Are you a Professional involved in regulatory information management, regulatory intelligence, electronic regulatory submissions, or electronic document management? If so, DIA wants to hear from YOU!

The Regulatory Submissions, Information, and Document Management Forum will cover topics in four tracks: Electronic Regulatory Submissions (ERS), Regulatory Information Management (RIM) Business, RIM Technology, and Electronic Document Management (EDM).

The RSIDM Program Committee is seeking proposals for Sessions and Presentations on the following topics:

**Best Practices and Challenges of Mergers/Acquisitions and Product Divestitures**
- Keys to successful due diligence assessments
- Critical aspects of managing documents, repositories, submissions, and regulatory information
- Impact to processes supporting management of regulatory information across organizations

**Outsourcing Trends**
- Functional and programmatic outsourcing
- CRO and vendor relationships
- Offshoring, quality management, and sponsor oversight
- Challenges with global information management and solutions to overcome obstacles
- Outsourcing strategies
- Challenges with system access by third parties and solutions to overcome obstacles

**Regulatory Intelligence/Policy**
- Regulatory intelligence monitoring and information sharing
- Integration of regulatory intelligence information throughout the drug development process
- Using regulatory intelligence tools to aid business decisions
- Regulatory policy challenges, issues, and opportunities

**eTMF**
- Transitioning from paper to electronic documentation
- eArchiving: Sponsor, CRO, or Site
- Digitizing site documents: benefits and challenges to people, process, and technology
- Introduction of systematic advances enabling remote access and monitoring
- eTMF: Metrics for effective management and oversight
- Handling of wet inks – keep or destroy?

**Best Practices from Sponsors/CROs**
- Enablement of CRO/Sponsor quality checks within an eTMF
- Inspection readiness

**Structured Content**
- Structured content authoring – current and future plans
- Master Data Management challenges and opportunities

**Submission Management**
- Submission life cycle management
- Submission challenges – major versus daily submissions
- Electronic submission validation strategies
- Portfolio and global submission management
- Operational efficiencies and reuse
- Planning, tracking, and metrics
- Authoring considerations: styles, templates, and communication
- Effective use of approval packages for setting strategy

**Regulatory Information Management**
- Scope and management of regulatory information – how do you define it in your organization?
- Effective management of regulatory information - what is it and are you doing it?
- Successful practices for management of correspondence and commitments
- Effective management of regulatory changes (CMC, labeling, local requirements, etc.)
- Master data management influences on regulatory information

**Successful Practices and Regulatory Standards**
- Reference Models
- Data (CDISC, SDTM, ADaM, SEND, GInAS)
- eCTD v4 (RPS)
- IDMP/XEVMPD
- HL7 (CDA, SPL, FHIR, etc.)

**Technology**
- Digital identities, signatures, and technology enabling security
- Success stories for deploying RIM systems in the cloud
- Partner, regulator, affiliate, or other third party access
- Structured authoring
- Build versus buy decision-making
- Challenges for multi-national organizations with implementation of RIM tools
- Opportunities to secure content in electronic platforms and clouds
- Ensuring success of global systems at the corporate and local level

**Industry and Trade Group Collaborations (i.e., PhRMA, EFPIA, IRISS, TransCelerate, PHUSE, ACRES)**
- IDMP and other globalization trends and challenges faced
- IDMP preparation activities
- Synergies of global health authorities and requirements
- Global process harmonization initiatives for companies
- Impact and effect of regulations of major/minor markets

**Essential Document Management**
- Selection and implementation of Document Management Systems (eTMF, Regulatory, Archives, etc.)
- Inspection readiness: paper and repository content, training, roles, security
- Challenges and success factors of unplanned inspection
- Risk-Based Monitoring

**Compliance Monitoring**
- Preparing system access for planned inspection: training, roles, and security of sponsor systems (i.e. registration tracking, eTMF, etc.)
- Challenges and success factors of unplanned inspections of sponsor systems
- Using RIM tools to achieve compliance
- Inspection readiness: system, paper, and repository content, training, roles, and security
- Ensuring label compliance globally

**Promotional and Advertising Submissions (OPDP and APLB)**
- eCTD readiness and lessons learned
- Planning and changes to prepare for full electronic review environment

**Labeling Management**
- Labeling life cycle management
- Moving from CCDS to local labels
- Managing prescribing information and packaging components across all regions
- Labeling readiness for IDMP clinical particulars
- Managing and tracking global CCDS

**Metrics for Successful Management and Oversight**
- Labeling management
- Submission management

**Business Focus/Business Cases**
- Maximizing resources/best practices for RIM
- Creating a business case for a RIM/eTMF system
- Process development/optimization/harmonization
- Change management: lessons learned
- Transitioning a business to a global RIM system
- Opportunities to improve regulatory information management

**Successful Professional Development and Leadership in Operations: eSubmissions, IT, Document Management, Medical Writing, and Regulatory**
- Legal
- Policy
- Guidance and specifications

Submit Your Abstract at DIAglobal.org/Abstract
CALL FOR ABSTRACTS  Due by Tuesday, August 1

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Regulatory Submissions, Information, and Document Management Forum

FEBRUARY 5-7, 2018
BETHESDA NORTH MARRIOTT HOTEL AND CONFERENCE CENTER
NORTH BETHESDA, MD

GENERAL SUBMISSION REQUIREMENTS

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

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 use of 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)
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)
90 minute, lecture style presentations delivered from podium. Abstract author is considered the chair and will be responsible for:
• Adhering to the program development guidelines and timelines
• Recruiting speakers and ensuring good representation/diversity in their selection.
• Communicating with speakers regarding their role in the session and reviewing presentation materials (note: PowerPoint presentations are required from each speaker)
• Managing the session, including the facilitation of audience questions and answers from the podium

Submitting a SHORT COURSE ABSTRACT (All abstracts must be submitted online)
3 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

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.

Abstract Submission Deadline: Tuesday, August 1
Notification: Week of September 18
Final PowerPoint Presentations Due: January 2018 (exact date TBA)
Forum Dates: February 5-7, 2018

Please submit all abstracts using the online form at DIAglobal.org/Abstract
Questions: Contact Jessica Roman, Project Manager, at Jessica.Roman@DIAglobal.org

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