many payors and investors are “skittish” about the digital therapeutics space, so following a tried-and-true commercialization route through the FDA is one way that Floreo is legitimizing itself as a medical product.

In 2022, Floreo introduced a new Current Procedural Terminology (CPT) III Code to the American Medical Association as an add-on code to the speech, behavioral and occupational therapy codes, which are commonly used for children with autism.

The CPT III Code 0770T allowed providers to create “billing scenarios [that] use of the Floreo system in their practice,” Ravindran explained, but that’s just one step of many.

VIJAY RAVINDRAN, FOUNDER AND CEO OF FLOREO

Floreo is hoping to graduate the CPT III code into a permanent CPT I code, which are codes for common medical procedures and services.

The code took effect on 1 January 2023 and will expire in 2028 unless converted to a permanent CPT code or renewed for another five years.

While waiting for reimbursement from private and public payors, Floreo has partnered with schools and health systems to license the program to neurodivergent children. (Also see "*Industry Finds Innovative Revenue Streams For Digital Therapeutics*" - Medtech Insight, 14 Jun, 2024.)

School districts can get the product “into action” more quickly than providers sometimes, Ravindran said during the Digital Therapeutics Alliance’s Annual Summit on 6 June.

There are also students without an official autism diagnosis who can use Floreo, and the company has received valuable feedback that they’ve integrated into their product.

There’s also the issue of getting the VR headset into the user’s hands, which can cost anywhere from $3,500 for Apple’s Vision Pro to a simple $20 set-up of goggles and a phone or tablet.

Floreo is available on *three platforms*: the Meta Quest VR headset, the PICO VR headsets and on iPhones with a plastic google set-up. The program also requires the use of an app on an iPhone or iPad.

Customers also can lease hardware from Floreo, including iPhones and iPads through Floreo's partnership with Apple Education.

"Once a provider wants to use something ... it's really about how much can you bring down the friction [for them]," Ravindran said. "You have to make it really easy for them."

Health care providers are also the "best advocates" to convince payors to cover products.

"We believe that ultimately Floreo is successful if the health care providers in the autism therapy space are successful using Floreo," he said.