

# Expert Perspective



**Jennifer Goldsack**  
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Jennifer C. Goldsack co-founded and serves as the Executive Director of the Digital Medicine Society (DiMe), a 501(c)(3) non-profit organization dedicated to advancing digital medicine to optimize human health. Jen's research focuses on applied approaches to the safe, effective, and equitable use of digital technologies to improve health, healthcare, and health research.

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

Funnily enough, the typical industry life-cycle model

does not work for me here. Developing digital biomarkers/ measures requires such close collaboration across a variety of disciplines that Tuckman's "forming, storming, norming, performing" model for team building serves us better.

And I think we're currently in the 'storming' phase where the group — our industry — sorts itself out and begins to gain each others' trust.

Meaningful partnerships between vendors and clinical experts are emerging, we're starting to see success in clinical applications, and trust in this interdisciplinary approach is growing. It's exciting!

## **What impact is Covid-19 having on the potential of digital biomarkers and measurements?**

Covid-19 hasn't impacted the potential of these digital tools. The potential for digital biomarkers/measurements to

1) transform how we define health and disease, 2) provide more complete and holistic information about of an individuals' condition, 3) reduce the burden of seeking medical care or participating in clinical research, and 4) inform better clinical decisions and improve outcomes long preceded the Covid-19 crisis. However, Covid-19 has impacted the appetite of the medical industry to embrace these new tools.

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

The healthcare landscape has never changed so quickly as it has through this Covid-19 crisis: at the peak of the crisis in the U.S., telehealth utilization was up nearly 5,000% on the same day in 2019. Clinical trials have stalled and the industry is scrambling to implement decentralized designs, including a huge reliance on remote monitoring. There is a

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push to use digital biomarkers/measures to power public health initiatives. Right now, all of the doors aren't just open for digital biomarkers/measures, they've been blown off!

## Where is the FDA in their thinking about digital biomarkers/measurements?

I can't speak for our FDA colleagues, but I have heard them tell industry for years that they are very open to the use of digital biomarkers/measurements and welcome discussions to advance them.

We saw strong signals around the use of remote monitoring technologies to power both care and research in temporary guidances issued by the industry.

And most importantly, I've always heard our FDA colleagues say that the development of high quality digital biomarkers/measurements requires forward movement by both regulators and industry. Our [DiMe endpoints library](#) now lists over 100 unique digital measures being used in industry sponsored studies of new medical products. We can likely attribute this to both forward thinking regulators and innovative industry approaches.

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

Common frameworks for evaluating digital biomarkers/measures are emerging and being broadly adopted. Operationalizing

them within clinical workflows and ensuring equity must be next on deck.

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

The Summit could not be coming at a better time. The agenda brings all of the disciplines necessary to advancing the safe, effective, ethical, and equitable use of digital biomarkers/measures to the table. This will provide an important opportunity to think collectively about how to implement these measures at scale for improved outcomes.

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*Jennifer will be sharing more of her thoughts on November 17th, where she is the chair of the Digital Biomarkers and Digital Measurements Summit Day 1. She is also giving a presentation titled "Clearing The Cloud and Clarifying The Space: Defining Digital Biomarkers, Digital Measurements and Digital Endpoints".*