Regulatory Submissions, Information, and Document Management Forum

North Bethesda, MD | February 2-4, 2026

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Overview

The last few years have shed light on the importance of operational efficiency of the management of regulatory information to ensure quality regulatory submission to health authorities. We have seen how the ability to perform at this level has allowed drug companies to bring therapeutics and vaccines to patients faster. At DIA's *Regulatory Submissions, Information, and Document Management (RSIDM) Forum*, we will hear from industry and regulatory stakeholders working across the scope of regulatory information to examine current and evolving data standards and requirements and effective regulatory information management approaches to align related people, processes, and technology. Our Forum brings a set of tracks and focus areas, equipping our attendees with invaluable insights on how to build and sustain successful RSIDM foundations, optimize their current processes and procedures, adopt innovative technologies, and achieve regulatory excellence. This Forum provides multiple opportunities for networking, knowledge sharing, and education for both business and technology-focused attendees at all levels.

Learning Objectives

- Describe current global trends and regulatory initiatives impacting regulatory submissions, information, and document management
- Explain how evolving standards (e.g., eCTD 4.0, structured content, IDMP) and digital technologies (cloud, AI, automation) are transforming regulatory processes and expectations
- Identify practical strategies to improve regulatory data and content quality, governance, and interoperability across systems and functions
- Apply insights from global regulators, industry case studies, and cross-functional collaborations to enhance their organization's regulatory operating models and readiness for future change

Who Should Attend

Forum Designed For:

- Clinical Data/Data Managers
- Clinical Operations and Processes
- Contract Research and Service Support Providers
- Document and Records Management/Specialists
- Emerging Pharmaceutical/Biotech/Device Professionals
- Essential Document Process and Business System Owners
- Informatics/Bioinformatics Professionals
- Information Technology and Support Personnel
- Medical, Technical, and Regulatory Writers
- Outsourcing/Clinical Outsourcing
- Quality Assurance/Quality Control and Compliance Professionals
- Quality Management
- Regulatory Affairs and Operations
- Regulatory Informatics
- Regulatory Information Management
- Regulatory Standards Implementation Specialists and Associates
- Strategic Planning and Operations
- Submissions and Global Submissions Management/Project Management
- TMF and eTMF Management
- Vendor Relationship Managers

Track Descriptions

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. 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. This focus area nurtures and expands your acumen to achieve pioneering achievements in your field.

Track 4: Strategic Leadership and Organizational Readiness

This focus area explores the critical organizational, leadership, and strategic factors that drive successful regulatory transformation and prepare companies for future demands. This track dives into how leadership, governance, and forward-thinking planning contribute to building future-ready regulatory capabilities. Topics in this track move beyond foundational execution and technological optimization to examine broader structural and strategic enablers of regulatory excellence. Sessions will highlight case studies and success stories from companies that have effectively aligned regulatory strategy with enterprise vision, fostered cultures of innovation, and implemented agile governance and continuous improvement frameworks.

Track Key:
Track 1: Building and Sustaining Successful RSIDM Foundations | Track 2: Optimizing Processes and Procedures
Track 3: Adopting Innovative Technologies | Track 4: Strategic Leadership and Organizational Readiness
All times listed in Eastern Time

Schedule At-A-Glance

DAY ONE | MONDAY, FEBRUARY 2		ROOM
10:00AM-5:05PM	Forum Registration	Ballroom Foyer (Upper Level)
10:50-11:20AM	Hosted Session: Case Study Sponsored by AlphaLife Sciences: AI-Orchestrated Authoring and QC across the R&D Document Network	Strathmore AB
11:30AM-12:30PM	Networking Luncheon in the Exhibit Hall	Ballroom A-E
12:30-1:00PM	Welcoming Remarks and Presentation of the Excellence in Service Award	Ballroom E-H
1:00-1:45PM	Session 1: Opening Plenary - Achieving Regulatory Excellence: A Sponsor and Patient Perspective	Ballroom E-H
1:50-3:05PM	Session 2: FDA Electronic Submissions Update	Ballroom E-H
3:05-3:50PM	Refreshment and Networking Break in the Exhibit Hall	Ballroom A-D
3:10-3:40PM	Hosted Session: Case Study Sponsored by InteliNotion LLC: GenAI in a Global Biopharmaceuticals Company – Progress Update	Strathmore AB (Lower Level)

3:50-5:05PM	Session 3: FDA – Ask the Regulators	Ballroom E-H
5:05-6:05PM	Networking Reception in the Exhibit Hall	Ballroom A-D
DAY TWO | TUESDAY, FEBRUARY 3		**ROOM**
7:45AM-4:30PM	Registration	Ballroom Foyer
7:45-8:15AM	Networking Breakfast in the Exhibit Hall	Ballroom A-D
8:15-8:30AM	Welcome to Day Two and DIA Community Update	Ballroom E-H
8:30-10:00AM	Session 4: eCTD 4.0 in Action: Readiness and Alignment Across Global Health Authorities	Ballroom E-H
10:00-10:45AM	Refreshment and Networking Break in the Exhibit Hall	Ballroom A-D
10:05-10:35AM	Hosted Session: Case Study Sponsored by Weave Bio: Human + AI -- Weave + Parexel: Revolutionary Collaborations in 2026	Strathmore AB
10:45AM-12:00PM	Session 5: BREAKOUT SESSIONS Track 1: Enhancing Data Reliability and Acceptability of RWD to Support Harmonized Regulatory Decision Making Across US, China and EU Track 2: Demystifying Digital Submissions: Successful Journey to Automation, AI, Content & Data Transformation Track 3: Has Cloud Innovation Stalled in Regulatory Exchange — And Why We Can't Afford to Let It Stay That Way Track 4: The Future of Regulatory: Reimagining Operating Models for the Digital and AI Revolution	 White Oak (Lower Level) Brookside AB (Lower Level) Ballroom FGH Brookside C (Lower Level)
12:00-1:15PM	Networking Luncheon in the Exhibit Hall	Ballroom A-E
1:15-2:30PM	Session 6: BREAKOUT SESSIONS Track 1: Shaping the Future of Regulatory: Trends, AI, and Practical Success Track 2: Moving Beyond Fragmentation through Integrated Data and Content for Modern Regulatory Processes Track 3: Drive Global Safety with Semantic Alignment: Implementing IDMP Global Identifiers and FHIR for Smarter Pharmacovigilance Track 4: Achieving Regulatory Operational Excellence: People, Process, Data, Tech	 White Oak (Lower Level) Brookside AB (Lower Level) Ballroom FGH Brookside C (Lower Level)
2:30-3:15PM	Refreshment and Networking Break in the Exhibit Hall	Ballroom A-E
2:35-3:05PM	Hosted Session: Case Study Sponsored by Veeva Systems Inc.: Veeva AI for Regulatory: Agentic AI for Next Gen Submissions	Strathmore AB

3:15-4:45PM	Session 7: BREAKOUT SESSIONS	
	Track 1: Data-driven Submissions - How Pharmaceutical Companies are Getting Ready for a New Era	White Oak (Lower Level)
	Track 2: Interactive Workshop: Using Hackathons to Identify Regulatory Process Bottlenecks and Develop AI-Enabled Solutions	Brookside AB (Lower Level)
	Track 3: Beyond Faster: Humans + AI and the Next Chapter of Regulatory Writing	Ballroom FGH
	Track 4: Leading Regulatory Transformation: Strategic Change, Data Innovation, and Human-Centered Leadership	Brookside C (Lower Level)

DAY THREE | WEDNESDAY, FEBRUARY 4		ROOM
7:15AM-12:45PM	Registration	Ballroom Foyer
7:15-7:45AM	Networking Breakfast in the Exhibit Hall	Ballroom A-E
7:45-9:00AM	Session 8: BREAKOUT SESSIONS	
	Track 1: Preparing for and Implementing eCTD 4.0 Implementation: Strategies, Challenges, and Lessons Learned	White Oak (Lower Level)
	Track 2: Global Submissions Without Borders: Harmonizing Processes, Data, and Technology Across Diverse Health Authorities	Brookside AB (Lower Level)
	Track 3: Lessons Learned from the FDA GenAI Community Challenge	Ballroom FGH
	Track 4: Co-Managing a Complete Regulatory Program with AI: A Sponsor–Technology Co-Design Case Study	Brookside C (Lower Level)
9:10-10:25AM	Session 9: BREAKOUT SESSIONS	
	Track 1: Federating the Forgotten: Unlocking the Content Supply Chain for AI and Data Submission	White Oak (Lower Level)
	Track 2: Structured Content Implementations across the Drug Development Lifecycle	Brookside AB (Lower Level)
	Track 3: Enabling Efficient Regulatory Submissions: A Cloud-Based Approach to Structured CMC Dossiers	Ballroom FGH
	Track 4: Cross-Functional Collaboration for Regulatory Excellence: Integrations, Digital Innovation, and Inspection Readiness	Brookside C (Lower Level)
10:25-11:10AM	Refreshment and Networking Break in the Exhibit Hall	Ballroom A-D
10:30-11:00AM	Hosted Session: Case Study Sponsored by GlobalVision: Your Competitive Edge: The AI Readiness Roadmap for Regulatory Labeling	Strathmore AB
11:10AM-12:30PM	Session 10: Global Regulators in Focus: Key Updates Shaping the Future of Regulation	Ballroom E-H
12:30-12:45PM	Closing Remarks	Ballroom E-H
12:45PM	Forum Adjourns	

Continuing Education Credit Allocation

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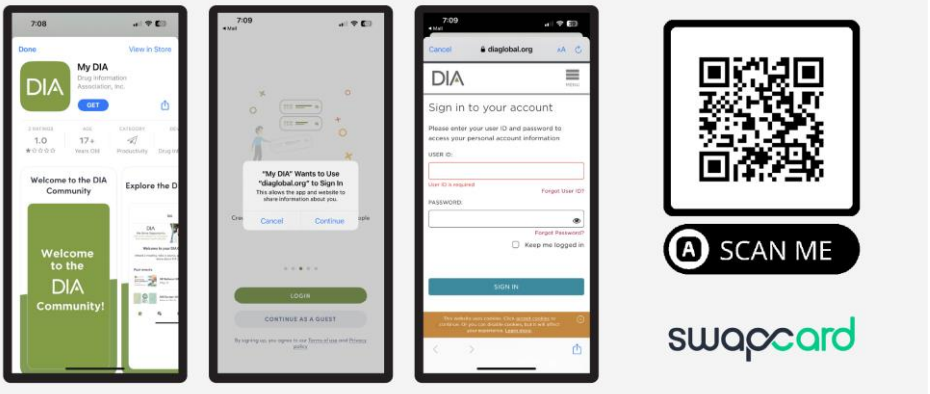

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DIA 2026 is the premier gathering for industry leaders, regulatory authorities, governmental representatives, academia, innovators, and patients. Set against the vibrant backdrop of Philadelphia, PA, DIA 2026 will beckon stakeholders from around the world to converge, collaborate, and catalyze transformative change within the life sciences realm.

At DIA 2026, we will transcend boundaries, inviting diverse voices to the table to address both local and global challenges. From regulatory hurdles to technological innovations, from healthcare disparities to patient-centric solutions, our agenda is comprehensive and forward-thinking.