

Regulatory Submissions, Information, and Document Management Forum

FEBRUARY 3-5, 2025 | BETHESDA NORTH MARRIOTT HOTEL & CONFERENCE CENTER | BETHESDA, MD

CALL FOR ABSTRACTS

ABSTRACT SUBMISSION DETAILS AND GUIDELINES SUBMISSION DEADLINE: AUGUST 9

Are you a professional involved in regulatory informatics, data, intelligence, electronic submissions, or document management? If so, DIA wants to hear from YOU! The *Regulatory Submissions, Information, and Document Management (RSIDM) Forum* will cover topics crossing all areas of regulatory information management!

To ensure that we have the most comprehensive and cutting-edge program, we are seeking abstract submissions from professionals like yourself, who are pushing the boundaries in their respective fields. We encourage you to **submit abstracts** that reflect the latest trends, innovations, and best practices in regulatory submissions, information, and document management. We will be accepting the following formats:

- **Presentations:** 15-20-minute presentation to be bundled with other presentations to create a session
- **Sessions:** 75-minute total session
- **Short Courses:** three-hour interactive workshop delivered in a small group format (these will be delivered virtually and require a separate fee from attendees)

The RSIDM Program Committee is seeking abstracts on the following topics (keep in mind, business use cases and lessons learned are encouraged in all topic areas). Please note that this forum is attended by many regulatory professionals, service providers, and health authority representatives, and therefore, topics in addition to those listed below, that you feel are relevant, may be submitted for evaluation and possible selection.

Interest Areas:

- Business Process Excellence
- Change Management
- CMC and CMC Variation Management
- Cross-Collaboration Efforts and Initiatives
- Data Quality and Migration
- Data Standards and Governance Management (e.g., Identification of Medicinal Products [IDMP])
- eCTD 4.0
- Global Regulatory Gateways and Portals
- Global Submission Management (e.g., Content Planning, Content Management, Distribution, Archive)
- Global Submission Planning and Forecasting
- Global Submission Production (e.g., Assemble, Publish, QC, Dispatch)
- Health Authority Commitment Management
- Health Authority Engagement and Interactions (e.g., Q&A, Correspondence)
- Inspection Readiness
- Intelligent Automation, Artificial Intelligence, and Machine Learning
- International Consortia (e.g., Regulatory Collaboration Initiatives)
- Medical Devices, Combination Products, and Diagnostics
- Mergers, Acquisitions, Partnerships, Divestitures
- Organizational Roles, Responsibilities, and Outsourcing
- Reporting, Analytics, and Dashboard
- Product Labeling: Standards, Submissions and Management (e.g., Electronic Product Information [ePI], Ad Promo, SPL)
- Product Registration and Lifecycle Management
- Regulatory Intelligence
- Structured Content Authoring
- Unique Device Identification (UDI)

Selected abstracts will then be added to the program agenda within one of the below refreshed tracks for 2025!

Track 1: Building and Sustaining Successful RSIDM Foundations: This focus area evaluates and provides insights on how to effectively build and sustain successful regulatory submission, information, and document management foundations within your company or organization. Gain knowledge on how to ensure compliance and stay up to date with the current state of affairs, enabling your business to continuously operate and thrive. The topics covered in this focus area are tailored to accommodate attendees who are either new to the field or seek a comprehensive review of the evolving dynamics and intricacies that shape their day-to-day work.

Track 2: Optimizing Processes and Procedures: This focus area provides attendees the opportunity to explore what is needed to improve and optimize their organization's processes, procedures, and data to foster a culture of innovative practices and forward-thinking. Gain knowledge on industry best practices and discover techniques to transcend conventional approaches through problem-solving methodologies and investigation of the impact of new global regulations on your organization's processes and procedures. Tailored to meet the needs of intermediate-level professionals, the topics covered in this focus area provide a valuable platform for attendees seeking to elevate their expertise in the field.

Track 3: Adopting Innovative Technologies: This cross-cutting focus area provides thought-provoking insights and new perspectives on how to effectively adopt innovative technologies into a company or organization and the systematic approach that is needed to assess the effectiveness and impact of the adopted innovations. This focus area equips attendees with the knowledge and expertise to propel their endeavors even further through the utilization of artificial intelligence, automation, and cutting-edge technologies. Gain first-hand knowledge from global regulatory health authorities on the implementation of new technologies, policies, and guidelines. Geared towards professionals operating at the intermediate to advanced levels of their careers, this focus area nurtures and expands your acumen to achieve pioneering achievements in your field.

Track 4: Achieving Regulatory Excellence: Developing the ability to achieve regulatory excellence in the life sciences industry necessitates a unique blend of visionary leadership, a culture that embraces transformative change and innovation, strategic decision-making integrated into the company's fabric, an unwavering commitment to continual improvement, and bold actions that challenge conventional norms. This focus area will take a deep dive exploring examples and use cases from companies and organizations that have achieved this successfully while also delving into a wide range of professional and business-related topics. Engage in invigorating panel discussions, absorb invaluable best practices, and acquire tangible and practical implementation strategies to steer your company or organization towards regulatory excellence. This area of focus has been tailored specifically for individuals at an advanced or senior level position within their careers.

Abstract Submission Deadline: Friday, August 9, 2024

Notification: Week of September 30

Final PowerPoint Presentations Due: Monday, January 13, 2025

Forum Dates: February 3-5, 2025

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

Questions: Contact Lynda Fisher, Project Manager, at Lynda.Fisher@DIAGlobal.org

CALL FOR PRESENTATION ABSTRACTS

SUBMISSION DEADLINE: AUGUST 9

GENERAL SUBMISSION REQUIREMENTS

- All submissions must be submitted online
- For complete submission requirements and to submit your abstract go to DIAglobal.org/Abstracts

SUBMISSION TIPS

- Ideal submissions will contain practical content and shared experiences
- Theoretical topics and content is acceptable, however, it should be supported with proof of concepts and use cases
- Diverse topics and sessions are welcomed and encouraged within the scope of the forum
- 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 any 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. If you are proposing an abstract on behalf of the author, as the submitter you will not be asked to disclose. However, should the abstract be accepted, the author will be informed that he or she must complete and submit a Participant Disclosure in order to participate in the program
- All submitters and 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 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 chair and other presenters in creating a balanced program offering
- Preparing and delivering a PowerPoint presentation

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

75-minute total session. Abstract author will be responsible for:

- Adhering to the program development guidelines and timelines
- Recruiting speakers and ensuring good representation/diversity in their selection. Maximum of 3 speakers per session
- Working with the Session Chair to communicate with speakers regarding their role in the session

Submitting a SHORT COURSE ABSTRACT (All abstracts must be submitted online)

Three-hour, interactive presentation delivered in small group format. Abstract author is considered the Short Course Lead Instructor and will be responsible for:

- Adhering to the program development guidelines and timelines
- Recruiting co-instructors and ensuring good representation/diversity in their selection
- Communicating with co-instructors regarding their role in the short course and reviewing presentation materials (note: PowerPoint presentations are required from each instructor)
- Managing the short course, including the facilitation of audience questions and interactions

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