



# DIGITAL BIOMARKERS & DIGITAL MEASUREMENTS EUROPE

## FOSTERING THE NEW AGE OF HEALTH

Tuesday, 21st & Wednesday 22nd, June 2022  
London, UK and Online | GMT

### Conference Day 1 - Tuesday, 21st of June

8:00am Registration, Breakfast and Networking

9:00am Chair's Opening Remarks

9:10am Keynote Presentation: Digital Biomarkers & Digital Measurements - Setting the Scene

- How have we got to this point with digital biomarkers and digital measurements?
- Understand the key challenges and opportunities in this space
- A look ahead to what will be discussed throughout the event

Lucia Cesnakova, Program Lead, [DiMe Society](#)

9:35am Keynote Panel Discussion and Open Q&A: Digital Biomarkers & Digital Measurements - What Factors are Holding us Back and How Will We Overcome Them?

Digital biomarkers / measurements aren't new but there remain several core challenges that need to be addressed if these promising approaches are to have real impact. Showcasing leading, multi-stakeholder perspectives, this panel will tee-up the main themes of the meeting before diving into them deeper later on.

- How are companies dealing with a complex, fragmented European landscape?

- What regulatory conversations need to be had to advance the industry?
- How has the impact of COVID-19 accelerated the adoption of digital approaches in healthcare?
- Where are digital biomarkers / measurements having tangible impact on clinical trials?
- How are companies using digital and traditional biochemical biomarkers together to yield greater results?
- What do we hope to achieve by the end of this event?

Moderator: **Lucia Cesnakova**, Program Lead, **DiMe Society**

**Yosef Safi Harb**, Founder & CEO, **Happitech**

**Katrine Christensen**, Global Access & Strategy Lead, **Biogen**

**Matteo Lai**, Co-Founder & CEO, **Empatica**

**Edouard Gasser**, Co-Founder & CEO, **Tilak Health**

**Marco Viceconti**, Full Professor of Computational Biomechanics, **University of Bologna**

10.20am

**Morning Refreshments & Networking**

## **Integration into Healthcare**

**11:00am Presentation: Digital Biomarkers / Measurements and The Impact of COVID-19 on Remote Patient Monitoring in Cardiovascular Disease**

- What has been the short term, and what will be the long-term impact of COVID-19 on remote patient monitoring?
- Understand how digital biomarkers / measurements are being integrated into existing workflows
- A look at the key disease states where impact is being felt today

**Benjamin Vandendriessche**, Chief Medical Officer, **Byteflies**

### **11:25am Presentation: Digital Biomarkers for Neurodegenerative Diseases**

- Detecting and monitoring the symptoms of Parkinson's disease using digital biomarkers of motor impairment extracted from a 5-minute smartphone-based test of voice, gait, balance, finger tapping, reaction time, rest tremor, and postural tremor
- Using smartphone-based testing to identify people who are at risk of developing Parkinson's disease
- Investigating remote technologies as a diagnostic support tool for neurodegenerative diseases by predicting a range of self- or researcher-administered clinical scores that quantify participants' motor symptoms, cognition, daytime sleepiness, depression, and the overall state of health

**Siddharth Arora**, Departmental Lecturer, [University of Oxford](#)

### **11:50am Panel Discussion and Open Q&A: How are Digital Health Tools Being Integrated into Existing Healthcare Workflows?**

Digital health products hold a lot of promise in healthcare and whilst pockets of integration have been achieved, scalability remains a core challenge. Hear from leaders from across healthcare and industry as they deep-dive into where success has been achieved and how they are tackling long-term scalability.

- What are the main challenges facing digital tools being integrated into a physician's workflow today?
- What are the foundational factors that companies need to understand when approaching healthcare systems as it relates to digitisation?
- How are healthcare decision makers thinking about digital tools such as digital biomarkers / measurements?
- Once initial integration is achieved, how should digital companies work with the ultimate distributor of these approaches to achieve maximum impact?
- Is there a trade off between prediction accuracy and interpretation of results by healthcare professionals? If so, how do we help them achieve greater clarity?
- How should we be tying digital approaches together to assist with integration?
- What should we expect in the upcoming 2-3 years from digital health, and how will it impact the various players (regulators, healthcare professionals, health funding and investments, patients and caregivers)?

Moderator: **Edouard Gasser**, Co-Founder & CEO, [Tilak Health](#)

**Siddharth Arora**, Departmental Lecturer, [University of Oxford](#)

**Lana Ghanem**, Managing Director, [Hikma Ventures](#)

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

**George Roussos**, Full Professor, [Birbeck College - University of London](#)

**12:30pm**

**Lunch & Networking**

## Digital Biomarkers, Measurements and Endpoints in Clinical Trials

### 2:00pm Lessons Learnt from a Decade of Digital Biomarker Utilization in Clinical Trials

- Sharing the top takeaways from clinical trials that have utilised digital biomarker / measurements
- Where has the needle genuinely been moved by these approaches?
- How are we tackling the core challenges moving forward?

**George Roussos**, Professor of Pervasive Computing, [Birbeck College - University of London](#)

### 2:25pm Remote Collection of Multi-modal Data for Decentralised Clinical Trials

- Remote monitoring of cancer outpatients during the COVID-19 pandemic
- Feasibility of video to allow at-home assessment for patients with Duchenne Muscular Dystrophy
- Application of computer vision techniques to enhance data available from video

**Clare Matthews**, Senior Data Scientist, [Aparito](#)

**Sandra Komarzynski**, Senior Data Scientist, [Aparito](#)

### 2:50pm Why is Real World Walking Speed so important as a Digital Biomarker in Movement-related Disorders?

- The experience with outcome measures in MS trials
- Dialogue with EMA & FDA about regulatory acceptance, including MDR/GDPR
- The future: Cloud computing, multi-sensor tools and understandable AI

**Martin Daumer**, Scientific Director | Honorary Professor, [Sylvia Lawry Centre for Multiple Sclerosis | Technical University of Munich](#)

**3:15pm Panel Discussion and Open Q&A: The Future of Clinical Trials - Digital Biomarkers, Decentralisation and Beyond**

The future of clinical trials is being shaped before our very eyes. The impact of COVID-19 forced us to adapt quickly but the jury is still out on the longer-term digitisation of clinical trials. Join industry leaders as they set out their future visions and share lessons from the front line of digital biomarker / measurement integration in pharma.

- What is here to stay in the wake of COVID-19 as it relates to clinical trial digitisation?
- How are pharma utilising digital biomarkers / measurements for clinical trial decentralisation?
- How do we need to continue creating organisational change to drive forward digitisation?
- What do we wish we knew now when starting out with these approaches in clinical trials?
- What does the future of clinical trials look like?

**Martin Daumer**, Scientific Director | Honorary Professor, **Sylvia Lawry Centre for Multiple Sclerosis | Technical University of Munich**

**Ariel Dowling**, Director of Digital Strategy, **Takeda**

**Kai Langal**, Senior Director, Strategy & Innovation, Global Regulatory Policy & Intelligence, **Janssen**

**Hiromasa Miro**, Head of Early Asset Technologies, **UCB**

**3:55pm**

**Afternoon Refreshments & Networking**

**Combining Biochemical and Digital Biomarkers / Measurements**

#### **4:25pm Panel Discussion and Open Q&A: Combining Digital and Biochemical Biomarkers / Measurements - The New Normal?**

Healthcare and drug R&D have changed forever. Digital biomarkers / measurements hold a lot of promise but established approaches will continue to yield new insights. Hear from those at the cutting edge of the industry as they share insights into how they are combining the old with the new with biomarkers / measurements.

- Where are the main challenges when looking to combine digital and biochemical biomarkers / measurements?
- What do digital companies need to know before approaching pharma / healthcare organisations?
- What disease states are primed for these two approaches to come together?
- How would improved standardisation of approaches help combine these two areas?
- How can digital companies, pharma and healthcare organisations all work together to improve care and drug development for patients?

**Emilio Merlo Pich**, Global R&D Head, Corporate Executive Director, **Alfasigma**

**Ciara Clancy**, Founder & CEO, **Beats Medical**

**Stephanie Campbell**, Founder & CEO, **OKKO Health**

**Chris Richter**, Senior Data Scientist, **Kaia Health**

#### **5:05pm Panel Discussion -A Case Study of Industry Collaboration on the Development of a Novel Digital Endpoint: Measurement of Nocturnal Scratch in Atopic Dermatitis**

The development of novel digital endpoints does not always need to happen in isolation and siloes. Listen to a discussion about the case of a pre-competitive collaboration of pharma industry leaders to pave the way for development and acceptance of a specific measure: digital measurement of nocturnal scratch for atopic dermatitis. The participating partners of the initiative will tackle motivations, approaches, challenges and outcomes of this successful collaboration and implications for the future of this novel digital endpoint.

- Why is measuring nocturnal scratch a valuable new digital endpoint for atopic dermatitis?
- How did industry partners approach this pre-competitive collaboration on new endpoint development?
- What are the outlooks for the close future in regards to adoption and acceptance of novel digital measurements?

Moderator: **Lucia Cesnakova**, Program Lead, **DiMe Society**

**Stefan Avey**, Principal Data Scientist, Digital Health, **Janssen**

**Aude Clement**, Global Drug Development & Digital Health Regulatory Affairs, **Novartis**

**Terttu Haring**, Global Head for Clinical Innovation Office, **Sanofi**

**Doina Sirbu**, Medical Device Innovation Lead, **UCB**

**5:45pm Chairs Closing Remarks of Day 1**

## Conference Day 2 - Wednesday, 22nd of June

**8:00am Sign in, Breakfast & Networking**

**9:00am Chairs Opening Remarks**

### **Digital Biomarkers / Measurements Regulation**

**9:10am Keynote Presentation: Digital Health Regulation in Germany**

- A look at the recent history of digital health regulation in Germany
- What has already been learnt since laws were passed to enable more digital health products to be approved?
- What impact is being felt specifically on the digital biomarkers / measurements space?

**Lina Behrens**, Managing Director, **Flying Health**

**9:40am Panel Discussion and Open Q&A: Where are Regulations Helping and Hindering Digital Health in Europe?**

Digital health regulation is on the move in Europe but the landscape remains fragmented. Groundbreaking research is taking place, partnerships are being struck and these approaches are being integrated but crucial discussions still need to take place for digital biomarkers / measurements to reach their potential. Hear from leaders from multiple stakeholder groups as they untangle where we are and where we are going with regulation.

- How can we overcome the fragmented European landscape for increased adoption?
- What lessons are being learnt when dealing with regulatory bodies across Europe?
- What conversations need to be had to set standards and definitions across Europe, and with who?
- What advice do start-ups need to hear as they begin their regulatory discussions?
- How can we work together as an industry to continue to push forward regulatory discussions?

Moderator: **Lina Behrens**, Managing Director, **Flying Health**

**Stephen Gilbert**, Clinical Evaluation Director, **Ada Health**

**Kai Langal**, Senior Director, Strategy & Innovation, Global Regulatory Policy & Intelligence, **Janssen**

**Vincent Vercamer**, Head of Health Solutions & Public Affairs Europe, **Withings**

**Kathrin Pfeiffer**, Head of Market Access, **Sympatient**

10:40am

**Morning Refreshments and Networking**

## Case Study Showcase: Digital Biomarkers / Measurement Moving the Needle

**11:10am How To Take Digital Biomarkers From A Research Setting Into Actual Implementation**

- Insights into the key learnings from Happitech - scaling digital cardiology biomarkers from 5 to 1000 patients in a year

**Yosef Safi Harb**, Founder & CEO, **Happitech**

**11:35am Digital Biomarkers in Parkinson's Disease**

- Understand how digital biomarkers are moving the needle in Parkinson's Disease
- A look at clinical results from recent studies
- Discussion will focus around the long-term potential of digital biomarkers for patients in this space

**Diane Stephenson**, Executive Director - Critical Path for Parkinson's, **Critical Path Institute**

12:00pm

**Lunch and Networking**

**1:00pm Closing Panel Discussion & Open Q&A: Where Does The Future Lie for Digital Biomarkers and Digital Measurements?**

Recapping the previous two days, it is clear that digital biomarkers / measurements hold a lot of promise but we still have much to work on before they become the norm. This closing panel will summarise the key takeaways from the event and outline what we need to do as an industry moving forward to move the

needle for patients in need.

- How can we continue working together to accelerate the development of this space?
- Who else needs to be part of this conversation to ensure that this industry can reach its full potential?
- What can we learn from other related industries and apply to this space?
- What do we expect to be talking about at The Digital Biomarkers & Digital Measurements Summit next year?
- What is each panelist's final piece of advice for the audience?

**Carrie Northcott**, Director, **Pfizer**

**Bert Hartog**, R&D - Senior Director, Clinical Innovations, **Janssen**

**Katarzyna Wac**, Full Professor, **University of Geneva**

**Roozbeh Ghaffari**, CEO & Co-Founder, **Epicore Biosystems**

**2:00pm End of Digital Biomarkers & Digital Measurements Summit**