Global Clinical Trial Disclosure and Data Transparency Conference

September 23-24, 2024 | Arlington, VA

PROGRAM CHAIR

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Overview

As clinical trial disclosure continues to evolve, sponsors and academic institutions face increasing pressure to meet global disclosure requirements. Navigating various regulatory landscapes presents challenges but also opens doors for invaluable cross-regional strategic considerations, alignment on best practices, and process modernization. DIA's *Clinical Trial Disclosure and Data Transparency Conference* brings together industry and regulatory experts to explore the latest trends, strategies, and innovations in the field. During the conference, attendees will learn about the complexities of global disclosure practices, understand the impacts of regulatory modernization, and discover practical applications that can elevate global compliance and transparency efforts.

Event Goals and Offerings

- **Enhance Understanding**: Equip participants with the latest knowledge and updates about clinical trial disclosure standards and practices, focusing on regulatory compliance across different regions
- **Promote Best Practices**: Share and promote the best practices for maximizing transparency in clinical trials, including the use of plain language summaries and innovative tools like the EU Clinical Trials Information System (CTIS)
- **Encourage Networking and Collaboration**: Facilitate networking opportunities among professionals from biopharma companies, regulators, and other stakeholders to foster collaboration and sharing of insights
- **Support Implementation of Technologies**: Explore and discuss the integration of advanced technologies in improving the transparency and efficiency of clinical trial processes
- **Increase Compliance and Awareness**: Highlight and address the enforcement initiatives and legal consequences of non-compliance with clinical trial transparency requirements
- **Advocate for Patient-Centric Approaches**: Emphasize the importance of patient-centric approaches in clinical trial communication, ensuring that trial results and summaries are accessible and understandable to non-specialist audiences

Who Should Attend

Professionals involved in:

- Academia
- Biometrics
- Clinical Operations / Development
- Clinical Trial Disclosure
- Clinical/Medical Research
- Compliance/Legal
- Data management
- Data transparency/data sharing
- External Health Authorities (comp and ethics committees)
- Internal Regulatory / Regulatory Submissions/Regulatory Leads
- Medical Writing, Medical Affairs, and Medical Communications
- Marketing
- Communications
- Compliance
- Medical Information and Affairs
- Legal
- Patient Engagement
- Patient Advocacy
- Patient registries
- Publications
- Real-World Data
- Transparency policies and compliance (Clinical Data)

Why You Can't Miss It

- **Regulatory Updates**: Critical updates on new and evolving regulatory requirements across various regions, which is critical for ensuring compliance and staying abreast of changes that could impact how clinical trials are conducted and reported
- **Expert Insights**: Gain direct insights from industry leaders and regulators, offering attendees a unique opportunity to learn from and interact with key thought leaders
- **Technological Advancements**: Emphasis on the latest advancements in technology, including the application of artificial intelligence in clinical trial transparency. Attendees will explore innovative tools and methodologies that have the potential to transform their operational processes
- **Patient-Centric Approaches**: Understanding and implementing patient-centric communication strategies, including plain language summaries, is increasingly important. This conference will provide strategies and examples of how to effectively communicate with trial participants and the public
- **Global Perspective**: The global focus of the conference helps attendees understand and navigate the international landscape of clinical trial transparency, which is particularly important for organizations that operate or plan to operate on a global scale

Schedule At-A-Glance (All times listed are Eastern Time)

DAY ONE | MONDAY SEPTEMBER 23		ROOM
7:30AM-5:00PM	Conference Registration	Ballroom Foyer
7:30-8:30AM	Networking Breakfast	Ballroom Foyer
8:30-8:45AM	Opening Remarks	F. Scott Fitzgerald Ballroom CDE
8:45-10:00AM	**Session 1:** Increase Value of Publicly Disclosed Clinical Trial Information	F. Scott Fitzgerald Ballroom CDE
10:00-10:30AM	Refreshment and Networking Break	Ballroom Foyer
10:30AM-12:00PM	**Session 2:** EU Clinical Trials Information System (CTIS)	F. Scott Fitzgerald Ballroom CDE
12:00-1:00PM	Networking Luncheon	Ballroom Foyer
1:00-2:15PM	**Session 3:** Global Perspectives on Disclosure	F. Scott Fitzgerald Ballroom CDE
2:20-3:20PM	**Session 4:** Enforcement Initiatives by FDA and a UK Research Funding Agency to Ensure Compliance with Clinical Trial Transparency Requirements	F. Scott Fitzgerald Ballroom CDE
3:20-4:00PM	Refreshments and Networking Break	Ballroom Foyer
3:25-3:55PM	Hosted Session: **Case Study Spotlight hosted by TrialAssure** The Role in AI Safeguarding Privacy and Confidential Company Information (CCI)	F. Scott Fitzgerald Ballroom B
4:00-5:25PM	**Session 5:** Clarity in Clinical Trials: Unlocking the Potential of Plain Language Summaries for Patients and the Public	F. Scott Fitzgerald Ballroom CDE
5:25-6:30PM	Networking and Poster Reception	Ballroom Foyer
DAY TWO | TUESDAY, SEPTEMBER 24		**ROOM**
8:00AM-5:00PM	Registration	Ballroom Foyer
8:00-8:30AM	Networking Breakfast	Ballroom Foyer
8:30-9:45AM	**Session 6:** Results Reporting according to EU Clinical Trials Regulation via CTIS, EU Clinical Data Publication/Policy 0070 and Canada: Public release of clinical Information (PRCI) (Session continues in Session 7)	F. Scott Fitzgerald Ballroom CDE
9:45-10:30AM	Refreshments and Networking Reception	Ballroom Foyer
10:30-11:45AM	**Session 7:** Continuation of Session 6: Results Reporting according to EU Clinical Trials Regulation via CTIS, EU Clinical Data Publication/Policy 0070 and Canada: Public release of clinical Information (PRCI)	F. Scott Fitzgerald Ballroom CDE
11:45AM-12:45PM	Networking Luncheon	Ballroom Foyer
12:45-2:00PM	**Session 8:** Information (CCI) in Clinical Trial Applications and Documents	F. Scott Fitzgerald Ballroom CDE
2:05-3:20PM	**Session 9:** Use of Artificial Intelligence in Clinical Trial Transparency	F. Scott Fitzgerald Ballroom CDE
3:20-3:30PM	Closing Remarks	F. Scott Fitzgerald Ballroom CDE
3:30PM	Conference Adjourns	

Learning Objectives

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

- Identify and Understand Regulatory Changes: Recognize the latest regulatory developments and understand their implications on clinical trial disclosure practices globally
- Implement Best Practices: Apply best practices for enhancing the transparency and accessibility of clinical trial information to the public and participants
- Leverage Technological Innovations: Understand how the latest technological advancements can be used to streamline clinical trial documentation, improve transparency, and enhance public communication
- Navigate Global Disclosure Requirements: Analyze and navigate the diverse requirements for clinical trial transparency across different countries and regions to ensure compliance and effective communication
- Develop Effective Communication Strategies: Assess effective plain language summaries and other patient-centric communication strategies to meet regulatory requirements and improve participant understanding
- Assess Enforcement and Compliance Strategies: Describe the enforcement mechanisms used by health authorities and understand the legal and ethical consequences of non-compliance
- Enhance Professional Skills: Improve skills related to the preparation, submission, and management of clinical trial data in accordance with global transparency standards

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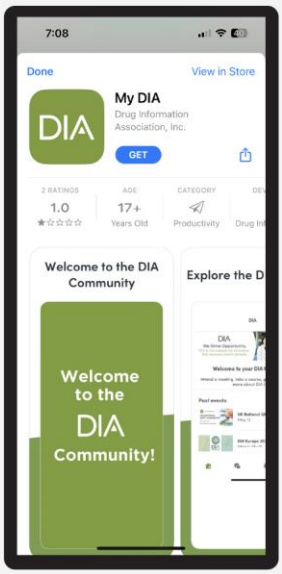

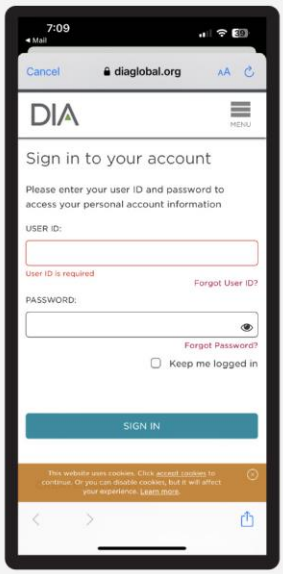

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DIA 2025 is the premier gathering for industry leaders, regulatory authorities, governmental representatives, academia, innovators, and patients. Set against the vibrant backdrop of Washington, DC, DIA 2025 will beckon stakeholders from around the 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.