DIGITAL BIOMARKERS & DIGITAL MEASUREMENTS

June 21-22, 2023
Bay Area, CA

Conference Day 1
8:00 AM Registration, Breakfast and Networking
9:00 AM Chair's Opening Remarks
9:10 AM Keynote Presentation: The Current Landscape of the Digital Biomarkers and Digital Measurements Field Digital medicine continues to evolve at a rapid pace. From payers to providers to drug developers and tech innovators, stakeholders across our field are paving the way for the future of digital biomarkers and digital measures. But what lies ahead? Join Jen Goldsack, the CEO of the Digital Medicine Society, to discuss the current state of the field, the most pressing challenges we collectively face, and the opportunities we have to achieve the promise of digital medicine to redefine healthcare and improve lives. ● Show, don't tell: the value of digital measures ● Preparing for the scale of digital biomarkers and digital measures

- Leveraging partnerships to drive the continued growth of our field

Jennifer Goldsack, Chief Executive Officer, **DiMe**

9:35 AM Keynote Panel Discussion with Open Q&A: DiMe Project Update

Leaders from across the field are laying the foundation to scale digital biomarkers and digital measures more broadly in their organizations and beyond. Join some of the leaders and pioneers at the forefront of this space to learn how they've applied industry best practices to develop measures targeting specific meaningful aspects of health, contexts of use, and concepts of interest. Hear the importance of designing measures and technologies that are fit for purpose and meaningful in order to build a trustworthy evidence base and continue progressing our field.

- Developing a core digital measure set across Alzheimer's Disease and Related Dementias
- Taking an omni-therapeutic area approach to develop digital measures in Physical Activity and Sleep
- Paving the way for usability and human-centered design in digital measure development

Jennifer Goldsack, Chief Executive Officer, **DiMe**
Thomas Switzer, Head, Digital Health – Genentech Research and Early Development (gRED) Early Clinical Development Informatics, **Genentech**
Geoff Wylde, Head of B2B and BD, **Oura**

10:20 AM Morning Refreshments & Networking

Regulation

11:00 AM Presentation: An Overview of the Regulatory Landscape: What has been Done, What is Happening Now and Where Will it Go?

- A deep dive into the current regulatory landscape
- What strategies have been successful with working through the regulatory pathway?
- Exploring how the regulatory landscape is going to evolve over the coming years

Elizabeth Kunkoski, Health Science Policy Analyst, **FDA**

11:25 AM Panel Discussion with Open Q&A: Navigating the Regulatory Landscape: Strategies for Success

Successfully translating a new and innovative product from concept to clinical use is complex and requires overcoming a variety of challenges. One hurdle in particular is navigating the regulatory pathway to obtain regulatory approval. This process is challenging and requires collaboration between a variety of stakeholders. This panel discussion will highlight strategies and best practices to successfully work through the regulatory process, highlighting case studies which have gone through this process.

- What success stories have you seen with a digital biomarker working through the regulatory pathway?
- What challenges have arisen when navigating the regulatory landscape, and how were these challenges overcome?
- How can we build a defined route towards regulatory approval?
- When in the process should regulatory bodies be brought into the discussion?
- Are multi sector partnerships key to driving policies and regulations?

Steve Berman, Director, Translational Regulatory Affairs, **AstraZeneca**
Kyle Zebley, Senior Vice President, Public Policy**, American Telemedicine Association**

12:10 PM Lunch & Networking

Commercialization and Reimbursement

1:30 PM FireSide Chat with Open Q&A: An Overview of the Current Reimbursement Landscape

- A deep dive into what has been done and where we are now.
- Covid created a lot of dynamics in this field, but as we move to a post Covid era, what is this space going to look like?
- How can we navigate the reimbursement landscape?

Benjamin Vandendriessche, CMO, **Byteflies**
Jay Ahlman, Vice President, Coding and Reimbursement, **American Medical Association**

2:00 PM Panel Discussion with Open Q&A: What's the Payoff: Why Should We Invest Time and Energy into Developing Digital Biomarkers

and Digital Measurements?

The pandemic has catalyzed huge interest and drive in the digital biomarker space but we are yet to see the uptick with adoption from stakeholders. This panel will dive into the business cases to convince executives from pharma, payers, providers, and venture capital firms to invest in these innovative tools.

- What would incentivise faster adoption from different stakeholders?
- What is the incentive for venture capital firms to invest in companies developing digital biomarkers?
- From the pharma perspective, what is the business case for pushing digital biomarker development and utilization?
- Are payers looking to reimburse these tools? How do we convince payers to reimburse digital biomarkers?
- How do we get providers on board with integrating digital tools into their workflow?

Raj Pallapothu, Executive Chairman, **Bio 9 Ventures**
Ron Li, Medical Informatics Director for Digital Health, **Stanford Health Care**

2:45 PM Afternoon Refreshments & Networking

Increasing Adoption Throughout Healthcare

3:30 PM Presentation: Increasing Provider Adoption of Digital Biomarkers and Digital Measurements in the Clinic

- What is the provider's perspective of using these digital tools within the clinic?
- How would these digital tools integrate into the current clinicians workflow?
- How can these digital tools innovate the pathway to high quality care?

Yauheni Solad, Vice President of Innovation, **UC Davis Health**

3:55 PM Presentation: Developing a Generalized Framework to Predict Achievement of End-Study Clinical Targets

- Shorten iteration cycles for development of digital health interventions, and thereby increase rate of product improvement

- Identify patients unlikely to achieve treatment response and correct course earlier, often by switching and/or intensifying ("right sizing") the intervention
- Help identify, early in product development, whether clinical value may differ in historically underserved patient groups.

Jordan Silberman, Director of Clinical Analytics and Research, Digital Care Delivery, **Elevance**
Brad Wagner, Clinical Research Data Director/Data Scientist, **Elevance**

4:20 PM Closing Panel Discussion with Open Q&A: Increasing Adoption of Decentralized Clinical Trials

It is generally accepted, even before the pandemic, within the industry that decentralized clinical trials have many benefits, can decrease the costs of clinical trials, increase adherence and ultimately improve clinical trial success. Despite this understanding, decentralized clinical trials are still not commonplace, and we still have a long way to go with adoption. This panel will dive into the challenges of decentralized clinical trials, and how we overcome these to increase adoption.

- How can digital biomarkers and measurements streamline clinical trials and make them more efficient?
- What are the challenges with decentralized clinical trials, and how do we overcome these challenges?
- What is stopping decentralized clinical trials becoming commonplace? Despite the interest, why are we not there yet?
- How do we ensure the data we are collecting from digital tools is of high quality? Can we trust the data?
- How can we improve data acquisition and tackle the issue of data 'missingness' with decentralized trials?
- What do patients think of these new digital tools? Do they want to be monitored?
- Have we seen success with decentralized clinical trials

Andrea (Andy) Coravos, Co-founder and CEO, **HumanFirst**
Michelle Holko, Principal Architect Public Sector Cloud for Healthcare and Life Sciences, **Google**
Larsson Omberg, VP, Systems Biology, **Sage Bionetworks**
Thomas Switzer, Head, Digital Health - Genentech Research and Early Development (gRED) Early Clinical Development Informatics, **Genentech**

Chairs Closing Remarks

Conference Day 2

8:00 AM Registration, Breakfast and Networking

9:00 AM Chair's Opening Remarks

Case Studies

10:00 AM Panel Discussion with Open Q&A: DiMe Resources in Action - How Have DiMe's Resources been Leveraged to Develop Digital Tools?

DiMe's core activities of applied research and education bring together cross-ecosystem partnerships to address the greatest opportunities and needs of our field and result in actionable resources that are publicly available. Join thought leaders and experts as they discuss how they've put DiMe's resources in action and how they've been able to leverage toolkits and partnerships with other organizations to advance digital innovation more broadly.

- Explore practical implementations of DiMe resources and toolkits
- Discover how organizations are systematically embedding industry best practice and external insights into internal processes
- The less tangible benefits of pre-competitive collaboration: opportunities for market development and thought leadership

Jennifer Goldsack, Chief Executive Officer, **DiMe**
Emily Lewis, Global Digital Transformation Lead, Neurology**, UCB**
Celine Marquez, Global Medical Director, Digital Health Technologies**, Genentech**

10:45 AM Morning Refreshments & Networking

The Future for Digital Biomarkers

11:00 AM Presentation: Scaling Digital Measurement Tools

- Where must we innovate to successfully and sustainably scale digital biomarkers and digital measurements?
- What challenges must we overcome, and what infrastructure needs to be put in place to scale these tools?
- Are partnerships key for scaling digital biomarkers?

Andreas Caduff, DiMe Founding Council Member

11:25 AM Presentation: Increasing Trust in Digital Biomarkers Through Establishing Data Privacy and Security Requirements

Nick Bott, Global Head, Bioethics, Technology Ethics & Responsible Innovation, **Takeda**

11:50 AM Closing Panel with open Q&A: What is the Next Frontier for Digital Biomarkers and Digital Measurements?

The pandemic fueled a surge of interest for the use of Digital Biomarkers and Digital Measurements, and we are currently seeing a lot of noise in the space. We are just scratching the surface with the possibilities that Digital Biomarkers and Digital Measurements can achieve. What is the future for digital biomarkers, and what is the roadmap for getting there?

- What challenges still need to be overcome to push digital biomarkers and digital measurements further?
- How can we truly establish digital biomarkers as a pillar within the healthcare system?
- What needs to be implemented to ensure greater success for digital biomarker development and adoption?
- What are the opportunities for cross organizational collaboration that is going to move the field forward?
- How do we get Digital Biomarkers into the Hands of the Consumer or Patient?
- How do we ensure sustainable innovation?

Anders Strömberg, Director, Head of Health Solution Division, **Sony Network Communications Europe**
Aman Thukral, Director, Clinical Systems And Digital Operations, **AbbVie**
Yasaman Damestani, Director, Head of Digital Medicine, **Karyopharm Therapeutics Inc.**
Bhaskar Dutta, Head of Digital Health Program Management, **Alexion Pharmaceuticals, Inc.**
Sheraz Khan, Director Data Science, **Pfizer**

Eli Snell, Head of Engineering - Digital Health Solutions, **Roche**
Chair's Closing Remarks