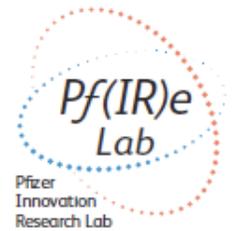


Clinical Trials & IoT Forum

How mHealth, Wearables, and the Internet of Things will Create the Clinical Trials of the Future



NOVEMBER 8-9, 2017
PFIZER INNOVATION RESEARCH LAB - CAMBRIDGE, MA



CORE THEMES:

1. How the Internet of Things can Improve the Clinical Study Participation Process for Patients
2. Bringing Wearables, mHealth, the Internet of Things, ePRO, & Data Capture into the Trials of Today
3. How Digital Tools & Data Analytics can Aid the Treating Physician and Drive Trial Participation
4. How to Evaluate, Validate & Scale Enterprise deployment of Technologies for Current & Remote Trials
5. Increasing Study Effectiveness with Tech to Connect Patients, the Treating Physician, and Investigator

Day One – Wednesday, November 8th

8:00 – 9:00 am Conference Registration Open in Pfizer Lobby

9:00 – 9:15 am Opening Remarks from Conference Chairman

Dan Karlin, Head of Digital Medical, Informatics, Regulatory Strategy, Pfizer

9:15 – 10:00 am **KEYNOTE PANEL:** The Internet of Things to Support Clinical Trials – The Next Frontier

The internet of things, mHealth, wearable and sensor-enabled devices paired with remote trials and telehealth present an unprecedented opportunity for how clinical trials monitor, communicate and work with patients. What does it mean for the pharmaceutical clinical trial industry – where are the best applications for connected devices, wearables and IoT?

Craig Lipset, Global Head, Clinical Innovation, Pfizer

Matthew Bryant, Head, Clinical Technology & Experience Lab, Amgen

Jacob LaPorte, Head of Digital Development, Novartis

Moderated by: Dan Karlin, Head of Digital Medical, Informatics, Regulatory Strategy, Pfizer

10:00 – 10:25 am

CASE STUDY: Health Technology Inflection Points and Novel Digital Endpoint Strategy at Amgen

Are biopharmaceutical organizations information technology companies? Perspectives on recent inflection points in health technology, and how organizations may be grappling with their identity. A discussion on how Amgen is prioritizing resources on the Patient Experience and their approach with Novel Digital Endpoints.

Matthew Bryant, Head Clinical Technology & Experience Lab, Amgen

10:25 – 10:45 am

CASE STUDY: Improving Patient Experience in Clinical Trials using Mobile

- Clinical trial dedicated mobile apps can improve patient experience in clinical trials and increase data collection and yield
- Key considerations in clinical trial mobile patient engagement:
 - HIPAA compliance, data collection & analysisface

Michelle Longmire, CEO, Medable

10:45 – 11:15 am

NETWORKING BREAK AT PFIZER INNOVATION RESEARCH LAB

11:15 – 11:45 am

CASE STUDY: The Imperative to Scale Digital Innovation

Increasing observations suggest that the underlying technologies powering the digital revolution are evolving at an exponential rate. The pharmaceutical industry, however, is significantly behind in its digital transformation. Moreover, we know that the industry is ripe for disruption given the significant advancements of these technologies and the ROI of R&D for large companies has been declining over the last decade and by many estimations is below the cost of capital. Recognizing this, the Global Drug Development Division at Novartis has been grappling with how to successfully innovate at scale. Jacob LaPorte, Head of Digital Development at Novartis, would like to share their journey in the hope of catalyzing a broader discussion amongst peers around how to effectively innovate at scale.

Jacob LaPorte, Head of Digital Development, Novartis

11:45 – 12:15 pm

CASE STUDY: Lower the Patient Burden – How to Deliver a Unified Mobile Technology Experience

Jeff Lee, CEO, mProve

Craig Lipset, Global Head, Clinical Innovation, Pfizer

12:15 – 12:45 pm

CASE STUDY: How the Internet of Things can make Clinical Trial Participation Easier for all Stakeholders and most importantly, the patient!

A look at how digital tools and innovations can better improve connections in the clinical research “triad” - the patient, treating physician and investigator - to ease the burden of clinical trial participation.

Joe Mather, Executive Director, Innovation Research Lab, Pfizer

12:45 – 2:00 pm

EXECUTIVE NETWORKING LUNCHEON

2:00 – 2:25 pm

CLINICIAN'S PERSPECTIVE: Challenges to Adoption of Wearable Technology in the Clinic

- Feasibility studies 10 years ago and where we are today
- Challenges in the clinic both for physician and patient (clinical documentation needs, time constraints)
- Skepticism from clinicians about technology-derived data driving clinical decision-making

Ludy Shih, Associate Medical Director, Early Clinical Development, Biogen

2:25 – 3:10 pm

PANEL DISCUSSION: The State of Remote & Virtual Studies in Clinical Research

- What are the latest success stories, and failures that we can learn from?
- What are patients saying about their experience with remote studies?
- What indications and therapy areas are the best fit for remote trials?
- What it means for patient safety, HCP engagement, and lines of communication

Craig Lipset, Global Head, Clinical Innovation, Pfizer

Kevin Bateman, Distinguished Scientist, Bioanalytics, Merck

Jason Laramie, Exec Dir, Head, Quantitative Sciences & Innovation, Novartis

Ludy Shih, Associate Medical Director, Early Clinical Development, Biogen

Abezer Tapia, VP, Global Head of Business & Partner Relations, MC10

Moderated by: **Joe Mather, Executive Director, Innovation Research Lab, Pfizer**

3:10 – 3:40 pm

CASE STUDY: Merck's 'Smart Trials' Initiative: Enabling Patient-Centricity and More Informed Decisions in Clinical Trials through Digital and Home Blood Sampling Technologies

Smart Trials is a cross-functional innovation project at Merck focused on leveraging digital and new technologies to improve data quality and enrich datasets by accessing clinical endpoints in the outpatient setting. As part of this initiative, clinical pilot studies are conducted to evaluate clinical trial readiness of new technologies in three primary areas: smart sampling (technologies for collection of date/time stamped outpatient PK and PD samples), smart dosing (technologies to accurately record and transmit dosing information), and smart analytics (methods to collect, integrate, and visualize data in real-time). Results from two recent clinical studies will be presented together with key learnings and future opportunities. Challenges and barriers for implementation of digital technologies in clinical trials will also be discussed.

Kevin Bateman, Distinguished Scientist, Bioanalytics, Merck

3:40 – 4:00 pm

NETWORKING BREAK AT PFIZER INNOVATION RESEARCH LAB

4:00 – 4:30 pm

Is your Big Data Solution Ready for Streaming Data?

With the advent of wearables and streaming data in the fold, disparate data in clinical systems create difficulties in understanding how trials will perform. The process, technology, and people will require a transformative approach. We'll review a use case where a cloud-enabled, scalable environment was implemented to perform data lifecycle management, analytics on the fly, and intuitive reporting including:

- Conceptual data landscape and flow of information
- Look at various analytic solutions and how they are built for various objectives
- Reflect on learnings and possible innovations

Using the right analytic solution that can incorporate your unstructured IoT data provides tremendous benefits including faster time to commercialization and better business and patient outcomes.

Karim Damji, SVP Product, Saama

4:30 – 5:00 pm

CASE STUDY: Innovation Starts With Insights; Not Ideas

Blockchain. Biosensors. Internet of Things. Can all these *innovative* technologies truly help us improve clinical trial operations or have we diluted the term “innovation” into nothing more than a buzzword that represents coming up with new ideas? This talk will briefly cover three easy steps that are used by MIT Hacking Medicine -- a student organization that runs health hackathons around the world -- to help hack innovative solutions for medicine and healthcare. The approach draws principles of Design Thinking, Lean Startup and other innovation processes, but in particular, this session will focus on the value of insights as the underlying driver of creative, valuable solutions...Even for clinical trials.

Shwen Gwee, Head of Digital Strategy, Global Clinical Operations, Biogen
Steve Reeves, Director, Social Intelligence, DRG Digital

5:00 – 6:30 pm

Tours of Pfizer Innovation Research Lab & Networking Drinks Reception

Day Two – Thursday, November 9th

8:00 – 9:00 am

Conference Registration Open in Pfizer Lobby

9:00 – 9:15 am

Chairman’s Day One Recap and Opening Remarks

Dan Karlin, Head of Digital Medical, Informatics, Regulatory Strategy, Pfizer

9:15 – 9:50 am

MORNING PANEL: Hearing the Voice of the Patient – How Ambient Listening Devices Can Improve the Clinical Trial Experience

The healthcare industry, and in particular, the clinical research sector, has recently focused its attention on achieving “patient-centricity”. Driven by the desire to better engage clinical trial volunteers, coupled by the need to demonstrate value-added medical products, this has become much more than the latest buzz word. Within the planning stages of clinical research, we are seeing physicians and patients actively contribute to the design of the protocol. However, once the trial begins, the patient oftentimes may feel isolated in the process – quite simply, they need to ask questions and receive answers that they can understand. Is this an opportunity to effectively & efficiently use ambient listening devices?

Megan McBride, Associate Director, RDO-Innovation, Janssen

Cindy Geoghegan, CEO, Patients and Partners LLC

Jacob LaPorte, Head of Digital Development, Novartis

Moderated by: ***Bill Tobia, Lead Clinical Research Instructor, GSK***

9:50 – 10:20 am

The Road to Real World Evidence – Are we there yet?

Wearables, mHealth, sensors, EHR/EMR, imaging are great examples of eSources. Every day new amazing technology is released that can be plugged into a patient, track their every movement, measure their vital signs in real time, and understand their mood. Add to that a vast array of compute technology, analytics, machine learning, and the odd cool kid from Harvard, and you suddenly find new biomarkers, can provide healthcare remotely 500 miles away from the patient, and find disease cures within hours. Really? This presentation will discuss various industry use cases, along with associated technology approaches, and consider how close we are to making this prime time

Jonathan Palmer, Sr. Dir, Product Digital Trials, Oracle Health Sciences

10:20 – 10:50 am

Driving Healthcare Innovation from within: Opportunities & Challenges

- How traditional pharma perceives the Digital Healthcare Innovation?
- Exploring best practices for implementing a Digital Healthcare Strategy
- Opportunities & Challenges in the era of Digital Innovation

Georgia Mitsi, Sr. Director Search and Evaluation, Digital Healthcare Initiatives, Sunovion Pharmaceuticals

10:50 – 11:15 am

NETWORKING BREAK AT PFIZER INNOVATION RESEARCH LAB

11:15 – 11:40 pm

Power up the Impact Level of Emerging Tech in Clinical Trials Operations with Blockchain

Patient data is the new gold in the future of healthcare regardless the data source - IoT, health facility, AI, or the patient themselves. Blockchain technology, the underlying ledger enabling the management, security and tamper-proof distribution system of the peer-to-peer digital currency known as Bitcoin. There has been a great deal of hype around blockchain applications across many industries. This session will present a balanced perspective to the usage, challenges, and benefits of blockchain applications for optimizing clinical trials/research & understanding the difference of public vs private blockchains.

Maria Palombini, Director, Initiative and Community Development, Emerging Technology, IEEE-SA

11:40 – 12:20 pm

PANEL DISCUSSION: Now that we have the DATA, what do we DO WITH IT?

- Patient data is coming in from every direction and source on the market today – how can the industry collaborate to identify what is most important? Data layering for trend ID
- Considerations for pharma companies interested in a wearable device pilot program

Jyoti Shah, Sr. Scientist, Scientific Data Strategy, Merck

Jason Laramie, Exec Dir, Head, Quantitative Sciences & Innovation, Novartis

Rich Napoli, CEO, ObjectFrontier, Inc

Moderated by: Moe Alsumidaie, Annex Clinical

12:20 – 12:45 pm

REGULATORY UPDATE: Hear about the Industry's Top Concerns around Patient Data and the Internet of Things

PanAgora Pharma has polled top industry minds to gather questions that the industry is struggling with. Austin from Precision for Medicine will address these key concerns with relevant research right from the source!

Austin Speier, VP, Emerging Technologies, Precision for Medicine

12:45 – 1:00 pm

CTTI's Mobile Clinical Trials Stakeholder Perceptions Project

This presentation will share new survey results from the Clinical Trials Transformation Initiative (CTTI) on patient perspectives of mobile technology in clinical trials. Key insights will be highlighted, including preferences for trial data collection via mobile technology preferred attributes of mobile technology, data sharing expectations, and willingness to participate.

Cindy Geoghegan, CEO, Patients and Partners LLC

1:00 – 2:15 pm

EXECUTIVE NETWORKING LUNCHEON

2:30 pm

END OF CONFERENCE