DIGITAL BIOMARKERS & DIGITAL MEASUREMENTS

REVOLUTIONIZING HEALTHCARE THROUGH DIGITAL INNOVATION

Tuesday 18th & Wednesday 19th October 2022

Boston, Massachusetts

Conference Day 1 - Tuesday, 18th October
8:00am Registration, Breakfast and Networking
9:00am Chair's Opening Remarks **Emily Lewis**, Global Digital Transformation Lead, Neurology, **UCB**
9:05am Keynote Presentation: Preparing For the First Digital Endpoint to be Accepted by Regulators as Part of an Approval or Label for a New Drug: Are you Ready? **Jennifer Goldsack,** Chief Executive Officer, **DiMe**
9:30 Keynote Panel Discussion: Beyond Regulators: How DiMe is Working to Define the Value of Digital Endpoints to All Stakeholders • What steps must be taken by digital measure developers to successfully demonstrate the value of digital biomarker and digital measurement tools? • What is the current appetite of different stakeholders to rely on sensor generated data for decision making? • How can digital health companies optimize their evidence generation plans to meet the needs of all users?

Jennifer Goldsack, Chief Executive Officer, **DiMe**
Marissa Dockendorf, Executive Director, Head of Global Digital Analytics & Technologies, **Merck**
Ronnie Sharpe, Co-Founder & COO, **Savvy Cooperative**

10.10am	**Morning Refreshments & Networking**

Commercialisation and Reimbursement

10:40am Case Study: Learnings From the First Pre-Competitive Development of a Digital Endpoint for Use in Clinical Trials: DiMe's Nocturnal Scratch Initiative

Jennifer Goldsack, Chief Executive Officer, **DiMe**
Carrie Northcott, Director, Digital Medicine & Translational Imaging - Early Clinical Development, **Pfizer**
Alexander Everhart, Post-Doctoral Fellow, **Harvard Business School & The Harvard-MIT Center for Regulatory Science**

11:10am Presentation: The Clinical Imperative for the Establishment of Digital Biomarkers

- Published data demonstrating the significance of real-world data and digital biomarkers are broad and deep, spanning virtually all major TAs
- Digital measures from the real-world setting take on disease-specific significance when applied intentionally to a target population or study cohort
- The process for digital biomarkers to be advanced to qualified study endpoints for research and clinical development has begun

Arthur Combs, Senior Clinical Advisor, **Activinsights**

Activ insights

11:35am Presentation: Low-cost Self Administration of Digital Health Measures in Studies Using Collaborative Development and Validation Measures

- Consortia methods for developing and validating novel digital measure.
- Crowd sourcing methods for deriving new digital biomarkers
- Mobile Toolbox - A collaborative open source platform for building research studies using digital health technologies. Including abilities for others to contribute new measures and technology to the community.

Larsson Omberg, Vice President, **Sage Bionetworks**

12:00pm Panel Discussion: Can We Scale Digital Biomarkers and Digital Measurements Across the US and Beyond?

Even off the back of the COVID-19 pandemic it is evident that even with digital health technological advancement, reimbursement, regulation and adoption remain an obstacle. In this panel discussion we assess whether or not digital endpoints can be successfully integrated into healthcare on a global scale given the challenges currently posed by the industry.

- Where must we innovate commercial strategies to successfully scale digital endpoints globally?
- Who do digital biomarker companies need to be partnering with to help scale their business effectively?
- What is the risk profile for digital biomarkers companies and how can we define this?
- How are companies managing to stay afloat whilst reimbursement and adoption continue to be an issue?
- How can digital health companies successfully approach payers and improve their communication to get their products reimbursed?
- What is the ecological validity of digital biomarkers? Can we truly use these products in real-world settings?
- Moving forward, what actions must be taken by all stakeholders in the space to break digital biomarkers and digital measurements tools into mainstream healthcare?

Moderator: Wasim Malik, Managing Partner, **Iaso Ventures**
Benjamin Vandendriessche, Chief Medical Officer, **Byteflies**
Sarah Ernst, Senior Director of Digital Strategy & Partnerships, **Sanofi**
Everett Crosland, Chief Commercial Officer, **Cognito**

VivoSense

Ieuan Clay, DIrector of Science, **Vivosense**

12:45pm	**Lunch & Networking**

1:45pm Presentation: Building Confidence in Digital Biomarkers and Remote Monitoring Solutions

- How do you integrate digital measurement into clinical trials as novel endpoints?
- What are the barriers and enablers to digital biomarker adoption for early detection of diseases?
- How do you leverage digital biomarkers to drive therapeutic value to patients?

Amir Lahav, Digital Healthcare Innovation, Head of Strategic R&D, **Mitsubishi Tanabe Pharma America**

2:10pm Presentation: Why Interoperability is the Next Milestone for Digital Measurement

Anzar Abbas, Director of Digital Solutions, **Cambridge Cognition**

CAMBRIDGE COGNITION

2:35pm Presentation: The Challenges and Significance of Measuring Digital Sleep Endpoints in Clinical Trials - A Concrete Use Case

- What are the biggest unmet needs in digital biomarkers in sleep?
- How do you redefine the gold standard in sleep assessment ? A consensus approach
- How digital biomarkers apply in the diagnosis of Narcolepsy and the monitoring of treatment response?

Pierrick Arnal, Chief Science Officer, **Dreem**

dreem

3:00pm Panel Discussion: What Steps Still Need to be Made Before Decentralized Clinical Trials Are Adopted into Healthcare Strategy?

Decentralized clinical trials has fallen on the lap of the industry over the past few years and continues to be at the forefront of the discussion within digital health. Regardless, the adoption of this practice is still yet to take off. Here, we explore why clinical research has been reluctant to explore this route and what leaps are yet to be made within the healthcare industry to accelerate the adoption of decentralized clinical trials.

- A look into the benefits and limitations of using decentralized clinical trials over a site-based system - where are we today?
- How are sensors and wearable technologies used to better patient engagement and outcomes in remote clinical trials?
- What are the biggest challenges that come with launching decentralized clinical trials?
- COVID-19 helped bring measurement tools to light, but has this truly kickstarted the adoption of decentralized clinical trials?
- How can digital biomarkers and measurement tools streamline clinical trials and make them more efficient?
- How do you validate novel digital endpoints?
- How can companies approach concerns regarding socio-economic and racial equity in clinical trials?
- What are the next steps for the digital biomarker community to successfully adopt decentralized clinical trials?

Moderator: **Thomas Switzer**, Head, Digital Health - gRED Early Clinical Development, **Genentech**
Abhishek Pratap, Head of Data Innovation, Biogen Digital Health, **Biogen**
Dexter Hadley, Chief of Artificial Intelligence, **UCF**
Andy Coravos, Co-Founder & CEO, **HumanFirst**
Tim Callahan, VP Scientific Affairs, **Philips Pharma Solutions**
Rob Wilson, Vice President of Marketing Strategy, **Vivosense**

3:45pm	**Afternoon Refreshments & Networking**

Collaboration

4:15pm Fireside Chat: Real-time Sensor Data and Digital Health: Harnessing Actionable Insights in Managing Chronic Conditions

- Insights into how digital biomarkers can consist of interoperable components giving them modularity.
- How can additional sensors be stacked onto your product to enhance sensitivity and specificity of data collection?
- How can companies collaborate so digital biomarkers can be compatible with multiple devices and electronic interfaces treating a disease?

Anand Iyer, Chief Strategy Officer, **Welldoc**
Keri Leone, Senior Director Global Medical Science & Communications, **Dexcom**

4:45pm Presentation: Utilizing Smart Insoles to Assess Early Signs and Progression in Parkinsonian Gait – Application in Clinical Research in Neurodegenerative Diseases and Beyond

- Gait can be difficult to assess and quantify through the usual clinical evaluation and in addition patient performance is associated with huge variability due to daily fluctuation. Hence, gait parameters as assessed objectively by a digital tool have a huge potential as biomarkers in relation to diagnosis/differentiation, tracking of disease progression, clinical trial outcome, etc., and therefore can support both researchers and clinicians in their decision making.
- The FeetMe devices provide a platform for digital gait measurement the application of which can be adapted to the scope. The smart insoles can collect data ranging from fully controlled settings using standard gait tests to completely remote real life home monitoring, in an objective, quantifiable way, overcoming the limitations of the currently available technologies.
- First insights from a study : monitoring of motor symptoms and disease progression with home based assessments

Alexis Mathieu, Co-Founder & Senior Advisor, **FeetMe**

5:10pm Panel Discussion: How Can We Standardize Clinical Research in the Pre-competitive Stage: Is This the Future of Digital Biomarker Partnerships?

Within the industry there seems to be a recurring conflict where companies are producing too many endpoints but not enough therapeutic products. Digital health companies are working towards producing the same endpoints however this time could be better allocated through collaboration and working with one another in the pre-competitive phase. In this discussion we take a deep dive into the likelihood of these partnerships coming to life in the industry and explore what the best ways for companies to work collaboratively will be.

- Why is it important for the industry to begin strategizing pre-competitive collaboration on new endpoint development?
- Why are we seeing so many endpoints being developed and not enough therapeutic products coming together?
- What strategy can we adopt to ensure the right protocol is followed and right partnerships are made in these collaborative projects?
- How can we think about sharing our research and compliance data?
- How can industry leaders partnering together improve novel endpoint development?
- Is this a viable solution to novel endpoint development in the future?
- Which companies are already adopting this strategy?

Moderator: **Vaibhav Naryan**, Chief Strategy Officer, **Davos Alzheimer's Collaborative**
Siva Nadarajah, President & Co-Founder, **JOGO Health**
Jessica Robin, Director of Clinical Research, **Winterlight Labs**
Srinivasan Vairavan, Director of Neuroscience Data Science & Digital Health, **Janssen**

5:55pm Chairs Closing Remarks of Day 1
Emily Lewis, Global Digital Transformation Lead, Neurology, **UCB**

6:00pm End of The Digital Biomarkers & Digital Measurements US Summit Day 1

Conference Day 2 - Wednesday, 19th October

8:00am Registration, Breakfast and Networking

9:00am Chair's Opening Remarks

Ariel Dowling, Senior Director, Head of Sensing & Measurement, **Takeda**

Adoption

9:10am Panel Discussion: From Development to Clinical Adoption: An End-to-End System Leveraging Data for Therapeutic Value - Click Therapeutics

Traditional "gold-standard" measurements are known to have bias, come with undue patient burden, and are not scalable given the time for administration. Digital therapeutics (DTx) offer the promise of a scalable and safe therapeutic as well as the ability to more objectively measure clinical outcomes and inform the delivery of treatment. At Click, we have established a process we call 'The Diamond', which is the core of how we build our DTx. This panel will focus on how we (a) approach the exploration and validation of digital biomarkers within our internal R&D team, (b) integrate digital biomarkers and measurement into our products, (c) tailor digital biomarkers and measurement to maximize therapeutic value, (d) how digital biomarkers and digital measurement can be integrated to overcome physician barriers, and (e) how we place people with lived experience at the core of this process.

- What is an example of a product development model for building validated prescription digital therapeutics?
- What is the process for developing and validating digital biomarkers and measurement?
- How do you integrate digital biomarkers and measurement into a digital therapeutic subject to regulatory review?
- How do you leverage digital biomarkers and measurement to drive therapeutic value to patients?
- What are barriers and enablers to digital biomarker and measurement adoption?
- How can you ensure that people with lived experience are at the core of developing digital biomarkers and measurement?

Moderator: **Shaheen Lakhan**, Chief Medical Officer, **Click Therapeutics**

Cassandra Snipes, Associate Director of Clinical Science, **Click Therapeutics**
Dan Rimm, Director of Product Science, **Click Therapeutics**
Jesse Mursky-Fuller, Senior Prototype Engineer, **Click Therapeutics**
Alankar Gupta, VP of Clinical Development, **Click Therapeutics**

10:00am Presentation: Glasses-based Measurement of Facial Expressions and Context to Develop Biomarkers for Mental Health Conditions and Chronic Neurological Diseases

- Changes in facial expressivity and displays of positivity or negativity (emotional valence) are embedded within existing clinical assessments of mental health
- Measurement of head motion via glasses is far more accurate than measurement of limb motion for detection of activities of daily life

  New technologies that combine the measurement of facial expressions, physical activity from head motion and context, will revolutionize the assessment of complex behavioural conditions ranging from depression, to Parkinson's disease.

Charles Nduka, Chief Executive Officer & Chief Scientific Officer, **emteq labs**

10.25am **Morning Refreshments & Networking**

11:00am Presentation: Patient Reported Outcome Metrics – Improving Health on a System and Individual Level

Digital analytics in healthcare often use a macro lens to improve how systems function, but in doing so, are too far removed from an individual and their unique condition journey. Patient reported outcome metrics (PROMs) allow us to do both by bringing the individual's voice into their own care – and improving care for others. By capturing metrics specific to a patient's symptoms and functional status, we can not only optimize their individual treatment plan, but we can also apply machine learning to gather insights that could apply to – and improve care for – a much larger patient population with the same condition.

- Bringing the patient's voice into their own care to understand their day-to-day experience, both with their specific condition and their overall health
- Predicting co-morbidities, gaps in care, common side-effects, and potential adverse events in a large patient population
- Using PROMs to lower the overall cost of care by avoiding wasted spend

Daniel Knecht, Chief Clinical Innovation Officer, **CVS Health**

11:25am Presentation: Digital Biomarker Evolution in the Shifting Clinical Development Landscape

Digital biomarkers hold the promise of superior early signal detection with reduced participant burden and expedited timelines. Their ability to complement traditional measures with more frequent, sensitive, and objective data has fueled their popularity, and their prevalence is expected to rise as the regulatory landscape evolves toward greater acceptance of digital health technologies (DHT) in drug development.

- Understanding the nuances of various digital endpoints to select the DHT-enabled measures best suited to enhance your drug development programs
- Navigating the path to regulatory approval based on recent industry guidance
- Exploring real-world applications for leveraging digital biomarkers to generate insights with increased efficiency — bringing novel therapies to patients sooner

Chris Benko, Chief Executive Officer, **Koneksa**

koneksa

11:50am Panel Discussion: An Overview of How the Industry Plans to Tackle the Cyber Security Barriers Posed by Digital Biomarkers

As the digitization of healthcare continues to accelerate, the digital tools utilized for data collection begin to raise ethical concerns. Ensuring the data produced from digital biomarkers and measurement tools is managed safely, whilst remaining accessible, is essential. Here we bring you a panel of experts to both define and strategize how we can tackle the barriers posed by data safety concerns in digital health.

- What are the key concerns for users regarding data protection and data safety?
- How can the approaches that are currently in place be redefined and improved?
- Can we define a data management system leveraging the security of a decentralized approach and the accessibility of a centralized approach?
- How can data be made available to other companies in a decentralized security management system?
- How do we collect raw data?
- Where do we encrypt the data?
- How can we establish a faster, cheaper, and more transparent process to encrypt data?
- Looking ahead, what steps must be taken on all sides of the industry to tackle the barriers posed by cyber security and data safety?

Michelle Holko, Principal Architect Public Sector Cloud for Healthcare & Life Sciences, **Google**
Anders Strömberg, Director, Head of Health Solution Division, **Sony**
Andreas Caduff, Strategic Advisory Board, **DiMe**

12:40pm Chairs Closing Remarks of Day 2.

Ariel Dowling, Senior Director, Head of Sensing & Measurement, **Takeda**

12:50pm End of The Digital Biomarkers & Digital Measurements US Summit