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Digital Health Roundup: Digital Therapeutics Navigate GLP-1, Immersive Gaming; DHCoE AI Framework; Hello Heart

by Marion Webb

In this week's Digital Health Roundup, *Medtech Insight*'s Ryan Nelson highlights Click Therapeutics' FDA-cleared digital therapeutics (DTx) for depression and Sinaptica Therapeutics' personalized neuromodulation for Alzheimer's patients. Marion Webb discusses her interview with MindMaze's John Krakauer on their gaming-focused DTx to help people recover from serious brain injuries. Elizabeth Orr introduces new voting members of the new Digital Health Advisory Committee and Natasha Barrow discusses Hello Heart's new symptom-tracking feature in their heart-focused app.

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Pharma Cozying Up To Digital Drugs

Click Therapeutics, Inc. and partner Otsuka Precision Health, a subsidiary of Tokyo-based *Otsuka Pharmaceutical Co. Ltd.*, announced on 13 August the commercial launch of Rejoyn, the first prescription digital therapeutic cleared by the US Food and Drug Administration for the adjunctive treatment of major depressive disorder symptoms in patients age 22 or older who are on antidepressant medication.

Rejoyn, a six-week treatment program, targets and helps to alter neural connections necessary to

appropriately process emotions, according to the release. Patients can obtain a prescription for Rejoyn from their current provider or have the option of a frictionless, fully digital prescribing and dispensing pathway, with virtual consultations provided by Wheel Health, Inc. and BlinkRx serving as exclusive pharmacy provider.

The innovative DTx is available for a limited time at the discounted price of $50 for patients and, at launch, will be priced at $200 for payors. The companies expect health insurance coverage to be forthcoming.

Click CEO David Benshoof Klein discussed the present and future of DTx in a June interview with *Medtech Insight*, noting the vast potential for digital medicines to complement marketed drugs and help pharmaceutical companies improve patient outcomes and differentiate their offerings in ways that could be enticing to payors, among other benefits. He cited the growing GLP-1 opportunity as a prime example of a space where Click's DTx platforms and others could make a significant impact.

Going forward, he expects that "many pharma are going to start incorporating these software as medical devices directly into their clinical stage program." (Also see "*Click Therapeutics Anticipates Pharma Will Begin Developing Digital Drugs From Clinical Stage*" - Medtech Insight, 17 Jun, 2024.)

MindMaze, 'A Ratio Of Luke Skywalker And R2-D2', Navigates The DTx Galaxy

MindMaze's chief medical officer John Krakauer believes the company's technology platform is uniquely positioned in the digital therapeutics space, offering an immersive gaming experience to patients recovering from brain injuries such as stroke.

MindMaze's technology requires patients to do full body movements requiring both cognitive and physical skills. One of the company's interactive games MindPod Dolphin trains fine-motor skills of the upper limb as the user controls the movement of an animated dolphin called Bandit to catch fish or explore the ocean.

MindPod has already shown promising results in clinical trials. In the SMARTS2 clinical trial, the game doubled the effectiveness of conventional rehabilitation therapy for the upper limbs (using the Acute Research Arm Test (ART) scale) during the sub-acute phase after a stroke, a period which lasts for a few months.

This October, the firm plans to announce preliminary results of the Enhancing Spontaneous Recovery After Stroke Study (ESPRESSo), a single-site, randomized, controlled Phase IIa trial conducted in partnership with the University of Aucklan, which evaluates the effects of using MindPod for recovery in stroke patients, the company said.

In 2022, MindMaze also teamed up with Mount Sinai Health System in New York to deploy an outpatient restorative program followed by a home-based digital neuro-care assessment, leveraging MindMaze's software and custom-built hardware. (Also see "*MindMaze, 'A Ratio Of Luke Skywalker And R2-D2', Navigates The DTx Galaxy*" - Medtech Insight, 13 Aug, 2024.)

Big Health Wins FDA Clearance For SleepioRx

In other digital therapeutics news, *Big Health* announced on 9 August it scored FDA clearance for its digital therapeutic, SleepioRx, for treating chronic insomnia as an adjunct to usual care for patients ages 18 and older.

SleepioRx, a six-week digital program to help people improve quality of sleep, had already been recommended by the National Institute for Health and Excellence as an effective alternative to sleeping pills in the UK and has been widely available at no cost to all residents in Scotland. Now providers in the US will be able to prescribe the therapy for insomnia patients. (Also see "*Big Health Gets Good Night Sleep With FDA Approval Of Insomnia Digital Therapeutic*" - Medtech Insight, 9 Aug, 2024.)

"This clearance, coupled with newly proposed reimbursement codes, will for the first time motivate US health care providers to prescribe safe and effective treatment alternatives to traditional medication," says Big Health CEO Yael Berman.

A new proposed 2025 Medicare Physician Fee Schedule includes three new digital therapeutics codes (GMBT-1, GMBT-2 and GMBT-3) to treat mental health disorders, which could potentially establish a pathway for SleepioRx and other DTx.

Caresyntax Secures $180M In Series C To Build AI-Enabled Surgical Software

Caresyntax, which offers an AI-powered, vendor-neutral platform integrating data from pre-planning to post-op surgery secured $180m in a series C extension and debt financing round.

The firm, based in San Francisco and Berlin, plans to use the new funds to accelerate the adoption and development of its AI-enabled surgical software and fund strategic M&A activity.

Caresyntax's platform is used by 30,000 surgeons and across more than 3,500 operating rooms worldwide. It works with robotic surgery providers on its platform including *Medtronic plc*, Cambridge Medical Robotics and B. Braun Medical Inc. (Also see "*Caresyntax Secures $180M In Series C To Build Out AI-Enabled Surgical Software*" - Medtech Insight, 15 Aug, 2024.)

Sinaptica Goes Where Pharma Dare Not

Machine learning is key to *Sinaptica Therapeutics, Inc.*' non-invasive precision neuromodulation, which combines repetitive transcranial magnetic stimulation (TMS) targeting the precuneus – a

“key node” of the default mode network that’s responsible for episodic memory – with electroencephalography monitoring and advanced algorithms to personalize treatment in mild to moderate Alzheimer’s cases. (Also see "*Sinaptica’s Breakthrough Device Could Slow Brain Atrophy In Alzheimer’s Patients – Study*" - Medtech Insight, 10 Jul, 2024.)

Importantly, said CEO Ken Mariash in a recent interview, “these are the toughest patients. No drug is daring to go after moderate patients – they've all failed.” (Also see "*Sinaptica On Precision Neuromodulation To Combat Alzheimer’s: ‘No Drug Dares Go After Moderate Patients’*" - Medtech Insight, 19 Jul, 2024.)

Sinaptica is preparing for a Phase 3 trial in mid-2025, guided by regular consults with the US FDA as part of the agency’s Total Product Life Cycle Advisory Program (TAP).

The Cambridge, MA-based company, which will pursue mild cognitive impairment as its next indication, believes that pairing its neuromodulation approach with Alzheimer’s drugs such as donanemab and lecanemab could be “a very synergistic possibility.”

Hello Heart Launches New Symptom-Tracking Feature

Hello, Heart has launched a new symptom-tracking feature in its app, enhancing users' ability to monitor their cardiovascular health. This feature allows users to log symptoms such as dizziness or shortness of breath alongside their blood pressure readings. It is particularly beneficial for women who can experience different heart attack symptoms from men, like nausea or shoulder pain. (Also see "*Hello Heart Says Update To Cardiovascular Health Tracker Could Benefit Women Especially*" - Medtech Insight, 13 Aug, 2024.)

The Hello Heart platform combines a wireless monitor with an AI-driven coaching app that tracks various health metrics, including blood pressure, pulse, cholesterol, activity, and weight. By integrating symptom tracking, the app empowers users to maintain accurate records of their health, facilitating informed discussions with healthcare providers. This proactive approach aims to catch serious conditions earlier, as cardiovascular disease remains the leading cause of death worldwide.

Founded in 2013, Hello Heart has raised over $138m from notable venture firms and serves a wide range of users through employer health plans. A third-party analysis by the Validation Institute revealed that clients typically save about $2,382 per enrolled user in the program's first year.

According to Vision Research Reports, the global digital cardiovascular health market was valued at $35.34bn in 2023 and is expected to grow at a compound annual growth rate of about 22% to reach roughly $263bn by 2033.

In addition to symptom tracking, the app's personalized insights and coaching aim to help users make better lifestyle choices to manage their cardiovascular risks effectively. The introduction of this feature is a significant step in supporting users in understanding and managing their heart health, particularly for those at higher risk due to conditions like hypertension and high cholesterol.

FDA's Digital Health Center of Excellence Develops New AI Lifecycle Framework

The Digital Health Center of Excellence (DHCoE) at the FDA has released a new AI Lifecycle Framework, or AILC.

The Framework was announced in a *blog post* authored by Troy Tazbaz, DHCoE director, and DHCoE employee John Nicol. It presents a map of the AILC with *considerations* for each phase. The phases included in the map are planning and design, data collection and management, model building and tuning, verification and validation, model deployment, operation and monitoring, and real-world performance evaluations, which then cycle back into planning and design. (Also see "*DHCoE AI Lifecycle Management Plan To Serve As 'Playbook' For Standards*" - Medtech Insight, 26 Jul, 2024.)

Tazbaz and Nicol explained that the map "identifies key activities, compiled from literature and reviews of consensus standards, covering each phase of the AILC." It is intended to be more detailed than existing AI standards. For example, the "data suitability" element within the data collection and management phase might include identifying relevant standards and applicable metrics, like data quality, population coverage, and provenance.

Stakeholders can offer feedback on the AI lifecycle by emailing digitalhealth@fda.hhs.gov.

Digital Health Advisory Committee Announces Voting Members, Pool Of Industry Representatives

The FDA's Digital Health Advisory Committee (DHAC) has named its nine voting members and industry representatives. The Digital Health Center of Excellence announced plans to form the group in October 2023.

The advisory committee's chair until July 2028 will be Ami Bhatt, chief innovation officer of the American College of Cardiology. Its designated federal officer is James Swink, director of the advisory panel program within the Center for Devices and Radiological Health.

Voting members of DHAC are: Ray Dorsey, professor of neurology at the University of Rochester; Yaniv Kerem, emergency medicine physician at Kaiser Permanente Redwood City Medical Center; Joyce Ho, computer science associate professor at Emory University; Jessica Jackson, founder and CEO of Therapy Is For Everyone; Thomas Maddox, professor of medicine and

cardiology at the Washington University School of Medicine; Chevon Rariy, chief health officer and senior vice president of digital health at Oncology Care Partners; and Laura Stanley, computing associate professor at Montana State University.

The consumer representative is Melissa Denise Clarkson, internal medicine assistant professor at the University of Kentucky College of Medicine. (Also see "*Digital Health Advisory Committee Announces Voting Members, Pool Of Industry Representatives*" - Medtech Insight, 9 Aug, 2024.)

Two industry experts will represent the digital therapeutics industry as nonvoting members. They are Medtronic chief regulatory officer Yarmela Pavlovic and Joseph Smith, president of Joseph M. Smith LLC Digital Transformation Consulting. Additionally, Digital Therapeutics Alliance (DTA) CEO Andy Molnar will serve as an alternate.