MONDAY, SEPTEMBER 16, 2019

8:00 am
Registration, Coffee & Tea

8:30 am
Co-Chairs' Opening Remarks
Daniel Karlin, MD
Assistant Professor of Psychiatry, **Tufts University** and *Former Head of Clinical, Informatics, and Regulatory Strategy, Digital Medicine,* **Pfizer Inc**

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

8:40 am
Industry Overview: What Does a Successful Digital Trial Look Like?
- Different stakeholder definitions
- How are companies investing to go digital?
- What race are you trying to win?
- What is digital success? Fully remote, data sharing, device/tool implementation?

Panelists:
Munther Baara
Head of New Clinical Paradigm, **Pfizer**

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

Jacob LaPorte, PhD
Global Head of Digital Development, **Novartis**

Craig Lipset
Former Head of Clinical Innovation, **Pfizer**

Pharma Reporting on Mobile / Digital Implementation Efforts

9:10 am
Case Study: Lupus Mobile App and Golden Assessment
Munther Baara
Head of 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, Merck's Director of Digital and Analytics Technologies, Kai Bode, 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, Digital and Analytics Technologies, **Merck**

9:50 am
Unifying Patient Facing Technology Capabilities
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. However, this is a daunting task due to the availability of siloed solutions and difference focused functions within the development organizations. The goal of this presentation is to provide the framework for converging patient-facing technologies and share experiences in this endeavor.
Aman Thukral
Associate Director, DSS, **AbbVie**

10:10 am
Pfizer Update: Results and Next Steps in an Atopic Dermatitis Clinical Trial with Validated Digital Wearables
Carrie Northcott, PhD
Project Team Lead, Early Clinical Development, Digital Medicine, **Pfizer**

10:30 am
Networking Break

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?

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

11:30 am
Mitigating the Risks Holding Us Back in Reducing Patient Burden
We want to decrease the burden to patients. We have technology to make it easier for patients to participate in trials. We can get more meaningful and accurate data and outcomes. In this session CTTI addresses what it is that's holding us back and provides guidance on risk management.
Annemarie Forrest
Director of Projects, **CTTI**

11:50 am
Utilizing Technology and the Human Touch in Remote Clinical Trials: an MRN Case Study
Graham Wylie, MBBS
CEO, **MRN**

12:05 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

Adama Ibrahim
Associate Director, Global Clinical Operations, **Biogen** *(invited)*

12:30 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:
Data Cubed

1:00 pm
Luncheon and Technology Showcase

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
Case Study: DPharm Idol 2018 Winner Returns
Michelle Longmire, MD
Co-Founder and CEO, **Medable**

3:25 pm
Networking Break

4:00 pm	Breakout Choices:	
4:05 pm	**Operational Realities of Mobile / Digital Tool Implementation: How's it Going?** The CRA perspective – what's the reality on the ground? How are you actually getting it done? Experiences at the site. • The PI perspective – experience in using technology • The clinical trial site perspective • What support is required? • What worked and what did not **Moderator: Dan Karlin, MD**, *CEO*, **Healthmode** **Invited Panelists: Sarah Charland,** *Site Affairs and Operations Manager*, **Pfizer** *(invited)* **Casey Orvin**, *President,* **SCRS** *(invited)* **Gina Ricciardelli**, *CRA,* **AstraZeneca** *(invited)*	**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 **Panelists: Michelle Campbell,** *Reviewer, Clinical Outcome Assessments, CDER,* **FDA** *(invited)* **Jennifer Goldsack, MBA**, *Executive Director,* **Digital Medicine Society (DiMe)** **Carrie Northcott, PhD,** *Project Team Lead, Early Clinical Development, Digital Medicine,* **Pfizer** **Elektra Papadopoulos,** *Associate Director, Clinical Outcome Assessments, CDER,* **FDA** *(invited)*
4:35 pm	**How to Effectively / Efficiently Engage with IRBs – a Q&A Session** If you want to deploy an app, wearable or device in your clinical trial you must seek IRB approval. In this session, gain insight and understanding into: • How to prepare for the meeting? • How to have the right conversations? • Advice on how to get it done? **Michelle Shogren,** *Director of Innovation, Pharma R&D Clinical Operations,* **Bayer**	**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 **Panelists: Andrea (Andy) Coravos**, *Co-founder and CEO,* **Elektra Labs** **Megan Doerr, MS,** *LGC, Principal Scientist, Governance*, **Sage Bionetworks** *(invited)* **Charlie Semenchuk,** *Director of Systems, Analytics & Reporting, DDO Business Operations,* **Allergan**

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

Led by:
Mohanad Fors
Head of Biome, Digital Innovation Lab, **Novartis**

5:45 pm
Conference Concludes