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DIGITAL MEDICINE SOCIETY

What would you say has been the greatest challenge facing the digital biomarkers industry in 2022?

The field of digital clinical measurement has matured dramatically in recent years. We have moved beyond the initial questioning of whether these new, digital streams of data are valuable and if we should have a digital measurement strategy.

Now we are facing questions of scale – how do we find vendor partners who can deliver full stack solutions that meet our needs? How can we integrate high-velocity flows of sensor data from multiple sources into our systems without needing to engineer bespoke point solutions each time? How can we ensure that we advance equity and inclusion in our trials as we reach for new digital solutions? These new questions are remarkably different from those we were asking a few short years ago, which demonstrates the rapid advancement in this part of our field. Medical product developers that aren't asking these questions of scale risk being left behind.

This shift underscores the imperative for a robust digital strategy, and one that is thoughtfully addressed to drive further progress. I'm proud of how we're tackling these challenges at DiMe and the resources we've already created with our partners to guide the way forward.

What are the key changes needed to be made at the regulatory level to help integrate digital into healthcare?

To take this question in a different direction, I think that we need to stop over-anchoring the regulatory requirements of market access for digital products. That's not to say it's not important – we have a thriving project addressing exactly this issue here at DiMe – but we're not poised for success if we believe that the regulatory environment is the limiting factor to the effective digitization of healthcare.

First, we need to make products that address real needs for patients and clinicians and that actually contemplate 1) the complexities of the clinical environment and workflows, and 2) real life for patients from every walk of life.

Second, and as we've seen with several digital therapeutic products, regulatory acceptance doesn't unlock unfettered market access. We also need distribution channels, data infrastructure, and reimbursement mechanisms that support the integration of digital into healthcare.

Finally, we need to move beyond the mentality that regulatory requirements are an impediment to forward progress and start embracing regulatory strategy as part of the overarching business strategy for digital health companies.

How has digital medicine changed over the past two years?

This is a big one! To some extent, it hasn't. We've seen some evolution in technologies, like sensors and algorithms, and we've seen solutions continue to mature and become more complete, moving from individual point solutions to integrated tech stacks. But I think the primary driver of digital innovation change has been the evolving ecosystem.

Leading organizations are embracing collaboration and increasingly working in the pre-competitive environment to commoditize parts of the industry to promote differentiation at the bleeding edge. An example of this is DiMe's work on pre-competitive development of digital endpoints (our work on

Nocturnal Scratch, Alzheimer's and Related Dementias, and upcoming projects on Physical Activity and Sleep). We're also seeing regulations continue to mature through new guidances from FDA and FTC activity on critically important topics such as data privacy. New payment mechanisms are emerging, such as new therapeutic monitoring billing codes, and we're starting to see coordinated efforts at the federal level to support data infrastructure suitable for the digital era of health.

It's this ecosystem level change that I think marks the beginning of a new wave of advancements in digital medicine, supporting the use of digital technologies to improve lives.

What steps are DiMe taking to help reshape healthcare in the near future?

I'm proud to share that we've launched our educational programming, The Digital Medicine Academy, to further support our project activities. Building on an initial round of CME courses for physicians that we launched earlier this year, we're now offering corporate education licenses to pharma and their partners to ensure that foundational digital capabilities are understood and supported at the organizational level. As we look to scale the use of digital solutions to speed the development of effective new therapies to patients, it's insufficient to have digital expertise siloed within digital or innovation teams. Effective digital strategies in drug development require upskilling and supporting every member of the organization to ensure they are positioned for success.

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

The agenda is tremendous and reflects the tip of the spear of innovation in our field. I'm excited that the focus is on implementation and that we'll have the opportunity to hear from expert presenters who have already proven successful in implementing digital at scale to improve the lives of patients.