Clinical Innovation and Biostatistics Summit

Virtual Summit
April 28, 2025

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Overview

This revamped one-day virtual event will present case studies and lessons learned from oncology and neuroscience, followed by roundtable discussions on master protocols, complex innovative designs (CIDs), and external data borrowing to assess bottlenecks and create solutions. Key findings, recommendations, and prioritized next steps will be published to drive continued collaboration.

Engage in vibrant group discussions with experts involved in clinical development, including biostatisticians, clinical researchers, technology experts, and regulators, and immerse yourself in cutting-edge insights—all from the comfort of your own space.

Registered attendees for this virtual summit will receive access to the session recordings for 2 full months post-summit! This allows you to remain flexible with your schedule and not worry if you need to step out momentarily.

Key Agenda Highlights

- **Opening Remarks** – Senior leaders from DIA, Pfizer, and the FDA set the stage for discussions on regulatory and scientific advancements in clinical trial design
- **Regulatory Updates and FDA Initiatives** – Overview of the FDA's new Clinical Trial Innovation Initiative (C3TI), guidance on adaptive clinical trials (ICH E20), and insights on benefit-risk assessments for new drug and biological products
- **Innovative Clinical Trial Designs** – Exploration of Master Protocols and seamless phase 2/3 designs to improve efficiency in clinical trials, with industry perspectives on implementation challenges
- **Case Studies on Novel Trial Approaches**: (1) *Master Protocols in Oncology* – Practical examples of how these designs improve trial execution. (2) *Innovative Neuroscience Trials* – Cutting-edge approaches to trial design in neurological disorders
- **Challenges and Opportunities in Master Protocols** – Focus on platform and basket trials, regulatory perspectives, and discussions on external data borrowing
- **Implementation of Innovative Designs** – Panel discussion on real-world challenges and best practices for applying innovative trial methodologies

Why You Can't Miss It

- Play a key role in creating a path towards effective, cross-disciplinary collaborations that drive innovative approaches to clinical trial design and execution
- Engage in thought-provoking discussions that bridge the gap between statistical and clinical perspectives
- Be at the forefront of the most recent academic, regulatory, and industry insights
- Take deep dives into real-world applications, focusing on cutting-edge methodologies in diverse therapeutic areas
- Gain a deeper understanding of new regulatory initiatives and guidances on clinical trial innovations, adaptive clinical trials, and benefit-risk assessments of new drugs and biological products
- Explore cutting-edge approaches, lessons learned, and innovative solutions
- Connect with experts, peers, and industry leaders to expand your professional network and open doors to collaboration and future opportunities

Who Should Attend

Forum Designed For:

- Academics
- Biostatisticians
- Clinical Development, Research, and Operations Professionals
- Clinical Safety & Pharmacovigilance
- Data & Data Standards
- Good Clinical Practice
- Nonprofit and Federal Government Representatives
- Patient Engagement
- Preclinical & Early Phase Research
- Project Management
- Quality Assurance & CMC
- Rare & Orphan Diseases
- Regulators
- Research & Development
- Statistics and Data Science
- Strategic Planning
- Technology
- Value & Access

Schedule At-A-Glance

MONDAY, APRIL 28	
9:00-10:35AM	Opening Remarks and Session 1: Regulatory Updates and Experiences
10:35-10:45AM	Break (on your own)
10:45AM-12:30PM	Session 2: Clinical Trial Innovative Designs and Approaches – Setting the Context and Presenting the Industry Perspectives
12:30-1:00PM	Break (on your own)
1:00-2:00PM	Session 3: Case Study 1: Master Protocol Implementation in Oncology
2:00-2:30PM	Session 3: Case Study 2: Borrowing External Data
2:30-2:45PM	Break (on your own)
2:45-3:45PM	Session 4: Challenges and Opportunities for Implementing Innovative Designs Including Master Protocols and Borrowing External Data
3:45-4:00PM	Next Steps and Closing Remarks
4:00PM	Summit Adjourns

Learning Objectives

- Understand recent regulatory developments and guidance from the FDA impacting the design and conduct of clinical trials, including key takeaways from newly released documents and initiatives
- Describe the principles and potential benefits of innovative clinical trial designs, including master protocols and seamless phase 2/3 trials, and evaluate their application from an industry perspective
- Identify practical challenges and considerations in conceptualizing and implementing advanced trial designs across different therapeutic areas
- Analyze real-world case studies demonstrating successful use of master protocols and innovative approaches in oncology trials, with a focus on overcoming operational and regulatory hurdles
- Apply insights from regulatory updates and case studies to inform strategic decisions and improve the efficiency and quality of clinical research programs

If you would like to receive an attendance certificate for the virtual summit, you must attend the summit, sign into the Learning Center for each session, and request attendance credit online through My Transcript (see instructions below). Participants will be able to download an attendance certificate upon successful submission. My Transcript will be available for attendance certificate requests beginning Monday, April 28, 2025.

If you are claiming an attendance certificate for this event you must:

1. Attend the virtual summit

Attendance Certificate Allocation

April 28, 2025 – Clinical Innovation and Biostatistics Summit: 1 Attendance credit

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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.

DIA 2025 is the premier gathering for industry leaders, regulatory authorities, governmental representatives, academia, innovators, and patients. Set against the vibrant backdrop of Washington, DC, DIA 2025 will beckon stakeholders from around the world to converge, collaborate, and catalyze transformative change within the life sciences realm.

At DIA 2025, we will transcend boundaries, inviting diverse voices to the table to address both local and global challenges. From regulatory hurdles to technological innovations, from healthcare disparities to patient-centric solutions, our agenda is comprehensive and forward-thinking.