DIA

CALL FOR ABSTRACTS

SUBMISSION DEADLINE: AUGUST 14

Regulatory Submissions, Information, and Document Management Forum

FEBRUARY 8-10, 2021 | BETHESDA NORTH MARRIOTT HOTEL AND CONFERENCE CENTER | NORTH BETHESDA, MD

CALL FOR ABSTRACTS

PRESENTATION ABSTRACT SUBMISSION DETAILS AND GUIDELINES
SUBMISSION DEADLINE: AUGUST 14

Are you a Professional involved in regulatory informatics and 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, separated into four tracks: Electronic Regulatory Submissions (ERS), Regulatory Informatics for Business and Technology, and Electronic Document Management (EDM). Please select the track that best fits with your proposal. If your topic is relevant to more than one track, please indicate that in your abstract summary as cross-track sessions are available.

The RSIDM Program Committee is seeking proposals for Presentations, Sessions, and Short Courses on the following topics (keep in mind, business use cases and lessons learned are encouraged in all topic areas):

Regulatory Informatics: NEW FOCUS *(formally known as Regulatory Information Management (RIM))*

The Regulatory Informatics track is the foundation of regulatory data across the product development lifecycle to post-marketing Health Informatics for patient and health provider interactions. Foundationally, regulatory informatics focuses on data quality, data interoperability, and governance. This area focuses on data across two tracks—business and technology. Topics in these tracks include:

- Data Quality
  - Processes to ensure data quality and measure data quality
  - Methodologies for data quality remediation/sustaining data quality
- Data Standards
  - Global adoption of standards as implemented to comply with specific health authority requirements and support data interoperability
  - Reference models
- Data Governance, Management, and Modeling
  - Implementation and management of data governance programs, organizations, and processes
  - Technology uses, applications, and approaches to data governance and data modeling
  - Innovative technologies and approaches to data governance and management
- Product and Registration Tracking
  - Experiences enhancing registration management
  - Global package set control and association to labeling management
  - Product details and manufacturing
- Reporting Analytics and KPI
  - Experiences where data-driven decisions are enhanced supporting regulatory activities
- Organizational Change Management for Data First Adoption
- Regulatory Strategy
  - Intelligence/Policy
  - Experience evaluating/implementing regulatory policy (e.g., RWE/RWD)
  - Data driven regulatory strategic development
- Mergers/Acquisitions and Product Divestitures
- Partnerships/Outsourcing
- Industry and Trade Group Collaborations

Electronic Regulatory Submissions (ERS)

- Dossier Lifecycle Management
- Global Filings Strategies
- Validation/Quality Strategies
- Specialty Submissions (e.g., AdPromo or Establishment Registration)
- Portfolio and Global Submission Management
- Operational Efficiencies and Reuse
- Planning, Tracking, and Metrics
- Mergers/Acquisitions and Product Divestitures
- Partnerships/Outsourcing

Electronic Document Management (EDM)

- Automation and Emerging Technologies
- Trial Master File (TMF) and eTMF Operations
- TMF Reference Model
- Collaboration with CROs and Vendors
- Regulatory Submission Documents
- Inspection Preparation and Readiness
- Quality Management Systems, Quality Control
- Labeling
- Structured Authoring and Workflows - Case Studies/Experiences
- Effective Change Control Management (e.g., labeling, CMC, supply chain)
- Integration Between Regulatory Informatics and EDM systems (business process, not just technology)
- Mergers/Acquisitions and Product Divestitures
- Partnerships/Outsourcing

Abstract Submission Deadline: Friday, August 14

Notification: Week of September 22

Final PowerPoint Presentations Due: January 18, 2021

Forum Dates: February 8-10, 2021

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

Questions: Contact Jessica L. Roman, MS, CMP, Project Manager, at Jessica.Roman@DIAglobal.org

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

CALL FOR PRESENTATION ABSTRACTS

SUBMISSION DEADLINE: AUGUST 14

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 track that best fits with your proposal. If your topic is relevant to more than one track, please indicate that in your abstract summary as cross-track sessions are available.
- 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.**

Submitter or Author Information

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First Name:	**Address Line:**
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Company:	

NOTE: If you are submitting on behalf of author, you are considered the SUBMITTER and will need to complete the required information for yourself and also for the AUTHOR. Submitters will be the contact for author regarding the status of the abstract.

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