DIA

CALL FOR ABSTRACTS

SUBMISSION DEADLINE: AUGUST 12

Regulatory Submissions, Information, and Document Management Forum

FEBRUARY 13-15, 2023 | BALTIMORE MARRIOTT WATERFRONT | BALTIMORE, MD

CALL FOR ABSTRACTS

ABSTRACT SUBMISSION DETAILS AND GUIDELINES
SUBMISSION DEADLINE: AUGUST 12

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: Regulatory Informatics for Business and Technology, Trial Master File (TMF) Inspection Readiness, Electronic Document Management (EDM), and Electronic Regulatory Submissions (ERS). 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). As this forum is attended by many regulatory professionals, service providers and health authority representatives, topics in addition to those listed below that you feel are relevant may be submitted for evaluation and possible selection.

Regulatory Informatics:

The Regulatory Informatics track provides the forum for discussions, information sharing, and best practices on managing regulatory data for pharmaceuticals, medical devices, diagnostics, consumer products, and more from R&D to post-marketing activities within organizations and health authorities and the broader healthcare ecosystem.

- Business process implications of regulatory data
- RIM implementation case studies and best practices
- Data governance: methodologies, technologies, operating models, and data governance programs
- Data strategy and (master) data management: use of technology, applications, methodologies, and operating models
- Data quality: measuring, sustaining, remediating
- Data standards: interoperability, reference models, and regulatory requirements (e.g., IDMP, PQ-CMC, ePI)
- Streamlining the management of manufacturing changes
- Planning, tracking and management of regulatory activities and information
- Regulatory analytics: reporting, operational KPIs, metrics and insights for forecasting, and strategic decision making
- Organizational change management
  - Evolving work models and application of agility (e.g., adopting changes during the pandemic - geography, remote work, etc.)
  - Changing mindset when digitizing
  - Assessing value of new processes & technologies
- Regulatory intelligence and regulatory strategy
- Cross-functional dependencies on regulatory data (e.g., clinical, labeling, supply chain, manufacturing, safety, and commercial)
- Convergence of clinical and regulatory processes, data, and content related to EU Clinical Trials Regulation (CTR) and Clinical Trial Information System (CTIS)
- Digital transformation of regulatory through intelligent automation (e.g., robotic process automation (RPA), artificial intelligence (AI), and machine learning (ML))
- Regulatory capabilities to support medical devices and diagnostics: regulatory information management (RIM) and software as a medical device
- Impact of mergers/acquisitions and product divestitures and product divestitures on regulatory information
- Partnerships/outsourcing
- Health authority, industry and trade group vision and collaborations
- Structured content management – (both internal standardization and agency requirements)
  - How one manages business processes, selecting technologies, etc.
  - Labeling and submissions

Trial Master File (TMF) Inspection Readiness and Electronic Document Management (EDM)

This track examines the processes, systems, and best practices for content management and inspection readiness across the product lifecycle, including alignment between TMF and other regulated content systems for optimal use of regulatory information.

- Trial Master File (TMF) and eTMF operations (e.g., quality processes, TMF impact of E6 updates, and site document ingestion)
- Optimizing the clinical, regulatory, and quality common content and processes
- Study and vendor oversight processes
- Inspection preparation and readiness
- Quality management systems and quality control
- Structured authoring and workflows: case studies, experiences, and workshops
- Integration across departmental and systems silos (e.g., RIM and regulatory content; eTMF and CTMS)
- Mergers/acquisitions and product divestitures (e.g., due diligence process and TMF transfers)

Electronic Regulatory Submissions (ERS)

This track explores the submission process, regulatory requirements and new developments, best practices and case studies in regulatory submissions and industry adoption techniques.

- Intelligent automation and AI
- Dossier lifecycle management
- Global filings strategies (e.g., agency pilots)
- Validation/quality strategies
- Specialty submissions (e.g., AdPromo or establishment registration)
- Portfolio and global submission management
- Operational efficiencies and reuse
- Planning, tracking, and metrics
- Partnerships: contracting considerations, content collaboration and re-use, and shared systems
- Outsourcing: vendor selection, oversight, and relationship management
- Topics relative to small pharmaceutical companies and organizations
- Building a regulatory operations team: expanding infrastructure and skill sets, training, and managing increasing demands
- Future of submissions: documents to data
  - Global submission specifications
  - PQ/CMC and other digitalized quality initiatives
  - EMA CTIS impacts
  - Brexit
  - DADI and application forms
  - Structured data submissions (IDMP/SPOR, UDI)
  - eCTD 4 pilot activities

Abstract Submission Deadline: Friday, August 12

Notification: Week of September 20

Final PowerPoint Presentations Due: January 23, 2023

Forum Dates: February 13-15, 2023

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

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

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

CALL FOR PRESENTATION ABSTRACTS

SUBMISSION DEADLINE: AUGUST 12

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

Prefix:	**Country:**
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**