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HLTH 2022 Roundup: Mirvie, Grail, Biofourmis, Komodo Health, Babson Diagnostics

by Marion Webb

This year's annual HLTH meeting drew more than 9,000 people to Las Vegas from 13-16 November and hundreds of exhibitors. In this first part of a two-part roundup, *Medtech Insight* highlights interviews with C-suite executives at Mirvie, Grail, Biofourmis, Komodo Health and Babson Diagnostics.

The fifth annual HLTH conference in Las Vegas delighted attendees with a full schedule, sessions focusing on hot topics such as women's health and health equity, interesting panel discussions on fun-themed stages, and a jam-packed exhibit hall with healthtech companies strutting their stuff. (Also see "*HLTH Conference Promises Festival Vibe On One Big Stage; Health Equity, Women's Health, Digital Health*" - Medtech Insight, 10 Nov, 2022.)

Medtech Insight sat down with top executives of *Mirvie, Inc.*, *GRAIL, Inc.*, *Biofourmis*, Komodo Health and *Babson Diagnostics* to learn more.

Mirvie

Mirvie developed an RNA diagnostic platform that uses a simple blood test to detect complications during pregnancy, such as pre-eclampsia and pre-term birth, in the second trimester, which is earlier than most complications are detected today. This allows expecting mothers and physicians to intervene and take personalized, preventive measures in pregnancy care. (Also see "*Mirvie Granted Breakthrough Device Designation For Test To Identify Risk Of Preeclampsia*" - Medtech Insight, 3 May, 2022.)

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> *Great chat with Mirvie's CEO Maneesh Jain #HLTH2022 about the company's blood test to predict pregnancy complications. There about 300,000 cases of preeclampsia and 400,000 pre-term complications in the US a yr. The test done in 2nd trimester. #hlth #medtech pic.twitter.com/UTnMVRCNci*
>
> *— Marion Webb (@medtechMarion) November 14, 2022*

"There are roughly about 300,000 cases of preeclampsia and pre-term birth overall is about 400,000 – so roughly 10% of pregnancies [in the US]," Maneesh Jain, co-founder and CEO of Mirvie told *Medtech Insight*.

This May, the San Francisco-based company announced that the US Food and Drug Administration granted its test breakthrough device designation to detect risk of developing pre-eclampsia, which is high blood pressure that can led to serious complications.

However, the company's initial path to market will be Clinical Laboratory Improvements Amendments (CLIA) accreditation, Jain said.

"It's a quicker path to market and also it allows you to update as you improve the performance of the test, which happens in the early days more easily," Jain explained. "The FDA discussion is important because we want to continue discussions with the FDA and file at the right time."

The Mirvie RNA platform combines analysis of tens of thousands of RNA messages from the baby, the placenta, and mom, with machine learning. After several retrospective studies, the company is now sponsoring a prospective study to "make sure that the clinical evidence is at the highest standard." The validation studies will be followed by utility studies, which will be relevant for payers during discussions of reimbursement.

Jain did not want to give a timeline for when the test may become commercially available, but noted that there is a "high unmet need" for the test.

Grail

Grail's chief medical officer, Jeffrey Venstrom, told *Medtech Insight* he was honored to be invited to a panel discussion at HLTH to discuss bringing innovation such as Grail's groundbreaking multi-cancer early detection test called Galleri to the most vulnerable cancer communities.

“It’s really important for medicine, for bending the cancer mortality curve that this test – which is a simple blood test designed to provide that impact on health disparities – we just want to make sure that we can do everything we can through partnerships primarily to [bring this] test to those underserved populations.”

The Galleri test took a major step forward when it was launched last June after years in development supported by $2bn in venture capital. In clinical trials, the Galleri test detected a shared cancer signal across more than 50 types of cancer and has a false positive rate of less than 1%, which is a major differentiator compared to other screening tests, Venstrom stressed.

> *Great to chat with Grail’s CMO Jeff Venstrom about Galleri blood test to detect cancers early. Hope is to make test more widely available to create health equities. Current cost $949 in US. Test not designed to replace standard of care, but add to it. #HLTH2022 #liquidbiopsy pic.twitter.com/VofKreutH1*
>
> *— Marion Webb (@medtechMarion) November 15, 2022*

The test is designed to screen people who may be at an elevated risk for cancer, people aged 50 and above in particular.

The company has received breakthrough designation from the FDA, which in Venstrom’s words, “shows their appreciation of how much a gamechanger this test is because there is no current standard of care for pancreatic cancer, head and neck cancer.” The designation also gives the company access for requesting meetings with regulators around the evidence strategy and feedback on putting together clinical trials with the ultimate goal of receiving FDA approval, he said.

Grail has eight clinical trials underway and published results on several studies, including most recently, final results from the prospective, multi-cancer *PATHFINDER study* in which 6,200 participants were enrolled.

Reimbursement remains a major hurdle. The test is available through prescription by a doctor under the *Clinical Laboratory Improvement Act* at a cost of $949 and is not widely covered by payers. The ongoing studies and ultimately FDA approval will be pivotal to show the value of the

test.

According to the Multicancer Early Detection Consortium, multi-cancer early detection (MCED) holds the "potential to be a 'disruptive technology,' identifying a broad range of cancers early when treatment is more likely to lead to better outcomes," but will "require careful risk-benefit analyses." The group is also concerned about health equity. (Also see "*Liquid Biopsy Revolutionizing Cancer Care, But Costs Continue To Inhibit Global Potential*" - Medtech Insight, 29 Sep, 2022.)

Venstrom said Grail is working with more than 20 employers who offer the Galleri test to their employees as a health benefit, which Venstrom considers a "strong recognition of the importance of the test." Some 52,000 individuals have been tested with the Galleri test.

The company offers testing to consenting individuals through six mobile units in the United Kingdom, "parking at mosques, parking on farms, parking at warehouses to really make sure to get these diverse individuals into our study." One of the mobile units was also at the HLTH expo.

"The UK has this very sophisticated deprivation index to identify the lower socio-economic status individuals and so we're specifically targeting with these buses areas of high deprivation," he said.

Biofourmis

Biofourmis, a rapidly growing virtual care and digital therapeutics company, developed an end-to-end solution that allows providers to remotely manage acute-care patients, and more recently, patients with chronic diseases.

Biofourmis also partners with biopharmaceutical companies to develop software-based therapeutics for patients with unmet clinical needs.

Biofourmis raised $300m in a series D round in August, boosting the company to unicorn status. (Also see "*Minute Insight: Biofourmis Raises $300M To Fund Digital Drug-Companion Therapies*" - Medtech Insight, 29 Apr, 2022.)

Maulik Majmudar, chief medical officer and co-founder of Biofourmis, told *Medtech Insight* that the biggest evolution of the company was the move from a technology company to adding its own care delivery platform and "becoming a provider trying to manage patients [remotely] to ultimately drive the right clinical outcomes."

What makes the platform different from other virtual care solutions on the market is it is disease-agnostic, acuity-agnostic and site-of-care agnostic, Majmudar said.

> *"We actually have machine learning models that are FDA cleared to interpret that data in a way that has more clinical relevance but also reduces the false alarm burden and alarm fatigue. " - Biofourmis co-founder Maulek Majmudar #HLTH #medtech #HLTH2022 pic.twitter.com/fxUnlSL8J5*
>
> *— Marion Webb (@medtechMarion) November 16, 2022*

More than 30 hospital clients use the Biofourmis platform for acute care or hospital-at-home patients, post-acute care for patients who were discharged from a hospital bed, and chronic disease management where patients receive devices for at-home monitoring, Majmudar said.

In 2023, Majmudar plans to expand the customer base to include risk-bearing payers and scaling health system partners. On the data side, Biofourmis will focus on building more sophisticated and disease-specific models to provide "personalized predictive care" as to predict adverse events before they happen.

The platform integrates 20-30 agnostic devices, which means that patients can be managed for the right clinical disease process, he said. Physicians can access patient data on a clinical dashboard, respond to alerts and communicate with patients via audio and video chats.

"The dashboard is so critical because medication recommendations come from the doctors," and the software automatically recommends new medications for eligible patients, he explained. Biofourmis also has a 24/7 clinical care team that can escalate issues to doctors.

"That combination of a technology platform, plus some optional services, really makes a true end-to-end system," he said. Patients can also access data via a companion app on their smartphone.

Asked about the biggest opportunity in remote patient management, Majmudar said, that the hospital-at-home model is new and disruptive, post-acute care is a huge opportunity, but with tens of millions of Americans having chronic disease, the latter is by far the biggest opportunity in terms of volume.

Under the business model, Biofourmis can provide the technology platform to providers. It can also provide the entire service themselves – the technology platform and the clinicians – to

manage patient cohorts. In the latter model, Biofourmis takes on more risk for the opportunity of achieving cost-savings by demonstrating better outcomes.

"I think we're probably in inning two out of four," Majmudar said using a baseball analogy. "We're taking shared risk right now, but not full risk yet. Majmudar pointed out that Biofourmis uses the acronym RPM as "remote patient management" not "remote patient monitoring."

"The difference between monitoring and management is, [in] monitoring, you're just sending a bunch of data to people – 'But are you actually driving some change in outcomes?' We believe to truly succeed and for RPM to grow and scale and be effective, people want to start managing people and actually drive the right outcomes."

Komodo Health

Komodo Health's co-founder Web Sun explained that Komodo Health's "health care map," an artificial intelligence platform that compiles de-identified, anonymized health care data from hundreds of sources and now tracks 330 million patients across "all of their encounters with the health care system."

"We essentially serve as insights regarding those patient journeys through our platform," Sun told *Medtech Insight*. The next level, the "application level," are workflows that are imbedded with insights around patients costs and outcomes for different health care stakeholders.

KOMODO'S CO-FOUNDERS WEB SUN, ARIF NATHOO *Source: Medtech Insight*

The company's customers include life science companies, medtechs, consultancies, health plans and payers. Sun said the firm also inked partnerships such as with *AppliedVR Inc.*, which provides therapeutic virtual reality for pain management and Turquoise Health, which enables price shopping for health care, as well as the Chan Zuckerberg Initiative's Rare As One Network and Stanford University, among others.

Arif Nathoo, co-founder of CEO Komodo Health, said as the "largest aggregator of medical data in the US," Komodo can help medical device companies identify new trial sites and patients in the community that should get to their existing trial site, giving an example. AppliedVR uses the Komodo platform to understand how patients are using their VR-based therapeutics. Last March, Komodo raised $220m in a series E financing round, led by Tiger Global Management, bringing its total funding to $314m, according to Crunchbase reports. The company has made two acquisitions: Mavens, a cloud

computing company, and Breakaway, which provides real-time insights and policy decisions to market access teams.

"It's all about the platform" and expanding on it, Sun said about plans for 2023.

Babson Diagnostics

Babson Diagnostics is hoping to bring broad, routine blood testing with a simple fingertip prick to a pharmacy near you in less than 10 minutes.

At HLTH, Babson Diagnostics focused on demos and "showing people" their work so when it is launch time, "people know about us," David Stein, Babson Diagnostics' CEO told *Medtech Insight*. Stein is the former global head of strategy and president of molecular diagnostics for *Siemens Healthineers AG*, which has a partnership with Babson Diagnostics on the analytics side.

> ***Blood collection co Babson Diagnostics CEO David Stein hopes to bring collection into pharmacies in 2023, pending reg clearance. #hlth2022 pic.twitter.com/0Aj1hcdFxZ***
>
> ***— Marion Webb (@medtechMarion) November 15, 2022***

"We're the only company in the world able to miniaturize assays on the premier Siemens Atellica platform," he said.

In February, Babson Diagnostics announced a long-term strategic partnership with *Becton Dickinson* to bring laboratory testing to retail pharmacies. The partnership builds on a previous collaboration dating back to 2017 to enable retail pharmacies to offer laboratory-quality diagnostic testing by combining BD's capillary blood collection device – in development – with Babson Diagnostics' automated sample handling and analytical technologies, also in development. (Also see "*Digital Health Roundup, July 2021: Exec Chat With DTA, Start-Ups Grab New Funds, Agency Nods*" - Medtech Insight, 24 Aug, 2021.)

BD is developing a collection device to collect blood without accessing a vein, which makes blood testing easier for patients and allows for blood collection from health care workers who aren't trained phlebotomists.

Stein said convenience and having a "more human experience" by avoiding a needle stick in the

arm are the two main benefits that Babson's blood test will offer individuals in the future.

"There's really very limited downside – there might be a few specialty assays that we don't offer," Stein said. The main competitors will be big laboratory testing companies such as LabCorp and *Quest Diagnostics Incorporated*, he said.

The company hopes to introduce its testing services in 2023, pending 510(k) clearance from the FDA. The marketing plans call for launching in metro areas first in Texas where the firm is based, followed by the East Coast. Stein said that there is also a lot of interest for the technology in Europe and Latin America, but the company wants to "have a great launch in the US first."

"Number one is building trust with them [people who want to get their blood tested]," he said. "Number two is with providers, telling them the benefit they will get by their people getting tested."