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‘Training People To Be Healthier’: Digital Therapeutics Programmed For Growth

by Marion Webb

Experts foresee the digital therapeutics market growing to $6bn-$9bn by 2025, driven in part by tech-empowered consumers and patients looking for solutions to better manage their own health and conditions. For medtechs, collaborations with software-driven start-ups will be key to harnessing personalized data and differentiating themselves in the marketplace.

Health techs’ push to digitize medicine has led to an explosion of innovative solutions that seek to engage and empower consumers and patients to participate in their own health.

Digital therapeutics, a subcategory of digital health solutions that represents a wide range of technologies and services including wearables, sensors, virtual reality and video games, are expected to play an ever-rising role in treating and managing diseases.

Defined by the Digital Therapeutics Alliance as “delivering evidence-based therapeutic interventions driven by high-quality software programs to prevent, manage, or treat a medical disorder or disease,” this sector has seen tremendous growth and investor interest during the pandemic. (Also see "*CTA’s Standards For Digital Therapeutics Clears Up ‘Industry Confusion’*" - Medtech Insight, 21 Oct, 2021.)

Medtech consultant Jaunt expects the digital therapeutics market to grow from $1.7bn in 2019 to $6bn in 2025, a

Exec Chat: New CEO Of Digital Therapeutics Alliance Says Reimbursement Remains Big Issue

By Marion Webb

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In an interview with *Medtech Insight*, Andy Molnar, new CEO of the Digital Therapeutics Alliance, outlines some of the big issues facing the digital therapeutics industry, which has seen tremendous growth during the

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compound annual growth rate of 23.4%. Pedro Arboleda, managing director in Deloitte's Consulting LLP's Strategy practice, told *Medtech Insight* he has seen forecasts that put the market value for the digital therapeutics sector even higher -- $6bn-$9bn by 2025.

pandemic.

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Digital therapeutics are used independently or in concert with medications, devices or other therapies to optimize patient care and health outcome.

Arboleda noted that several medtechs including *Abbott* , *Zimmer Biomet Holdings, Inc.*, *ResMed, Inc.*, *Philips Healthcare* and *LifeScan Inc.* have invested in this space. He expects to see more collaborations between medtechs and digital therapeutics developers, pointing to the power of digital therapeutics in generating data.



PEDRO ARBOLEDA, MANAGING DIRECTOR DELOITTE'S CONSULTING LLP'S STRATEGY PRACTICE *Source: Deloitte*

Simply put, there's a larger perspective to be gained on the patient experience, including patient compliance following surgical interventions and relation to outcomes, for medtechs that tap into digital therapeutics and the data they collect, aided by machine learning, artificial intelligences and other new technologies.

"You're starting to see companies [Philips as an example] really make a strategic pivot and a substantial effort to become a lot more software-friendly and savvy and centric," Arboleda told *Medtech Insight*. "That really is where the differentiation is likely to happen. ... Looking at the data in an automated way, that's really a low-cost way to differentiate clinically from the data that's coming from the devices and the data that's coming from the users."

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Julia Croxen, an expert in digital therapeutics and consultant for digital health venture capital company Rock Health, told *Medtech Insight* that early on, investor activity focused on companies that replicated the types of treatments that were formerly delivered in person, such as cognitive behavioral therapy (CBT) or diabetes prevention programs.

Over time, digital therapeutics companies expanded into new clinical indications including women's health, cardiovascular conditions such as hypertension, pulmonary disease such as asthma and COPD, neurological disorders such as Alzheimer's and Parkinson's disease, and gastrointestinal disease, enabled in large part by technological advancements.

She pointed to *Pear Therapeutics, Inc.* , which is considered a leader in the digital therapeutics space. Pear started off in substance use disorder with its lead product reSET, the first prescription digital therapeutic (PDA) to receive marketing authorization from the US Food and Drug Administration. Its second product, reSET-0 for treating opioid disorder, was the first PDA to receive the agency's breakthrough designation; its third product, Somryst for treating chronic insomnia, was the first product the FDA reviewed under the *Software Precertification Pilot Program*. (Also see "*Exec Chat: Pear Therapeutics' CEO Charts Future For Digital Therapeutics Following SPAC Deal*" - Medtech Insight, 25 Jun, 2021.)

On 22 November, the company announced it received breakthrough designation from the FDA for reSET-A designed for treating alcohol use disorder. Pear's current *pipeline* shows activity in multiple therapeutic areas: behavioral health, neurology, gastrointestinal, oncology and cardiology. This month, Pear also completed its merger with blank-check company Thimble Point Acquisition Corp., a deal valued at about $1.6bn. It started trading on the Nasdaq on 6 December.

"It will be interesting to learn more about their [Pear's] traction when they become public," Croxen said.

Not Just Complementary Add-On

Other companies are developing truly "novel interventions," Croxen said.

She pointed to Portland-based *MedRhythms, Inc.*, which is developing a direct stimulation PDA,

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combining prescribed music, software and sensors to improve walking impairment and cognition. The company's digital therapeutic received FDA breakthrough device designation last June for treating chronic stroke walking deficits.

"Sometimes in our deal flow, we're seeing companies where it's not just potentially treating the main diagnosis that somebody has, but actually supporting some of the side-effects," Megan Zweig, Rock Health chief operating officer, told *Medtech Insight*.

Blue Note Therapeutics, Inc., which raised $5.2m in a series A round and a total of $31m as of September, is working with cancer research and patient communities on developing clinically validated digital therapeutics to help reduce anxiety, depression and other forms of cancer-related distress.

Geoffrey Eich, Blue Note Therapeutics' CEO, said in a statement, "nearly half of all patients diagnosed with cancer experience some form of psychosocial distress but for far too many these symptoms go untreated."

Zweig said the development of digital therapeutics that supports people who suffer co-morbidities or side-effects as a result of a diagnosis presents a "big, big opportunity," adding that this has already led to significant partnerships with pharmaceutical companies.

The major difference between digital therapeutics and wellness applications is that digital therapeutics are developed to target specific diseases and often target conditions that are poorly addressed by the health care system such as treatment-resistant depression or opioid addiction.

"When we think about digital therapeutics, we highly align that with the value proposition of treating, managing, preventing a specific disease and using software that is evidence-based and clinically validated to do so," Croxen told *Medtech Insight*. In terms of the value proposition of digital therapeutics, Croxen said, access to care is key, and "really the idea of having an opportunity for treatment to be more accessible, more continuous, discrete, and in the hands of the patient all the time."

Consulting group McKinsey & Company wrote in a report that investor enthusiasm for digital therapeutics products is driven by two main trends – the ever-growing amount of data from wearables, smart phones and other devices that provide insights, and a growing body of evidence that digital therapeutics work.

Nick Talamantes, director of market intelligence at LSI, a globally recognized medtech market research and advisory firm, agreed with the experts that the treasure hunt lies in the data.

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“Data is huge now and having this patient data and learning from thousands, if not hundreds of thousands of patients going through similar things, you’re going to learn how to more effectively train people to be healthier,” Talamantes told *Medtech Insight*. Though, he noted, it remains to be seen whether digital therapeutics can show that they improve patient outcomes, which is critical for reimbursement and buy-in from providers.

“Many digital therapeutics companies have partnered with large pharmaceutical companies and their investment arms for developing, licensing and commercialization of their products,” wrote UC San Francisco researcher Nisarg Patel in an article published in *Nature* last December. He noted that “understanding and overcoming obstacles to effective regulation and reimbursement of digital therapeutics” remains key in developing long-lasting partnerships with pharmaceutical companies and moving these candidates into the clinic.”

However, the ultimate test of the value of a digital therapy is the amount a customer will pay for it, McKinsey said. Payers will typically value a therapy if it has proven to cut health care costs, particularly by lowering acute-care use and improving outcomes.

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Business Model Flexibility

Digital therapeutics are interesting because they offer multiple business models, Zweig said.

Arboleda finds that many start-ups in the digital therapeutic space lend themselves to a self-directed model where patients pay for the treatment themselves or the insurance provides incentives for members to self-pay. These business models allow companies to collect revenues and build scale while collecting data from consumers and patients that can show the clinical evidence needed to seek regulatory approval.

“You certainly see evidence of that in a number of these digital therapeutics, then maybe the next stage is the payers become a lot more comfortable because of the data that’s been collecting evidence in the first two models and they end up paying for most of it, because they see it will lower the cost of care for their members,” he said. The last stage would then be the prescription model, which follows a more traditional regulatory pathway.

Employers have an incentive to pay for digital therapeutics that would reduce their medical health care costs and enhance nonclinical outcomes such as reduced absenteeism and increased productivity by improving employees’ health, McKinsey said.

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Arboleda noted that 31% of all covered workers in the US are on *high-deductible health plans*, an all-time high as a percentage of the total covered workforce, which means that "31% are paying for most of their health care during the year and are already making decisions on traditional medical devices and they are certainly going to make a decision whether to use a digital therapeutics product."

Digital therapeutics companies that are successful in communicating the benefits of their treatment and strike a chord with consumers in terms of the behavior they want to change have the best chances for success.

"The posterchild to me is what Noom has been able to accomplish," Arboleda said.

Noom has witnessed a surge in its weight-loss app, generating $400m in revenues in 2020, up from $237m the year prior. The company, which boasts more than 45 million users worldwide, announced in May it raised $540m in a series F round, led by Silver Lake. This October, Noom launched a new app to help individuals manage stress and anxious thoughts. Digital mental health was the top investment during the first half of 2021, bringing in $1.5bn, according to a *Rock Health report*.

Another major success story is *Livongo Health, Inc.*, which was acquired by telehealth giant Teladoc in 2020 for $18.5bn in cash and stock. Livongo offers behavioral intervention for people with diabetes, such as stress management, healthy eating and weight management, one-on-one coaching, as well as monitoring of blood glucose levels on the Livongo app. Behind Livongo's success is a vast partnership network including employers, insurances, providers and associations, as well as gaining reimbursement. (Also see "*HLTH 2020: Teladoc And Livongo Say Clients, Doctors Excited About Merger, Cross-Selling Deal With Florida Blue*" - Medtech Insight, 13 Oct, 2020.)

Teladoc Health, Inc. reported that its access fee revenues grew to $451,583 in the third quarter this year, a sharp rise from $226,519 in the third quarter of 2020, driven by Livongo's subscription-based chronic disease management platform.

Croxen noted San Francisco-based Big Health, which developed the Daylight and Sleepio apps for helping people with anxiety and sleep respectively. The apps deliver cognitive behavioral therapy through virtual training. The company announced in October that the Scotland National Health Service will offer national access to its products at no cost for users. In the US, CVS Caremark, a major insurer, included both products in its Point Solutions Management Platform last July.

Propeller Health, a subsidiary of San Diego, CA-based ResMed, Inc., developed a digital inhaler for asthma and COPD management that uses sensors that automatically track where, when and how often the medication is used and displays the information on a mobile app to help patients

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stick to their treatment plans and understand what causes flare-ups. It also leverages real-time air quality information to correlate actual medication use and symptom flare-ups with environment triggers.

Propeller Health and Dignity Health announced on 5 October they have integrated the Propeller platform into Dignity's electronic health record system, which allows physicians to order and manage the Propeller solution through the EHR.

"Propeller can allow a more expansive view of our patients' respiratory medication management," said Christine Braid, medical director of virtual care and innovations at CommonSpirit Health. "We can watch for albuteral medication overuse and initiation of maintenance inhalers and intervene when delicate life situations change."

A *study* of asthma patients that enrolled in a program that used Propeller's inhaler sensors at one of CommonSpirit's Dignity Health medical groups saw asthma-related emergency room visits fall by 54% and combined asthma-related emergency room and hospitalization events fall by 57% during the 365 days post-enrollment when compared to the one-year period before enrollment, Propeller said.

Arboleda also foresees more opportunities to use digital therapeutics in the orthopedics space and in renal care.

Zimmer Biomet is one major player that has been steadily building up its digital surgery platform, gathering data at various points of the care continuum including the use of its mymobility app which works with the Apple Watch to track a patient's progress post-surgery and provides instructions and education pre-surgery. A study published in the 9 August edition of the Journal of Arthroplasty found that using the *smartwatch with an app* produced similar outcomes to going through traditional physical therapy. (Also see "*AAOS 2021: Digital Tools In Surgical Ecosystem, Software-Enabled Tech, Robots, Wearables, Sensors*" - Medtech Insight, 9 Sep, 2021.)

In August, Zimmer Biomet and its partner, medical data company Canary Medical, received de novo authorization to market Persona IQ, which combines Zimmer Biomet's knee implant Persona with Canary's sensor technology that measures and determines range of motion, step count, walking speed and gait metrics. (Also see "*Zimmer Biomet, Canary Medical Win FDA De Novo For First Smart Knee Implant*" - Medtech Insight, 30 Aug, 2021.)

Health systems and providers have an incentive to avoid Medicare penalties, which can occur when patients are readmitted to the hospital or have complications following orthopedic surgery. Tracking patients' progress during rehabilitation via remote monitoring tools can help avoid some of these issues.

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“Increasing use of [remote monitoring tools] across the implant manufacturers and embedding that in the care management plan for hip and knee replacement surgery patients could be a really interesting add-on and a meaningful one,” Arboleda said. “There is a vested interest on the part of the surgical teams to take a serious look.”

Several digital health rehabilitation companies have already garnered investor interest. Among them is San Francisco-based Hinge Health, which developed a platform for chronic joint and back pain that combines wearable sensors, an app and health coaching to remotely deliver physical therapy, and Sword Health, which provides virtual and digital physical therapy.

He also sees opportunities in renal care, noting that many dialysis patients also suffer from comorbidities. Diabetes and high blood pressure are the number one and two conditions leading to chronic kidney disease in the US, according to Davita Kidney Care.

“Patients with comorbidities often take multiple medicines and may need to spend time following the best diet, fitting in physical activity, scheduling doctors’ appointments and going to dialysis or other treatments,” according to Davita’s *website*. Arboleda suggested that renal care leaders could link up with digital therapeutics makers to address some of these issues. The Hello Heart hypertension platform may be an ideal partner to help dialysis patients manage their blood pressure, he says

The biggest hurdle right now is that the Center for Medicaid and Medicare Services (CMS), the largest payer in the US, has yet to define a medical category for software as a medical device, which is the category that digital therapeutics falls into, Therapeutic Alliance CEO Andy Molnar told *Medtech Insight* in July. (Also see "*Exec Chat: New CEO Of Digital Therapeutics Alliance Says Reimbursement Remains Big Issue*" - Medtech Insight, 28 Jul, 2021.)

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In January, CMS finalized a *rule* called the Medicare Coverage of Innovative Technology, which would make technologies with a breakthrough status from the FDA eligible for reimbursement under Medicare for four years. However, on 12 November, CMS announced that it is rescinding

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the Medicare Coverage of Innovative Technology and Definition of "Reasonable and Necessary" *final rule*, which would have become effective on 15 December. In a *press release*, CMS raised concerns that the provisions in the final rule may not have been sufficient to protect Medicare patients and rescinding the rule will allow it to "take action that will better address those safety concerns in the future." (Also see "*It's Official: CMS Repeals MCIT Rule, Leaves Door Open For Alternatives*" - Medtech Insight, 12 Nov, 2021.)

Still, Arboleda and other experts see a bright future for digital therapeutics. (Also see "*When Medtech Meets Consumer Tech It Comes Down To Machine Meets Human*" - Medtech Insight, 13 May, 2021.)

"Consumerism is here to stay," Arboleda said, pointing to technologies such as smartphones and wearables that are empowering patients to gain access to therapies and be an active participant in their health care. "Medical device companies that make a concerted effort to go to market together and create solutions for those consumers will stand to gain."Zweig noted that already, "We're all attached to our phones. ... You see these devices and technologies being used so profusely when it comes to our entertainment and when it comes to our connections, our community and social media."

She continued, "Imagine leveraging all of that for good, for the health of people where you can actually get them engaged in something that is so convenient, so accessible, something that is actually potential 'dare I say fun' to use, but is really helping someone manage a health condition, that's really, really exciting."

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