MOBILE@Dpharm

5th Annual

MOBILE IN CLINICAL TRIALS

September 24, 2018 **Boston Marriott Copley Place, Boston, MA**

Downloadable Agenda

Who Should Attend

This conference is designed for Mid to Large Pharmaceutical and Biotech Companies:

- Clinical Development Innovation Directors
- VPs/Directors of Clinical Operations & Outsourcing
- Therapy Area Heads
- CMOs
- Clinical IT Directors
- Clinical External Alliance Directors
- Business Development Managers/Directors

From Emerging Life Science Companies:

- Chief Medical Officers
- Heads of R&D
- Head of Clinical Operations/Clinical Outsourcing

App Developers
Digital Health Care Investors

Executive Sponsors

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#MobileClin2018

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MONDAY, SEPTEMBER 24, 2018

8:00 am
Registration, Coffee & Tea

8:45 am
Chair's Opening Remarks
Daniel Karlin, MD
Head of Clinical, Informatics, and Regulatory Strategy, Digital Medicine, **Pfizer Inc**

9:00 am
A Bayer Perspective: The Good The Bad and The Ugly of Mobile Health
What are the key things you should consider when adding apps and devices to your clinical trials? Bayer shares valuable lessons learned on customer insights and data discovery. Bayer ran a 3-month user acceptance and data flow study with 20 subjects to look at the possible adoption of a multi-functional application combined with an Actigraph and a Bluetooth Weight Scale.

In this session, Bayer's Chrysanthi Dori brings her expertise in data science:

- What was hoped to be accomplished, described in the practical language of business or decision-making
- Data inventory and understanding
- Assessment of Data for Suitability
- Prepare and explore the data
- Evaluation/Interpretation/Understanding

Bayer's Michelle Shogren shares insights from an operations, site, and patient experience:

- How to onboard sites to new technology
- What training is needed for sites and patients
- Recommendations for training and support tools
- Views from the patient point of view on devices and apps fitting into their lives

Chrysanthi Dori, MBA
Associate Director, Clinical Digital Data, Technology and Analytics, **Bayer**

Michelle Shogren
Head of Innovation, Portfolio and Operations, **Bayer**

9:30 am
Merck's Digital Health and AI Strategy: Progress Report

- What Merck is doing in Digital Health and AI
- External collaborations on AI
- Smart trials initiative to enable patient-centric studies
  - Strategy development and leadership buy-in
  - Lessons learned
  - What's next?

Joseph Lehar
Executive Director, Computational Biology, **Merck Research Laboratories**

Jyoti Shah
Associate Director, Data Development MRL IT, **Merck & Co, Inc**

10:00 am
A Novartis Case Study: Utilizing ResearchKit Apps to Accelerate Drug Development
This session is an exciting example of how to utilize the ResearchKit platform and make clinical trials more accessible and flexible. Hear from the team on what it took to design and implement mobile apps into a phase II ophthalmology study and the ELEVATE MS study.
Mohanad Fors, MBA
Global Head Digital Innovation Lab, Global Drug Development, **Novartis**

10:30 am
Networking Break

11:00 am
Eli Lilly: How to Launch Multiple Mobile Devices in a Hybrid Setting both Siteless and Traditional
This session reports on incorporating a variety of mobile devices – including a smart phone, smart insulin pens, connected devices, mifi, and laptops, into a clinical trial. Considerations and lessons learned for:

- Connecting all the devices
- Implementation differences between traditional vs siteless
- Coordinating the equipment; challenges and successes
- Lessons learned
- What's next?

Joseph Kim, MBA
Sr Advisor, Patient Experience and Design Innovation, Design Hub Foundations, **Eli Lilly & Co**

11:30 am
Pfizer: Considerations and Lessons Learned from a Regulatory Interaction for a Parkinson's Disease Trial with Digitally Collected Data
Pfizer Speaker TBA

12:00 pm
Philips Case Study
Jessie Bakker, PhD
Senior Manager, Clinical Trials, **Philips Respironics**

12:15 pm
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:

BBK Worldwide

Additional companies TBA

12:45 pm
Luncheon and Technology Showcase

1:45pm
Hands-on Interactive Group Activity
In this session, the group is led in an interactive task to gather a 360-degree view on data sharing in clinical research. The audience will be broken into four stakeholder groups:

1. FDA & regulatory
2. IRB
3. Researchers & clinical trial leaders
4. Patients

Each group will be asked to consider the following questions from the perspective of the stakeholder group they've been assigned:

1. What is your goal of data sharing?
2. What information do you still require to make this a reality?
3. Do you have any concerns?

Led by:
Daniel Karlin, MD
Head of Clinical, Informatics, and Regulatory Strategy, Digital Medicine, **Pfizer Inc**

2:45 pm
Aces Health Case Study
Speaker TBA

3:00 pm
How to Align the Promise of Technology with the Patient Voice

- How do we identify shared value for both pharma and patients?
- Patient perspective on being monitored continuously
- What data is appropriate to share?
- Data privacy: pharma perceptions of what patients want versus what patients really want

Cindy Geoghegan
Patient Advocate

Daniel Karlin, MD
Head of Clinical, Informatics, and Regulatory Strategy, Digital Medicine, **Pfizer Inc**

3:30 pm
Networking Break

4:00 pm
Panel: Pre-Competitive Collaborations to Maximize the Impact of Mobile/Digital Tools

- Understanding how mobile can benefit a therapeutic collective
- Identify measures and streamline for trial registration purposes
- How can we better cooperate to make this more efficient for everyone?
- Does ownership of the algorithm really matter?
- What is it going to take to make this happen so that we can drive acceptance of these technologies?

Moderator:
Jennifer Goldsack, MChem, MA, MBA, CPHW
Clinical Project Manager, **CTTI**

Panelists:
Stephen Arneric, PhD
Executive Director, **C-PATH** *invited*

Rob DiCicco
Principal Consultant, **TransCelerate** *invited*

4:30 pm
Panel Discussion: A Roadmap to Organizational and Digital Restructuring to Scale Mobile Clinical Trials
With the number of datasets collected in clinical research rapidly expanding, how can these novel data streams be integrated into existing pharma structures for meaningful use? In this session the panel discuss the internal infrastructure that is required for the successful scaling of mobile/digital tools in clinical trials. More specifically:

- How to come to terms with the weight and demand of data
- Understanding the skillsets/talent required to purposefully use the data
- Implementing an internal system to allow for efficient and effective scaling of mobile trials

Moderator:
Mohammad Ali
Global Head Digital Trials- Global Clinical Operations, **Boehringer-Ingelheim**

Panelists:
Bill Kesil
Director, Program Lead, and Clinical Data Sciences, **Pfizer** *(invited)*

Irene Pak
Lead R&D Data Architect, **Bristol-Myers Squibb** *(invited)*

5:00 pm
Panel Discussion: Moving Beyond the Accelerometer, What's Next for Mobile Clinical Trials?

- How can the industry shift it's focus to sense modalities more broadly?
- What will it take to penetrate different domains?

Dina Katabi, PhD
MacArthur Fellow, Andrew & Erna Viterbi Professor and Director of MIT Center for Wireless Networks & Mobile Computing, **MIT**

5:30 pm
Conference Concludes