Global Clinical Trial Disclosure and Data Transparency Conference

September 23-24, 2024 | Arlington, VA

PROGRAM COMMITTEE

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Citeline

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Clinical Disclosure and Transparency Expert
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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)

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

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	
7:30AM-5:00PM	**Conference Registration**
7:30-8:30AM	**Networking Breakfast**
8:30-8:45AM	**Opening Remarks**
8:45-10:00AM	**Session 1:** Increase Value of Publicly Disclosed Clinical Trial Information
10:00-10:30AM	**Refreshment and Networking Break**
10:30AM-12:00PM	**Session 2:** EU Clinical Trials Information System (CTIS)
12:00PM-1:00PM	**Networking Luncheon**
1:00-2:15PM	**Session 3:** Global Perspectives on Disclosure
2:20-3:20PM	**Session 4:** Enforcement Initiatives by FDA and a UK Research Funding Agency to Ensure Compliance with Clinical Trial Transparency Requirements
3:20-4:00PM	**Refreshments and Networking Break**
3:25-3:55PM	Hosted Event/Non-CE: Case Study Spotlight Sponsored by TrialAssure: The Role of AI in Safeguarding Privacy and Confidential Company Information (CCI)
4:00-5:25PM	**Session 5:** Clarity in Clinical Trials: Unlocking the Potential of Plain Language Summaries for Patients and the Public
5:25-6:30PM	**Networking and Poster Reception**
DAY TWO | TUESDAY, SEPTEMBER 24	
7:30AM-5:00PM	**Registration**
8:00-8:30AM	**Networking Breakfast**
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)
9:45-10:30AM	**Refreshments and Networking Reception**
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)
11:45AM-12:45PM	**Networking Luncheon**
12:45-2:00PM	**Session 8:** Information (CCI) in Clinical Trial Applications and Documents
2:05-3:20PM	**Session 9:** Use of Artificial Intelligence in Clinical Trial Transparency
3:20-3:30PM	**Closing Remarks**
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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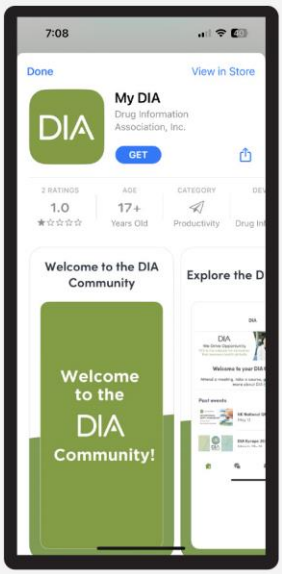

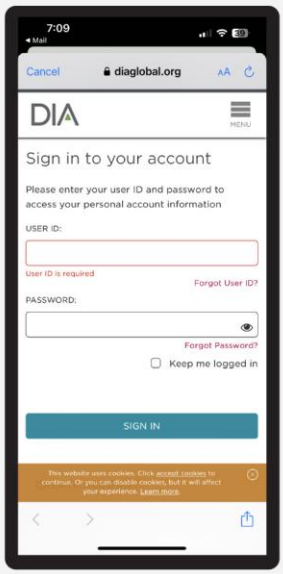

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EXHIBITOR DIRECTORY

GLOBAL CLINICAL TRIAL DISCLOSURE AND DATA TRANSPARENCY CONFERENCE

SEPTEMBER 23-24, 2024

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September 23-24, 2024
The Westin Arlington | Arlington, VA

CITELINE

Website: https://www.citeline.com/en
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Citeline (a Norstella Company) powers a full suite of complementary business intelligence offerings to meet the evolving needs of health science professionals to accelerate the connection of treatments to patients and patients to treatments. These patient-focused solutions and services deliver and analyze data used to drive clinical, commercial, and regulatory related-decisions and create real-world opportunities for growth. Our global teams of analysts, journalists and consultants keep their fingers on the pulse of the pharmaceutical, biomedical and medtech industries, covering it all with expert insights: key diseases, clinical trials, drug R&D and approvals, market forecasts and more.

GENINVO

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At GENINVO, we're defined by our fusion of expertise in Life Sciences, cutting-edge technologies, and software development. This unique blend empowers us to offer truly innovative and transformative solutions, attuned to the clinical, technological, and business landscapes our clients navigate. Our handpicked teams, comprising technology mavens and Life Science subject matter experts, bring a distinctive problem-solving approach to the pharmaceutical industry. Transparency lies at the core of our client relationships, with excellence in clinical trials as our hallmark. We provide automation tools like DocQC, Shadow, Data Transformation Package, ApoGI, and more, catering to evolving needs with a promise of further advancements. Our forte lies not only in technological implementation but also in clinical technology and the caliber of our people.

With a global footprint spanning the USA, Canada, Europe, the UK, and India, we transcend geographical barriers to forge strategic partnerships with our clients. Continual investment in cutting-edge technologies underscores our commitment to optimizing services and solutions, ensuring we remain at the forefront of industry innovation.

KRYSTELIS

Website: *www.krystelis.com*
LinkedIn: *https://www.linkedin.com/company/krystelis-ltd/*
Twitter (X): *https://x.com/KrystelisLtd*

Krystelis, based in the UK, provides a full suite of clinical trial transparency services to trial sponsors of all sizes across all regions. This includes registries, document redaction & anonymization, plain language writing and regulatory consulting support. We are recognized for achieving high-quality deliverables that create value for our customers through a highly collaborative approach.

MMS HOLDINGS, INC.

Website: *https://www.mmsholdings.com/*
LinkedIn: *https://www.linkedin.com/company/mms-holdings-inc-/*
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MMS is an award-winning, data-focused clinical research organization (CRO) that supports the pharmaceutical & biotech industries with a proven, scientific approach to complex trial data and regulatory submission challenges. Strong industry experience, an 18-year track record, AI technology-enabled services, and a data-driven approach to drug development make MMS a valuable CRO partner. With a global footprint across four continents, MMS maintains an industry-leading customer satisfaction rating.

REAL LIFE SCIENCES

Website: *https://www.rlsciences.com*
LinkedIn: *https://www.linkedin.com/company/28120112*

Real Life Sciences supports data privacy initiatives for Life Sciences organizations by anonymizing and redacting clinical data and documents for regulations such as Health Canada PRCI, EMA Policy 0070, EMA CTR, FDA and voluntary data sharing initiatives.

TRIALASSURE

Website: *http://www.trialassure.com/*
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TrialAssure is an award-winning, global data transparency company with fast, affordable, and intelligent software and service solutions for the pharmaceutical industry and beyond. A leader in the use of artificial intelligence (AI) and machine learning (ML), TrialAssure built The Ultimate Transparency Suite® to meet compliance goals through data, document, and image anonymization, development of technical and non-technical content using generative AI, compliance tracking, and more. Established in 2009, TrialAssure's global team has a proven track record in building strong technology that adapts to ever-changing data transparency requirements and was named Data Solution of the Year in the Data Breakthrough Awards.

XOGENE SERVICES LLC

Website: *https://www.xogene.com*
LinkedIn: https://www.linkedin.com/company/xogene

Xogene provides an end-to-end solution in clinical trial disclosure and transparency with offices in the US, EU and India. Leveraging our "best shore" model, we can meet urgent deadlines and ensure around-the-clock coverage. Whether you need regulatory guidance, process optimization, or outsourcing of disclosure work, Xogene will help pave the way to better transparency.

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