DIA

Regulatory Submissions, Information, and Data Management Forum

February 8-10, 2027 | Bethesda North Marriott Hotel & Conference Center | Bethesda, MD

CALL FOR ABSTRACTS

ABSTRACT SUBMISSION DETAILS AND GUIDELINES
SUBMISSION DEADLINE: August 4, 2026

Are you a professional working in regulatory affairs, regulatory operations, regulatory information management (RIM), regulatory data management, regulatory intelligence, electronic submissions, digital transformation, AI and emerging technologies, or regulatory technology? If so, DIA wants to hear from you!

The Regulatory Submissions, Information, and Data Management (RSIDM) Forum continues to evolve to meet the needs of organizations at all levels of regulatory maturity—from emerging biotech companies and to large global enterprises. As regulatory environments become increasingly data-driven, interconnected, and technology-enabled, RSIDM provides a forum for sharing practical experiences, innovative approaches, and lessons learned that advance regulatory excellence.

We strongly encourage abstract submissions from small, mid-sized, and large organizations and welcome diverse perspectives from across the life sciences ecosystem. As part of your submission, please include the stakeholder groups your session aims to engage (e.g., industry representatives, regulators, academia, technology providers, or patients).

Let your voice help shape the future of regulatory submissions, information, and document management. Submit your abstract today!

We will be accepting the following formats:

- Presentations: 15-20-minute presentation to be bundled with other presentations to create a session
- Sessions: 60-75-minute total session
- Workshop: 60-minute workshop delivered in an interactive/simulation or role-playing format
- 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.

Submit Your Abstract at DIAglobal.org/Abstracts

CALL FOR PRESENTATION ABSTRACTS

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Track 1: Establishing Robust Foundations for a Sustainable Regulatory Ecosystem

How do I build the capability?

This track focuses on the practical establishment and execution of core RSIDM capabilities across process, data, and technology. It examines how organizations define and implement foundational processes spanning document authoring, structured data management, regulatory submissions, and compliance outputs while adhering to the latest technical guidelines and data standards.

Priority Themes:

- Regulatory Operational Foundations: Building foundational RIM capabilities across document, data, and submission processes
- Connected Workflows: Integrating document and data workflows into cohesive regulatory operations
- Submission-Ready Data: Enabling structured data for submission readiness and compliance
- Standards in Practive: Early-stage adoption and operationalization of data standards (IDMP, eCTD 4.0, ICH M11, M4QR2, PQCMC/PQS)
- eCTD Transition Readiness: Global Best Practices for eCTD Transitions, Including eCTD v4.0 and v3.2.2
- Implementation Experience: Lessons learned from RIM implementation, including organizational and technical challenges
- Quality, Governance, and Compliance: Foundational data quality, compliance, governance, and submission best practices
- Global Alignment: Aligning global processes with regional regulatory expectations and technical capabilities

Questions to be Addressed in this Track:

- What specific regulatory capability, process, or standard is being implemented or evolved, and what problem or need is it addressed?
- What were the key challenges encountered (e.g., process, data, technology), and what approaches were taken to address them?
- What outcomes, lessons learned, or early wins can be shared to help others to establish their RSIDM foundations?

Track 2: Optimizing Processes and Procedures

How do I make the capability perform better?

This track is designed for regulatory professionals focused on improving day-to-day execution of regulatory submissions and data processes in a complex, global environment. The typical attendee is a regulatory leader (Examples: senior manager, director, or global process owner) working in mid-to-large pharmaceutical, biotech, or regulatory service organizations, where they are responsible for delivering submissions, improving process efficiency, and scaling operations across regions and systems.

Priority Themes:

- Process Optimization and Continuous Improvement: Practical approaches to improving submission, information, and data management processes while maintaining quality, compliance, and operational continuity
- Regulatory Execution Excellence: Proven practices for improving day-to-day submission planning, coordination, tracking, publishing, and lifecycle management activities across global organizations
- Scaling Operations Across Products and Regions: Strategies for managing increasing submission volumes, expanding portfolios, and global operations while maintaining efficiency, consistency, and control
- Process Performance and Measurement: Leveraging KPIs, metrics, benchmarking, and operational analytics to identify bottlenecks, measure effectiveness, and drive continuous improvement
- Cross-Functional Process Integration: Improving collaboration and handoffs across regulatory affairs, operations, CMC, labeling, quality, IT, and other functions involved in regulatory execution
- Change Adoption and Process Sustainability: Lessons learned from implementing process improvements and ensuring successful adoption, stakeholder engagement, and long-term sustainability
- Business Process Innovation: Practical examples of improving regulatory processes through reliance pathways, convergence initiatives, workflow redesign, standardization, and operational best practices

Questions to be Addressed in this Track:

- How can organizations optimize and scale regulatory submission, information, and data management processes while maintaining quality, compliance, and operational efficiency?
- What process improvements, technologies, and best practices have delivered measurable business value, and how can organizations assess success and sustain results?
- How can regulatory teams successfully implement and adopt new ways of working while minimizing disruption and improving outcomes for the stakeholders affected by change?

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Track 3: AI, Automation and Emerging Technologies

What technologies can help me?

This track explores how organizations can translate AI, automation, and emerging technologies into practical, trusted, and scalable capabilities. Sessions move beyond the promise of innovation to examine where technologies are delivering value today, where implementation remains challenging, and how organizations are addressing validation, compliance, integration, human oversight, and platform/tool selection. Attendees will gain practical insights from real-world deployments, failed or stalled pilots, and novel digital approaches, including how organizations are balancing existing enterprise platforms and new technologies. This focus area will help attendees assess what technologies are fit for purpose, establish the controls needed for sustainable operations, and accelerate modernization across submissions, information exchange, and technology-enabled workflows.

Priority Themes:

- AI and Automation in Practice: Real-world examples of AI, automation, and digital tools being used to support submissions, RIM activities, authoring, review, QC, change impact assessment, publishing, and data/content workflows
- Implementation Readiness: Moving from experimentation and pilots to making technology reliable, repeatable, controlled, and sustainable for everyday business use
- Technology and Tool Selection: Selecting use cases, evaluating tools and vendors, assessing solution maturity, making build-versus-buy decisions, and determining whether a technology is suitable for a specific business need
- Validation, Compliance and Risk-based Controls: Approaches for validating, monitoring, documenting, and controlling AI-enabled or automated systems in regulated environments
- Application Integrations and Interoperability: Practical approaches for connecting new tools with existing RIM, EDMS, authoring, review, publishing, submission, and collaboration environments, including the use of APIs, metadata-enabled connections, coexistence models, and migration approaches to improve flexibility
- Measurable Value and Impact: Determining whether technologies are improving quality, consistency, speed, compliance, user experience, cost, or operational resilience
- Intelligent Technologies: New and evolving uses of agentic AI, digital assistants, orchestration, and decision-support to coordinate multi-step tasks, reduce manual effort, and support ways of working across submissions and information exchange

Questions to be Addressed in this Track:

- Where are AI, automation, and emerging technologies delivering value today, and what opportunities are next?
- What does it take to scale pilots and experimentation into sustainable operational use?
- What practical controls help validate, monitor, and govern AI-enabled automation?
- How should organizations select, integrate, and measure tools to demonstrate clear business value?

Track 4: Strategic Leadership and Organizational Readiness

How do I transform the organization?

This track explores the organizational, leadership, and strategic forces that drive successful regulatory transformation and prepare companies for the rapidly evolving global landscape. The track examines how forward-thinking planning, agile governance, and enterprise-aligned regulatory strategy enable organizations to build truly future-ready regulatory capabilities.

Sessions will move beyond foundational execution and technology optimization to address the broader structural enablers of regulatory excellence. Key themes include defining and building next-generation regulatory organizations; transforming operating models across centralized and decentralized structures; strengthening global and regional governance; and addressing capability gaps through talent development and workforce transformation.

Priority Themes:

- Future-Ready Regulatory Organizations: Defining and building future-ready Regulatory Organizations
- Global Regulatory Convergence and Reliance: Harmonization initiatives and their impact on development timelines and market access
- Global Collaboration: Cross-agency initiatives and partnerships to streamline global drug development and post-market changes
- Organizational Readiness & Operating Model Transformations: Centralized vs. Decentralized models, Global and Regional governance structures, Capability gaps and Talent Transformation.
- Leadership in Regulatory Transformation: Operational to Enterprise influence and importance of regulatory as a strategic advisor for an organization.
- Readiness for Advanced Therapeutics and Technologies: Organizational readiness for cell and gene therapies, utilization of companion diagnostics, AI enabled therapeutics, digital health and precision/personalized medicines
- Data Governance: Establishing in the organization, coordination across functions, and how it enables digital submissions

Questions to be Addressed in this Track:

- How can organizations actively shape regulatory frameworks, rather than react to them?
- How should organizations balance global standardization vs. local regulatory requirements?
- How are organizations adjusting to emerging policies (AI, RWE, Modernized Therapeutics)?
- What operating models best support global scale and local agility?
- Where are the biggest capability gaps?
- What does a future-ready regulatory organization look like?
- What type of leadership is required to drive enterprise-wide regulatory transformation?
- What KPIs truly reflect transformation success?

CALL FOR PRESENTATION ABSTRACTS

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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)

60-75-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 (including author) and 1 speaker per company
- Working with the Session Chair to communicate with speakers regarding their role in the session

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

60-75-minute total workshop. Abstract author will be responsible for:

- Adhering to the program development guidelines and timelines.
- Recruiting co-instructors and ensuring good representation/diversity in their selection. (3 speakers maximum, must all be from different companies).
- Ensuring the workshop provides onsite learning in the form of activities or demonstrations.
- 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. (3 speaker max, must all be from different companies)
- 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

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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

Track: Select "Track 1, 2, 3, or 4"

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)

Abstract Submission Deadline: August 4, 2026

Notification: Week of October 5, 2026

Final PowerPoint Presentations Due: January 18, 2027

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

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

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