DIA

Digital Technology in Clinical Trials

Short Course: October 21 | Virtual Conference: October 27-29

Co-Sponsored with ePRO Consortium – Critical Path Institute

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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.

Who Should Attend?

Executive, Leadership, and Management Professionals from Biotechnology, Pharmaceutical, Device, CRO, Regulatory Agency, and Academic Research Sponsors Involved In:

- Business Development
- Clinical Trials Design and Development
- Clinical Research
- Study Endpoint Development
- Clinical Operations
- Clinical 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
- Data Strategy
- Data Technology
- Information Technology, Systems, and Programming
- Regulatory Affairs, Regulatory Specialists
- Patient Engagement
- Patient Advocacy, Partnerships
- Patient Recruitment and Retention
- Patient Services
- Legal and Compliance
- Ethics, IRBs
- Medical Affairs
- Medical 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 | FRIDAY, OCTOBER 21

Sessions are held in ET

9:00AM-1:00PM	**Short Course 1:** Approaches for Developing Novel Digital Endpoints for Medical Product Development

DAY ONE | WEDNESDAY, OCTOBER 27

9:30-10:30AM	**Welcome, Opening Remarks, Keynote Address**
10:30-10:45AM	Break
10:45-11:45AM	**Session 1:** CONCURRENT SESSION **Track A:** The Patient Experience with Digital Technology **Track B:** Data Principles & Solution Patterns to Unlock our Data Wealth
11:45AM-12:15PM	Break
12:15-1:15PM	**Session 2:** CONCURRENT SESSION **Track A:** Implementing Clinical Trial Surveys: 60 Countries of Challenges **Track B:** The Data Deluge: Automating the Delivery of Quality Clinical Data
1:15-1:30PM	Break
1:30-2:30PM	**Session 3:** CONCURRENT SESSION **Track A:** Practical Application of A.I. to Keep Patients Engaged and to Inform Study Endpoints **Track B:** On-Demand Abstract Presentations
2:40-3:25PM	Exhibitor Event/Non-CE Sponsored Round Table *See Page 16 for more information and instructions on how to RSVP!*

DAY TWO | THURSDAY, OCTOBER 28

9:00-10:15AM	**Session 4:** Regulatory Approaches to Use of Digital Tools: Where Are We Now and Where do We Need to go?
10:15-10:30AM	Break
10:30-11:30AM	**Session 5:** CONCURRENT SESSION **Track A:** Better, Faster, Stronger: Building Successful Digital Clinical Teams for Today's World **Track B:** What's Really Needed to Transform Information Flow in Clinical Development
11:30AM-12:00PM	Break
12:00-1:00PM	**Session 6:** CONCURRENT SESSION **Track A:** Paperless Clinical Trials During the Time of COVID-19 and Beyond **Track B:** Solving Clinical Data Challenges: Advancing Research Through New Technology
1:00-1:15PM	Break
1:15-2:15PM	**Session 7:** CONCURRENT SESSION **Track A:** Role of Public-Private Partnerships in Generating Evidence for Remote Monitoring Technologies: Rewards and Challenges **Track B:** Patient Data Technologies for Real-World Evidence, Epidemiology and Clinical Research
2:15-2:30PM	Break
2:30-3:30PM	**Session 8:** CONCURRENT SESSION **Track A:** On-Demand Abstract Presentations **Track B:** Technology Enablers for Increased Remote Measurement of Outcomes Data

DAY THREE | FRIDAY, OCTOBER 29

10:30-11:00AM	Exhibitor Event/Non-CE Case Study Spotlight *See Page 16 for more information and instructions on how to RSVP!*
9:00-10:30AM	**Session 9**: Regulatory Sprint: Can We Develop an Agile Regulatory Decision Matrix for Digital Measurement?
11:00-11:15AM	Break
11:15AM-12:15PM	**Session 10**: CONCURRENT SESSION **Track A:** Are PRO Measures Becoming Obsolete in the Digital Era? **Track B:** Measuring Gait In-the-wild Using Wearable Technology: Advantages and Challenges
12:15-1:15PM	**Session 11**: CONCURRENT SESSION **Track A:** Decentralized Trials and Research: Sustaining the Momentum Post-Pandemic **Track B:** On-Demand Abstract Presentations
1:15-1:30PM	Closing Remarks

Learning Objectives

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

- Identify operational challenges arising due to emergence and integration of technology in clinical trials.
- Describe related policy, legal, and regulatory concerns
- Discuss current digital technology solutions that meet the needs of patients, site staff, and organizations in the conduct of clinical trials
- Identify gaps where digital technology solutions could be developed to improve patient, clinician, and organizational experience, value, and outcomes
- Examine use cases or case studies addressing challenges

Continuing Education Credit

ACPE CREDIT REQUESTS MUST BE SUBMITTED BY FRIDAY, DECEMBER 3, 2021

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No CE credit is available for On-Demand Track recordings.

Continuing Education Credit Allocation

October 21 | Short Course 1: Approaches for Developing Novel Digital Endpoints for Medical Product Development 3.5 contact hours or .35 CEUs, Type of Activity: Knowledge, 0286-0000-21-080-L04-P

October 27 | Digital Technology in Clinical Trials: Day 1: 3.75 contact hours or .375 CEUs Type of Activity: Knowledge, 0286-0000-21-081-L04-P

October 28 | Digital Technology in Clinical Trials: Day 2: 5.5 contact hours or .55 CEUs Type of Activity: Knowledge, 0286-0000-21-082-L04-P

October 29 | Digital Technology in Clinical Trials: Day 3: 4 contact hours or .4 CEUs Type of Activity: Knowledge, 0286-0000-21-083-L04-P

Continuing Education Credit and My Transcript

If you would like to receive a statement of credit for the days you attend the live virtual conference, you must virtually attend (in their entirety) the short course and/or one or all three days of the conference, complete and return a CE Verification of Attendance Form (see instructions below), complete the post program evaluation and request CE credit online through My Transcript (see instructions below). 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 **Friday, November 12, 2021**.

If you are claiming CE credit for this event you must:

1. Complete a Verification of Attendance Form
2. Send back to **CE@DIAglobal.org** by **November 5, 2021**

Access your DIA account and select My Transcript to claim your CE credit, available on **Friday, November 12, 2021**

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It is DIA policy that anyone in a position to control the content of a continuing education activity must disclose to the program audience (1) any relevant financial relationships related to the content of their presentation and/or the educational activity, and (2) discussions of unlabeled or unapproved uses of drugs or medical devices. Disclosures will be included in the handout materials.

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Disclosure statements are included with each speaker's biographical sketch.

Planning Committee

DIA staff members have no relevant financial relationships to disclose.

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SHORT COURSE | FRIDAY, OCTOBER 21

Sessions are held in ET

9:00AM-1:00PM

Short Course 1: Approaches for Developing Novel Digital Endpoints for Medical Product Development

Digital endpoints offer the opportunity to measure what matters to persons living with a disease, enhancing and/or replacing classical clinical outcome measures to improve the patient centricity and efficiency of medical product development, and generate more valuable information. There is evidence of increasing regulatory acceptance for the use of digital endpoints in medicine development. But how are meaningful digital endpoints identified and incorporated into a trial? And what can be done to drive their acceptance and use? For continued progress, it is important for sponsors to have access to multi-stakeholder-developed frameworks.

In this session, panelists will present several approaches that may assist with advancing the use of meaningful digital health technology derived novel endpoints in clinical trials for labeling claims. Attendees will be introduced to a number of tools to use when developing digital outcome measures.

These include: TransCelerate's efforts to clarify concept development, validation approaches acceptable to regulators, clinical interpretations, evidentiary requirements, and global pathways in an effort to accelerate Novel Digital Endpoint (NDE) use. Illustrative case studies will be included; the Clinical Trial Transformation Inititative's (CTTI) pathway for novel endpoint development including new work to create additional resources and recommendations to drive the use of digitally derived, functional outcomes as key endpoints in clinical trials to support regulatory decision-making; and the Digital Medicine Society's (DiMe) open access digital endpoint library, the V3 evaluation framework for digital measurement performance, and the five part evaluation framework for digital measurement technologies. Discussion will include and how to put these resources, and more, into action today.

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

- Identify key considerations for developing novel digital endpoints for use in medical product development
- Describe approaches to advancing the use of novel digital endpoints for use in medical product development
- Evaluate the value of novel digital endpoints to different stakeholders including patients, clinicians, researchers, medical product developers, regulators, and payers

Instructors

Jennifer Goldsack, **MA, MBA, MS**, Executive Director, Digital Medicine Society (DiME)

Lindsay Stiles Kehoe, MS, Project Manager, Clinical Trials Transformation Initiative (CTTI)

Michelle Crouthamel, PhD, Director of Digital Health and Innovation, AbbVie, Inc

DAY ONE | WEDNESDAY, OCTOBER 27

Track A: Trial Design and Execution

Track B: Data and Technology

9:30-10:30AM

Welcome, Opening Remarks, Keynote Address

Courtney Granville, PhD, MSPH, Global Asssociate Director, Research and Scientific Programs

Scottie Kern, Executive Director, Critical Path Institute, United Kingdom

Jonathan Andrus, MS, Chief Data Officer, Clinical Ink

Speaker

Demetris Zambas, Vice President and Global Head, Data Monitoring and Management, Pfizer

10:30-10:45AM

Break

10:45-11:45AM

Session 1: CONCURRENT SESSION

Track A: The Patient Experience with Digital Technology

Courtney Granville, PhD, MSPH, Global Asssociate Director, Research and Scientific Programs

Digital devices for clinical trials are tested thoroughly by device manufacturers to ensure they work - but will they work for YOUR patients in YOUR trial? This session explores "digital experience testing," where devices are tested by the target patient population in ways that mirror their use in your actual trial. We will outline essential steps to gaining valuable insights into how patients experience the use of the device, and whether clinical data will be collected accurately and consistently. Our panel will present case studies where sponsors learned that device use would positively or negatively impact recruitment or retention, and where device manufacturers learned of changes that needed to be made for successful implementation in a trial. We'll complete the session by challenging participants to consider optimal ways to assess the patient experience with digital devices in both hybrid and decentralized trials.

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

- Identify keys for successful digital experience testing with the target patient population
- Differentiate device company usability testing and patient digital experience testing
- Describe examples of impactful learnings from patient digital experience testing

The Patient Experience with Digital Technology
Valerie Powell, MS, Vice President, Research Services, Healthivibe, A Division of Corevitas, LLC

Speakers

Glen Wunderlich, PhD, Senior Program Leader, CNS, Boehringer Ingleheim Pharmaceuticals, Inc.

Amy Mason, Sickle Cell Disease Advocate

Madeline Geday, Senior Director, Head of Patient Engagement, ERT

Track B: Data Principles & Solution Patterns to Unlock our Data Wealth

Keith Wenzel, Senior Director, Scientific Data Organization, Parexel International

Clinical Trials generate enormous tombs of data. EDC generates many gigabytes of data for each trial. Verbose auditing increase datasets by 10x. Wearables and other sensors increase datasets (again) by 10x to 100x. RWE datasets are only bounded by the potential candidate pool of all people with their health records digitized. How are we to deal with our data explosion? From the fable “The Miser and his Gold”, how do we ensure our data is “a wealth we use” as wealth not used is the same as wealth that does not exist. This session will discuss maintaining data principles, embracing proven big data patterns, and leveraging the benefits of cloudification with cost vigilance to achieve the data agility our clinical trials demand.

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

- Propose a set of data principles to guide big data strategy
- Describe big data solution patterns
- Defend that successful DataOPS requires cloudification with cost vigilance

Data Principles & Solution Patterns to Unlock our Data Wealth
Steven Chartier, MS, Senior Director of Engineering, Calyx

Speaker
Patrick Nadolny, MS, Global Head, Clinical Data Management, Sanofi France

11:45AM-12:15PM **Break**

12:15-1:15PM

Session 2: CONCURRENT SESSION

Track A: Implementing Clinical Trial Surveys: 60 Countries of Challenges

Session Chair
Jules Mitchel, PhD, MBA, President and CEO, THI Pharma Services

The use of surveys to obtain feedback from clinical trial participants has become a "hot topic," but these surveys have been successfully used to garner patient feedback for over 3 years. In this presentation, we will share lessons learned through the development and implementation of thousands of clinical trial experience surveys by industry leaders.

This session will present a scalable, repeatable model that can be used to gather patient insights feedback during clinical trials. Numerous examples of regulatory and operational challenges (and solutions) will be provided based on implementations in over 60 countries.

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

- Describe the concept of clinical trial experience surveys
- Understand regulations associated with study feedback questionnaires
- Detail best practices of developing actionable guidance from patient experience feedback

Implementing Clinical Trial Surveys: 60 Countries of Challenges –
Jennifer Kelly, Vice President, Operations, HealthiVibe, a division of CoreEvitas, LLC

Speakers
Stephanie Manson, Senior Director, HEOR Excellence at Novartis

Stéphane Millet, General Manager - Operations, Acolad

Ally Ferlito, Healthcare Advocate

Track B: The Data Deluge: Automating the Delivery of Quality Clinical Data

Session Chair
Jonathan Andrus, MS, Chief Strategy Officer, Clinical Ink

In recent years, with the advent of artificial intelligence (AI) and machine learning (ML), technology has been explored throughout clinical development - with a particular focus on algorithms for managing risk. The most commonly used and mature machine learning and AI applications are part of RBQM (risk-based quality management). The next big opportunity for AI/ML is within data review and analysis activities, with the goal to accelerate timelines while achieving high quality data deliverables and submissions. With the data proliferation of the past decade and data complexity only increasing with decentralization, finding concrete ways to incorporate AI and ML has the potential to reduce cycle times and dramatically enhance clinical development processes. This session will address the areas being explored and operationalized within AI/ML, and what prerequisites are needed to adopt these approaches within your own organization.

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

- Discover potential benefits and opportunities for AI/ML within clinical development data activities
- Illustrate algorithms and models for applying AI/ML
- Outline foundational prerequisites needed on the path to automation

The Case for a Unified and Integrated eSource and EDC System
Raj Indupuri, MBA, Chief Executive Officer, eClinical Solutions

1:15-1:30PM **Break**

1:30-2:30PM **Session 3:** CONCURRENT SESSION

Track A: Practical Application of A.I. to Keep Patients Engaged and to Inform Study Endpoints

Session Chair
Keith Wenzel, Senior Director, Scientific Data Organization, Parexel International

The term Artificial Intelligence is often bandied about with respect to the possible application for clinical trials, but more practical applications are needed to move life sciences clinical research forward. In this session, our esteemed presenters will present two use cases: one discussing the use of Conversational AI to improve participant recruitment, engagement, and retention; the second will present research on extracting of patient-reported outcomes from publicly available data via a bespoke combination of artificial intelligence (AI) and natural language processing (NLP). These presentations place an emphasis the patient voice and patient

engagement to improve clinical research via artificial intelligence.

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

- Formulate Conversational AI applications for patient recruitment, engagement and recruitment
- Recommend new methods for the extraction of patient-centered endpoints based

Rapid Concept Elicitation by AI-Assisted Coding of Online Patient Conversations
Conrad Bessant, PhD, Mebomine, United Kingdom

Conversational AI: Virtual Assistants for Clinical Trial Participants
Stephen Ruhmel, MPS, Clinical Innovation Lead, Janssen Research & Development

2:40-3:25PM **Exhibitor Event/Non-CE Sponsored Round Table**
See Page 17 for more information and instructions on how to RSVP!

DAY TWO | THURSDAY, OCTOBER 28

9:00-10:15AM **Session 4:** Regulatory Approaches to Use of Digital Tools: Where Are We Now and Where do We Need to go?

Session Chairs
Megan Doyle, JD, MPH, Global Policy Lead, Digital Health, Diagnostics, and Combination Products Amgen

Anindita Saha, Assistant Director, Digital Health Center of Excellence, CDRH, FDA

This session will provide an overview of open regulatory questions related to use of digital tools in clinical trials. The session will ground participants in the current regulatory issues in this space, to set a baseline for the rest of the meeting. Panelists will discuss where we are now, where we are going, and what questions need to be answered to get us there.

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

- Educate meeting participants in the regulatory issues pertaining to use of digital tools in clinical trials
- Discuss important regulatory questions related to the use of these tools in clinical trials
- Identify where sponsors are going in the future and what regulatory questions need to be answered to advance the field

Existing Frameworks for Use of Digital Tools in Clinical Studies of Medicinal Products
Beth Kunkoski, MS, Health Science Policy Analyst, CDER FDA

Device Regulations and Digital Tools in Clinical Trials
Matthew Diamond, MD, PhD, Chief Medical Officer, Digital Health Center of Excellence, CDRH FDA

Implications of the Regulatory Status of Different Tools
Samantha Roberts, PhD, Group Director, US Regulatory Policy, Genentech, A Member of the Roche Group

10:15-10:30AM **Break**

10:30-11:30AM **Session 5:** CONCURRENT SESSION

Track A: Better, Faster, Stronger: Building Successful Digital Clinical Teams for Today's World

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

For the first time, drug development teams include not only 'traditional' clinical team members such as clinicians and clinical operations colleagues, but also software developers, machine learning engineers, and big data scientists: simply, siloed teams are a thing of the past. The digital transformation requires multilingual colleagues who well-versed in clinical operations, biostatistics, patient engagement, data management, and other sections of clinical development. This panel will bring together leaders who understand how today's clinical trial landscape has evolved in response to the demands of digital, including how to grow the current workforce to meet these demands and share data-driven approaches on how to identify unique talent when building better, faster, and stronger digital clinical teams.

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

- Identify how workforce skills have evolved to support the digital transformation in clinical trials
- Apply data-driven techniques to cultivate a diverse team poised for successful execution of digital clinical trials
- Develop an informed strategy for how to hire new and develop existing colleague skillsets to understand and conquer digital clinical trials

Developing Digital Teams for Clinical Development: Leveraging Baseball Sabermetrics Approach for Digital Team Formation
Aman Thukral, Pharm, MS, Director, Global Head – Digital Operations and Clinical Systems, Abbvie, Inc

The Digital Discipline: Cultivating the Data-Driven Workforce
Katrina Rice, MS, Chief Delivery Officer, Data Services, eClinical Solutions

Speaker

Susan Foose, MLIS, Director/Enterprise Solutions, Labcorp Drug Development

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Track B: What's Really Needed to Transform Information Flow in Clinical Development

Session Chair
Prem Sreenivasan, PhD, Director, HITLAB

Sound familiar?

"Automation, AI, and digitization are buzz words – my team is stuck with manual processes and too many systems to use."

"The technology exists; organizations aren't ready to use it."

"We have to customize data standards to use them, and there are still too many gaps."

We need to approach transformation of clinical information flow from multiple angles. This session will discuss how three different TransCelerate initiatives can be used to guide industry toward a future in which digital data flows seamlessly across the various systems and software used in clinical development.

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

- Summarize an open, vendor-agnostic, digital flow of data relevant to improving and optimizing study designs
- Understand the study design data available to other systems that can utilize this data in order to configure and execute a study design
- Articulate use cases in registry/disclosure and other valuable information extractions from protocol, SAP and CSR
- Identify approaches utilized to improve data flow in clinical trials

From Point Solution to Data Exchanged Across Platforms - TransCelerate's Digital Data Flow Initiative
Alison Luckman, Development Operations Innovation Director, Amgen, Ltd, United Kingdom

From Documents to Content As Data: TransCelerate's Clinical Content & Reuse Initiative
Tatiana Gabriella Piotroff, MS, Senior Manager, Medical Writing, Johnson & Johnson

From Transcription to Interoperability: TransCelerate's Esource Initiative
Mehek Mohan, Product Manager for Technology Development and Artificial Intelligence, Genentech, Inc.

11:30AM-12:00PM **Break**

12:00-1:00PM **Session 6**: CONCURRENT SESSION

Track A: Paperless Clinical Trials During the Time of COVID-19 and Beyond

Session Chairs
Jules Mitchel, PhD, MBA, President and CEO, THI Pharma Services

Estelle Haenel, DrSc, PharmD, Medical Director, Kayentis, France

Direct data capture has been involved since decades now, and the COVID-19 pandemic acted as a catalyst to accelerate further digital developments in clinical trials. The session will investigate all aspects of the direct data capture paradigm, including the improvement of data quality, time to data review, time to database lock, and quality of life of all the ones involved (patients, sites, caregivers…).

The goal is also to interact with the session participants, have them share their experiences in modern day approaches to clinical trials, explore added value for every clinical trial stakeholder, and start to address standards for direct data capture.

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

- Learn how the paperless clinical trial can change the clinical trial paradigm
- Understand how direct data capture improves data quality
- Assess the value for all the ones engaged in the data capture

Introduction to the Paperless Trial & Regulatory Perspectives
Jules Mitchel, PhD, MBA, President and CEO, THI Pharma Services

Telemedicine in Clinical Trials Paves the Way for Paperless Trials
Bryan McDowell, MSc. MBA, Chief Executive Officer, DataFusion GmbH, Switzerland

Introducing Additional Perspectives to Paperless Clinical Trials
Estelle Haenel, PharmD, PhD, Medical Director, Kayentis, France

How and Why do Paper-Removing Technologies Help Patients, Sites, Caregivers, Medical Experts and Others Running Clinical Trials
Sheila Khawaja, MA, Patient Engament Expert| EURORDIS Alumni; Board Chair, World Alliance of Pituitary Organizations, Italy

Track B: Solving Clinical Data Challenges: Advancing Research Through New Technology

Session Chair
Sheila Rocchio, MBA, Chief Marketing Officer at eClinical Solutions

A majority of clinical trials now use more than five data sources, sponsors are increasingly challenged to reduce cycle times. The impact of this exponential growth in data has resulted in significant challenges and delays in clinical research that have necessitated the use of new strategies that leverage technology to improve trial efficiencies. Using the findings from The Tufts-eClinical Solutions Data Strategies & Transformation Study, this session will incorporate perspectives from sponsor roles, technology experts and clinical researchers to frame the challenges in today's digital health landscape. As revealed in the study, no matter the size of the organization, all sponsors are contending with how to maximize the value of their clinical data, integrate disparate data, improve their analytics capabilities, and prepare for automated processes with AI and machine learning models. The session will also discuss the strategies to solve these clinical data challenges, which includes developing a modern infrastructure and implementing technology platforms effectively.

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

- Define key elements of a clinical data strategy and why it matters
- Identify technology architectures and components that support modern clinical trials
- Discuss interoperability versus integration and why it matters for analytics

The Need for Clinical System Interoperability & Benefits for Analytics
Megan Dunham, Associate Director, Clinical Data Innovation, Jazz Pharmaceuticals

Speaker
Vijay Koduru, MSc, Associate Director, Statistical Programming, Jazz Pharmaceuticals

1:00-1:15PM **Break**

1:15-2:15PM **Session 7:** CONCURRENT SESSION

Track A: Role of Public-Private Partnerships in Generating Evidence for Remote Monitoring Technologies: Rewards and Challenges

Session Chairs
Sonya Eremenco, MA, Executive Director, PRO Consortium, Critical Path Institute

Scottie Kern, Executive Director, Critical Path Institute

The Critical Path Institute (C-Path) creates precompetitive public-private partnerships that bring together stakeholders to improve the process of medical product development. Several consortia within C-Path are pursuing research related to remote monitoring technologies, e.g., wearable devices or activity monitors, in order to support their use in clinical trials and research. This session will highlight two case examples: one from the Critical Path to Parkinson's (CPP) Consortium digital drug development tool 3DT project and the other from the PRO Consortium's Chronic Heart Failure (CHF) Working Group, which is pursuing qualification of an activity monitor-based endpoint measure by the US Food and Drug Administration's Clinical Outcome Assessment Qualification Program. Both projects involve industry sponsors willing to collaborate to achieve regulatory endorsement of drug development tools for use in clinical trials. In both cases, individual sponsors were willing to share data from non-interventional observational studies within each consortium in order to accelerate progress toward the collective goal. The session will highlight the challenges and rewards of data sharing within each project, and why sharing of remote monitoring technology data in particular will be crucial to the long-term success of each project. The panelists for this session will include a representative of the Patient-Reported Outcome (PRO) Consortium at C-Path, who will discuss the need for data sharing to advance the effort to qualify an activity monitor-based endpoint measure in chronic heart failure, an industry representative from CPP, and an FDA representative, who will share their perspectives on the promise and the challenges of data sharing in the context of studies involving remote monitoring technologies.

Critical Path to Parkinson's (CPP) Consortium Digital Drug Development Tool 3DT Project
Diane Stephenson, PhD, Executive Director, Critical Path Institute

Role of Public-Private Partnerships in Generating Evidence for Remote Monitoring Technologies: Rewards and Challenges
Sonya Eremenco, MA, Executive Director, PRO Consortium, Critical Path Institute

Speakers
Josh Cosman, PhD, Director, Digital Health Strategy, Abbvie

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

Track B: Patient Data Technologies for Real-World Evidence, Epidemiology and Clinical Research

Patient Data Technologies for Real-World Evidence, Epidemiology and Clinical Research
Douglas Drake, MBA, Senior Director, Customer Solutions Clinerion Ltd, Switzerland

Speakers
Sébastien Wischlen, RN, Chief Executive Officer, CancerDataNet GmbH, Switzerland

Romain Finas, Vice President, Real-World Evidence, Alira Health, France

2:15-2:30PM — **Break**

2:30-3:30PM — **Session 8:** CONCURRENT SESSION

Track B: Technology Enablers for Increased Remote Measurement of Outcomes Data

Session Chair
Bill Byrom, PhD, Principal, eCOA Science, Signant Health, United Kingdom

Greater decentralization is associated with an aim to collect more outcomes data directly from patients away from the clinic. This session explores a number of approaches that facilitate greater capture of outcomes data in remote settings including: the greater use of the patient's own mobile device (BYOD) to collect ePRO data; the use of integrated wearables and sensors to collect objective outcomes measures while retaining a simple user experience for sites and patients; and the development of performance outcome tests leveraging the smartphone sensors to provide additional measures embedded in the ePRO workflow.

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

- Understand the considerations involved in determining a BYOD strategy for ePRO data collection
- Determine solution design elements to simplify site and patient experience when using sensors and wearables alongside ePRO

- Discuss the potential and challenges in deriving novel PerfO endpoints using onboard smartphone sensors

BYOD: And So What?
Estelle Haenel, DrSc, PharmD, Medical Director, Kayentis, France

eCOA + Connected Devices: Lessons Learned on Flow to Successfully Configure and Deliver a Unified Experience
Lindsay Hughes, PhD, MS, Principal Scientific Advisor, ERT

Leveraging Smartphones as Measurement Devices for Remotely Conducted Performance Outcome Tests – Notes from the Field
Bill Byrom, PhD, Principal, eCOA Science, Signant Health, United Kingdom

DAY THREE | FRIDAY, OCTOBER 29

9:00-10:30AM

Session 9 Regulatory Sprint: Can We Develop an Agile Regulatory Decision Matrix for Digital Measurement?

Session Chairs
Lauren Oliva, PharmD, RPh, Global Regulatory Policy Lead, Regulatory for Biogen Digital Health

Megan Doyle, JD, MPH, Global Policy Lead, Digital Health, Diagnostics, and Combination Products Amgen

Anindita Saha, Assistant Director, Digital Health Center of Excellence, CDRH, FDA

This interactive panel session will explore a fictional case study of a digital health technology (DHT) used as a measurement tool in a drug clinical trial. An expert panel will engage in a dialogue, including audience polls and Q&A, about regulatory considerations for selection of the most appropriate endpoint, how to measure the endpoint, and verification and validation as it applies to the hypothetical case study.

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

- Explore evidence criteria to be addressed for digital health technologies (DHTs) in clinical trials through a case example
- Evaluate regulatory questions based on drug program goals and DHT medical device status and intended use

Anindita Saha, Assistant Director, Digital Health Center of Excellence, CDRH FDA

Jeffrey Siegel, MD, Director, Office of Drug Evaluation Sciences, Office of New Drugs, CDER FDA

Elizabeth Kunkoski, MS, Health Science Policy Analyst, OMP, CDER, FDA

Matthew Diamond, MD, PhD, Chief Medical Officer, Digital Health Center of Excellence, CDRH FDA

Samantha Roberts, PhD, Group Director, US Regulatory Policy, Genentech, A Member of the Roche Group

Simon Bennett, MSc, Director, EU Regulatory Policy, Biogen, United Kingdom

10:30-11:00AM

Exhibitor Event/Non-CE: Case Study Spotlight

See Page 17 for more information and instructions on how to RSVP!

11:00-11:15AM

Break/Visit the Exhibit Hall

11:15AM-12:15PM

Session 10: CONCURRENT SESSION

Track A: Are PRO Measures Becoming Obsolete in the Digital Era?

Session Chair
Paul O'Donohoe, MS, MSc, Senior Director, eCOA Product and Science, Medidata Solutions

Investigators are increasingly seeking ways to use sensor data in clinical research. Some researchers have suggested that sensor data can be equivalent, or even superior, to similar data already being collected via patient reported outcome (PRO) measures due to the perception that such data are an 'objective' measurement whereas PRO measures provide 'subjective' data and are thus, apparently, inferior, or less reliable sources of information. This line of reasoning has led some to claim that PRO measures can, and will, be replaced by mobile sensors to measure symptoms and functioning in future clinical trials. This session will

debate whether PRO measures are becoming obsolete and discuss ways in which these measurement tools are likely to be used in clinical trials moving forward. Panelists will represent industry, mobile technology expert, PRO researcher, and FDA perspectives.

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

- Summarize the pros and cons of using PRO measures and technology tools to assess endpoints in clinical trials
- Identify appropriate strategies for the implementation of various measurement tools for use as a clinical trial endpoints
- Understand the synergies different data sources can bring to understanding the patient experience in clinical research

Speakers
Sonya Eremenco, MA, Executive Director, PRO Consortium, Critical Path Institute

Ieuan Clay, PhD, Chief Scientific Officer, Digital Medicine (DiMe) Society, Germany

Elizabeth Nicki Bush, MHS, Senior Advisor and Head, Patient-Focused Outcomes Center of Expertise, Eli Lilly and Company

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

Track B: Measuring Gait In-the-wild Using Wearable Technology: Advantages and Challenges

Session Chairs
Bill Byrom, PhD, Principal, eCOA Science, Signant Health, United Kingdom

Gait is emerging as a powerful tool for monitoring disease progression, detecting fall risk, and testing the efficacy of an intervention across a range of diseases (e.g., Parkinson's disease (PD), Multiple Sclerosis (MS)). While quantitative gait assessment has been limited to specialized gait laboratories, wearable sensors afford the possibility to measure gait in the wild through performance outcome tests. This session explores the benefits and challenges of measuring gait in remote settings, types of studies and criteria needed, data analysis considerations, and challenges associating daily life mobility to prescribed gait tests.

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

- Identify potential benefits and real challenges of characterizing mobility during daily life with wearable technology
- Discuss potential solutions for use of wearable technology to quantify gait in daily life

Technical Challenges for Defining Gait in the Wild
James McNames, PhD, Professor, Portland State University

Analytic and Interpretation Challenges for Defining Gait in the Wild
Vrutangkumar Shah, PhD, Postdoc Scholar, Oregon Health & Science University

Benefits of Measuring Gait in the Wild for Clinical Trials
Fay Horak, PhD, Chief Scientific Officer, ERT, APDM Digital Technology

Measuring Gait In the Wild Using Wearable Technology: Benefits and Challenges
Kristen Sowalsky, PhD, Director, Clinical Science and Consulting - Wearables & Digital Biomarkers, ERT

12:15-1:15PM

Session 11: CONCURRENT SESSION

Track A: Decentralized Trials and Research: Sustaining the Momentum Post-Pandemic

Session Chair
Courtney Granville, PhD, MPH, Global Associate Director, Research and Scientific Programs, DIA

The rapid adoption of decentralized trials and research is a silver lining of the coronavirus pandemic. Stakeholders across the medical product development continuum moved to integrate decentralized approaches to maintain continuity and respond to the demands of COVID-19. Many organizations developed processes and practices to integrate new technology, while patients and investigators adapted to new ways to interacting, receiving, and delivering care and collecting data. As we emerge from the pandemic, what approaches should be retained and how can our community implement process and procedure that is fit for purpose, taking into account the needs and preferences of all stakeholders?

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

- Demonstrate how robust clinical trial processes can be developed and optimised ensuring introduction of new technology into decentralised clinical trials to allow patient centric data collection
- Recognize the impact of decentralization on patients – explain how choice and optionality in clinical trials can be incorporated
- Identify remaining challenges to the adoption of decentralized approaches and recognize ways of overcoming barriers

Developing Processes for Patient Centric Decentralised Clinical Trials
Karla Mackenzie, MS, Head of CRA Oceania, LEO, Australia

The Voice of the Patient in Decentralized Research and Trials
Sarah Krüg, MS, Chief Executive Officer, Cancer101

Multistakeholder Collaborations to Advance Decentralized Trials and Research
Craig Lipset, MPH, Co-Chair, Decentralized Trials & Research Alliance

1:15-1:30PM **Closing Remarks**

ON-DEMAND ABSTRACT PRESENTATIONS

On-Demand

Session 3: Track B: Connected Injection Devices in Clinical Trials

1) Connected Injection Devices in Clinical Trials

Accurate collection of drug administration data, prompt detection and resolution of protocol non-compliance, and strong retention of participants are key factors in an efficient and well-run clinical trial. Manual capture and transcription of drug administration data in clinical trials can lead to errors, resource-intensive follow-up, compromised data quality, and delayed analysis, contributing to longer and more costly trials. In the ever-increasing practice of decentralized trials, it may be advantageous to measure outcomes or adverse events in correlation with time of drug intake. However, this can be challenging when the precise timing is unknown.

To address these needs, we are developing connected solutions for use with injection systems, which are intended to seamlessly transmit injection data via a smartphone to the cloud. From the cloud, these injection data could integrate with the data management systems used by the contact research organization or clinical trial sponsor.

Our research revealed that the ideal solution is a data capture system that does not alter behavior or add extra burden on the user. To this end the connected injection device would act as a 'silent reporter', automating the capture and transmission of injection data, with minimal user involvement and minimal impact on the design and usability of the base injection device.

Details will be provided in this presentation of the first embodiment of a connected injection device (BD Ultrasafe Plus™ Passive Needle Guard) and how the captured data can be integrated into a third-party platform.

BD connected solutions are products in development; some statements are forwarding looking and are subject to a variety of risks and uncertainties. BD, the BD Logo, and BD UltraSafe Plus are trademarks of Becton Dickinson and Company or its affiliates.

Learning Objectives

- Recognize the benefits that automatic capture of injection data can provide for clinical trial efficiency
- Assess the potential of the proposed solution for their own clinical trial needs

Speaker
Herve Monchoix, Strategic Innovation Leader, BD

On-Demand

Session 8: Track A: Using Novel Speech-Based Endpoints in CNS Clinical Trials

Changes to speech and language occur in a broad range of neurological diseases and psychiatric disorders. Differences in both the acoustic patterns and linguistic characteristics can result from changes in cognition, mood, and motor function. Tools to assess speech and language based on recent advances in natural language processing and machine learning techniques offer novel ways of detecting and quantifying these changes. In contrast to traditional clinical measures, these digital speech assessment tools can also be administered remotely, at high frequency, and with minimal training or instruction. Speech assessment tools therefore have the potential to enhance clinical trial design by providing sensitive measures of behavior, highly relevant to everyday function. In this presentation, we will present the speech assessment tools developed by Winterlight Labs and provide an overview of how they have been used in different CNS clinical trials. We will review research using the Winterlight technology, showing how speech and language patterns are relevant to disease and can be used to capture change over time.

Learning Objectives

- Define speech-based digital measures.
- Identify the advantages of using digital speech assessments for monitoring neurological and psychiatric diseases and disorders.
- Describe how speech assessments have been implemented in clinical trials and how they can provide flexible options for remote and high frequency assessment.

Speaker
Bill Simpson, PhD, Senior Director Clinical Operations, Winterlight Labs Adjunct Lecturer, McMaster University, Dept Psychiatry and Behavioural Neuroscience

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On-Demand

Session 11: Track B: Engage Now, Benefit Later: How Early Supply Management Design Considerations Improve Master Protocol Development

Master protocols can study beneficial treatments with fewer patients, fewer patient failures, in less time, and greater probability of success than traditional randomized trials. For patients, it provides access to multiple targeted therapies and it reduces the chance of being enrolled in a control arm, with the use of a single control arm across all therapies. The design of master protocols comes with challenges, especially regarding the management of medication supplies and the recruitment of patients to the right sub-protocol, with the right treatment assignment. Experts in IRT (Interactive Response Technology) know which challenges such protocol designs present and can suggest mitigating actions. Engaging with those experts as early as possible in the master protocol design process is a good way for sponsors to understand those challenges and arm themselves with the right mitigating actions to increase the success of their master protocol.

The presentation will be focused on how to shift medication management from single trial to master protocol in IRT. We will share how to plan medication needs across several protocols and what type of solutions are available to trial teams to manage medication for multiple trials at the same time. The audience will learn how to anticipate new drug types that often come with new sub-protocols.

We will also cover the planning of randomization requirements and the flexibility that master protocols require regarding treatment group allocation. The evolutive aspect of basket and umbrella trials increases the risk of mis-randomization and imbalance between treatment groups and sub-protocols. We will discuss how IRT design enables evolution over time, adapting to future sub-protocols, whilst providing the right level of robustness to control those risks.

Learning Objectives

- Understand the challenges to overcome from a clinical supplies point of view when designing a master protocol
- Learn about the different ways that patient randomization can adapt to master protocols

Speaker

Sylvain Berthelot, Global Head, IRT & EDC Technical Solutions, Calyx, AUS

Malcolm Morrissey, Associate Director Statistics and Product Support Services, Calyx UK

Craig Mooney, Vice President, Scientific E-tech Enabled Services, Calyx

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On-Demand

The Case for a Unified and Integrated eSource and EDC System

eSource collection methods have been available for decades with a slow and steady stream of adoption by sponsors, CROs, and Investigator sites. The challenges the industry faced in 2020 forced an increase in the adoption of eSource, and from that, there were many lessons learned. While the FDA defines eSource as any and all electronic source data, Transcelerate Biopharma has determined that eSource is classified in four groups: non-case report form, devices and apps, direct digital entry at the trial site, and patient-sourced EHRs. For the purpose of this presentation, we are focused on direct digital entry at the trial site.

Third-party integrations between investigator site eSource database (eSource) and a Sponsor's eCRF database (eCRF) are common but often result in costly delays, maintenance, and multiple warehousing. In this presentation, we will discuss how a unified database system of eSource and eCRF can streamline your data collection, accelerate your clinical trial, provide cleaner more accurate data, reduction in errors, and preparation for regulatory submissions.

We'll provide use case examples from pharma, biotech, and animal health spanning preclinical to Phase IV, and the key factors that contributed to their successful results from using this model. We will cite examples of build timelines being accelerated to under three weeks as opposed to the industry average of twelve, the standardization of data collection, and same-day query resolution. This presentation will underscore the value of real-time data access and analysis with examples of how sponsors and CROs have leveraged this functionality in a unified system. We'll also discuss how system maintenance and downtime have not impacted productivity due to Medrio's offline capabilities."

Learning Objectives

- Learn the value and outcomes of a unified data capture system through three use case examples from different industry segments (bio/pharma, animal health, and CRO)
- Recognize the benefits of real-time data, particularly as it relates to queries
- Discover how a unified system allows for a level of data standardization that you cannot achieve with multiple vendors

Speaker

Muhammad Bilal, Sr. Director, Clinical Data Management and Biostatistics, Topstone Research, Canada

Digital Technology in Clinical Trials Sponsored Events

Separate RSVP is required for each event. These sponsored sessions are open to all, including those not registered for the full conference. These sponsored sessions are separate to the conference content included in registration. Upon completion of your RSVP a login link will be sent to you for the session. By registering for this sponsored session, you are agreeing to share full contact information with the Solution Provider. You also understand that the Solution Provider, and DIA, may contact you with messages regarding products and/or services.

WEDNESDAY | OCTOBER 27

2:40-3:25PM

Exhibitor Event/Non-CE: Round Table hosted by ZS

Round Table hosted by ZS: Wearables in Clinical Trials

Sensor-based wearable devices are becoming a common feature of decentralized clinical trials, allowing researchers to collect accurate activity data from trial participants through the course of a study. With the growing importance of quality of life and activity metrics as primary and secondary endpoints, wearables offer a new window to the daily lives of patients. They may improve trial participation and improve adherence to investigational medications. However, choosing, implementing, and supporting the optimal wearables for a planned study can be challenging to stakeholders, especially as technology options and requirements continue to evolve. Join this discussion to learn and share what it takes to adopt wearables in clinical trials.

- What are the biggest challenges?
- How do you pick the right wearables?
- How do you know that wearables are validated against measures you care about?
- How do you pilot, proof of concept wearables before investing in a large trial?
- Where can sponsors collaborate to modify primary endpoint from traditional endpoint to novel digital endpoint?
- How do you ensure that wearables don't overburden the patient?

Speakers:

Fan Gao, PhD, Principal, ZS

Todd Greenwood, PhD, MPH, Senior Director of Client Solutions, ZS Medullan

Separate RSVP is required. **Click here to RSVP.**

FRIDAY | OCTOBER 29

10:30-11:00AM

Exhibitor Event/Non-CE: Case Study hosted by Curebase

Round Table Hosted by Curebase: Telemedicine in Clinical Trials, Beyond Video Calls

In this session we explore 2 case studies in which telemedicine was applied in our clinical trials, showcasing how telemedicine platforms for clinical trials need to be fit-for-purpose to meet specific needs of individual studies. In these two case studies we will discuss how our fit-for-purpose telemedicine platform was used in an atopic dermatology drug trial, and an infectious disease study. This included capturing images for assessing skin abnormalities, to ensure alignment with eligibility criteria and monitor treatment response. We'll dive into the specifics of how the telemedicine platform was applied to meet these needs and other future use cases.

Featured Topics

- Telemedicine as a fit-for-purpose solution in clinical trials
- Integration of telemedicine with clinical visits
- Implementation of specific tools within telemedicine to meet individual study needs
- Future of telemedicine and adapting it to meet optimal user experience on a study-by-study basis

Speaker

Adam Samson, Sr. Director of Clinical Operations & Customer Success, Curebase Inc.

Separate RSVP is required. **Click Here to RSVP.**