DIA

Digital Technology in Clinical Trials Conference

Short Course October 11 | Conference October 13-14 | Virtual

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Overview

The DIA's Digital Technology in Clinical Trials Conference discovers how digital technology is transforming the drug, device, and diagnostics development process in clinical trials.

Join thought leaders from regulatory agencies, biotech, pharma, patients, and academia to discuss the latest advances, challenges, and forward-thinking approaches in the field.

Co-Sponsored with Critical Path Institute's eCOA Consortium

eCOA CONSORTIUM CRITICAL PATH INSTITUTE

Members of the Electronic Clinical Outcome Assessment (eCOA) Consortium are firms that provide electronic data collection technologies and services for capturing COA data in clinical trials. The eCOA Consortium provides a pre-competitive environment in which a critical mass of experts can collaborate to generate measurement equivalence data, develop specification documents and data standards, and provide guidance on methodological considerations related to eCOA applications. All of these activities are aimed at enhancing the quality, practicality and acceptability of electronic capture of clinical trial endpoint data.

Event Goals and Offerings

- Discuss digitalization in clinical trials of today
- Explore future applications enabling clinical trials of tomorrow
- Strategize implementation methods to innovate trial designs, improve patient experience, utilize recruitment/retention tools, and establish end points
- Address industry changes created by the introduction of:
- Wearable and mobile technologies along with cloud technology
- Artificial intelligence and related platforms enabling timely data collection and analysis
- Potential of multidimensional data throughout the length of trials

Why You Can't Miss It

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Who Should Attend

Professionals involved in:

- Digital Strategies and Technologies
- (e)Clinical Technology and Solutions
- Clinical Site Management and Operations
- Business & Data Development, Strategy, and Analysis
- Patient Advocacy, Engagement, and Recruitment
- Compliance & Regulatory Affairs
- Ethics, Health Economics & Endpoint Development
- Security, IT, Systems, and Programming
- Medical Affairs & Communications
- R&D and Quality Management

All times listed are in EST

VIRTUAL SHORT COURSE | TUESDAY, OCTOBER 11

10:00-2:00PM	**Short Course:** Digital Health – From Concept to Implementation

DAY ONE | THURSDAY, OCTOBER 13

9:45-10:45AM	**Welcoming Remarks and Session 1:** Welcoming Remarks and Keynote: Site and Investigator Perspective on Digital Technology in Clinical Trials - Keynote Address by Elena Christofides, Chief Executive Officer, Endocrinology Associates Inc
10:45-11:15AM	**Break**
10:45-11:15AM	**SPONSORED SESSION:** Case Study Spotlight hosted by IQVIA Technologies: Accelerate Your Trial and Enhance Patient Experience Please note that this is an exhibitor sponsored event and is not eligible for CE credit. Separate RSVP is requested – **click here** or sign up on the Mobile App.
11:15AM-12:30PM	**Session 2:** Lessons Learned and Best Practices for Decentralized Clinical Trials: Can We Plan and Execute More Patient-Friendly Clinical Trials?
12:30-12:45PM	**Break**
12:45-2:00PM	**Session 3:** Regulations and Digital Health Technologies: Where Do We Stand and What Do We Do Next?
2:00-2:15PM	**Break**
2:15-3:15PM	**Session 4:** Strategies for Managing Complex Digital Health Data Sets for Successful Regulatory Submissions

DAY TWO | FRIDAY, OCTOBER 14

11:15AM-12:30PM	**Session 5:** Innovating in the Gray Space: How do we Successfully Advance Digital Health Tools as the Regulatory Science Evolves?
12:30-12:45PM	**Break**
12:45-1:30PM	**Session 6:** The Intersection of Patient Experience, Digital Technology and Clinical Trials: How to Leverage the Patient Voice?
1:30-1:45PM	**Break**
1:45-2:45PM	**Session 7:** Artificial Intelligence (AI) and Machine Learning (ML) Use in Clinical Trials: How Do We Use Artificial Intelligence (AI) and Machine Learning (ML) in Clinical Trials?
2:45-3:00PM	**Break**
3:00-4:30PM	**Session 8:** State of the Union of Real-World Evidence (RWE) and Real-World Data (RWD): How Can we use RWD Technology in the Drug Development Space?
4:30PM	**Closing Remarks**

Learning Objectives

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

- Identify best practices in planning and executing decentralized trials and assess the challenges that remain for broad scale decentralized trial adoption
- Discuss the role of regulators in addressing DHT during the review process and describe how to bridge modern technology with current and past regulations
- Discuss how relationships with sites and trial participants are integral to digital health technology implementation success
- Explain the main gaps in current regulatory expectations in the United States (US) and European Union (EU) as of today and evaluate different resources that can supplement existing regulatory guidance and help to inform globally harmonized guidelines
- Describe the regulatory concerns or requirements for using AI and ML in clinical trials
- Identify opportunities and constraints in improving the patient experience using digital health technology in clinical trials and recognize the value of patient input by prioritizing patient preferences and priorities in the development and design of study protocols, deploying DHTs, and collecting data

Continuing Education Credits

DIA is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. This program is designated for up to 12.5 contact hours or 1.25 continuing education units (CEU's). Type of Activity: Knowledge

ACPE CREDIT REQUESTS MUST BE SUBMITTED BY FRIDAY, NOVEMBER 25, 2022

DIA is required by the Accreditation Council for Pharmacy Education (ACPE) to report pharmacy-requested CEUs through the CPE Monitor system. All ACPE-certified activity credit requests need to be submitted through DIA's My Transcript within 45-days post activity. If ACPE credit is not requested by Friday, November 25, 2022, the CEU request will not be transmitted through to the CPE Monitor. Pharmacists will need to provide their National Association of Boards of Pharmacy (NABP) e-Profile ID and date of birth (MMDD) to ensure the data is submitted to the ACPE and NABP properly. If you need to obtain your NABP e-Profile, please visit **www.cpemonitor.net**

October 11 Short Course: Digital Health – From Concept to Implementation 3.5 contact hours or .35 CEUs Type of Activity: Knowledge, 0286-0000-22-082-L04-P

October 13 Day 1: Digital Technology in Clinical Trials – Day 1: 4.5 contact hours or .45 CEUs Type of Activity: Knowledge, 0286-0000-22-083-L04-P

October 14 Day 2: Digital Technology in Clinical Trials – Day 2: 4.5 contact hours or .45 CEUs Type of Activity: Knowledge, 0286-0000-22-084-L04-P

Continuing Education Credit and My Transcript

If you would like to receive a statement of credit for the days you attend the virtual conference, you must attend one or both days of the virtual conference, (in their entirety) complete and return a CE Verification of Attendance Form (see instructions below), 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, October 28, 2022.

Drug Information Association (DIA) is accredited by the International Association for Continuing Education and Training (IACET) and is authorized to issue the IACET CEU.

As an IACET Accredited Provider, DIA offers CEUs for its programs that qualify under the ANSI/IACET Standard. DIA is authorized by IACET to offer the up to .4* CEUs for this program.

*IACET CEUs are only available for the Short Course(s). Participants must attend the entire short course in order to be able to receive an IACET statement of credit. No partial credit will be awarded.

If you are claiming CE credit for the virtual conference, you must:

1. Attend one or both days of the virtual conference, in their entirety
2. Complete a CE Verification of Attendance Form, submit by October 21, 2022
3. Access your DIA account and select My Transcript to claim your CE credit, available on Friday, October 28, 2022

DIA Disclosure Policy

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.

This educational activity may include references to the use of products for indications not approved by the FDA. Opinions expressed with regard to unapproved uses of products are solely those of the faculty and are not endorsed by the DIA or any of the manufacturers of products mentioned herein. Faculty for this educational activity was asked to disclose any discussion of unlabeled or unapproved uses of drugs or medical devices.

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

Planning Committee

DIA staff members have no relevant financial relationships to disclose.

To view DIA's Disclosure and Grievance Policies, visit **DIAglobal.org/CE**

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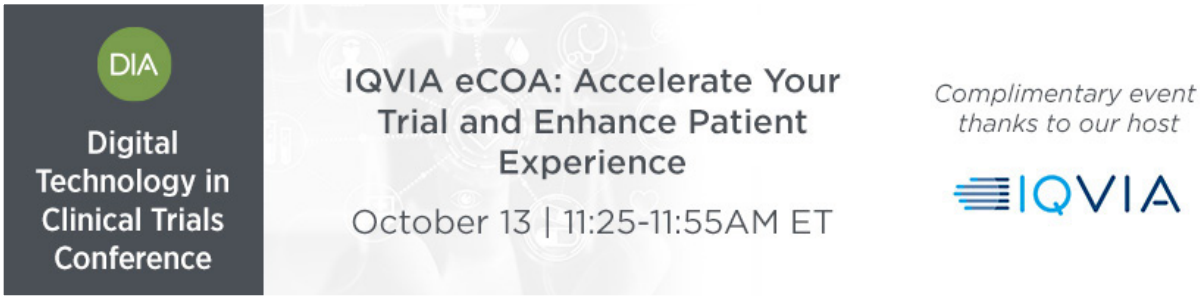
Please Note: DIA User ID and Password are needed to access presentations. If you have forgotten your DIA User ID and Password, or this is your first time logging into the DIA website, please use our Login Reminder. **Presentations will be available for six months post conference.*

Exhibitor Event/Non-CE: Case Study Spotlight hosted by IQVIA Technologies



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

Fast, flexible, and proven, IQVIA eCOA combines best-in-class technology with industry-leading expertise to improve the patient experience, enhance data quality, and accelerate clinical trials. Join Anthony Mikulaschek as he discusses how IQVIA eCOA helps sponsors reduce study start-up timelines, provide a flexible experience for patients and sites, while utilizing the industry's largest digital library of assessments to enhance overall trial efficiency.

Featured Topics include:

- How an IQVIA sponsor realized an accelerated study start-up time of only 2 weeks
- How IQVIA's BYOD solution helped a sponsor achieve 95% patient compliance
- How IQVIA's library of assessments not only enables rapid study-build but, eliminates potential error in start-up and improves data quality

Attendees for the Case Study will receive an Amazon Gift Card ($10 USD) from DIA. You must be registered for **DIA's Digital Technology in Clinical Trials Conference** to qualify.

Please note that this is an exhibitor sponsored event and is not eligible for CE credit. You do not have to be registered for the conference to register for this event.

Anthony Mikulaschek, Vice President, eCOA, IQVIA