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June 12-14 2017, **Boston, MA**



2nd Annual

mHealth[®] for Clinical Trials

**Dedicated to Helping Trial Sponsors and Sites
Harness the Power of mHealth Technologies in
Transforming Clinical Trial Success**

20+ Speakers, Including:



Rob DiCicco

Vice President - Clinical Innovation, Digital
Platforms, Clinical Pharmacology Sciences &
Study Operations
GSK



Todd Townsend

Principal Investigator & Staff Fellow
FDA
Pending Final Approval



Craig Lipset

Head of Clinical Innovation
Pfizer



Lauren Bataille

Associate Director
**Michael J. Fox Foundation for Parkinson's
Research**



Jeremy Sohn

Vice President & Head of Digital Business
Development & Licensing
Novartis

■ This was a very well
organized meeting with
great, relevant content and
engaging speakers. ■

Kathleen Thrush, Abbott



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mHealth for Clinical Trials LinkedIn Group





Welcome to the 2nd Annual mHealth for Clinical Trials Summit

The explosion of medical sensors and devices, combined with advanced data collection, management and analytical technologies, provides a **tremendous opportunity to enhance the way we conduct clinical trials and accelerate the delivery of new therapies to patients**. Now, with regulators continuing to encourage the use of mHealth technologies in clinical research, the pressure is increasingly on sites and sponsors to **address the technical and cultural concerns that are preventing wider adoption**.

Designed with input from leaders across the mHealth, clinical innovation and clinical data, the **mHealth for Clinical Trials Summit** will provide new insights and experiences into technologies evolving m-clinical strategies. The aim is to improve patient enrolment, adherence and engagement across biopharma.

Through a series of case study driven presentations, this is your chance to **assess the critical challenges facing the implementation and utilization of these technologies within your organization**. Join industry leaders in forging the path forward in transforming the clinical trial process through the revolutionary impact of mHealth.

Top 5 Reasons to Attend mHealth for Clinical Trials Summit 2017

- 1 Overcome 'pilotitis' and operationalize your mHealth trials** from early exploratory studies to larger scale explanatory ones
- 2 Tackle the increased complexity and richness of data collected as well as ultimately how to overcome the challenges of data integration, analysis and security**
- 3 Explore the regulatory landscape with insights from the FDA**, to discover how regulators want mobile and wearable technology applied in clinical trials
- 4 Demonstrate a clear return on investment and build buy in from top down – bottom up**
- 5 Learn through example** as leading organisations and institutions divulge their successes and failures during their journeys in implementing mHealth solutions within clinical trials

Hear What Previous Attendees Have To Say:

“The meeting content was great! The best part was that it was not all about the vendor and their products (unlike a lot of other conferences). The contents of the talks were very informative.”

Devyani Gupta, Abbott Vascular

“A very useful meeting. Companies shared their experiences in implementing mHealth solutions in their drug development programs.”

Jang-Ho Cha, Novartis Institute for Biomedical Research

“This conference did a great job of attracting the top minds, influencers and leaders in mobile health all in one place. These are the people that will change the face of research.”

Joe Dustin, Medidata Solutions





Speakers



Austin Speier
Director
Emerging Technologies Precision For Medicine



Charles Wolfus
Head of Digital Health and Technology
MyoKardia



Craig Lipset
Head of Clinical Innovation
Pfizer



Daragh Ryan
mHealth Program Manager
Actelion Pharmaceuticals Ltd



David Wang
Founding CEO
Striiv



Elena Izmailova
Senior Director, Capabilities and Devices, R&D Informatics
Takeda Pharmaceuticals Inc



Faith Gunning
Associate Professor of Psychology in Psychiatry
Weill Cornell Medical College



Georgia Mitsi
Senior Director, Search & Evaluation, Digital Healthcare Initiatives
Sunovion Pharmaceuticals Inc



Gowri Murthy
Principal Scientist, Translational Medicine
Merck & Co, Inc



Jyoti Mishra
Assistant Professor
University of California San Francisco



Jeremy Sohn
Vice President & Head of Digital Business Development & Licensing
Novartis



Lauren Bataille
Associate Director
Michael J. Fox Foundation for Parkinson's Research



Marc Foster
COO
Transparency Life Sciences, LLC



Matthew T. Roe
Professor of Medicine, Division of Cardiology – Faculty Director Global Outcomes Commercial Megatrials
Duke Clinical Research Institute (DCRI)



Mohammed Ali
Director, R&D Operation Innovation Leader
Janssen Pharmaceuticals



Patricia Areán
Professor in Psychiatry and Behavioral Sciences
University of Washington School of Medicine



Ray Dorsey
David M. Levy Professor of Neurology; Director, CHET
University of Rochester



Rob Diccio
VP, Clinical Innovation
GSK



Rosalind Picard
Professor, MIT Media Laboratory & Director of Affective Computing Research
MIT



Spyros Papapetropoulos
VP & Global Head, Neurodegenerative Diseases, Movement Disorder & Clinical Research Transformation
Teva Pharmaceuticals



Todd Townsend
Principal Investigator & Staff Fellow
FDA
Pending final approval



Conference Day One | June 13 2017



Spyros Papapetropoulos,
Vice President, Global
Head Clinical
Development
Neurodegenerative
Diseases, **Teva
Pharmaceuticals**

8.30 Chairman's Opening Remarks: Where Are We Now & A Vision for the Future

Overcoming Cultural Barriers to mHealth Implementation



Jeremy Sohn, Vice
President & Head of
Digital Business
Development &
Licensing,
Novartis

8.40 Novartis' Story: Overcoming Cultural Barriers to Achieve Wide Scale Organizational Adoption

- Disrupting preconceptions and conservatism to achieve an organizational ethos that truly supports innovation, where:
 - Failures are milestones to success and risk is accepted as the price of reward
 - Standard operating procedures are continuously challenged and improved upon, raising the bar for every new study
 - Top down leadership and objectives are aligned and reinforced
- Highlighting Novartis' journey on this path, along with successes & failures, and lessons learned



Craig Lipset, Head of
Clinical Innovation,
Pfizer

9.10 mClinical: Technology and Culture to Make Mobile Tools "Business As Usual" in Development

- Discuss Pfizer's approach to making mobile tools from the exception to the norm for development programs
- Explore the culture shift and leadership engagement required to make an enterprise change
- Review the anticipated impact of pervasive use of mobile tools in development programs



Craig Lipset, Head of
Clinical Innovation,
Pfizer

9.40 Panel Discussion: Innovation, Adoption, Implementation: Infrastructure Needed to Deploy Digital Tools in Clinical Trials

- Unravelling the possibilities behind remote real-time data acquisition during clinical trials
- Return on investment – understanding if the results driven from wearables compensate implementation and maintenance costs
- Exploring risks and risk appetites in experimenting with new technologies and championing change within your organization
- Addressing partnering strategies with biotech, CRO and tech organisations to enhance the adoption process.
- Selling the new approaches to internal therapeutic area heads



Jeremy Sohn, Vice
President & Head of
Digital Business
Development &
Licensing, **Novartis**



Rob Diccio, VP,
Clinical Innovation,
GSK

10.25 Morning Refreshments and Speed Networking

Facilitating the Conduct of Clinical Trials



Matthew T. Roe,
Professor of Medicine,
Division of Cardiology
– Faculty Director
Global Outcomes
Commercial
Megatrials,
**Duke Clinical
Research Institute
(DCRI)**

11.25 Electronic Facilitation of Clinical Trials Using mHealth Technologies to Enhance Patient Engagement and Trial Conduct

- Showcase the lessons learned from the ADAPTABLE trial which is the first, large-scale pragmatic clinical trial being conducted in the United States solely using electronic health record data
- Discuss options for leveraging mHealth technologies and approaches for trial recruitment
- Delineate a framework for evaluating clinical trial quality metrics using electronic facilitation and mHealth technologies for trial conduct



Mohammed Ali,
Director, R&D
Operation Innovation
Leader, **Janssen
Pharmaceuticals**

11.55 Building in Stakeholder Perspectives To Enhance Trial Design

- Exploring why patient/site feedback is critical for success
- Redefining the operating model through ecosystem partnerships by integrating the entire value chain from end to end
- Different approaches for obtaining this feedback and ultimately measuring success

12.25 Lunch & Networking

Wearables, Sensors and the Next Generation of Patient Focused Tools



Jang-Ho Cha, Global
Head Translational
Medicine,
**Neuroscience
Novartis IBR**

1.25 Harnessing Big Data & Wearable Technology to Advise Clinical Readouts

- Debating big data vs. objective measures for specific conditions
- Evaluating wearable devices consumer vs. medical grade; what should we use and when?
- Understanding the difference between what patients are willing to use and what researchers are looking for



David Wang,
Founding CEO,
Striiv

1.55 Spotlight Presentation: Upcoming Wearables for Clinical Trials that are Consumer Friendly and Clinically Validated

- Exploring how the next-generation wave of wearables will be applied across various phases of clinical trials
- Answering what is necessary to accelerate the trend towards a "clinical trial in a box" at scale
- Beyond geolocation and heart rate data – looking towards the next set of sensors to achieve data collection for essential biomarkers and study adherence



Gowri Murthy,
Principal Scientist,
Translational
Medicine,
Merck & Co, Inc

12.05 Mobile Health Technologies in Clinical Development: A Patient-Centric Approach

- Utilization of mobile health technology to augment clinical data through at-home dosing and sampling
- Demonstration of dosing adherence devices and trial participant response
- Integration and reconciliation of data from devices

2.35 Afternoon Refreshments & Dedicating Poster Session



Barriers to Innovation: Regulatory Frameworks for mHealth Applications

 Todd Townsend, Principal Investigator & Staff Fellow, FDA <i>(Pending Final Approval)</i>	3.15 Exploring Opportunities to Address Gaps in the Regulatory Environment for mHealth Technologies • Overview of regulatory framework: how mobile health and connected technologies may enhance this framework • Historical perspective on compliance, quality control and quality assurance for mHealth generated data • Balancing innovation, validation and qualification in a risk: benefit manner to maximize value and avoid unnecessary risk to patients • Tips on how best to navigate the regulatory environment • Discussion on common miscomprehensions and recurrent themes arising across diverse stakeholders
 Austin Speier, Director, Emerging Technologies, Precision For Medicine	3.45 Reinventing mHealth Tool Validation • Questioning the current clinical validation cascade and exploring the drive to re-think the current process • Regulated research for mobile health and connected technologies • Understanding the path forward for clinical trial innovation and how best to navigate the regulatory environment • Achieving robust, rich and validated new endpoints through mHealth
 Charles Wolfus, Head of Digital Health and Technology, MyoKardia  Todd Townsend, Principal Investigator & Staff Fellow, FDA <i>(Pending Final Approval)</i>  Austin Speier, Director, Emerging Technologies, Precision For Medicine	4.15 Panel Discussion: Collection & Reporting from Wearable Devices Cloud, in Supplementing or Replacing Standard Measures in Clinical Trial Reporting? • Maximizing data collection and analytic capacity to enrich clinical trials – balancing the power of data volume with outcome fidelity and measurement accuracy • Identifying, testing and mitigating risk by (theoretically and experimentally) exploring worst case scenarios • Ensuring biometric validation and physician sign-off – formalizing the process and preventing data manipulation • Understanding fit-for-purpose device accuracy and adequacy for diverse case studies – high level overview • Evaluating the reality of challenges of combining (unapproved) devices and drug discovery in (FDA-Centre crossing) clinical research – approval and implementation considerations for wearable devices • Is real time data acquisition a necessity? What level of sampling is sufficient? • Patient compliance and device wearability – how to find the right balance between technical accuracy and reliability and patient comfort
	5.00 Close of Conference Day One

Perfect networking opportunities with true value. Great meeting with decision makers and scientists mixing well.

TMO, Past Attendee, Hanson Wade Event

A great meeting. The networking opportunities were fantastic

Pfizer, Past Attendee, Hanson Wade Event



Conference Day Two | June 14 2017

 Spyros Papapetropoulos, Vice President, Global Head Clinical Development Neurodegenerative Diseases, Teva Pharmaceuticals	8.50 Chairs Opening Remarks
Implementing mHealth Technology on a Global Scale	
 Daragh Ryan, mHealth Program Manager, Actelion Pharmaceuticals Ltd	9.00 Moving Beyond the Hype. Operationalizing mHealth in Pharmaceutical Sponsored Clinical Trials • How to build buy-in, from the top down and the bottom up • How to scale from experiment to full roll-out • Understanding risks and risk appetites in experimenting with new technologies and championing change within your organization
 Rob Diccio, VP, Clinical Innovation, GSK	9.30 Clinical Research and the Internet of Things: Leveraging Connected Devices to Gain Patient Insight • Exploring the role of IoT in advancing clinical research • Sharing emerging data from GSK's Patient Rheumatoid Arthritis Data from the Real World (PARADE) Study
 Daragh Ryan, mHealth Program Manager, Actelion Pharmaceuticals Ltd  Elena Izmailova, Senior Director, Capabilities and Devices, R&D Informatics, Takeda Pharmaceuticals Inc	10.00 Panel Discussion: Overcoming Barriers in mHealth Adoption: Digital Data Privacy, Security & the Implications of Globalizing mHealth Trials • Exploring how can we begin to successfully navigate the ongoing concern of privacy and security especially in areas involving sensitive behaviour or treatment • Understand what safeguards we should be utilizing to balance the type of information being used, the intended use of the tool and the method of sharing information • Investigating initiatives and technologies such as Blue Button as a means to gain patient backing • Addressing the apparent disconnect between patient perception of privacy in daily life compared with that in the research setting: is there a need to support overall efforts to increase the public's knowledge of privacy and security risks? • Is it necessary to move away from a sectorial system, where there separate laws for different systems, towards one where privacy is encoded in robust data protection laws similar to the European Union? • What lessons can be learned from solutions commonly used Internet/eHealth, telemedicine, and cybersecurity research?
	10.45 Morning Refreshments & Networking
Establishing the Governance and Strategy Essential for Data Driven Trials	
 Lauren Bataille, Associate Director, Michael J. Fox Foundation for Parkinson's Research	11.30 A Collaborative Approach to End-to-End Algorithm Development and Validating Project Data for Parkinson's Disease Research • Providing an overview of open-source datasets with digital data in Parkinson's disease • Highlighting a collaborative research strategy to develop publicly available clinical outcome assessments for use in Parkinson's disease research • Presenting MJFF's computational science portfolio: data challenges and grants to incentivize innovative analytical approaches



 Rosalind Picard, Professor, MIT Media Laboratory & Director of Affective Computing Research, MIT	12.00 Using Machine Learning to Enable the Next Generation of Mobile Health Tools - Combining data capture from wearable and mHealth tools with novel analysis methods to achieve more in tune diagnostic information - Exploring diagnostic guidance algorithms for clinical data analysis to predicting patient states and understanding disease
 Rosalind Picard, Professor, MIT Media Laboratory & Director of Affective Computing Research, MIT  Jang-Ho Cha, Global Head Translational Medicine, Neuroscience Novartis IBR  Lauren Bataille, Associate Director, Michael J. Fox Foundation for Parkinson's Research	12.30 Panel Discussion: Overcoming Barriers in mHealth Adoption: Digital Data Privacy, Security & the Implications of Globalizing mHealth Trials - Exploring the prospects for digital health and data science in clinical research - Data collection – addressing the major challenges around data intellectual property, data sharing and data standards - Assessing the variability of collected data and how to deal with the different paces of technology development - Evaluating data privacy approaches – the struggle behind handling privacy issues - Reaching actionable insight – data collection is just the first step towards data-driven decision-making
	1.15 Lunch & Networking
The Challenges & Opportunities in Trial Virtualization	
 Spyros Papapetropoulos, Vice President, Global Head Clinical Development Neurodegenerative Diseases, Teva Pharmaceuticals	2.15 Re-wiring Clinical Development in CNS: Biometric Monitoring, Smart & Virtual trials - Questioning how biometric tech platforms can contribute to clinical development and can ultimately replace the search for accurate surrogate biomarkers? - Exploring how we can make clinical trials 'smarter' as well as identifying what components are needed for trial virtualization - Addressing whether or not patients are ready for the use of mHealth in the clinical setting
 Ray Dorsey, David M. Levy Professor of Neurology; Director, CHET, University of Rochester	2.45 Studies of mHealth in Clinical Trials - Highlight incorporation of a smartphone application into Parkinson disease clinical trials - Study of feasibility of virtual visits in a Phase 3 Parkinson disease clinical trial - Incorporation of virtual visits into a Huntington disease clinical trial
	3.15 Afternoon Refreshments
mHealth as Tools for Achieving Rich, Robust and Reliable Endpoints	
 Georgia Mitsi, Senior Director, Search & Evaluation, Digital Healthcare Initiatives, Sunovion Pharmaceuticals Inc	3.45 The Need for Novel Endpoints in Neuroscience Clinical Trials - Addressing current success rates in neuroscience drug development, which are too low to be sustainable - Evaluating modern technologies that hold promise for more direct, more continuous assessment of disease severity and medication effect - Exploring the integration of novel endpoints could revolutionize drug development in Neuroscience
 Patricia Areán, Professor in Psychiatry and Behavioral Sciences, University of Washington School of Medicine	4.15 Retaining Remote Clinical Samples - Discussion of engagement theory - Use of coaches, gamification, and incentives - Exploring the relative cost of engagement strategies and potential return on investment
	4.45 Chairman's Closing Remarks & Close of Conference



Workshop A

Collecting Clinical Outcome Data Remotely: Advanced Analytics for mHealth Collected Data

Date: June 12 2017 | Time: 9am - 12pm

Big data analytics and new clinical mHealth technology promise to significantly change how trials are conducted and increase the value of the data and insights that come out of these trials.

Advancements in computing power and predictive analytics tools enable us to process vast amounts of information and develop insights in mere seconds. But what methods are available to collate disparate data sources so that we can share data and use advanced analytics to make better decisions — all with the goal of getting effective drugs to market faster?

In this workshop we will address:

- Challenges and potential solutions of deploying wearable devices in the clinic, in forging a path to novel outcome measures
- Consumer and medical grade devices – fit-for-purpose principle
- Areas of opportunity and successes in utilizing big data for wearable and sensor enabled trials
- The major challenges around ensuring data integrity, intellectual property, sharing and data standards
- Current methodologies and food for thought in overcoming the variability of the collected data and how to deal with the different sources of data
- Diving into the detail of defining novel digital disease biomarkers, phenotypes and end types



Workshop leader

Elena Izmailova, Senior Director of Devices & Novel Data Streams, Data Science Institute, **Takeda Pharmaceuticals Inc.**

Elena has a unique background of technology innovation, scientific strategy and business management. She is a Senior Director of Devices and Novel Data Streams at Takeda Pharmaceuticals Inc., working on implementation of innovative technologies in drug development. Elena demonstrated a consistent record of achievement in pharmaceutical industry and academic research. She successfully lead teams, improved business processes, and delivered timely, impactful results.

CHOOSE
A OR B

Workshop B

Combining Crowdsourced Protocol Design & Digital Study Execution - Putting Patients & Clinicians at the Center of the Clinical Development Process

Date: June 12 2017 | Time: 9am - 12pm

Recent applications of open innovation and mobile health in biopharma R&D create an opportunity for an all-digital approach to clinical trial design and execution that promises to put key stakeholders at the center of the design process, lower costs and increase convenience of data collection, and pave the way for novel endpoints.

This workshop will focus on the intersection of protocol design and digital study execution, presenting case studies in diverse therapeutic areas from the perspectives of end-users, sponsors, and technology suppliers.

The goal is for workshop participants to leave with an enhanced toolkit for exploiting the potential for all-digital clinical development.



Workshop leader

Marc Foster, COO, **Transparency Life Sciences, LLC**

Marc brings 16 years of biotech and 15 years of high-tech experience to TLS. Prior to Transparency, he worked in business development for FoldRx Pharmaceuticals, where he helped craft and implement the business development strategy of the company's protein misfolding pipeline and discovery platform, leading to an acquisition by Pfizer in 2010. Marc began his biotech career working on behalf of Schrodinger in product development. Subsequently he co-founded and built Reify Corporation, developer of high-content assay systems for pre-clinical discovery and toxicology. During his high-tech career Mr. Foster held operating, co-founding, and advisory roles with numerous firms that created substantial shareholder value through acquisition or public offering, including NETBot, Apropos, and InTouch Systems. Mr. Foster holds a BS in Electrical Engineering and a BA in English from Brown University, and a MBA in Finance from The University of Chicago Booth School of Business. He served as a Research Fellow at BIDMC/Harvard Medical School in Endocrinology.



Workshop C

The Role of Games and Gamification in the Future of Clinical Trials

Date: June 12 2017 | Time: 1pm - 4pm

Games provide a fun and engaging approach to learning and equally provide a compelling environment to measure aspects of cognition and movement, when integrating real-time biosensing, neurostimulation, or motion-based approaches.

Gamified trials measuring health outcomes offer particular value in niche indications, but whilst still their infancy of use, a number questions remain as to their universal applicability and validity.

This workshop will explore:

- The use of neuroscience- inspired videogames to improve mood and cognitive control through:
 - Reviewing role of poor cognitive control across a number of cognitive and psychiatric conditions
 - Presenting rationale for the use of videogames to enhance functioning of cognitive control systems
- Interactive game-based technologies that are providing:
 - Better informed trial participants with associated reduced dropouts, and increased participation in clinical trials.
 - Engaging approaches to drive behavior and act as assessment tools in disease areas with a lack of end points.
- Learnings from training the brain from Silicon Valley to the streets of Delhi
 - The evolving state of clinical mental health research games – examples, goals, budgets.
 - Interfacing multiple intervention methods and technologies within a user-focused package.
 - Scale-up across diverse cultural settings.



Workshop leader

Faith Gunning, Associate Professor of Psychology in Psychiatry, **Weill Cornell Medical College**

Dr. Gunning is the Vice Chair of Psychology and Director of Neuropsychology. In addition she is a co-PI on an NIMH funded study focused on using therapeutic video games to treat cognitive and mood symptoms.



Workshop leader

Jyoti Mishra, Assistant Professor, **University of California San Francisco**

Dr. Mishra is a translational neuroscientist with expertise in attention, learning and brain plasticity. In her research, she has developed and implemented digital mental health in both local and global community setting and has been recognized by numerous awards.

CHOOSE
C OR D

Workshop D

Best Practices in Assessing Clinical Trial Quality to Drive Clinical Trial Performance

Date: June 12 2017 | Time: 1.00 – 4pm

Recently, clinical trial performance data has demonstrated how expensive and disruptive poor protocol design can be on clinical development performance and cost, ultimately delaying medicines to patients. This workshop will focus on best practices in assessing clinical trial performance to design higher quality clinical trials. The goal is for workshop participants to leave with a robust toolkit measuring clinical trial performance.

- Review current trends in protocol design; e.g. protocol complexity; protocol amendment prevalence; adaptive trial design; and management practices to enhance protocol design
- Utilize patient and investigator feedback to drive clinical trial protocol optimization
- Conduct root cause analyses by capturing meaningful impact measures on clinical trial performance



Workshop leader

Stella Stergiopoulos, Research Fellow, **Tufts Center for the Study of Drug Development**

Ms. Stella Stergiopoulos manages multi-sponsored and grant funded research projects at Tufts CSDD. She has experience conducting research on pharmaceutical industry practices and trends affecting pharmacovigilance, non-clinical drug development, pharmaceutical outsourcing practices, cycle time metrics, resource management, and protocol design. She has also been a speaker at conferences and has published articles in peer-reviewed and trade journals. Prior to joining Tufts CSDD, Ms. Stergiopoulos was a research associate at The Brattle Group and a researcher at Massachusetts General Hospital. She holds a BA from Brandeis University, and an MS and MPH from Tufts University.



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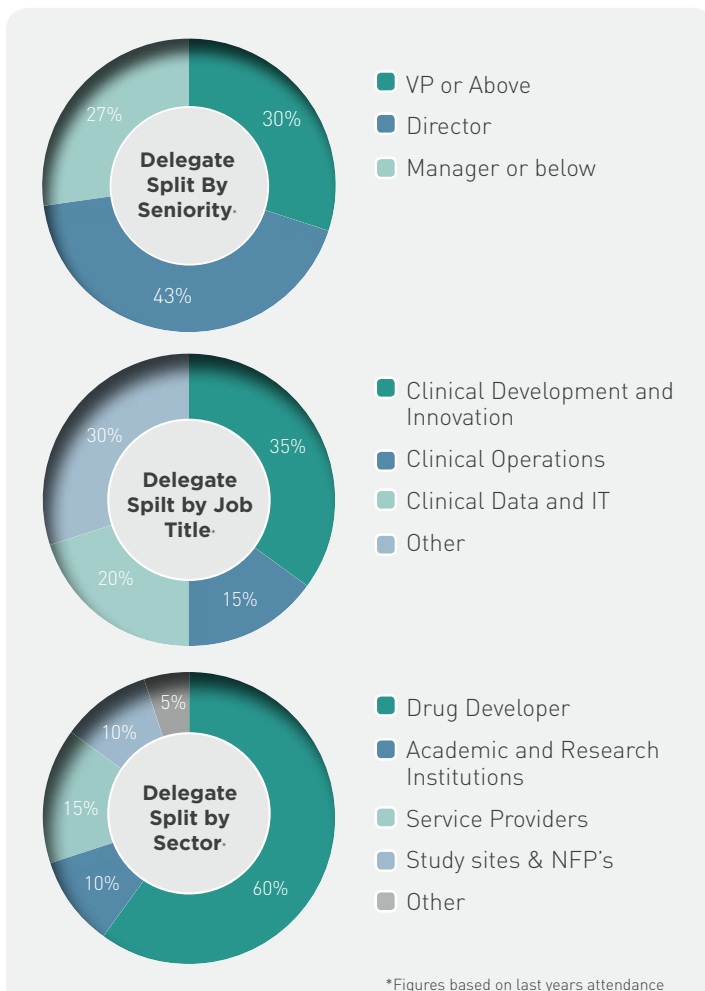
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Please note that discounts are only valid when three or more delegates from one company book and pay at the same time.

Top 3 Benefits of Attending

- 1** Demonstrate a clear return on investment and build buy in from top down – bottom up
- 2** Learn through example as leading organisations and institutions divulge their successes and failures during their journeys in implementing mHealth solutions within clinical trials
- 3** Overcome 'pilotitis' and operationalize your mHealth trials from early exploratory studies to larger scale explanatory ones

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PLATINUM Conference + 2 Workshops	\$3397 (save \$700)	\$3497 (save \$600)	\$3597 (save \$500)	\$3697 (save \$400)
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Venue

Aloft Boston Seaport Hotel

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Full payment is due on registration. Cancellation and Substitution Policy: Cancellations must be received in writing. If the cancellation is received more than 14 days before the conference attendees will receive a full credit to a future conference. Cancellations received 14 days or less (including the fourteenth day) prior to the conference will be liable for the full fee. A substitution from the same organization can be made at any time.

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