MEDTECH INSIGHT
CITELINE COMMERCIAL

30 Aug 2024 | **News**

News We're Watching: Regulatory Clearances For Illumina, GE, Boston Scientific; FDA Patient Group To Meet In October; Johns Hopkins Joins AI Accelerator

by Brian Bossetta

This week, Illumina announced its new CDx has FDA approval; GE and Boston Scientific nabbed CE marks; and the FDA's Patient Engagement Advisory Committee announced that its October meeting will focus on informed consent in clinical trials.

Illumina Gets FDA Nod For Comprehensive Biomarker Test

The FDA has approved a cancer biomarker test and its first two companion diagnostic indications, which manufacturer *Illumina, Inc.* says can examine more than 500 genes to profile a patient's solid tumor.

The company describes TruSight Oncology Comprehensive (TSO) as the first FDA-approved, distributable comprehensive genomic profiling in vitro diagnostic kit with pan-cancer companions diagnostic (CDx) claims.

While CDx tests can identify whether a patient's tumor has a specific gene change or biomarker that can be targeted by a therapy, most only target one type of cancer. Tests that target multiple genes, such as the TSO, increase the chances of identifying an immuno-oncology biomarker or clinically actionable biomarkers that enable targeted therapy options or clinical trial enrollment.

Specifically, Illumina says the TSO can identify treatment options for patients on Bayer's Vitrakvi (larotrectinib) and is also approved to identify patients with a certain type of lung cancer

that may benefit from treatment with Eli Lilly's Retevmo (selpercatinib).

Illumina says the TSO Comprehensive will begin shipping to customers this year.

The company also notes that comprehensive genomic profiling assays with CDx claims for solid tumors, like TSO Comprehensive, are reimbursable under Medicare.

October Meeting Planned For FDA's Patient Engagement Group

The Patient Engagement Advisory Committee (PEAC) of the FDA's Center for Devices and Radiological Health will meet virtually on 30 October to discuss a patient-centered approach to informed consent in clinical trials.

In the meeting announcement, the agency explained that clinical trial participants "play an integral role in advancing scientific knowledge and supporting the development of potentially life-saving therapies for patients in need." Meanwhile, informed consent forms are a key element in trials and can be one of the first times patients interact with the trial system. But too often, the FDA says, "informed consent forms are lengthy and difficult for potential research participants to understand."

During the meeting, the PEAC will make recommendations about the informed consent process, as well as factors to consider when communicating informed consent to clinical study participants to help participants understand key elements of the research. Meeting materials will be posted online two days before the meeting.

The FDA has worked to improve informed consent over the years, including in a 2023 guidance document. (Also see "*FDA Updates Guidance On Informed Consent In Drug And Device Trials*" - Medtech Insight, 17 Aug, 2023.)

CE Mark For Latest Boston Scientific TAVR System

Boston Scientific Corporation has been granted a CE mark for the Acurate Prime aortic valve system, the company announced on 27 August. The Acurate Prime is the newest transcatheter aortic valve replacement (TAVR) technology from Boston Scientific and is designed to build upon the Acurate neo2 platform. For example, Acurate Prime offers an additional valve size, allowing the device to be used in patients with a larger anatomy.

The Acurate Prime is indicated to restore aortic function to patients with severe aortic stenosis. It features a self-expanding design and an enhanced frame that equalizes force across the valve

for a stable fit against the native, diseased valve. Additionally, the redesigned deployment mechanism helps physicians to position the valve accurately to ensure better patient outcomes.

"We are thrilled to offer physicians a new valve with meaningful improvements for the treatment of an increasing number of patients with aortic valve disease," said Lance Bates, senior vice president and president, Interventional Cardiology Therapies, Boston Scientific.

The company plans to launch the Acurate Prime in Europe in the coming weeks.

GE HealthCare Announce Two CE Marks For Cardiac Imaging Solutions

GE HealthCare Technologies, Inc. announced CE marking of two cardiac imaging tools on 26 August: the Vscan Air SL wireless handheld ultrasound system with Caption AI and ECG-less cardiac computed tomography (CT) scanning on its Revolution Apex platform. The technologies will be showcased at the European Society of Cardiology (ESC) Congress in London from 30 August-2 September.

Both solutions aim to improve the speed and access to cardiac imaging, according to Eigil Samset, general manager, cardiology solutions, GE HealthCare. “Providing rapid, flexible, and at-the-point-of-care cardiac diagnostics is critical in terms of patient outcomes – however, timely care can be extremely difficult to deliver, particularly within already-stretched healthcare systems where clinicians face time and resource constraints,” he said.

Vscan Air SL with Caption AI, which debuted earlier this year in the US, can provide real-time step-by-step visual guidance to optimize probe movements and includes a quality meter to ensure the user obtains the best possible images, said GE Healthcare. Vscan aims to capture more cardiac images so even non-expert ultrasound users can take a look at patients’ hearts to inform diagnosis and treatment plans. (Also see "*News We're Watching: Abbott, Click, Otsuka, Prenosis Win FDA Approval; EU Health Data Space Proposal, And More*" - Medtech Insight, 5 Apr, 2024.)

The CE-marked and US FDA-approved ECG-less cardiac CT solution can acquire cardiac images without the aid of the patient’s ECG signal/trace, which helps clinicians make a quick assessment and appropriately prioritize the patient when the ECG signal is unavailable.

The technology is available as part of GE HealthCare’s Revolution Apex platform, a platform offering modern CT technology., said GE HealthCare.

Johns Hopkins Teams Up To Help AI Startups

Johns Hopkins Technology Ventures is joining forces with CareFirst BlueCross BlueShield and venture capital firm Techstars in launching a “health care accelerator” program to support startups looking to advance healthcare through AI.

The program, according to Johns Hopkins, combines the university’s expertise in transforming research into commercially viable businesses, CareFirst’s experience in advancing access to affordable, equitable, high-quality healthcare, and Techstars’ accelerator model that has helped entrepreneurs build thousands of successful companies, including more than 600 firms in the healthcare sector.

“The application of artificial intelligence to healthcare will enable new avenues of innovation, creating more powerful solutions for patients more quickly,” said Andrew Cleland, chief investment officer at Techstars.

Adam Phillips, the former managing director of Techstars Equitech, will lead the intensive, 13-week program focused on supporting entrepreneurs leading healthtech, medtech, and biotech startups.

Founders interested in the program can apply on the *Techstars website*. The program is accepting applications through 20 November.