Expert Perspective

Andy Coravos

Co-Founder & CEO

Elektra Labs

Andy Coravos is the CEO/co-founder of Elektra Labs, building a digital medicine platform focusing on digital biomarkers for decentralized clinical trials. She serves on the Board of the Digital Medicine Society (DiMe), and she's an advisor to the Biohacking Village at DEF CON.

In your mind, where is the digital biomarkers /measurements industry in its lifecycle?

We are in the early days of adopting digital measures into clinical trials. The Digital Medicine Society (DiMe), a 501(c)3 professional society released their crowdsourced Library of Digital Endpoints focused on industry-sponsored studies of new medical products or new applications of existing medical products. They found that over 35 sponsors have used 108 unique digital endpoints (54 as primary endpoints and the rest as either secondary, label claims or exploratory). Most of these were from studies that launched in the past 3 years — so we're early in the process!

If your team is using a digital tool in a clinical trial, submit it to the DiMe Library.

What impact is Covid-19 having on the potential of digital biomarkers/ measurements?

As the COVID-19 outbreak continues to rage on, healthcare practitioners and researchers are searching for better options to provide quality care and research for patients who are travel-constrained and urged to stay at home. Broadly, those running existing trials had to decide if they wanted to (a) not change the protocol and potential put the trial on pause for participants who needed to shelter-in-place and stay at home, (b) use video/phone and conduct the assessments remotely, (c) use a hybrid approach, or (d) develop novel endpoints that might be collected at home without any expert intervention (more described in the DiMe public comment to the FDA guidance on conducting clinical trials at home). As a result, more sponsors and trial providers have been thinking about ways technologies can support the trial and keep patients safely at home.

With all the changes in healthcare, what doors are now wider open for these approaches?

Remote monitoring using connected sensors can offer a more holistic view of a person's lived experience. Chronic conditions and their interventions impact a

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DIGITALBIOMARKERS & DIGITAL MEASUREMENTS

NOVEMBER 17 – 18, 2020 | EDT TIMEZONE

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person's daily life, from vitals to activity to sleep, and many of these remote monitoring tools can better collect that data - learn more in this Nature npj Digital Medicine piece.

What needs to happen next for this industry to reach its potential?

The fundamental goal of any biomedical product evaluation is to assure that, in the intended context of use, the benefits of deploying the technology outweigh the potential risks to the participant/patient and the organization. New technologies bring new benefits and new risks. Namely, with connected sensor technologies it's important to consider (1) validation, (2) security practices, (3) data rights and governance, (4) utility and usability; and (5) economic feasibility (npj Digital Medicine). For instance, people will often ask: "is this sensor validated?" - but the real question is for what purpose? There's new frameworks coming out like the V3 framework, which covers verification, analytical validation, and clinical validation processes and evidence types that can support answering that question (npj Digital Medicine), though I suspect these frameworks will take some time for people to learn about them and have broad adoption.

What are you most looking forward to at The Digital Biomarkers & Digital Measurements Summit?

I'm excited by the range of speakers. Not only are there sponsors, but also security researchers, like Beau Woods, who is a prominent "white hat" hacker. He's written pieces on a Hippocratic Oath for Connected Medical Devices (JMIR). To bring these types of digital measures to market safely and effectively for patients we'll need to have clinicians, sponsors, patients, hackers, regulators and a diverse multi-stakeholder group to be able to answer pressing issues around this new tech.

If you're interested in hearing more from Andy Coravos, she will be sharing more of her thoughts at the Digital Biomarkers and Digital Measurements Summit. On November 17th, Andy is giving a lightning talk titled "What Are the Regulatory Pathways Available?" at 11:20, and participating in the 11:40 panel discussion "What Level of Evidence is Needed to Evaluate Biomarkers and Measurements?" followed by open Q+A.