



DIGITAL BIOMARKERS & DIGITAL MEASUREMENTS

1-2nd November, 2023

Boston, MA

Conference Day 1 | 1st November, 2023

8:00am **Registration, Breakfast and Networking**

9:00am **Chair's Opening Remarks**

Tarik Yardibi, Director, Sensing and Measurement, [Takeda](#)

9:10am **Keynote Presentation: What does the Future of Drug Development look like with Integrated Digital Biomarkers, Digital Measurements and Digital Endpoints?**

The utilization of digital innovation and solutions are now integrated across the entirety of the healthcare system with success. However, uptake for digital solutions within the clinical trial process has been much more of a challenge. With the opportunity to reduce development time frames, improve patient experience and significantly lessen the costs of clinical trials, digital innovation in this field is paramount in the continuous and high quality development and delivery of new therapies for patients.

- Understanding the current landscape of digital biomarkers and digital measurements industry
- How can these digital solutions innovate within clinical trials to improve processes and increase patient outcomes?
- What is the most exciting part of this industry, where are the greatest opportunities and what are the key challenges?

Candice Taguibao, Program Lead, [Digital Medicine Society \(DiMe\)](#)

9:35am **Keynote Panel Discussion: Striding Past the 6-Minute Walk Test | Building a Consensus Set of Digital Measures for Physical Activity**

Physical activity, often recognized as a 'sixth vital sign', is essential for the maintenance of health across virtually all therapeutic areas. But with more than 70 unique digital endpoints for physical activity currently in use across the field,

our progress as a field is stifled by lack of alignment and consistency. This panel, represented by leaders of DiMe's Digital Measures Development in Physical Activity project, will discuss how we can move away from innovating in siloes and demonstrate how their multi-stakeholder collaboration has paved the way toward a consensus set of digital measures in physical activity. During the panel, we will:

- Define the value proposition for developing a consensus digital measure set that are meaningful to patients and reflect measurable concepts of interest
- Showcase the process of developing a consensus measure set for physical activity
- Discuss how we hope to translate the lessons learned in this collaboration to other aspects of digital measure development, adoption, and scale

Moderator: **Candice Taguibao**, Program Lead, [Digital Medicine Society \(DiMe\)](#)

Alan Hamilton, Senior Director of Research, [COPD Foundation](#)

Kieran Reid, Director, Laboratory of Exercise Physiology and Physical Performance, [Brigham and Women's Hospital](#)

Ankita Deshpande, Head Digital Health and Experience Innovation, [Alexion Pharmaceuticals](#)

Eric Mangin, Pharmacokinetic Associate, [Merck](#)



10:20am

Morning Refreshments & Networking

11:00am **Panel Discussion: Demystifying the Digital Biomarker & Digital Measurement Regulatory Landscape**

One of the greatest challenges faced by this industry has been navigating the regulatory landscape and, although there have been some recent success stories, there is still a long way to go until digital health measures are widely approved for clinical use. This panel will explore the complexities of obtaining regulatory approval, ensuring validity and quality, navigating evolving guidelines and identifying key strategies for the successful implementation of digital biomarkers and digital measurements.

- What are the current regulatory frameworks and guidelines governing the use of digital health measures, biomarkers, and measurements in clinical trials and healthcare?
- What are the key challenges and barriers in obtaining regulatory approval for digital biomarkers and measurements, and how can they be addressed?
- How are regulators adapting to the rapid pace of innovation in the digital health field to keep up with emerging technologies and novel measurement methods?
- What are the recent updates or initiatives in the regulatory landscape that impact the use of digital biomarkers and measurements in healthcare, and what implications do they have for industry stakeholders?

Moderator: **Regina Druz**, Digital Health Expert, [FDA Advisor](#)

Lori Roadcap, Senior Director, Global Regulatory Strategy and Policy for Precision Medicine, Diagnostics and Digital Health, [Bristol Myers Squibb](#)

Steve Berman, Senior Director, Science & Regulatory Affairs, [BIO](#)

Subramanya Prasad Peri, AVP Regulatory Affairs Connected Delivery, Devices, and Digital Health, [Eli Lilly](#)

11:45am **Panel Discussion: From Analog to Digital | Reinventing Endpoints for Clinical Trials**

The utilization of digital endpoints has been an ongoing process for the industry filled with peaks and troughs. In the past year, there have been newly approved digital endpoints and others that have shown success in trials despite the drug failing, and the importance and the innovative opportunities these can provide cannot be understated. This panel, led by experts from in the field, will explore the current pipeline of digital endpoints, the opportunities they can provide in the clinic and identify how best, as an industry, we can advance these into use for new drug development.

- Defining a digital endpoint and outlining why these endpoints can improve the clinical trial process
- What are the key considerations when selecting and validating digital endpoints for clinical trials?
- How can digital endpoints enhance the accuracy and efficiency of data collection? How do these compare with traditional endpoint data collection and monitoring and how can we prove the value of these novel endpoints?
- What are the regulatory barriers preventing wide scale adoption of digital endpoints and how can these be overcome?
- What are the unique considerations of handling continuously collected data from DHTs?
- Where are we seeing the most success with digital endpoints and how can this be developed across numerous disease states?

Moderator: **Andrea (Andy) Coravos**, Co-founder and CEO, [HumanFirst](#)

Carrie Northcott, Senior Director, Digital Medicine and Translational Imaging, [Pfizer](#)

Abhishek Pratap, Senior Clinical Program Leader, CNS, [Boehringer Ingelheim](#)

Ariel Dowling, Senior Director, Head of Sensing and Measurement, [Takeda](#)

Jen Blankenship, Senior Research Scientist, [VivoSense](#)



12:30 PM Lunch & Networking

⚡ Lightning Talk Sessions ⚡

The Lightning Talk Sessions in our conference agenda are a series of three succinct and dynamic 20-minute presentations by leading companies in the digital biomarker and digital measurements industry. These sessions aim to provide a quick but informative glimpse into the latest innovations, technologies, and trends shaping this field. Attendees will gain valuable insights and actionable knowledge to stay at the forefront of digital biomarkers, health and diagnostics

2:00pm Enabling Precision Medicine and Clinical Innovation in Neurology through Eye Movement Biomarkers

Explore how eye movement biomarkers are revolutionizing neurology, enabling precise diagnostics and groundbreaking clinical advancements in just 20 minutes. Join us on a journey into the future of personalized medicine in neurology.

Vivian DeWoskin, Chief Commercial Officer, [NeuraLight](#)



2:20pm Enrichment Based on Speech Features during Structured Psychiatric Interviews Improves Treatment Effect in a Clinical Trial

Clinical trials in the challenging landscape of CNS (Central Nervous System) research often face formidable hurdles. Low approval rates, the influence of placebo responses, the presence of "professional patients," heterogeneous symptom presentations, and reliance on subjective clinical ratings collectively underline the urgent need for innovative strategies to improve trial outcomes. In this presentation, we explore the potential of objective speech features as an enrichment tool, with a focus on their application in the context of bipolar depression trials.

Sam Tomioka, Executive Director, Clinical Analytics Head, [Sumitomo Pharma America](#)

2:40pm Unlocking Remote Patient Monitoring in Eye Care: Creating Digital Biomarkers for Ophthalmology using Simple Smartphone Games

Delve into the world of remote patient monitoring in eye care as we unveil how simple smartphone games create digital biomarkers for ophthalmology, revolutionizing patient care. Join us for a glimpse into the future of eye health through innovative technology.

Stephanie Campbell, Founder & CEO, [OKKO Health](#)

3:00pm Presentation: Clinical Intelligence Engine | Leveraging Digital Measures for Real-Time Personalized Medicine

This presentation will explore how remote patient monitoring combined with real-time AI analytics can improve clinical trials and provide the opportunity for healthcare to become much more personalized. Strategic adoption of decision-making models based on continuous digital data and dynamic clinical forecasting has the potential to accelerate early detection and facilitate rapid intervention.

- What is the role of digital health measures in matching patients to the right trial/treatment?
- How to deploy personalized digital measures that matter to patients?
- Should data from wearable devices become an integral part of EMR?
- What are the next steps in scaling digital solutions for improved personalized medicine?

Amir Lahav, Digital Health Advisor, [Pharma & MedTech](#)

3:25pm

Afternoon Refreshments & Networking

4:10pm Presentation: Paying for Progress | Understanding the Payer Perspective on Reimbursement for Digital Health Measures

The reimbursement landscape within the digital health industry has been an ongoing challenge and, although there have been a number of early successes, these have been few and far between. For the industry to truly stand on its own two feet, creating a path for replicable and reliable reimbursement is crucial.

- What challenges do payers encounter when determining reimbursement policies for digital health technologies, and how can these challenges be addressed?
- How do payers evaluate the value and cost-effectiveness of digital health measures and biomarkers for reimbursement purposes? Can this be aligned with evidence standards required for regulatory approval?
- With varying routes for reimbursement for digital health tools, where have we seen success within the industry?

Sara Parsons, Strategic Business Lead, Clinical Innovation, [Point32Health](#)

4:30pm **Panel Discussion: Unlocking Collective Potential | Collaborations and Partnerships for Driving Adoption and Implementation of Digital Biomarkers**

Collaborations and partnerships across the industry have proven crucial for the implementation and adoption of digital biomarker and digital measurement solutions. For continued success, it's important that these partnerships are built in the right way and each collaborator plays to their strengths. This panel, led by leading collaborators in the field, will explore what makes a strong partnership and the impact this can have in the successful implementation and adoption of digital biomarkers.

- How can collaborations between pharmaceutical companies, digital solution providers and healthcare organizations drive the adoption and implementation of digital biomarkers and digital measurements?
- Understanding the roles pharma, digital solution providers, payers and healthcare organizations play within partnerships and defining the optimum roadmap for partnership success
- How does the maturity and quality of evidence impact the structure or nature of the approach pharma takes in partnering?
- What are the key success factors and lessons learned from existing collaborations in the digital biomarkers space?

Moderator: **Tarik Yardibi**, Director, Digital Health, [Takeda](#)

Sarah Ernst, Head of Clinical Innovation Strategy and Implementation, [Sanofi](#)

Sara Parsons, Strategic Business Lead, Clinical Innovation, [Point32Health](#)

Jamileh Jemison, Medical Director, [MindMed](#)

5:15 PM **Chairs Closing Remarks**

Tarik Yardibi, Director, Sensing and Measurement, [Takeda](#)

Close of the Digital Biomarkers & Digital Measurements Summit Day 1

Conference Day 2 | 2nd November, 2023

8:00am Registration, Breakfast and Networking

9:00am Chair's Opening Remarks

Benjamin Vandendriessche, Chief Medical Officer, [Byteflies](#)

9:05am Keynote Fireside Chat: The Role of Digital Biomarkers and Wearables in Patient-Centric Care

The benefits of digital biomarkers and digital measurements within clinical trials and the benefits it can provide for pharmaceutical companies are routinely covered. However, to stay truly patient-centric, it's important to understand how these digital health measures can positively impact the patient experience while addressing any detrimental impact these novel solutions may have.

- How are digital health measures working to drive a truly patient-centric healthcare system?
- Can digital biomarkers and digital measurements build a patient-centric healthcare system and what will it take for us to get there?
- Are we seeing the desired results from these novel digital solutions and can we be sure there is no detriment to the patient experience or journey?

Moderator: **Benjamin Vandendriessche**, Chief Medical Officer, [Byteflies](#)

Robert Goldel, Health Tech Expert, [Formerly LG Electronics](#)

Viviktha Ramesh, Clinical and Evidence Expert, [Roche Information Solutions](#)

9:35am Keynote Panel Discussion: The Patient Perspective | Ensuring Privacy and Building Trust in Digital Health Measures for Patients

The use of digital health solutions can be a daunting task for patients that have been more used to traditional approaches. However, with digital here to stay, it's important that patients are introduced to these novel solutions in the right way and given every opportunity to be involved with their own healthcare. This panel, led by senior healthcare leaders, will explore how best to introduce these solutions to patients to ensure their continued adherence and improve patient adoption.

- Assessing the current patient perspective on the use of digital solutions and wearables within their healthcare journey.
- Are there certain disease areas that provide a more accessible digital experience for patients? How can we continue to explore additional areas to improve data collection, healthcare quality and patient outcomes?
- Are there patient segments or points in the patient journey that are more accepting of digital health solutions?
- How can we increase digital health adoption and acceptance to the wider population?

Moderator: **Viviktha Ramesh**, Clinical and Evidence Expert, [Roche Information Solutions](#)

Iraklis Kourtis, Director, Digital Strategy, [Takeda](#)

Jacqueline Lutz, Former Medical Science Lead, [Biogen](#)

Jamileh Jemison, Medical Director, [MindMed](#)
Laura Taraboanta, Director, Medical Operations & Strategy, [Click Therapeutics](#)

10:15 AM Morning Refreshments & Networking

11:00am **Presentation: Assessing the Net Financial Benefits of Employing Digital Endpoints in Clinical Trials**

Sarah Valentine, Partnerships Manager, [Digital Medicine Society](#)

11:25am **Panel Discussion: What will it take for Digital Biomarkers and Digital Measurements to Break Through the Glass Ceiling?**

Digital biomarkers and digital measurements are in a dynamic and evolving state, with ongoing advancements in technology and research indicating promising potential for transforming healthcare. This panel will explore the challenges and opportunities surrounding the widespread adoption and acceptance of digital biomarkers and measurements in healthcare, delving into key areas that need attention for these technologies to reach their full potential and overcome existing barriers.

- What are the benefits of digital biomarkers and digital measurements in improving patient outcomes and healthcare quality?
- How can we address the current challenges in adopting digital biomarkers and measurements in healthcare?
- How can cross-organizational collaboration be leveraged to advance the field and overcome challenges?
- What measures can be taken to promote the successful development, adoption, and integration of digital biomarkers?
- How can we implement strategies to ensure that digital biomarkers in healthcare achieve sustainable innovation and long-term viability?

Moderator: **Sarah Valentine**, Partnerships Manager, [Digital Medicine Society](#)
Carrie Northcott, Senior Director, Digital Medicine and Translational Imaging, [Pfizer](#)
Sachin Shah, Digital Biomarker Lead, [GSK](#)
Robert Goldel, Digital Biomarkers Advisor, [Why Profit?](#)

12:05 PM **Chair's Closing Remarks**

Benjamin Vandendriessche, Chief Medical Officer, [Byteflies](#)

Close of the Digital Biomarkers & Digital Measurements Summit Day 2