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July 16-18, 2019 | Boston, MA

www.impact-mhealth.com

IMPACCT mHEALTH IN CLINICAL TRIALS

Driving Digital Innovation Towards Truly Patient- Centric Clinical Studies

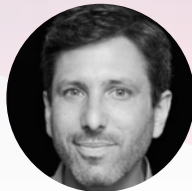
Expert Speakers include:



Kamal Jethwani
Senior Director,
Pivot Labs
**Partners
Healthcare**



Ching Tian
General Manager,
Digital Accelerator
Novartis



Craig Lipset
Head of Clinical
Innovation
Pfizer



Kyle Holen
Head of
Development
Design Center
AbbVie



Lindsey Riley
Associate Director
- Research
Partnerships
**The Michael J.
Fox Foundation
for Parkinson's
Research**

Partner:



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 [@mHealth_Trials](https://twitter.com/mHealth_Trials)



Welcome to the 4th Annual IMPACCT: mHealth in Clinical Trials Boston

Leveraging digital and mobile tools to enhance patient-centricity and outcomes in clinical trials

The clinical and digital innovation space continues to undergo huge growth and development, driven by an underlying maturity in implementation examples of digitally-enabled capabilities in clinical R&D, as well as an industry focus on patient-facing approaches.

The IMPACCT: mHealth in Clinical Trials series will again bring together the top clinical and digital leaders for a comprehensive and open discussion on how to **support and drive the clinical innovation needed to make trials truly patient-centric, through the use of digital tools.**

Join your peers at this collaborative discussion platform that aims to transform the way patient data is collected and utilized, rethink clinical trial methodologies, overcome key implementation challenges and promote patient-centricity in clinical studies with mobile and digital approaches.

Hear what previous attendees have to say

Very good presentations and topics, well aligned with what our company is interested in. Useful cases on how mobile is used, video game ePRO and digital library were highlights. Insights into sponsors level of activity in mHealth was important

Pfizer

The conference delivered some excellent insight on state of the art in mHealth in the pharmaceutical industry

Sage Therapeutics

This was a great event, great networking, great presentations. A fantastic platform for us to share new innovative ideas in mHealth, which will massively change clinical research

Oracle Health Sciences

5 Highlights You Cannot Miss



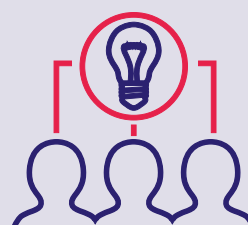
Pfizer, AbbVie, Novartis and LEO Innovation Lab discuss clinical innovation, examples of re-imagined clinical trial methodologies with digital and remote capabilities, and the what's next.



Sunovion Pharmaceuticals and Partners Healthcare address the challenges in implementation and scalability of digitally-enabled clinical trials, from the pharma and site perspectives.



Bristol Myers-Squibb, The Michael J. Fox Foundation and Amgen explore considerations and approaches to driving true patient-centricity in clinical research, including support for trial design, ePRO, or patient engagement apps.



UCB, the Clinical Trials Transformation Initiative (CTTI) and the Digital Medicine (DiMe) Society share thoughts on the multi-stakeholder collaboration needed to drive patient-facing digital innovation in clinical trials to the next level.



Delve into **interactive discussions**, from expert panel sessions with dedicated Q&A, to **round table group discussions**, or an in-depth **workshop**, to explore different views and approaches, shared challenges and new opportunities.

It was wonderful to spend two days immersed in mHealth and to understand the great work being done by other companies **Bristol-Myers Squibb**

YOUR EXPERT SPEAKERS



Amanda Centi
Research Program
Manager
Partners Healthcare



Ameya Phadke
Senior Manager,
Technology & Digital
Partnerships
Chiesi USA



Ching Tian
General Manager, Digital
Accelerator
Novartis



Christopher Tarolli
Instructor of Neurology &
Fellow, Movement Disorders
& Experimental Therapeutics
of Neurological Disease
**University of Rochester
Medical Center**



Cindy Geoghegan
Principal, **Patient & Partners**,
& Project Lead, Mobile Clinical
Trials: Engaging Patients &
Sites Project
**Clinical Trials Transformation
Initiative (CTTI)**



Craig Lipset
Head of Clinical
Innovation
Pfizer



Deb Farlow
Clinical Operations &
Research Manager
Akili Interactive Labs



Elena Izmailova
Co-founder, Strategic
Advisory Board Member
& Co-Chair of DiME
Research Committee
**Digital Medicine (DiMe)
Society**



Georgia Mitsi
Senior Director – Search
Evaluation, Digital
Healthcare
**Sunovion
Pharmaceuticals**



Gergely Vertes
Solution Accelerator,
Wearable for Epilepsy
UCB



Hassan Kadhim
Director, Head of Clinical
Trial Business Capabilities
Bristol-Myers Squibb



Jamie Adams
Assistant Professor,
Department of Neurology
& Center for Health +
Technology
**University of Rochester
Medical Center**



Jeremy Wyatt
CTO
ActiGraph



Kamal Jethwani
Senior Director, Pivot
Labs
Partners Healthcare



Kyle Holen
Head of Development
Design Center
AbbVie



Laura Cooke
Executive Director,
Global Clinical Program
Management
Amgen



Leyla Rich
Associate Director, Clinical
Trial Engagement &
Enrollment, Global Clinical
Operations
Bristol-Myers Squibb



Lindsey Riley
Associate Director –
Research Partnerships
**The Michael J. Fox
Foundation for
Parkinson's Research**



Rasmus Hogrefe
Head of Virtual Clinical
Trials
LEO Innovation Lab



Scott Kellogg
Senior VP, Medical
Devices
Akili Interactive Labs



Stacey Curtiss
Senior Director & Leader,
Medical Science Liaison
Team
Akili Interactive Labs



Zachary Kabelac
Senior Researcher
MIT

Great conference. One of the most targeted conferences I have
been to with lots of knowledgeable senior people
Shimmer Research Inc

CONFERENCE DAY ONE

WEDNESDAY, JULY 17

	8.45 Chair's Opening Remarks
Craig Lipset Pfizer Georgia Mitsi Sunovion Pharmaceuticals Jeremy Wyatt ActiGraph Kyle Holen AbbVie	9.00 'IMPACCT' Panel Discussion: Implementing Patient-Centric Clinical Transformation – A Guide on What We Know & What We Still Look to Achieve - Analyzing the changing clinical research paradigm and the role of digitally-enabled approaches in clinical innovation – enhancing research outcomes and patient-facing medicine - Old vs. New – balancing optimization of processes and approaches with digital tools vs. complete disruption of the clinical R&D model (e.g. virtual trials) - Are we transforming the traditional model of clinical research, or just disrupting it with technology? - Discussing technology implementation in clinical research – is it happening because it's available or are we solving any specific problems? - Ensuring the value and ROI of digital innovation in clinical trials – would we continue in our journey for patient-centric, technology-enabled trials without reductions in cost or time? - How can digital and clinical innovation teams be effectively organized and structured? And how can we integrate them in to the process? - Defining a holistic view on how to implement technology into clinical research: key challenges and what's next
Rethinking Clinical Trial Methodology	
Craig Lipset Head of Clinical Innovation Pfizer	9.45 From the Current State to the Future – What Digital Gaps Remain? - Reviewing the current state of digital in medicine development against a desired future - Identifying the gaps that remain to create the future of digital in clinical development - Exploring what it will take to create the future
	10.15 Speed Networking Session
	10.45 Morning Refreshments
Kyle Holen Head of Development Design Center AbbVie	11.15 The End of Manual Data Entry in Clinical Research - Why is our current system of data capture failing us? - How is AbbVie tackling this problem? – reviewing case-studies - Discussing the future of data capture in clinical research
Ching Tian General Manager, Digital Accelerator Novartis	11.45 Reimagining the Current Standard Clinical Trial Approach – The Patient Centric Remote Trial Model - Analyzing the patient centric remote trial model and the huge potential it offers to reimagine the current standard clinical trial approach - Discussing the possibilities and pathways to approach this promising new paradigm - Sharing Novartis experience on bringing trials to patients, the challenges and learnings in implementation, and considerations for scalability

Rasmus Hogrefe Head of Virtual Clinical Trials LEO Innovation Lab	12.15 Digitization of Dermatology – Is It Happening? • Overviewing the use of digital patient tools in dermatology • Digitization of clinical trials in dermatology – addressing real-world data generated in clinical trials from digital tools • Providing insight into LEO Innovation Lab's first virtual clinical trial
	12.45 Lunch & Networking
Zachary Kabelac Senior Researcher MIT	1.45 Using Passive Monitoring & AI to Characterize the Home Lives of those with Parkinson Disease • Describing a novel remote sensing technology, Emerald, and how artificial intelligence can enhance its capabilities • Demonstrating real world feasibility of Emerald to analyze and interpreting the clinical meaning of its output • Presenting initial results of a Parkinson Disease Study with a particular focus on gait, home activity, and time in bed
Digitization in Clinical Studies – Behind the Scenes	
Georgia Mitsi Senior Director – Search Evaluation, Digital Healthcare Sunovion Pharmaceuticals	2.15 Lessons Learned from Implementing Technologies in Large Scale Trials • Deciding on the right technology and the right trial • Ensuring seamless coordination among external stakeholders • Defining success
Amanda Centi Research Program Manager Partners Healthcare	2.45 Conducting a Successful Digital Clinical Trial – Key Considerations from The Field • Discussing what are the key stakeholders to involve when setting up your digital trial • Addressing data security & privacy from a patient and hospital perspective • Setting yourself up for success by matching your digital solution to the right trial setting and participant group
	3.15 Afternoon Refreshments & Networking
Jamie Adams Assistant Professor, Department of Neurology & Center for Health + Technology University of Rochester Medical Center	3.45 Mobile Measures in Parkinson's Disease & Huntington's Disease • Discussing the rationale for incorporating mobile measures into clinical trials • Reviewing Parkinson's disease and Huntington's disease wearable sensor and smartphone application studies conducted at the University of Rochester • Considering future directions
Ameya Phadke Senior Manager, Technology & Digital Partnerships Chiesi USA	4.15 AI, Blockchain & Wearables in Clinical Trials: A Dose of Reality • Analyzing the massive uptick in pharma industry's interest in technology, especially in artificial intelligence (AI), blockchain and wearables and how these can be leveraged to lower the time to market for specific drugs • Addressing some use cases – real-world viability and blockers preventing them from becoming a reality • Discussing new developments in the space that have the potential to significantly impact incumbent practices in clinical research • Focusing on the right questions to ask
	4.45 Chair's Closing Remarks

CONFERENCE DAY TWO

THURSDAY, JULY 18



	8.50 Chair's Opening Remarks
Driving Patient-Centricity with Digital-Enabled Approaches	
Leyla Rich Associate Director, Clinical Trial Engagement & Enrollment, Global Clinical Operations Bristol-Myers Squibb	9.00 Incorporating the Patient Voice to Inform & Support Trial Design • More details coming soon
Lindsey Riley Associate Director - Research Partnerships The Michael J. Fox Foundation for Parkinson's Research	9.30 Fox Insight: Driving Discovery with the Patient Voice • Addressing how patient reported outcomes (PRO) data complement traditional clinical research with scale & accessibility, as well as patient-centricity • Advancing patient-centered drug development and amplifying the potential impact the research stands to have on the field at-large – the MJFF sponsored study objectives • Discussing Fox Insight Study data (including PROs and genetic SNPs of interest), which will be made available to qualified researchers in April 2019
Laura Cooke Executive Director, Global Clinical Program Management Amgen	10.00 Implementing a Patient Facing App in a Phase III Clinical Trial • Overviewing the implementation of a patient engagement app in a Phase III clinical trial • Addressing the operational challenges faced and how these could inform future considerations
	10.30 Morning Refreshments & Networking
Kamal Jethwani Senior Director, Pivot Labs Partners Healthcare	11.00 Re-Imagining Clinical Trials Using Digital Technologies - The Healthcare Setting Perspective • Driving innovations in the conduct of trials using digital technologies at Partners Healthcare Pivot Labs – analyzing the advent and adoption of digital technologies and the huge opportunities generated to connect more meaningfully with research participants during clinical trials • Case-studies: highlighting opportunities to use sensors, wearables and other remote monitoring technologies to enrich data collection from participants, as well as use AI to improve the quality of the data collected • Using digital technologies to ease the burden on participant recruitment and retention in trials
Christopher Tarolli Instructor of Neurology & Fellow, Movement Disorders & Experimental Therapeutics of Neurological Disease University of Rochester Medical Center	11.30 Siteless Studies & Video-based Visits in Clinical Research • Discussing the rationale for video-based research visits in clinical trials and natural history studies • Reviewing the evidence for virtual visits with a focus on research in Parkinson disease and other neurological conditions • Discussing barriers to and next steps toward broader implementation
	12.00 Mastermind Session: Driving Digital Innovation Towards Truly Patient-Centric Clinical Studies This session facilitates in-depth discussions among participants in an informal environment. After splitting into groups, participants will discuss key challenges and opportunities regarding the current landscape in mobile and digitally-enabled clinical research.
	12.45 Lunch & Networking

Driving Innovation By Collaborating with Stakeholders

Elena Izmailova
Co-founder, Strategic
Advisory Board
Member & Co-Chair
of DiME Research
Committee
**Digital Medicine
(DiMe) Society**

1.45 The Digital Medicine (DiMe) Society

- Learning about the recently launched DiMe Society, established to serve professionals at the intersection of the global healthcare and technology communities, advancing the practice of digital medicine through interdisciplinary collaboration, research, teaching, and the promotion of best practices
- Discovering opportunities for engagement
- Discussing opportunities to advance digital medicine as part of this new professional society

Gergely Vertes
Solution Accelerator,
Wearable for Epilepsy
UCB

2.15 Driving a Cross Functional Consortium to Deliver Patient Value

- Addressing unmet patient need
- Epilepsy today: from R&D to RCT to daily practice and its outcome
- Discussing public private partnership pros and cons
- Overviewing key learnings from the project and defining next steps based on our current results (medical certification in EU/US)
- Defining a long term vision and its potential impact on patients

2.45 Afternoon Refreshments & Networking

Cindy Geoghegan
Principal, **Patient &
Partners**, & Project
Lead, Mobile Clinical
Trials: Engaging
Patients & Sites
Project
**Clinical Trials
Transformation
Initiative (CTTI)**

3.15 Engaging Patients & Sites to Drive Adoption of Mobile Technology in Clinical Trials

- Understanding the perspectives of patients and investigative site personnel and incorporating those perspectives into trial design and execution – maximizing opportunities and minimizing challenges in the use of mobile technology in clinical trials
- Sharing recommendations and resources developed by the Clinical Trials Transformation Initiative (CTTI) to:
 - Engage patients and investigative site personnel early and often in planning, including protocol design, technology selection, and pilot testing
 - Set participant expectations, protect privacy, return individual patient data, enhance participant-site interactions, and provide technical support
 - Address needs of sites, through contracting and budgeting to evaluating site readiness for mobile clinical trials and implementing effective and streamlined training

Cindy Geoghegan
**Clinical Trials
Transformation
Initiative (CTTI)**

Elena Izmailova
**Digital Medicine
(DiMe) Society**

Gergely Vertes
UCB

Hassan Kadhim
**Bristol-Myers
Squibb**

3.45 'IMPACCT' Panel Discussion: All Aboard the Clinical Innovation Boat! – A Multi-Stakeholder Collaboration to Drive Patient Engagement

- Establishing a collaborative community discussion on how advance digital innovation in clinical trials to the next level and work towards the same goal of patient-centricity and clinical innovation
- Defining best practice and key considerations for enhancing the incorporation of patients' perspectives in clinical trial access, design, conduct and post-trial follow-up
- The patient as a partner – exploring the unique opportunity digital tools present for how clinical trials monitor, communicate and work alongside patients
- Working with the regulators on understanding and defining the standards for acceptance and implementation of digital approaches for data collection in clinical research
- Collaborating with physicians and sites – how to close the loop at the site level
- Looking inwards and demonstrating the value to internal stakeholders – working with procurement teams to advance digital approaches

4.30 Chair's Closing Remarks

PRE-CONFERENCE WORKSHOP

TUESDAY, JULY 16

1:00pm – 4:00pm

Bringing Prescription Digital Therapeutics Through Development to Clinical Validation: Focus on the Patient

Building best practices in development and clinical validation of clinician-prescribed digital therapeutics provides many opportunities for novel solutions to unprecedented challenges. This workshop will address rapidly-developing innovative clinical and regulatory efforts to address the fluid nuances inherent in reaching evolving clinical goals in the context of patient-centric approaches.

Key topics to be addressed include:

• Rethinking Clinical Trial Design

- Study design to support regulatory pathways for digital therapeutic success
- Active control/sham considerations including expectation testing
- Advantages to remote access to devices throughout the course of a study
- Outcome selection to test transfer of benefit from practice on intervention to recognized cognitive and functional improvements, with emphasis on real world experience, as well as clinical trial data

• Case Studies

- Development of control conditions with appropriate expectation and minimal efficacy outcomes
- Selective Stimulus Management Engine (SSME™) in ADHD: Targeted treatment development for different disease populations
- Development of a disease-specific PRO/COA directed at measuring improvement in cognitive issues inherent in patients with MDD
- Commitment to patient and provider experience: Companion Applications

• Future Possibilities

- Personalized Digital Therapeutics (patient-based)
- Expansion of application of digital treatments to healthy individuals and non-traditional therapeutic indications
- Digital therapeutics in the community

Join this interactive focused session that will bring practical insights from DTx pioneers Akili Interactive Labs, into the challenges, learnings and opportunities in digital therapeutics.

Workshop Leaders



Deb Farlow

Clinical Operations & Research Manager

Akili Interactive Labs



Scott Kellogg

Senior VP, Medical Devices

Akili Interactive Labs



Stacey Curtiss

Senior Director & Leader, Medical Science Liaison Team

Akili Interactive Labs

“I think this was a fabulous meeting with interesting talks and great opportunity for networking. Loved the venue and how well it was organized”

Pfizer

“This Conference is very focused with all the right people in the room”

Abbott

PARTNER WITH US

WHY PARTNER

The IMPACCT: mHealth in Clinical Trials series brings together key decision makers and experts in digital and clinical innovation from leading drug developer organizations.

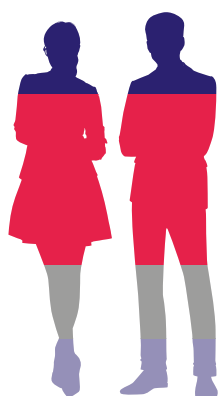
Do you have an innovative digital health solution or platform that can help them run mobile and digitally-enabled clinical studies?

Key players in this space are looking for solutions to enhance data collection, facilitate virtual trials or boost patient engagement, including:

- Wearable sensors and devices
- Remote data capturing
- eCOA and ePRO
- Virtual and decentralized trials
- Clinical data management
- Patient recruitment
- Patient engagement

Demonstrate your expertise and establish yourself as a partner of choice in this rapidly developing landscape.

EXPECTED AUDIENCE BY SENIORITY *



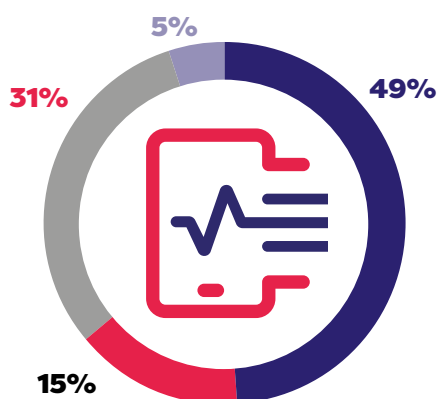
C-level & VP: 21%

Director & Head: 44%

Manager & Lead: 19%

Other: 16%

SENIORITY OF ATTENDEES*



Pharma & Biotech
Academic, Non-Profit & Research Institutions
Service Providers
Other

* Based on previous event's attendance.



Panel Partner

ActiGraph is the leading provider of medical-grade wearable physical activity and sleep monitoring solutions for the global

scientific community. Built on nearly two decades of real-world data capture and management expertise, ActiGraph's innovative ecosystem of hardware and software tools leverage cloud, mobile, and wireless technologies to deliver high quality patient insights, in real time.

www.actigraphcorp.com

Thank you for bringing together such a good group of vendors, CROs, biotech and pharma

Novartis

FOR MORE INFORMATION ABOUT PARTNERING PLEASE CONTACT:



Denvor Oorloff
Partnerships Director
Tel: +1 617 455 4188
Email: sponsor@hansonwade.com



READY TO REGISTER?

3 EASY WAYS TO BOOK



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- 1 Drive true patient-centricity in your clinical programs
- 2 Transform clinical research methodologies
- 3 Overcome key implementation challenges of running digitally-enabled studies

Team Discounts*

- 10% discount – 3 delegates
- 15% discount – 4 delegates
- 20% discount – 5+ delegates

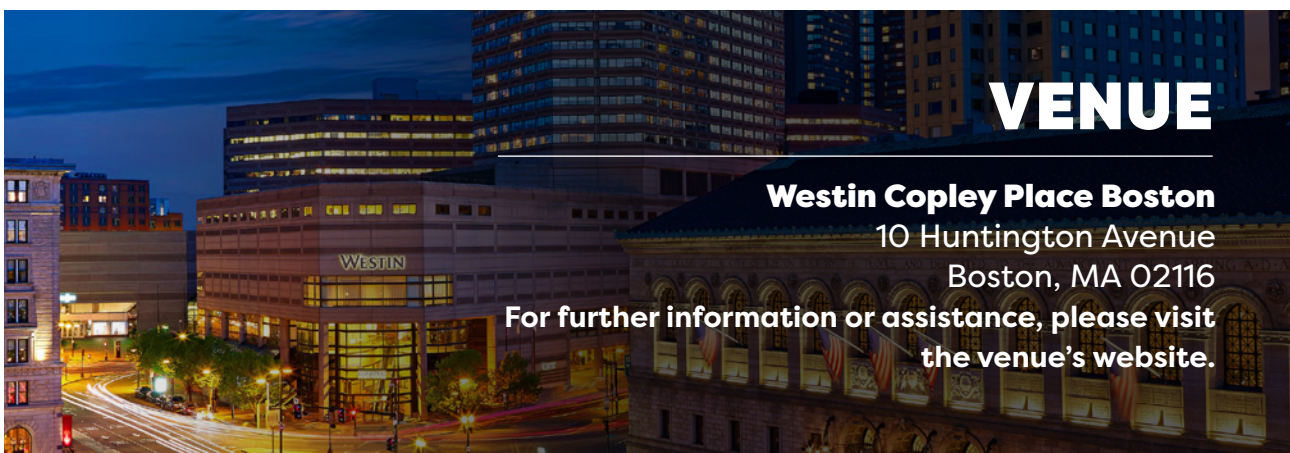
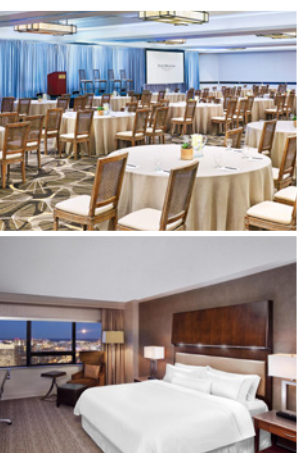
*Please note that discounts are only valid when three or more delegates from one company book and pay at the same time.

Contact: register@hansonwade.com

SECURE YOUR PLACE

Industry	Register & Pay by Friday, May 17	Standard Price
Conference + 1 Workshop	\$3298 (save \$300)	\$3498 (save \$100)
Conference Only	\$2699 (save \$200)	\$2899
Workshops (Each)	\$699	
Academic, Non-Profit & Start-Up	Register & Pay by Friday, May 17	Standard Price
Conference + 1 Workshop	\$1898 (save \$300)	\$2098 (save \$100)
Conference Only	\$1599 (save \$200)	\$1799
Workshops (Each)	\$399	

* Start-up rate is subject to organizer approval. Please visit event website for eligibility criteria.



VENUE

Westin Copley Place Boston

10 Huntington Avenue

Boston, MA 02116

For further information or assistance, please visit the venue's website.

TERMS & CONDITIONS

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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