SPEAKING FACULTY

Emma Bender
Marketing Manager
NIHR

Jennifer Goldsack, MChem, MA, MBA, CPHQ
Clinical Project Manager
CTTI

Christian Gossens, PhD, MBA
Global Head Early Development Workflows, pRED Informatics
Roche Pharmaceutical Research and Early Development (pRED)

Tilo Hache, MBA
Digital Endpoint Strategy Lead
Novartis

Bert Hartog, PhD
Senior Director, Clinical Innovation, R&D Operations
Janssen

Daniel Karlin, MD
Head of Experimental Medicine, Informatics, and Regulatory Strategy, Pfizer Innovative Research Lab
Pfizer, Inc

Carol Maguire, RN
Director of Clinical Research, Division of Cardiology
UCSF

Nuria Oliver, PhD
Director of Research in Data Science
Vodafone

Tushar Parlikar, PhD
Program Manager
Verily Life Sciences

Barry Pinnington
Patient Advocate

Hilde Vanaken, PhD
Director, R&D Operations Innovation
Janssen

TUESDAY, MAY 15, 2018

9:30 am
Chair's Opening Remarks
Daniel Karlin, MD
Head of Experimental Medicine, Informatics, and Regulatory Strategy, Pfizer Innovative Research Lab, **Pfizer, Inc**

9:45 am
How to Implement Mobile in a Fragmented Landscape with Cultural Barriers
Factors for consideration include:

- Roaming costs
- Data privacy regulations
- Different approaches in health care systems
- eConsent interpretations
- Addressing the challenges of remote clinical trials in Europe
- Scalability: the reality and challenges
- Assessing your internal IT architecture to handle the data
- Integration challenges internally and with third parties
- How to convince top leadership it's time to change the study design?
- How can the data be integrated into the trial?
- Factoring in regulatory and compliance guidelines
- Will the EMA and FDA accept the data?

Tilo Hache, MBA
Digital Endpoint Strategy Lead, **Novartis**

10:20 am
Balancing Patient Engagement with the Risk of Bias: The Effects of Mobile Technology on Clinical Trials

- Are mobile devices introducing a new type of bias in clinical research?
- Factors to consider when providing real-time data to patients
- Interaction between technology and placebo effect
- Positive and/or negative impact on clinical outcomes

Daniel Karlin, MD
Head of Experimental Medicine, Informatics, and Regulatory Strategy, Pfizer Innovative Research Lab, **Pfizer, Inc**

10:50 am
Janssen's Suite of Digital Tools for Clinical Trials: From Concept to Implementation
In this session, Dr Hilde Vanaken, Director, R&D Operations Innovation at Janssen, will walk the audience through how they implemented the iSTEP platform and why it was so impactful. More specifically:

- Identifying the tools
  - eTracking

  - eCommunication
  - eLabel
  - eAdherence
- Steps to implementation
- Challenges, obstacles and getting through them
- Tools used to manage data collection
- Regulatory response to the data
- Outcomes to date

Hilde Vanaken, PhD
Director, R&D Operations Innovation, **Janssen**

11:20 am
Networking Break

11:50 am
Verily's Study Watch Tackles Scalability of Wearables in Clinical Trials

Tushar Parlikar, PhD
Program Manager, **Verily Life Sciences**

12:30 pm
Tech Showcase

1:00 pm
Lunch

2:00 pm
Where Are They Now and What Can We Learn From: GSK's PARADE Study
GSK was the first to launch a real-world study using the Apple ResearchKit to look at the impact of Rheumatoid Arthritis had on patients' lives. The goal was to engage with patients in a new way that integrates the research into their daily lives. It sought to address the huge issue of patient attrition. In this session, Kevin Jenkins, Project Director, Clinical Innovation and Digital Platforms at GSK, will deliver an update on:

- Where is the PARADE team now and what's next?
- What challenges did they have to overcome and how?
- Findings from the joint learning session with other ResearchKit leaders to strategize on how to improve these technologies
- Lessons learned around patient attrition
- Strategies identified for scaling up

Kevin Jenkins
Project Director, Clinical Innovation and Digital Platforms
GSK *(invited)*

2:30 pm
Trials and Tribulations of an Ongoing Mobile Clinical Study: UCSF's Revolutionary Health eHeart Study

This session provides an excellent example of the trials and tribulations of an ongoing mobile clinical study. Learn what the obstacles and challenges have been and how they are managed. The study aims to gather more data about heart health from more people than any research study has done before. With 122,871 participants to-date, 16 studies in progress and 6 research studies published using their data, they are on track to produce meaningful benefit. In this session, Carol Maguire of UCSF's Division of Cardiology, will deliver an update on:

- Where are they now?
- What challenges have they faced? Expected and unexpected?
- Lessons learned, including those around geo-fencing
- Insights and realities on getting their data validated
- Strategies for integrating multiple digital components in a study
- What's next? The Eureka Research Platform?

Carol Maguire, RN
Director of Clinical Research, Division of Cardiology, **UCSF**

3:00 pm
Considerations in Selecting a Digital Technology Partner

- Is the platform fit for purpose?
- Is it reliable?
- Is it affordable?
- Does it have consumer grade elements that make it easy to use?
- Is the supplier ready to provide the product in bulk?
- Does your partner understand the pharma industry and/or are they willing to learn?
- Is your partner willing to share the risk and invest?

Led by:
Daniel Karlin, MD
Head of Experimental Medicine, Informatics, and Regulatory Strategy, Pfizer Innovative Research Lab, **Pfizer, Inc**

3:30 pm
Which Remote Clinical Trial Model is Right for You?
In a lively format, we will demo remote trial model options and where they are appropriate. You will find out what is considered to be a "fully remote" trial and what it truly requires. You will also find out what it takes and why it may make sense for a "less site-centric" trial. In this session, companies that offer different models will discuss:

- What needs to happen for a practical model to emerge?
- What are the pros and cons of the different models; site-less vs hybrid (less site-centric) model
- Which types of studies are most appropriate for each model?

- During what phase should you implement?
- How do you scale up and make the process ubiquitous?

If you are interested in participating, please contact Meredith Sands: Meredith@tcfllc.org

4:00 pm
Networking Tea

5:00 pm
Day One Concludes

WEDNESDAY, MAY 16, 2018

9:15 am
Chair's Opening Remarks
Daniel Karlin, MD
Head of Experimental Medicine, Informatics, and Regulatory Strategy, Pfizer Innovative Research Lab, **Pfizer, Inc**

9:30 am
Janssen's First of Its Kind Collaboration Using Mobile Devices to Remotely Monitor Safety
In this session, hear from Bert Hartog on their collaboration to test the quality of remote safety monitoring through the use of mobile devices. Specifically:

- How they selected their partner
- How they got management on board
- Implementation strategy
- Results to date
- Plans for phase II and III trials

Bert Hartog, PhD
Senior Director, Clinical Innovation, R&D Operations, **Janssen**

10:00 am
Roche's Parkinson's Disease Study and Digital Biomarker Measures: Where are They Now?
This session is a powerful example of how to implement and scale up mobile technology in clinical research. First launched in 2015, Roche pRED developed a smartphone-based monitoring app for those with Parkinson's disease that complimented the traditional physician-led assessments with automated tests that continuously measured their symptom fluctuations. In this session, get an update on the lessons learned.

Christian Gossens, PhD, MBA
Global Head Early Development Workflows, pRED Informatics
Roche Pharmaceutical Research and Early Development (pRED)

10:30 am
Visionary Keynote Address: Data-Driven Decision Making
Nuria Oliver, PhD
Director of Research in Data Science, **Vodafone**

11:10 am
Networking Break

11:40 am
CTTI Findings are in from their Mobile Clinical Trials Program: Recommendations on Novel Endpoints
CTTI's Mobile in Clinical Trials program was launched three years ago to propose recommendations that clarify the pathway for developing novel endpoints for use in clinical trials from data generated using mobile technology. Jennifer Goldsack shares recommendations and insights from their findings on:

- Developing an internal process for identifying endpoints
- Strategies for reducing friction throughout the process
- Executing the process
- The science required to validate an endpoint
- A suite of tools developed in the process to help facilitate implementation

Jennifer Goldsack, MChem, MA, MBA, CPHQ
Clinical Project Manager, **CTTI**

12:05 pm
Patient Point of View: How Do You Feel About Being Monitored Continuously?
Barry Pinnington
Patient Advocate

12:35 pm
NIHR Case Study: Strategizing for eConsent Across Clinical Research
The UK's NIHR have conducted a proof of concept trial for obtaining patient consent via mobile devices. Plans are underway to develop this concept work further. In this session, hear from Emma Bender on:

- Developing the vision
- Factors considered prior to launch
- Implementation strategy
- Lessons learned
- What comes next?

Emma Bender
Marketing Manager, **NIHR**

1:00 pm
Conference Concludes