DIA CALL FOR ABSTRACTS

SUBMISSION DEADLINE: MAY 10

Global Clinical Trial Disclosure and Data Transparency Conference

SEPTEMBER 23-24 | WESTIN ARLINGTON | ARLINGTON, VA

CALL FOR ABSTRACTS

ABSTRACT SUBMISSION DETAILS AND GUIDELINES
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Are you a professional involved in Clinical Trial Disclosure and Data Transparency? If so, DIA wants to hear from you! The DIA Global Clinical Trial Disclosure and Data Transparency Conference, to be held September 23-24 in Arlington, VA, will feature informative sessions relating to global clinical trial disclosure and data transparency from industry experts.

The Global Clinical Trial Disclosure and Data Transparency Conference Program Committee is seeking proposals for presentations related to the topics listed below. As this conference is attended by industry, academia, and regulatory authority professionals, topics in addition to those listed below that you feel are relevant may be submitted for evaluation and possible selection. Please keep in mind, specific use cases (both successful and unsuccessful) and lessons learned are encouraged in all topic areas.

Regulatory Compliance:

- Best practices in implementing transparency policies
- Challenges in overseeing and meeting global disclosure obligations
- EU big data initiative
- Recent US proposals on data sharing
- Guidance document with global implications

International Regulatory Impact on Data Transparency:

- Challenges / opportunities in regulatory landscape for data sharing
- How global clinical trial registries can help enhance transparency
- EMA Policy 70 -- implications for global workflow

Registering Complex Clinical Trials:

- Enhancing end user experience & modernizing ClinicalTrials.gov site
- Modernization of ClinicalTrials.gov site
- Ensuring compliance & enforcing ClinicalTrials.gov reporting requirements

Patient-Centric Approaches to CTD:

- Implications of patient-focused drug development programs on disclosure
- Informed consent in data sharing practices
- Transparency in rare disease and orphan drug development
- Individual participant data return

Plain Language Summaries/Protocol Synopses/Publications:

- Global application of AI in protocol development & result reporting
- Preparing plain language summaries and lay protocol synopses
- Impact of transparency rules on scientific publications and acceptance by journal editors

Data Transparency & Impact on Drug Development and Approval Processes:

- Open access initiatives and future of clinical trial data sharing
- Trust/public perception in clinical trial transparency efforts
- Transparency in clinical research regulations: global harmonization efforts
- Transparency in health technology assessment and market access decision-making

Miscellaneous:

- Effective communication with regulators
- Ethical considerations in CTD
- Impact of data transparency on clinical trial design & conduct
  - o RWE role in enhancing transparency and decision-making
- Data quality assurance in CTD
- Post-Market surveillance transparency & reporting of AE
- Transparency in investigator-initiated trials
- Challenges of registering complex clinical trials

EU Clinical Trials Information System (CTIS):

- Transition trial
- Revised transparency rules for protecting Commercially Confidential Information (CCI) in clinical trial applications and documents
- EU CTR results requirements – how are sponsors meeting?
- Ensuring Member State alignment to EU CTR requirements
- Experience using automation for CTIS redactions
- Trends and best practices in EU Protocol Synopsis
- Challenges / best practices in protecting CCI in clinical trial documents for public disclosure

Clinical Document Disclosure:

- Addressing backlog post-restart of Policy 0070
- Health Canada PRCI: harmonizing with EMA (joint submissions, anonymization report, feedback structure, EMA acceptance of Health Canada submissions.)
- Redaction and anonymization techniques

Abstract Submission Deadline: Friday, May 10

Notification: Week of May 20

Final PowerPoint Presentations Due: September 13

Meeting Dates: September 23-24

Please submit all abstracts online at: DIAglobal.org/Abstracts

Questions: Contact Damisha White, Project Manager, at Damisha.White@diaglobal.org

Submit Your Abstract at **DIAglobal.org/Abstracts**

CALL FOR PRESENTATION ABSTRACTS

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GENERAL SUBMISSION REQUIREMENTS

- All proposals must be submitted online
- For complete submission requirements and to submit your abstract go to **DIAglobal.org/Abstracts**
- DIA requires speaker presentations to be non-commercialized, objective, and fair balanced. Company logos are not permitted to be included in slide presentations, per ACCME Standards for Commercial Support. In addition, speaker clothing/backgrounds may not carry logos or other company specific emblems. In this way, DIA activities will be educational, rather than commercial and promotional. Please view **full policy concerning promotion of products and services from the podium**.

SUBMISSION TIPS

- Submissions with practical content and shared experiences are encouraged.
- Theoretical topics and content are acceptable but should be supported with proof of concepts and use cases.
- Diverse topics and sessions are welcomed and encouraged within the scope of the conference.
- Please select the interest area that best fits with your proposal. If your topic is relevant to more than one interest area, please indicate that in your abstract summary.
- Abstracts should be written using clear language and descriptions to provide enough clarity for the selection committee to review and understand.

REQUIRED DOCUMENTATION FOR ALL ABSTRACTS

- **Participant Disclosure Information:** All abstract authors must disclose relevant financial relationships with any commercial interest associated with this activity that exist or have existed within the past 12 months, as well as any discussion of unlabeled or unapproved drugs or devices.
- All authors must agree to the DIA Speaker Authorization for Use of Presentation Materials in order for the abstract to be a part of the Program. Accepted abstracts will be available on DIA's website for attendee download.

SUBMISSION GUIDELINES

Submitting a PRESENTATION ABSTRACT (All abstracts must be submitted online)

15-20-minute presentation, bundled with other presentations as deemed appropriate by the Program Committee to create a session. Abstract author is considered the presenter (co-presenters are not permitted) and will be responsible for:

- Adhering to the program development guidelines and timelines
- Working with Session Chair and other presenters in creating a balanced program offering
- Preparing and delivering a PowerPoint presentation

SUBMISSION GUIDELINES

The following information will be requested at the time of submission. ***DIAglobal.org/Abstracts***

To streamline your submission process and avoid possible delays, DIA strongly encourages you to submit your abstract as early as possible. **Do not wait until the last day.**

Prepare your abstract in advance of accessing the DIA website. Abstract information should be copied and pasted from a prepared document as plain text. **All of the below fields are required.**

Author Information

Abstract Information

Abstract Title: (125 characters including spaces)

Interest Area: Choose from the drop down

Keywords: Provide one or more keywords to highlight your abstract. Examples of keywords: Personalized Medicine, Health Technology Assessment, etc. (100 characters)

Level of Difficulty: Beginner, Intermediate, or Advanced

Learning Objectives: Provide 2-3 learning objectives that clearly explain what participants should be able to do after attending this event. For a list of suggested verbs to create these objectives, click here. (400 Characters)

Overview: *Please provide 2-3 sentences summarizing your abstract. This summary will be used as the overview description in the DIA program for marketing purposes (250 Characters including spaces)

Abstract Details: *Please provide complete details about your abstract. Information such as scientific, technical, process issues, design/methods, results/outcomes, case studies, statistics, key findings, etc., that would support your proposal should be included here. This information will be used by the Program Committee to learn more about the purpose of your abstract. Is there an interactive component to your topic? If so, please indicate in the abstract details how you would be able to include an interactive learning experience for attendees. (2000 Characters including spaces)

Submit Your Abstract at **DIAglobal.org/Abstracts**