6TH ANNUAL
MOBILE IN CLINICAL TRIALS

September 16, 2019
Renaissance Boston Waterfront Hotel, Boston, MA

Executive Sponsors

Produced by the Conference Forum | www.theconferenceforum.org | #MobileClin2019
MONDAY, SEPTEMBER 16, 2019

8:00 am
Registration, Coffee & Tea

8:30 am
Co-Chairs’ Opening Remarks
Daniel Karlin, MD
CEO, HealthMode
Michelle Shogren
Director of Innovation, Pharma R&D Clinical Operations, Bayer

8:40 am
Industry Overview: What Does a Successful Digital Trial Look Like?
• What is a digital trial?
• Is a common definition needed in order to scale for success?
• What does success look like? Fully remote, data sharing, device/tool implementation?
• How do we measure success? And when?
What about:
• accessibility?
• patient/investigator experience?
• tool/device effectiveness?
• data quality and usability?
• did digital help answer the necessary clinical question?
• did it ensure representative patients in the study?

Moderator:
Craig Lipset
Former Head of Clinical Innovation, Pfizer

Panelists:
Jennifer Goldsack, MBA
Executive Director, Digital Medicine Society (DiMe)

Jacob LaPorte, PhD
Co-Founder & VP, Global Head of Novartis Biome, Novartis

Pharma Reporting on Mobile / Digital Implementation Efforts

9:10 am
Pfizer Case Study: Utilizing Apple’s ResearchKit to Develop a Lupus Mobile App and Prove the Accuracy of ePROs
Sachin Karnik
Director, New Clinical Paradigm, Pfizer

9:30 am
Mobilizing Mobile Efforts and Engineering for Scale: Merck’s Digital Health Strategy 2.0
Mobile tool/device implementation has been widely accepted, tested and piloted in clinical research. With the bar set, Merck looks to challenge it and create an ecosystem that continues to set the bar higher with a scalable model. In this session, Kai Bode, Director of Global Data Analytics & Technologies, walks the audience through their approach to coordinating and prioritizing digital efforts, building a prototype to test devices, mobilizing their mobile devices, mobile patient screenings, finding a workaround to perceived barriers and/or premature acceptance of timelines/processes and lessons learned.
Kai Bode
Director, Global Data Analytics & Technologies, Merck

9:50 am
Unifying Patient Facing Technology Capabilities to Reduce the Burden on Patients
Biopharmaceutical sponsors are experimenting with multifold technologies to achieve patient centricity. These capabilities could range from newer data collection such as wearables, sensors, and patches or could be traditional data collection such as eCOA and patient engagement. These capabilities generate value due to the amount and type of data, but it increases the significant burden on the patient. To alleviate these challenges, one possible option is to converge patient-facing technologies and share experiences in this endeavor.
Aman Thukral
Associate Director, DSS, AbbVie

10:10 am
Quantitative Measurements of Nighttime Scratch and Sleep Using Digital Wearables, Chapter 2
Carrie Northcott, PhD
Project Team Lead, Early Clinical Development, Digital Medicine, Pfizer

10:30 am
Networking Break

Deployment, Scale & Flexible Trials

11:00 am
Escaping Pilotville: How to Scale Mobile / Digital Deployment in Clinical Trials
• What KPIs are used to evaluate success/failure of a pilot?
• What are the barriers to scale, even when a pilot is a success
• What are the operational models used by innovation teams to support deployment?
• Which models are working?
• Are study teams equipped to take on deployment efforts?
• What resources must be made available?
• How to position for scale?
• Digital efforts are currently in addition to traditional efforts and adding complexity. How can the industry remove the fear and transition from addition to replacement?
• Show good evidence of what works at scale
• What should this include?

Moderator:
Michelle Shogren
Director of Innovation, Pharma R&D Clinical Operations, Bayer

Panelists:
Arthur Combs, MD, FCCP, FCCM
CMO, MC10

Kent Thoelke
EVP, Chief Scientific Officer, PRA Health Sciences
11:25 am
Mitigating Risks to Embrace Mobile Technologies in Trials
Mobile technologies hold great promise for clinical trials—
capturing more meaning and accurate data, reducing burden on
sites and patients, and much more. So what’s holding us back? In
this session CTTI addresses what barriers are preventing us from
embracing mobile technologies in clinical trials, solutions to those
barriers, and guidance on risk management.
Hassan Kadhim
Director, Clinical Trial Business Capabilities, GCO, Bristol-Myers
Squibb

11:45 am
Integrating Technology and Human Touch in a 100% Virtual
Clinical Trial: An MRN and Clinical6 Case Study
Graham Wylie, MBBS
CEO, MRN

12:00 pm
Virtual Trials: What are We Striving for and Measurements of
Success
• How is it getting out of pilotville?
• What is the barrier to adoption?
• Factors that impact success:
  • Risks
  • Patient Preferences
Moderator:
Adama Ibrahim, EMBA
Associate Director, Performance Operational Capabilities, Global
Clinical Operations, Biogen
Panelists:
Christopher Ceppi
Chief Product Officer, Science 37
Jamileh Jemison, MD
Head of Clinical Development, Healthmode
Hassan Kadhim
Director, Clinical Trial Business Capabilities, GCO, Bristol-Myers
Squibb
Casey Orvin
President, Society for Clinical Research Sites (SCRS)
John Reites
Chief Product Officer, THREAD Research

12:35 pm
Annual Live Tech. Demos
In this section, hear from a select group of companies, who have
technologies that can impact your clinical trials. Each company
will present a five-minute demo of their technology and will be
present during the showcase at lunch for further demonstrations.
Presenting Companies:
Datacubed Health
David Kiger
COO
mdgroup
Richard Maguire
Director of Business Development and Data Scientist

AllLive Healthcare
Daniel Byung Il Lee, MBA
Founder and CEO

1:00 pm
Luncheon and Technology Showcase

Novel Digital Endpoints

2:10 pm
Hands-on Interactive Group Activity: How to Create Novel
Digital Endpoints?
• Utilizing the example of an assigned disease area, run through a
  side-by-side comparison of traditional endpoints in each.
• Where to start in reimagining the endpoints?
• How to re-measure to get the same impact?
• Who within your organization needs to be involved/in the room?
• Outline thoughts and concerns
• Address protocol design
• Who needs to review it?
• What is the long-term path for measuring and validating from
  exploration to registration?
• How to go from planning to process implementation?
Led by:
Mohammed Ali
Global Head Digital Development, Global Clinical Operations,
Boehringer-Ingelheim

3:10 pm
Building a Bullet-proof wearable and App Strategy for Your
Clinical Trial
Michelle Longmire, MD
Co-founder and CEO, Medable

3:25 pm
Leveraging Mobile to Collect Real World Evidence (RWE) and
Patient Journey Data Beyond the Point of Care
This presentation will provide examples of research incorporating
patient journey data covering study design through publication,
highlighting patient engagement strategies, considerations for
implementation, and the importance of social science
methodologies in understanding the comprehensive patient
experience.
Renee Willmon
Manager, Behavior Science, Self Care Catalysts

3:40 pm
Afternoon Networking Break
4:10 pm
Panel: Planning For and Addressing Missing Data in Mobile Clinical Trials
When a protocol dictates a set period of time for data collection, what happens when there’s a gap in the data due to technical glitches or human error? What are the regulatory and operational implications? In this session the group discusses:
• How to prepare for missing data?
• How do we handle missing data?
• How to rewrite protocols so that you avoid the trap?
• Forewarning and communicating with regulators
• Regulatory advice on how to address missing data
Moderator:
Jennifer Goldsack, MBA
Executive Director, Digital Medicine Society (DiMe)
Panelists:
Ariel Dowling, PhD
Associate Director of Digital Clinical Devices, Data Sciences Institute, Takeda Pharmaceuticals
Marie Mc Carthy, MBA
Senior Director of Product Innovation, Information Technology, ICON plc
Carrie Northcott, PhD
Project Team Lead, Early Clinical Development, Digital Medicine, Pfizer
Shyamal Patel, PhD
Director of Data Science, Digital Medicine & Translational Imaging, Pfizer, Inc

4:40 pm
Working Through the Latest Chapter: Patient Data Access, Ownership, Privacy and Security
• How does it affect the real world ecosystem?
• What does patient data access mean?
• With GDPR and new US based laws emerging, what does it mean for global clinical trials?
• Data transparency
• Legal perspective
• Define what ownership means?
• Ethics around data
• Impact on medical research
Moderator:
Charlie Semenchuk
Director of Systems, Analytics & Reporting, DDO Business Operations, Allergan
Panelists:
Andrea (Andy) Coravos
Co-founder and CEO, Elektra Labs
Megan Doerr, MS
LGC, Principal Scientist, Governance, Sage Bionetworks
Talley Mitchell, MS
Director, Patient Direct and Physician Referral Process and Delivery, Covance

5:10 pm
Open Mic Failures - Lessons Learned
The audience is invited to share ideas that failed. Expose your failure in 2-3mins so we can reap the benefits of lessons learned.
“It is fine to celebrate success, but it is more important to heed the lessons of failure.” – Bill Gates
Daniel Karlin, MD
CEO, HealthMode
Michelle Shogren
Director of Innovation, Pharma R&D Clinical Operations, Bayer

5:45 pm
Conference Concludes