Using Patient-Generated Health Data in Medical Device Development: Case Examples of Implementation throughout the Total Product Life Cycle

A Public Workshop | Virtual

June 26-27, 2024 | 11am-3pm ET

FDA

DIGITAL MEDICINE SOCIETY

Workshop Objectives

- ✔ Provide case examples to demonstrate how PGHD can be implemented throughout the total product life cycle (“TPLC”);
- ✔ Explore ways to use PGHD to help advance remote clinical trial data collection and support clinical outcome assessments;
- ✔ Demonstrate how PGHD can highlight the patient voice in the medical device ecosystem; and
- ✔ Develop a roadmap for the use of PGHD in the medical device TPLC.

Day 1 | Wednesday, June 26, 2024

11:00 am **Welcome & Workshop Objectives**

- Jacqueline Burgette | Associate Director of Emerging Initiatives, Center for Devices and Radiological Health (CDRH), FDA
- Smit Patel | Associate Program Director, Digital Medicine Society (DiMe)

11:07 am **Fundamentals of Patient-Generated Health Data (PGHD)**

- Robert Wright | Social Scientist, Division of Patient-Centered Development, CDRH, FDA

11:15 am **Keynote Address: Receiving a Cancer Treatment, Decoding My Own Data, & Advancing Clinical Research: My Dual Life – as a Patient & Clinical Scientist**

- Elena Izmailova | Chief Scientific Officer, Koneksa Health

11:30 am **Keynote Panel Discussion: Vision 2030: Advancing Clinical Research with Patient-Generated Health Data**

- Jeremy Wyatt | Chief Executive Officer, ActiGraph
- Kristin Schneeman | Senior Director, FasterCures, Milken Institute
- Anindita (Annie) Saha | Associate Director for Strategic Initiatives, Digital Health Center of Excellence, CDRH, FDA
- Elena Izmailova | Chief Scientific Officer, Koneksa Health (Moderator)

12:00 pm **Session I: From Traditional to Digital: A Full Spectrum of PGHD Driving Clinical Trial Advancements**

Landscape of Person-Generated Health Data in Everyday Life (10 mins)

- Joyce Nortey | Senior Director, Clinical Research & Digital Health Initiatives, Evidation

Jotting it Down To Building Library: The Classic PGHD Chronicles (10 mins)

- Pamela Tenaerts | Chief Scientific Officer, Medable

Half a Decade of Evolution of Clinical Trials - An Analysis from the Library of Digital Endpoints (10 mins)

- Rachel Chasse | Associate Director, Digital Science Strategy, AbbVie

Panel Discussion (30 mins)

- Vinay Pai | Digital Health Specialist, Digital Health Center of Excellence, CDRH, FDA
- Mike Mittelman | Board Secretary, The Light Collective
- Joyce Nortey | Senior Director, Clinical Research & Digital Health Initiatives, Evidation
- Pamela Tenaerts | Chief Scientific Officer, Medable
- Rachel Chasse | Associate Director, Digital Science Strategy, AbbVie (Moderator)

1:00 pm **Session II: Measuring Health: One that Actually Matters to (Real) Patients**

Measuring Sparks of Brilliance: Newer Modalities of Epilepsy Monitoring (10 mins)
- Marisa Cruz | Chief Medical Officer, Empatica

The Steady Touch: Fast-Tracking Progress in Parkinson's with Digital Biomarkers (10 mins)
- Erin Rainaldi | Head of Sensors Data Science, Verily

Everyday Tech, Extraordinary Health: Insights from Consumer World for the Medical Device Worlds (10 mins)
- Nikki Batista | Vice President, Digital Health, WHOOP, Inc.

Panel Discussion (30 mins)
- David White | Kidney Warrior, The Light Collective
- Marisa Cruz | Chief Medical Officer, Empatica
- Erin Rainaldi | Head of Sensors Data Science, Verily
- Nikki Batista | Vice President, Digital Health, WHOOP, Inc.
- Patrick Antkowiak | Team Lead, Neurodiagnostic Devices Team, Office of Product Evaluation and Quality, CDRH, FDA, (Moderator)

2:00 pm **Session III: Turning Up the Volume of Health Monitors: New Modalities of Measuring Health**

The Way Forward for Quantitative Assessment of Gait Impairments in Parkinson's Disease Clinical Trials (10 mins)
- Katharina Klapper | Director of Clinical Research, The Michael J. Fox Foundation for Parkinson's Research

Developing Novel Patient-Centric Digital Sleep Assessment Tools for People with Short and Disrupted Sleep (10 mins)
- Jen Blankenship | Senior Research Scientist, VivoSense, Inc.

Panel Discussion (30 mins)
- Kimberly Kontson | Biomedical Engineer, Office of Science and Engineering Laboratories, CDRH, FDA
- Alan Hamilton | Senior Director of Research, COPD Foundation
- Katharina Klapper | Director of Clinical Research, The Michael J. Fox Foundation for Parkinson's Research
- Jen Blankenship | Senior Research Scientist, VivoSense, Inc.
- Benjamin Vandendriessche | Vice President of Science, DiMe (Moderator)

2:50 pm **Closing Remarks**
- Grail Sipes | Senior Policy Advisor to the Chief Scientist, Office of the Commissioner, FDA

3:00 pm **Adjourn**

Day 2 | Thursday, June 27, 2024

11:00 am **Welcome**

- Jacqueline Burgette | Associate Director of Emerging Initiatives, CDRH, FDA
- Smit Patel | Associate Program Director, DiMe
- Robert Wright | Social Scientist, Division of Patient-Centered Development, CDRH, FDA

11:05 am **Opening Remarks**

- Owen Faris | Acting Director, Office of Product Evaluation and Quality, CDRH, FDA

11:15 am **Welcome Chat: Bring the Megaphone, Give it to the Patients First**

- Grace Vinton | Healthcare PR Pro, Patient Advocate, Podcast Host of HITea With Grace (Moderator)
- Grace Cordovano | Patient-In-Residence, Board Certified Patient Advocate, DiMe

11:30 am **Fireside Chat: A View from the Washington: Building the Clinical Trials Infrastructure in the U.S. for Healthier Future**

- Shari Targum | Deputy Director, Office of Clinical Policy, Office of the Commissioner, FDA
- Jennifer Roberts | Director, Resilient Systems, ARPA-H
- Catharine Young | Assistant Director for Cancer Moonshot Engagement and Policy, White House Office of Science and Technology Policy
- Grail Sipes | Senior Policy Advisor to the Chief Scientist, Office of the Commissioner, FDA (Moderator)

12:00 pm **Session I: What's Your Type? Digital Health Technologies has Got Diabetes Covered**

Tidepool Loop: Bridging Patient Led Innovation with Regulatory Reality (10 mins)

- Howard Look | President, CEO, Tidepool

Panel Discussion (50 mins)

- Katie Gagel | Type 2 Diabetes Patient Expert
- Willem van den Brink | Scientist, Netherlands Organisation of Applied Scientific Research (TNO)
- Howard Look | President, CEO, Tidepool
- Bray Patrick-Lake | Digital Health Specialist, Division of Digital Health Outreach, Digital Health Center of Excellence, CDRH, FDA (Moderator)

1:00 pm **Session II: From Rarity to Clarity: PGHD's Role in Rare Diseases**

Leveraging the Power of PGHD across the Spectrum of Rare Diseases (10 mins)

- Pamela Gavin | Chief Executive Officer, National Organization for Rare Disorders (NORD)

Journey to Innovative Digital Endpoints with Lessons Learned: A Case Study of Fibrotic Interstitial Lung Disease (10 mins)

- Christine Guo | Chief Scientific Officer, ActiGraph

Developing a Multi-Sensor Digital Movement Analysis System for Ataxia (10 mins)

- Kristen Sowalsky | Vice President, Product & Science, Clario

Panel Discussion (30 mins)

- Tracy Gray | Patient Engagement Lead, Division of Patient-Centered Development, CDRH, FDA
- Pamela Gavin | Chief Executive Officer, National Organization for Rare Disorders (NORD)
- Christine Guo | Chief Scientific Officer, ActiGraph
- Kristen Sowalsky | Vice President, Product & Science, Clario
- Jessie Bakker | Vice President, Clinical Development, Koneksa Health (Moderator)

2:00 pm **Session III: Paving the Way to Vision 2030: How to Make the Future of Clinical Research a Reality Today using PGHD**

Panel Discussion (50 mins)

- James Carroll | Head of RWE, Clinical Trials, Walgreens Boots Alliance
- Shaye Mandle | Executive Director, AdvaMed
- Elena Emmanuel | Group Product Manager, Google
- Daniel Caños | Director, Office of Clinical Evidence and Analysis, CDRH, FDA
- Christine Von Raesfeld | Board Member/Patient Advocate, The Light Collective
- Charles Viviano | Chief Physician/Associate Director, Office of Product Evaluation and Quality, CDRH, FDA (Moderator)

2:50 pm **Closing remarks**

- Suzanne Schwartz | Director, Office of Strategic Partnerships & Technology Innovation, CDRH, FDA
- Jennifer Goldsack | CEO, DiMe

3:00 pm **Adjourn**