



PROGRAM COMMITTEE

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Head, Smart Devices
Genentech
A Member of the Roche Group

Kristen Valdes

Founder and CEO
B. Well Connected Health

Dan Tierno, MA, MBA

Associate Director, Project and Portfolio Management
Daiichi Sankyo, Inc

Adria Martig, PhD

Senior Director, Research Programs
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Overview

Digital technology is transforming the drug development process. The rise of wearable and mobile technologies along with cloud technology, Artificial Intelligence and related platforms, now enable the collection of frequent, specific, and multidimensional data throughout the length of trials. These technologies have the potential to enable innovative trial designs, improve the patient experience, act as recruitment and retention tools, and establish novel end points in clinical studies.

With these technologies, large amounts of data are collected. How to best address evaluating fit-for-purpose, standardization, ethical concerns, and regulatory approaches, are key issues to address in the digital era.

DIA's *Digital Technology in Clinical Trials* Conference will bring together thought leaders from regulatory agencies, biotech, pharma, patients, and academia to discuss the latest advances, challenges, and forward-thinking approaches for implementing digital technology to improve clinical trials. While the conference will focus on the impact of digitalization in clinical trials today, we will make time to explore future applications and how they may enable the clinical trials of tomorrow.

Co-Sponsored with ePRO Consortium – Critical Path Institute



Who Should Attend

Professionals involved in:

- Business Development
- Clinical Trial Design and Development
- Study Endpoint Development
- Clinical Research, Operations, Site Selection, and Management
- Research and Development
- Clinical Monitoring and Oversight
- Quality Management
- Contracts Management
- Clinical Data Management
- Data and Biostatistical Sciences
- Health Economics and Outcomes Research
- eClinical Technology and Solutions
- Digital Strategies and Technologies
- Data Analytics, Strategy, and Technology
- Information Technology, Systems, and Programming
- Regulatory Affairs
- Patient Engagement, Recruitment, and Retention
- Patient Advocacy, Partnerships, and Services
- Legal and Compliance
- Ethics, IRBs
- Medical Affairs and Communications

Highlights

- Clinical Design and Clinical Operations
- Study Endpoints
- mHealth Technologies and Related Applications
- Data Analysis/Standards/Privacy/Ownership
- Regulations, Guidance, and Policy Issues (Associated with these Topics)

Schedule At-A-Glance

SHORT COURSE | MONDAY, AUGUST 17

9:00AM-12:30PM	Short Course 1: eCOA 101: The What, Why, and How of eCOA to Reduce Barriers to Adoption in Clinical Studies
1:30-5:00PM	Short Course 2: A Primer on Digital Biomarkers and Measurement in the Connected Era

DAY ONE | TUESDAY, AUGUST 18

8:00-9:15AM	Keynote Address: Patient Perspectives in Digital Health: Advances in Remote Assessments for Parkinson's Disease
9:15-9:30AM	Break
9:30-10:30AM	Session 1 BREAKOUT SESSION Track 1: Improving Clinical Trials Using Digital Tools: Opportunities Ready for Prime Time Track 2: Current and Emerging Technologies Track 3: Data Management Support for Novel Clinical Trial Technologies: Platforms, Integrations, and Organizational Impacts (On Demand)
10:30-10:45AM	Break
10:45AM-12:00PM	Session 2: BREAKOUT SESSION Track 1: Using Technology to Enhance Patient Engagement Track 2: Implications of Regulatory Requirements From the Digital Tool Regulators of Health Authorities Track 3: Interoperability Efforts and Challenges
12:00-1:00PM	Break
1:00-2:15PM	Session 3: BREAKOUT SESSION Track 1: Consenting in a Digital World: Opportunities and Challenges Track 2 & 3: How to Ensure Adequate Cybersecurity and Data Privacy Measures
2:15-2:45 PM	Break
2:45-3:45PM	Session 4: BREAKOUT SESSION Track 1 & 2: Evaluation of Digital Technologies to Demonstrate Clinical and Analytical Validation Track 3: Access to Consumer Data in a Privacy Concerned World
3:45-4:00PM	Break
4:00-4:25PM	Exhibitor Event/Non-CE - Happy Hour hosted by APDM Wearable Technologies, an ERT Company

DAY TWO | WEDNESDAY, AUGUST 19

9:15-10:15AM	Session 6: Plenary: Meaningfulness of Technology-Driven Measures
10:15-10:30AM	Break
10:30AM-12:00PM	Session 7: BREAKOUT SESSION Track 1 & 2: Can You Hear Me Now? How Platform Digital Technologies Can Amplify the Patient Voice Track 3: Data Validation and Integrity
12:00-1:00PM	Break
1:00-2:00PM	Session 8: Evaluation and Selection Criteria
2:00-2:15PM	Break
2:15-3:45PM	Closing Remarks: Technology's Role in Trials of the Future

Learning Objectives

At the conclusion of this forum, participants should be able to:

- Articulate and evaluate applications of digital technologies in clinical trials to: improve patient experience, ensure that trial endpoints are clinically meaningful and represent improved patient outcomes, improve trial design, facilitate the conduct and operation of clinical trials, and facilitate the collection and use of quality data for clinical study and regulatory decision-making
- Describe related policy, legal, scientific, and regulatory concerns
- Discuss the evolving roles, skills, and qualifications of medical product professionals in the application and use of these technologies in clinical trials

Continuing Education Credit



The Drug Information Association is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. The Drug Information Association designates this educational activity for up to 16.5 contact hours or 1.65 CEUs.

CE Allocation

Short Course 1: eCOA 101: The What, Why, and How of eCOA to Reduce Barriers to Adoption in Clinical Studies: 3.25 contact hours or .325 CEUs, Type of Activity: Knowledge, 0286-0000-20-059-L04-P

Short Course 2: A Primer on Digital Biomarkers and Measurement in the Connected Era: 3.25 contact hours or .325 CEUs, Type of Activity: Knowledge, 0286-0000-20-060-L04-P

Digital Technology in Clinical Trials: Day 1: 5.5 contact hours or .55 CEUs Type of Activity: Knowledge, 0286-0000-20-061-L04-P

Digital Technology in Clinical Trials: Day 2: 4.5 contact hours or .45 CEUs Type of Activity: Knowledge, 0286-0000-20-062-L04-P

ACRP Continuing Education Units

Attendance at this conference is approved for up to 16.50 contact hours of research specific continuing education on applications for Maintenance of ACRP's CCRC®, CCRA®, CPI®, or ACRP-CP® certification designations.

Please be sure to download your Attendance certificate via My Transcript to serve as record of participation at this conference for ACRP Maintenance of Certification. Instructions for accessing My Transcripts is located in the program.

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Continuing Education Credit and My Transcript

If you would like to receive a statement of credit, you must attend the entire primer, short course and/or all three days of the forum, sign in each day at the DIA registration desk upon arrival and complete the online credit request process through My Transcript. Participants will be able to download a statement of credit upon successful submission of the credit request. My Transcript will be available for credit requests beginning **Wednesday, September 2, 2020.**

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9:00AM-12:30PM

Short Course 1: eCOA 101: The What, Why, and How of eCOA to Reduce Barriers to Adoption in Clinical Studies

Evidence suggests that capturing clinical outcome assessment data electronically (eCOA) has many benefits over paper. However, barriers to adoption still remain. Poor adoption is in part attributable to unfamiliarity with benefits, but also poor experiences during study start-up, absence of clear expectations among sponsors and vendors, and misalignment among all stakeholders. This is also an area where no formal training exists for sponsors or eCOA providers. This short course is designed to introduce participants to key eCOA topics including:

- Benefits of and barriers to eCOA adoption
- Regulatory guidance applicable to eCOA vendors
- Key measurement science and design principles applicable when using eCOA
- Considerations when choosing a solution for your study based on study design and patient population
- Start-up processes and considerations for migrating from paper to electronic modes of data collection, developing specification documents, and conducting user acceptance testing
- Role of sponsors and sites in the trial technology implementation process and in optimizing quality of data collected with eCOA
- Best practice recommendations for training site staff and study subjects on eCOA data collection in clinical trials
- Considerations for the use of bring your own device (BYOD) in clinical trials

The interactive short course, created in collaboration with the Critical Path Institute's ePRO Consortium, will provide real world examples and case studies including challenges and proposed solutions for the audience to work through in small groups.

Instructors

Paul O'Donohoe, MS, MSc, Scientific Lead, eCOA and Mobile Health, Medidata Solutions

Katherine Zarzar, Manager, Outcomes Measurement, Patient-Centered Outcomes ResearchGenentech, A Member of the Roche Group

1:30-5:00PM

Short Course 2: A Primer on Digital Biomarkers and Measurement in the Connected Era

Technology is changing how we practice medicine. Despite rapid advances, healthcare lags behind other industries in truly putting these technologies to use. A major barrier is the cross-disciplinary approaches required to successfully create and implement these digital products.

The aim of the course is to provide a common framework of language and clarify core concepts to promote collaboration amongst stakeholders. We will accomplish this through three parts:

- An overview of digital medicine and the types of products available to measure and intervene in human health
- Regulatory, ethical, legal and security considerations when adopting digital products in research and clinical care
Define terms that categorize types of digital measurements including biomarker, ePRO, verification and validation.
- Define terms that categorize types of digital measurements including biomarker, ePRO, verification and validation.

Instructors

Christine Manta, MS, Research Manager, Elektra Labs

Rachel Chasse, MS, Director of Innovation, Digital Medicine Society (DiMe)

8:00-9:15AM

Keynote Address: Patient Perspectives in Digital Health: Advances in Remote Assessments for Parkinson's Disease

Session Chair

James Beck, Chief Scientific Officer of the Parkinson's Foundation

The use of mobile technologies for remote assessments of people with Parkinson's disease has the potential to streamline clinical trial procedures by reducing patient burden, increasing engagement, and providing ways to measure novel endpoints. To optimize the use of these technologies, it is critical to understand the perspectives of patients and ensure that these perspectives are incorporated into trial design and execution. This session will cover advances in telehealth assessments for Parkinson's disease and best practices for engaging patients in planning trials using mobile technologies.

Speakers

Ruth Schneider, MS, Assistant Professor - Department of Neurology, Movement Disorders (SMD), University of Rochester Medical Center

Karlin Schroeder, MA, Senior Director, Community Engagement Parkinson's Foundation

Dan Novak, PHD, MBA, Patient Advisor, Parkinson's Foundation

9:15-9:30AM

Break

9:30-10:30AM

Session 1: BREAKOUT SESSION

Track 1: Improving Clinical Trials Using Digital Tools: Opportunities Ready for Prime Time

Session Chair

Jennifer Goldsack, MA, MBA, MS, Executive Director, Digital Medicine Society

Digital tools offer the potential to improve the efficiency, probability of success, and patient centricity of clinical trials. In addition, opportunities for digital innovation exist throughout the clinical trials lifecycle. Consequently, sponsors today face a proliferation of digital products being touted as solutions. This session aims to first help identify challenges in our industry well suited to digital solutions, then support the evaluation and implementation of solutions available today.

Speakers

Bray Patrick-Lake, MS, Director of Strategic Partnerships Evidation Health

Daniel Rollings Karlin, DrMed, MA, FAPA, CEO HealthMode, Inc

Decentralized Clinical Trials (DCTs) Using Digital Health Technologies (DHTs)

Isaac R. Rodriguez-Chavez, Ph.D., M.H.Sc., M.Sc., FDA Officer, Clinical Research Methodology and Medical Policy, FDA CDER, Office of Medical Policy

Track 2: Current and Emerging Technologies

Session Chair

Keith Wenzel, Senior Director, Business Operations, Scientific Data Organization, Parexel

Despite being a risk adverse industry, the Life Sciences Industry currently has a stable of tried and true technologies which have been embraced and generate value, but we find ourselves beset by literal barrage of new technologies some of which show signs of promise, some where the jury is still out and others yet untested, but intriguing. This session will include two presentations on Current and Emerging Technologies followed by a panel discussing the state of play for digital technology and the trends and concepts around the next generation of tried and true technologies as well as the potential benefits of emerging technology.

Speakers

Keith Wenzel, Senior Director, Scientific Data Organization Parexel International

Stephen Ruhmel, Clinical Innovation Lead, Janssen Research & Development

Panelist

Paul Upham, Head, Smart Devices Genentech, A Member of the Roche Group

Track 3: Data Management Support for Novel Clinical Trial Technologies: Platforms, Integrations, and Organizational Impacts (On Demand)

Session Chair

Dan Tierno, MA, MBA, Associate Director, Project and Portfolio Management, Daiichi Sankyo, Inc

This session will provide a comprehensive understanding of Data Management platforms, integrations and organizational impacts with respect to Digital Clinical Trial Technology. Discussions will focus on requirements and specifications for technology platforms, the types of platforms that are available, considerations of integration and implementation of these platforms, as well as how to address impacts of these changes to an organization. Presentations will draw from experiences of design and implementation of these initiatives in anecdotal as well as case-study format. Attendees will have a clearer understanding of what to consider and what to expect when embarking upon Data Management technology implementation for Digital Clinical Trials.

Speakers

David King, MBA, Manager, R&D IT Innovation Bayer U.S.

Dan Tierno, MA, MBA, Associate Director, Project and Portfolio Management, Daiichi Sankyo, Inc

Louis C. Kauffman, MSc, Management Consulting Manager Accenture

10:30-10:45AM

Break

10:45AM-12:00PM

Session 2: BREAKOUT SESSION

Track 1: Using Technology to Enhance Patient Engagement

Session Chair

Julie Dietrich, MS, Vice President, Clinical Operations, Genfit Corp

Are you a clinical researcher looking to better connect and communicate with patients? We'll explore how technology can enable effective engagement between sponsors/CROs and patients at various stages of clinical development. This engagement can lead to clinical studies that are well-designed, better support participants, enroll faster, and provide more complete data that are meaningful to patients.

Benefits and Methods for Successful Patient and Vendor Engagement During Deployment of Technology in Clinical Trials

Melissa Dupont, TransCelerate Patient Technology Initiative - Toolkit Solution Lead, Sanofi Patient Network Manager, Clinical Operations Strategy & Collaboration

Clinical Trials in PBC: Educating and Connecting Our Members

Carol Roberts, PBCers Organization, Executive Committee and Patient

How to Integrate the Participant's Perspective into Your Research; and, Still Get Along with Your IRB

James Riddle, MCSE, CIP, CPIA, CRQM, MS, Vice President, Institutional Services, Advarra

Speakers

Betsy Williams, PhD, MS, Scientific and Strategic Lead Patient-Centered Endpoints Solution IQVIA

Elizabeth Esterl, DNP, MS, RN, BSN, Vice President, Operations and Research, ClinOne

Track 2: Implications of Regulatory Requirements From the Digital Tool Regulators of Health Authorities

Session Chair

Paul Upham, Head, Smart Devices, Genentech, A Member of the Roche Group

As new digital health tools (e.g., digital endpoints / biomarkers, etc.) are being developed and introduced into drug clinical trials and launched commercially, health authority regulators are seeking to ensure their safety and efficacy. While there is a growing consensus amongst regulators about how to classify and assess the risk of these new digital tools, there is significant variation across markets and geographies that is critical for the developers and users of these tools to understand. The compliance requirements differ depending on the market, the types and classes of tools (SaMD, sensors, etc.) and can have a significant impact on their development and the execution of the clinical trials that are using them.

Regulatory Considerations During Digital Clinical Innovation

Michael Benecky, PhD, Sr. Director, Global Regulatory Affairs, UCB

Addressing Regulators Needs While Conducting Clinical Studies with Digital Health Tools in Europe

Seya Colloud, PharmD, Global Regulatory Director, F. Hoffmann-La Roche Ltd, Switzerland

Track 3: Interoperability Efforts and Challenges**Session Chair****Christine Manta, MS**, Research Manager Elektra Labs

Despite many technological advances, interoperability remains a challenge for clinical research. Barriers to seamless data transfer between electronic health records (EHR) and electronic data capture (EDC) systems continue to be a source of frustration. Remote monitoring tools with the capacity to capture data continuously outside of the study site add new layers of complexity to data storage and exchange. This session aims to identify existing barriers and discuss solutions to overcoming the siloed infrastructure.

Person-Generated Health Data Standards (or the lack thereof)**Luca Foshini, PhD**, Co-founder & Chief Data Scientist, Evidation Health**Leveraging HL7 FHIR to Streamline Clinical Trials****Dan Gottlieb, MPA**, Healthcare Standards Consultant, Central Square Solutions LLC**CommonHealth and Mobile Personal Health Records****JP Pollak, PhD**, Senior Researcher-in-Residence at Cornell Tech

12:00-1:00PM**Break**

1:00-2:15PM**Session 3:** BREAKOUT SESSION**Track 1:** Consenting in a Digital World: Opportunities and Challenges**Session Chair****Jules Mitchel**, President, Target Health

As one of many steps for participation in a clinical trial, the informed consent process is based on a solemn and trusted interaction between a study subject and the clinical research site. Traditionally, the process involves a study subject being invited to participate in a clinical trial based on the study inclusion and exclusion criteria, reading the informed consent document (ICD) at the clinical trial site, and then having a dialogue to clarify matters. Finally, the ICD is signed manually by the study subject and the clinical investigator, and the paper copy is then given to the study subject and a hard copy stored in the subject's study folder. With the advent of paperless, virtual and remote trials, the paper process as we know it today is a deterrent. Yet, we must be ever diligent not to lose the key purpose of the informed consent process and assure full transparency to clinical trial subjects. The current session will present the challenges and opportunities of using the eICD for domestic and global trials.

Speakers**Susie Song**, Senior Manager, Informed Consent Management, Global Clinical Operations, Biogen**Jonathan Helfgott, MS**, Executive Director, Global Regulatory/Clinical Affairs Stage 2 Innovations**Michelle Eli**, Clinical Project Management Advisor, Chorus, Eli Lilly and Company

Track 2 & 3: How to Ensure Adequate Cybersecurity and Data Privacy Measures**Session Chair****Jonathan Andrus, MS**, Chief Business Officer, Clinical Ink

In today's technology enabled world, it seems like every time we turn around, there is another cyber-attack or penetration of computing environment that render sensitive data subject to malicious use. These incidents are broadly portrayed around the world and, as a result, have made organizations, patients involved in clinical trials and others involved in clinical research reticent to use new and burgeoning technologies in the conduct of clinical trials. In addition, global regulators and ministries of health have enacted exacting data privacy regulations and guidance that are aimed at ensuring patients' rights and desires are carried out in the use of their data. This current situation should not stymie innovation and the use of new technologies but rather should cause us to rise up and ensure that our vendors and technologies are architected in a way to withstand attacks and put into place policies and measures that will ensure the privacy of data. This session is aimed at providing participants with information that they can use to effect change within their own organizations and to put into place controls to ensure the privacy of data.

How to Ensure Adequate Cybersecurity and Data Privacy Measures**Veronica Contreras, JD**, Data Privacy Officer, Counsel, eResearchTechnology, Inc.

Best Practices for Ensuring Security in the Cloud

John Edwards, Senior Infrastructure and Security Architect, Clinical Ink

Auditing Vendors and Suppliers for IT Security

Sameer Jaiswal, MS, Consultant, MHM Consulting LLC

2:15-2:45PM

Break

2:45-3:45PM

Session 4: BREAKOUT SESSION

Track 1 & 2: Evaluation of Digital Technologies to Demonstrate Clinical and Analytical Validation

Session Chair

Paul Upham, Head, Smart Devices, Genentech, A Member of the Roche Group

A critical aspect in the introduction of digital tools to clinical trials is assuring that you can demonstrate a valid clinical association between the tool's output and the targeted clinical condition. You'll learn from experts about how to do that and how to provide analytical validation that your digital tool correctly processes input data to generate accurate, reliable, and precise output data. Finally, learn how to ensure that your output data achieves your intended purpose in your target population in the context of clinical care.

Speakers

Thomas Haag, Principal Consultant, Cardinal Solutions Consulting, LLC

Jesslyn Dunn, PhD, Assistant Professor of Biomedical Engineering, Duke University

Ariel Dowling, PhD, Director of Digital Strategy Takeda Pharmaceuticals

Thomas Switzer, MEd, Business Ops Leader, Digital Health Platforms, Genentech, A Member of the Roche Group

Track 3: Access to Consumer Data in a Privacy Concerned World

Session Chair

Kristen Valdes, Founder and Chief Executive Officer B.Well Connected Health

This session will provide an overview of the new consumer directed data policies from ONC and CMS called Interoperability and Information Blocking rules. The panel will provide detailed statistics and findings on consumer data access from both providers and payers and how the new rules will change the requirements and technology for access and use of data. The panel will also touch on consumer trust and best practices on informed consent in this privacy-concerned era.

Speakers

Ryan Howell, MHA, Principal, Leavitt Partners / CARIN Alliance

Kristen Valdes, Founder and Chief Executive Officer B.Well Connected Health

Deven McGraw, JD, LLM, MPH, Chief Regulatory Officer, Citizen

3:45-4:00PM

Break

4:00-4:25PM

Exhibitor Event/Non-CE - Happy Hour hosted by APDM Wearable Technologies, an ERT Company

Precision Movement Tracking: Beyond Activity Monitoring

Presenter

Fay Horak, PhD, Scientific Fellow ERT, Wearables & Digital Biomarkers

Mobility is freedom to a patient; freedom to go to the store, cross the street in time, visit family members. Mobility is also much more than how often they move, it's how well they move. Dr. Fay Horak will detail the last decade of scientific research and development of digital endpoints and supporting wearable technology. Findings suggest that actigraphy is useful for measuring intervention response in a select few populations, while precise movement endpoints such as turning speed, stride length, dorsiflexion, and trunk range of motion are useful in many others. When it comes to effective trial design, you need to understand the disease and endpoints before you choose a digital technology.

Featured topics to include:

- Analytical and Clinical Validity – What's the difference?
- Activity vs precision movement analytics
- In-clinic vs At-home Monitoring
- Parkinson's Disease Endpoints
- Multiple Sclerosis Endpoints
- Ataxia Endpoints

9:15-10:15AM

Session 6: Plenary: Meaningfulness of Technology-Driven Measures

Session Chair

Paul O’Donohoe, MS, MSc, Scientific Lead, eCOA and Mobile Health, Medidata Solutions

With the ever expanding availability and capability of both medical and commercial-grade wearable devices and mobile sensors there has been a corresponding growth in interest in including them in clinical trials to collect data to provide additional insight into patient experience. However, while these technologies can measure a wide range of physical and biologic variables, their use can sometimes have the appearance of a solution in search of a problem. Extending the idea of “content validity” from the patient-reported outcome measure developmental literature, identifying what one is measuring with a sensor and, most importantly, what this means to the patient using it, is a vital step that is currently not fully appreciated within the pharmaceutical, sensor, and medical device industry.

This session will provide attendees guidance on how to establish content validity for mobile sensors and wearables and the importance of clearly defined ‘concepts of interest’ for establishing clinical trial endpoints. Firstly, a case study in chronic heart failure, where in depth work is being done with patients to identify meaningful outcomes that can be measured by a wearable device; secondly, a discussion of some of the lessons that can be learned from performance outcome (PerfO) assessments, where similar challenges in demonstrating content validity and identifying appropriate individual change metrics are present; and finally, an outline of how the industry can ensure the intentional development of these tools, which have so much potential, to properly integrate the patient experience in clinical trials in the future. Developing meaningful measures from wearable/mobile sensor technology is the necessary foundation to their use to derive clinical trial endpoints that are meaningful assessments of clinical benefit.

Meaningfulness of Technology-Driven Measures – What Can We Learn From Performance Outcome (PerfO) Assessments?

Elizabeth (Nicki) Bush, MHS, Sr. Advisor and Head, Patient-Focused Outcomes Center of Expertise, Eli Lilly and Company

Endpoint Development Using Mobile Sensor Data

Bill Byrom, PhD, Vice President, Product Strategy and Innovation, Signant Health

Determining Meaningfulness of Activity Monitor Measures from the Patient’s Perspective

Sonya Eremenco, MA, Associate Director, PRO Consortium, and Acting Director, ePRO Consortium, Critical Path Institute

10:15-10:30AM

Break

10:30AM-12:00PM

Session 7: BREAKOUT SESSION

Track 1 & 2: Can You Hear Me Now? How Platform Digital Technologies Can Amplify the Patient Voice

Session Chair

Lauren Oliva, PharmD, RPh, New Technologies Global Regulatory Policy Lead, Biogen

As our knowledge of disease manifestations and treatment approaches becomes more sophisticated, new opportunities exist to quantify important features of serious diseases for the first time.

There are now digital tools available to sponsors with the potential to create value in the drug development process beyond a specific product or disease state. These so-called platform technologies are tools that enable sponsors to better measure and interpret symptoms that impact many disease indications. Examples include symptoms such as fatigue, pain, cognition, speech, and autonomic measures.

This session will explore the value of adopting platform technologies to drug development programs and the path to regulatory acceptance of data generated by these novel tools.

Speaker

Channing Barker, Patient Advocate

Industry Perspectives on a Platform Approach to Digital Endpoint Development

Michelle Campbell, PhD, Senior Clinical Analyst for Stakeholder Engagement, DNP, OND, CDER, FDA

Industry Perspectives on a Platform Approach to Digital Endpoint Development

Kelley Erb, PhD, Director, Digital and Quantitative Medicines, Head of Digital Medicines, Biogen

Operationalizing Digital Health and Virtual Visits for Clinical Trials

Mintu Turakhia, MD, MAS, Associate Professor, Executive Director, Center for Digital Health, Stanford University, Chief, Cardiac Electrophysiology, VA Palo Alto Health Care System

Track 3: Collecting Useful, High Quality Data From Digital Sensor Technologies

Session Chair

Jennifer Goldsack, MA, MBA, MS, Executive Director, Digital Medicine Society

High-quality data support useful endpoints and their interpretations. For data to have integrity, the data cannot be modified or corrupted in an undetectable and/or unauthorized way during the generation and flow of the data. This session will explore how to collect, transfer, and store high quality digital data generated by connected sensor technologies. The Endpoint Strategy for optimizing these processes will be explained and demonstrated.

Applying an “Endpoint Strategy” to Guide Data Collection

Barry Peterson, PhD, Wearable Devices, Independent Consultant

Leveraging Technology to Support Clinical Studies:

Perspectives as a Biotech Sponsor, Academic, and ex-FDA Officer

Jonathan Helfgott, MS, Executive Director, Global Regulatory/Clinical Affairs, Stage 2 Innovations

Data Quality: A RWE Perspective

Luca Foschini, PhD, Co-founder & Chief Data Scientist, Evidation Health

12:00-1:00PM

Break

1:00-2:00PM

Session 8: Evaluation and Selection Criteria

Session Chair

Dan Milam, Vice President, Global Engagement, Society for Clinical Research Sites

Site selection and feasibility, like many aspects of our work has changed significantly. Not only is selection criteria becoming much more specific, but the trials are becoming more complex - this means a narrower funnel for sites who are being asked to perform more tasks within a trial. This is coupled with the fact that digital technology is also having a significant impact on the site selection and feasibility process. Sponsors and CROs are using complex programs to better and more accurately assess sites for selection, and site are beginning to utilize technology more and more to find these specific patients they need within their own databases, or when assessing feasibility in an often rapid manner. This panel will address this change and how it is impacting our industry, as well as how technology is altering how site selection and feasibility criteria are determined and tracked against potential patients.

Speakers

Ahmed Namvargolian, MPA, President Care Access Research

Cindy Howry, MS, CEO assisTEK

Marisa Rackley, Director of Global Clinical Operations, Vertex.

2:00-2:15PM

Break

2:15-3:45PM

Closing Keynote: Technology’s Role in Trials of the Future

Session Chair

Matt Noble, Vice President, Product Management Medidata Solutions

Keynote Speaker

Matt Noble, Vice President, Product Management Medidata Solutions