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Digital Health Roundup: HLTH, LSX, AdvaMed; FDA And Pre-Determined Change Control Plans

by Marion Webb

In this month's Digital Health Roundup, *Medtech Insight*'s Marion Webb highlights interviews with behavioral health experts on implementing AI solutions to help ease the administrative burden on clinicians as well as recent coverage from the LSX Congress USA and HLTH conferences. Reed Miller discusses findings of EY's annual pulse of the medtech industry report and Hannah Daniel discusses FDA guidance on regulating AI/ML.

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In a new report on the state of the medtech industry, Ernst & Young argued the "acceleration of digitalization across the industry with new advances in the power of data analytics – most notably demonstrated by the rise of artificial intelligence, including the breakthrough generative [artificial intelligence] models in 2023 – opens new possibilities for the industry's future."

The industry needs to refresh its approach as a variety of economic challenges are impeding investment in medtech, including a slowdown in M&A and venture funding in medtech. (Also see "*EY Report Offers Advice For Medtech To Regain Its Pre-COVID Mojo*" - Medtech Insight, 12 Oct, 2023.)

An all-female panel of medtech leaders at the LSX Congress USA conference in Boston discussed

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the importance of diversity and inclusion in research, clinical trials, product development and services to advance health equity as well as fundamental business goals.

The DEI leaders also agreed that promoting health equity in medtech should be a business imperative. (Also see "*Medtech DEI Experts Talk Shop: 'It's Going To Transform Businesses'*" - Medtech Insight, 19 Sep, 2023.)

Another panel at the LSX Congress USA conference discussed the importance of establishing environmental, social and governance (ESG) factors to reduce greenhouse gas emissions and waste, digital privacy and employee safety for medtech companies, which rely heavily on global manufacturing and supply chain networks.

The medtech industry contributes significantly to health care's outsized footprint, according to an article by EY's global medtech leader Jim Welch and Jay Zhu, EY-Parthenon principal, strategy and transactions. (Also see "*Why Investing In ESG Measures Is Good For Medtech's Health And Sustainability*" - Medtech Insight, 3 Oct, 2023.)

Point-Of-Care

GE HealthCare Technologies, Inc. signed a $44m contract with the US government's Biomedical Advanced Research and Development Authority (BARDA) to develop advanced point-of-care ultrasound technology and artificial intelligence applications to improve the diagnoses and treatment of traumatic injuries.

"Point-of-care ultrasound is an essential tool in emergency situations to help clinicians quickly get the answers they need when treating patients," said Roland Rott, the CEO GE HealthCare' ultrasound business. (Also see "*News We're Watching: Illumina Looks At Grail Options, New AdvaMed Digital Health Division, Evolut FX Gets CE Mark*" - Medtech Insight, 13 Oct, 2023.)

Behavioral Health

AI tools are increasingly making their way into behavioral health clinics to decrease the administrative burden of notetaking and other support tasks.

Medtech Insight spoke with several experts in behavioral health to explore current use cases of AI solutions and found that ambient listening technologies such as Nuance Communications, *Microsoft Corporation*'s speech recognition subsidiary, could cut clinician's administrative burden by automating clinical documentation and enhancing the experience of the sessions.

AI that interacts with an electronic medical records system can also quickly get specific information about a patient, a summary of a person's health history, or find test results.

Everyone agreed, however, that chatbots for therapy, which gained popularity during the

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pandemic due to convenience, accessibility and affordability, cannot consistently identify a person in crisis, among other limitations, and therefore should not replace the human interaction. (Also see "*Generative AI Providing Behavioral Health Solutions, But Not Therapy … Yet*" - Medtech Insight, 12 Oct, 2023.)

At the recent HLTH conference, Oura, which markets Oura Ring, debuted stress-focused features aimed to help wearers identify stress triggers, reduce stress, and a new AI-powered tool that allows its members digital journaling.

Medtech Insight spoke with Oura's head of science Shyamal Patel at HTLH about the new features – Daytime Stress, which identifies stress triggers by continuously measuring small changes in biometrics; Reflections, an AI-powered journal function in the Oura app; and Stress Resilience, which will be introduced this winter to provide recommendations on how to manage stress and improve overall health. (Also see "*Oura Debuts New Stress Analyzers, Partnership With Headspace*" - Medtech Insight, 12 Oct, 2023.)

Results from an eight-week trial showed Hedonia's Mood Bloom game app can help patients with depression experience a clinically significant reduction in symptoms.

The app relies on Facilitating Thought Progression (FTP), an approach to disrupting cyclical, repetitive patterns of rigid thinking common in depression and anxiety.

The 101-patient trial randomized patients to treatment with conventional therapy with or without the app. The intervention group used the app for at least 15 minutes a day for four days a week for eight weeks. (Also see "*News We're Watching: FDA Announces Meetings On Ortho Safety And Radiology; News Orgs Sue FDA For Philips Docs, ITC Delays Apple Watch Case; And More*" - Medtech Insight, 6 Oct, 2023.)

The patients who used the app showed significant improvement across nine different validated measures and symptoms. (Also see "*News We're Watching: FDA Announces Meetings On Ortho Safety And Radiology; News Orgs Sue FDA For Philips Docs, ITC Delays Apple Watch Case; And More*" - Medtech Insight, 6 Oct, 2023.)

FDA Advisory Committees

Recognizing the growing complexity and importance of digital health, the US Food and Drug Administration has created a new advisory committee that will inform and help guide US regulators on digital health technologies (DHTs), the agency announced earlier this month.

The FDA said the new committee, which is expected to be fully operational in 2024, will advise the agency on a host of digital health matters, including AI/machine learning, augmented reality, virtual reality, digital therapeutics, wearables, remote patient monitoring and software.

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In its advisory role, the committee will provide regulators with expertise and perspective to help improve the agency's understanding of the benefits, risks, and clinical outcomes associated with use of DHTs.

The new advisory committee will consist of nine core voting members and one chair with the number of temporary members for any given meeting varying depending on the topic and will be comprised of experts from diverse disciplines and backgrounds to "ensure digital health medical devices are designed and targeted to meet the needs of diverse populations."

Digital health, the FDA noted, is rapidly evolving and cuts across a wide range of technologies and pertains to decentralized trials, patient-generated health data, and cybersecurity.

The FDA is currently seeking members and asking anyone who wants to be considered to serve — or nominate a candidate — to apply, visit *FDA's digital health advisory committee website*. (Also see "*FDA Launches Digital Health Advisory Committee*" - Medtech Insight, 11 Oct, 2023.)

Regulating AI

The FDA is still trying to determine the best way to regulate AI/ML devices to both protect innovation and patient safety.

Medtech Insight spoke to Sonja Fulmer, deputy director of the Digital Health Center of Excellence (DHCoE), about the agency's recent efforts during the MedTech Conference in early October.

One of the most significant steps was the introduction of pre-determined change control plans (PCCPs), which were approved by Congress as part of its omnibus appropriations bill, passed at the end of 2022.

PCCPs are pieces of premarket submissions that describe any minor, future changes companies plan to make to a device to keep it safe and effective. If approved, PCCPs allow manufacturers to update their devices efficiently without having to submit an entirely new 510(k) each time they need to tweak something. (Also see "*Future PCCP Training Coming In Finalized Documents, FDA DHCoE Deputy Director Says*" - Medtech Insight, 17 Oct, 2023.)

Since PCCPs are relatively new to companies and reviewers, Fulmer said a forthcoming final guidance on PCCPs for AI/ML will explain how to approve PCCPs and what changes are appropriate. The agency will also provide draft guidance focusing on medical devices.

Additionally, there are liaisons in each office in the Center for Devices and Radiological Health that serve as PCCP experts for reviewers that have questions.

The agency is also seeing the submission of PCCPs outside of the digital health space, indicating

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an agency-wide shift toward proactive regulation.

On the other end of the product lifecycle, acting assistant director of the DHCoE MiRa Jacobs said that postmarket surveillance of AI/ML devices continues to be a large challenge for regulators.

The agency has “a large amount of insight on the premarket in terms of assuring safety and effectiveness,” but not so much of a “pulse on the long-term monitoring of how these devices are functioning,” she said during a meeting run by the Alliance for a Stronger FDA. (Also see "*Postmarket Surveillance Continues To Challenge AI/ML Device Regulators*" - Medtech Insight, 22 Sep, 2023.)

These devices’ performance can “degrade over time” with outdated datasets, and the agency has not had enough time to understand these changes and their effect on a device’s safety, because most AI devices on the market were approved after 2019.

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