PANAGORA PHARMA

2nd Annual
Clinical Trials & IoT Forum
Kimpton Hotel Marlowe, Cambridge, MA
November 7-8, 2016

Day One, November 7th

8:00 – 8:50 am	Conference Registration Open – *Serrano Ballroom Conference Foyer*
9:00 – 9:10 am	Opening Remarks from Conference Chairman
9:10 – 9:55 am	KEYNOTE PANEL Clinical Trials & the Internet of Things – The Next Frontier Wearable and sensor-enabled devices present an unprecedented opportunity for how clinical trials monitor and work with patients. At no other time have we had greater access to our own personal health data. Big data, the cloud, and eventual interoperability will enable us to gather, store and connect data in new ways. So what does it mean for the pharmaceutical and clinical trial industry – and where are we going? *Kathy Vandebelt, Head, Clinical Innovation, Lilly* *Jane Rhodes, Sr. Director, Innovation Hub, Biogen* *Georgia Mitsi, Sr. Director, Digital Healthcare Initiatives, Sunovion* *Marc Sebes, VP of Product, Validic* *Chaired by Spyros Papapetropoulos, VP, Global Development Head, Teva*
9:55 – 10:30 am	KEYNOTE: Revolutionizing Clinical Trials: How Pharma Clinical Trials can become more Patient-Centric • Results from recent projects; testing and evaluation of new approaches • Keys to becoming more Patient-Centric – how to put the patient at the forefront and enable them with technology • How the latest technology can promote better collaboration and participation within clinical development *Kathy Vandebelt, Head, Clinical Innovation – Eli Lilly & Company*
10:30 – 11:05 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*
11:05 – 11:25 am	Networking Break in Pre-Function Foyer *Serrano Ballroom Conference Foyer*
11:25 – 11:55 am	Passive data collection entails active patients: Refocusing the UX lens in clinical trials Sensor technology and connected devices promise a wealth of real-world data for clinical trials without participants seemingly needing to effort. But it's wrong to conflate the notion of passive data collection with passive patient behavior. Trial subjects need to accept sensor technology and allow it into their lives. Successful trials using IoT connected devices require renewed focus on the user experience, considering how patients, many who may be digitally naïve, adopt and use connected devices. Even when data is collected passively, IoT trials require participants to be engaged, which has significant implications for the design of trials. *Todd Greenwood, PhD, MPH, Director of Digital Strategy, Medullan*

11:55 – 12:25 pm

REGULATORY UPDATE: Hear about the FDA's Top Concerns around The Internet of Things in Clinical Trials

Austin Speier, Director, Emerging Technologies, Precision for Medicine

12:25 – 12:50 pm

CASE STUDY: Using Technology to Collect Standardized, Reliable and Clinically Meaningful Patient Data

- Leveraging technology to develop effective measurement tools
- Empowering patients to self report quantitative data
- Creating efficiencies and improving the consistency of clinical data collection across sites

Jane Rhodes, Sr. Director, Innovation Hub, Biogen

12:50 – 2:00 pm

Executive Networking Luncheon
Serrano Ballroom Conference Foyer

2:00 – 2:25 pm

CASE STUDY: Moving Beyond Pilots: Implementation of a Biometric Solution for Remote and Continuous Monitoring of Motor Symptoms in a Ph2 Clinical Trial

The objective is to implement quantification of motor dysfunction in a Huntington disease (HD) clinical trial using machine learning algorithmic analysis derived from biometric monitoring through a smartphone and wearable sensor combination. Motor symptoms in Huntington Disease (HD) are typically evaluated by clinicians using rating scales, such as the Unified Huntington's Disease Rating Scale total motor score (UHDRS-TMS). Assessments are infrequent, inherently subjective, may lead to intra- and inter-rater variability and are prone to placebo response. The use of biometric solutions could enable objective, real-time monitoring of motor dysfunction for both clinical research and patient care purposes.

Spyros Papapetropoulos, VP, Global Development Head, TEVA

2:25 – 3:05 pm

PANEL DISCUSSION: Electronic Data Capture in Clinical Trials featuring Connected Devices

- How pharma are using the latest data capture solutions to visualize in-depth patient information, improve data coverage and compliance
- Validating and qualifying care management devices for the requirements of industry sponsored clinical research
- Analyzing source data gathered via mHealth and devices as well as data collected within an eCRF, ePRO, mobilePRO and more using analytics solutions
- Powering virtual clinical trials that have more measures, small samples and better patient experience

Elena Izmailova, Sr. Director, Novel Data Streams and Devices, Takeda R&D
Aman Bandari, Exec Dir, Center for Observational and Real World Evidence, Merck
Mark Foster, COO, Transparency Life Sciences

Moderated by Chris Benko, Koneksa Health

3:05 – 3:30 pm

CASE STUDY: Taking Your Mobile Medical App From iDea to iPhone

The mobile medical apps business has quickly become a major force for designers, developers, marketers, and consumers (professional and non-professional). Entrepreneurs that conceive ideas for mobile medical apps usually turn to professionals to transform these ideas into commercial products. For those with limited resources, there are viable alternatives. This session will provide you with the knowledge and tools to take a mobile medical app from concept to consumer, using the presenter's recently released app as a "real-world" example.

William Tobia, Lead Clinical Research Instructor, GlaxoSmithKline

3:30 – 3:50 pm

Networking Break in Pre-Function Foyer
Serrano Ballroom Conference Foyer

3:50 – 4:20 pm

CASE STUDY: Five Things Your Content Engineer Wants You to Know about the Internet of Things

- Participants will see that they are not alone in their search for information that can be aligned to their strategies. It doesn't exist because IoT technology companies aren't aligned to solve pharma-specific challenges…yet.
- IoT companies agile, innovative, and skilled at making everything sound great. We'll discuss ways to cut through solutions seeking problems and get to the core value proposition for your brand.
- Important steps for researching IoT technologies and considerations for aligning them to your brand strategy.

Matt Balogh, Sr. Content Engineer, The Medicines Company

4:20 – 5:00 pm

PANEL DISCUSSION: Internet of Things Technology Showcase – Hear from the latest tech companies' leadership on their challenges in implementation and outreach

- Hear from top innovators who are leading the charge with the latest IoT, wearable, connected device technology and systems integrations aimed at improving clinical trials
- Understand their concerns and hurdles that they must overcome when facing the FDA and gaining support within organizations

Featuring: InterVRx
Clinical Ink
Intercia
Integron

Moderated by: ***Victor Morrison, Next IT Healthcare***

5:00 – 6:15 pm

Networking Drinks Reception

6:15 pm

End of Day One

Day Two, November 8th

8:00 – 9:00 am

Day Two Registration Open

9:00 – 9:10 am

Chairman's Day One Recap and Opening Remarks

9:10 – 9:35 am

MORNING KEYNOTE
The Known Knowns, Known Unknowns, and Unknown Unknowns:
Bringing Wearables and IOT into Today's Clinical Trials

- Where is Pfizer actively incorporating digital and wearable strategies into development programs?
- What are the anticipated benefits of digital and wearables in today's research programs?
- How are tools being deployed and supported in trials today?

Craig Lipset, Head, Clinical Innovation, Pfizer

9:35 – 10:00 am

CASE STUDY: 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

10:00 – 10:25 pm

A Look at Standards from the ACRP

Jim Kremidas, Executive Director, Association of Clinical Research Professionals

10:25 – 11:00 am

KEYNOTE DISCUSSION: Digital Health Devices and Data in Clinical Trials

Jennifer Plumer, Director of Market Development, Validic

11:00 – 11:20 am	Networking Break *Serrano Ballroom Conference Foyer*
11:20 – 11:55 am	**CASE STUDY:** How Connected Devices can Aid in Patient Education - Transforming the way Healthcare is Experienced and Delivered • How engaging patient communities on their terms can lead to better recruitment and improve retention and outcomes • Understand the psychology behind patient experience and what patients want to see before committing to a trial • Additional considerations for site operations *Nariman Nasser, VP Site Operations, Continuum Clinical (formerly of Roche)*
11:55 – 12:30 pm	**PANEL DISCUSSION:** What Steps can Pharma, Sites and the Industry take Next to Drive Innovation in Clinical Trials around IoT? • Understand how pharma innovations, sites, and industry associations can work together to outline best practices to improve the patient experience in clinical trials *Craig Lipset, Head, Clinical Innovation, Pfizer* *Nariman Nasser, VP Site Operations, Continuum Clinical (formerly of Roche)* *Jim Kremidas, Executive Director, Association of Clinical Research Professionals*
12:30 – 1:30 pm	Executive Networking Luncheon *Serrano Ballroom Conference Foyer*
1:30 pm	End of Conference