DIA

Regulatory Submissions, Information, and Document Management Forum

Virtual Short Course February 6 | Virtual Short Course February 8
Primer February 9 - Virtual and February 12 - In-Person | Forum February 12-14

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. New for 2024, our Forum brings a refreshed 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. This Forum provides multiple opportunities for networking, knowledge sharing, and education for both business and technology-focused attendees.

Featuring:

27 educational sessions, 90+ diverse speakers from regulatory, industry and academia, 8 networking opportunities, 30+ exhibitors and sponors, 4 hosted case study spotlights, 2 pre-forum virtual Short Courses, 1 pre-forum hybrid Primer, and more!

Event Goals and Offerings

- **Gather insights** to hot topics impacting regulatory information in life sciences research and development
- Hear directly from **global regulators** on regulatory plans, priorities, and updates to incorporate into your everyday work and processes
- Identify how **advanced technologies and innovation** can be applied to impact functions and processes within regulatory affairs

Why You Can't Miss It

- **Network** with like-minded professionals focused on regulatory information in life sciences research and development to discuss best practices and lessons learned
- Learn how to apply successful use **cases**, real-world examples, and practical outcomes into your own company or organization
- Gain insights and discuss how stakeholders are impacted by everyday challenges and **how they overcome** these challenges
- Evaluate **future applications** of regulatory informatics, trial master file inspection readiness, electronic document management, and electronic regulatory submissions

Meeting Designed for

Professionals involved in:

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

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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 or company's processes and procedures 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. Tailored to meet the needs of intermediate-level professionals, 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. Designed specifically for companies or organizations that have already undergone process optimization and transformation, 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. Geared towards professionals operating at the intermediate to advanced levels of their careers, this focus area nurtures and expands your acumen to achieve pioneering achievements in your field.

Track 4: Achieving Regulatory Excellence - Developing the ability to achieve regulatory excellence in the life sciences industry necessitates a unique blend of visionary leadership, a culture that embraces transformative change and innovation, strategic decision-making integrated into the company's fabric, an unwavering commitment to continual improvement, and bold actions that challenge conventional norms. This focus area will take a deep dive exploring examples and use cases from companies and organizations that have achieved this successfully while also delving into a wide range of professional and business-related topics. Engage in invigorating panel discussions, absorb invaluable best practices, and acquire tangible and practical implementation strategies to steer your company or organization towards regulatory excellence. This area of focus has been tailored specifically for individuals at an advanced or senior level position within their careers.

VIRTUAL SHORT COURSE | TUESDAY, FEBRUARY 6

All times listed are Eastern Time

9:00AM-1:00PM	**Short Course:** Driving IDMP Readiness and Compliance: Impact, Business Benefits, Strategies, and Application of AI **Short Course requires an additional registration fee. You do not need to be registered for the Forum to attend**	

VIRTUAL SHORT COURSE | THURSDAY, FEBRUARY 8

10:00AM-2:00PM	**Virtual Short Course:** Mapping Common Regulatory Data Standards to FHIR **Short Courses requires an additional registration fee. You do not need to be registered for the Forum to attend**	

DAY ONE | MONDAY, FEBRUARY 12

11:30AM-5:00PM	**Forum Registration**	**Ballroom Foyer (Upper Level)**
1:00-1:25PM	**Welcoming Remarks and Presentation of the Excellence in Service Award**	**Ballroom E-H**
1:25-2:00PM	**Session 1:** Keynote Address: Fostering Trustworthy and Responsible AI  **Keynote: Reggie Townsend, MBA** Vice President, Data Ethics SAS	**Ballroom E-H**
2:00-2:45PM	**Refreshment and Networking Break in the Exhibit Hall**	**Ballroom A-D**
2:10-2:40PM	**Hosted Session: Case Study Spotlight hosted by Yseop:** 3 Use Cases: GenAI for Medical Writing	**Forest Glen**
2:45-3:30PM	**Session 2:** FDA Plenary: Data and Technology Strategy	**Ballroom E-H**
3:30-4:15PM	**Session 3:** FDA Plenary: ICH M11 Protocol Template: A Global Solution for Global Drug Development	**Ballroom E-H**
4:20-5:10PM	**Session 4:** FDA: Ask the Regulators – Part 1	**Ballroom E-H**
5:10-6:10PM	**Networking Reception in the Exhibit Hall**	**Ballroom A-D**

DAY TWO | TUESDAY, FEBRUARY 13

7:45AM-5:00PM	**Registration**	**Ballroom Foyer**
7:45-8:15AM	**Networking Breakfast in the Exhibit Hall**	**Ballroom A-D**
8:15-9:45AM	**Session 5:** FDA Plenary: Electronic Submissions Update	**Ballroom E-H**
9:55-10:40AM	**Session 6:** Ask the Regulators – Part 2	**Ballroom E-H**
10:40-11:15AM	**Refreshment and Networking Break in the Exhibit Hall**	**Ballroom A-D**

10:45-11:15AM	**Hosted Session: Case Study Spotlight hosted by Glemser:** How Automation Optimizes Quality and time for ePI Conversions	**Forest Glen**
11:15AM-12:30PM	**Session 7: BREAKOUT SESSIONS**	
	Track 1: eCTD 4.0 - Paving the Path for Streamlined Global Drug Submissions	**Brookside (Lower Level)**
	Track 2: Optimizing Affiliate Engagement: Learnings from a Landmark Affiliate Study	**White Oak (Lower Level)**
	Track 3: The Future of Regulatory Submissions: Innovation of the Possible using a Non-disruptive Framework	**Ballroom FGH**
	Track 4: Achieving Operational Excellence through Master Data and Optimizing Digital Processes	**White Flint Amphitheater (Lower Level)**
12:30-1:45PM	**Networking Luncheon in the Exhibit Hall**	**Ballroom A-D**
1:45-3:00PM	**Session 8: BREAKOUT SESSIONS**	
	Track 1: Submission Standards and Efficiencies	**Brookside (Lower Level)**
	Track 2: The Value of Reference Models and Data Governance for RIM	**White Oak (Lower Level)**
	Track 3: Modern Applications of Innovative Technologies in Regulatory Processes	**Ballroom FGH**
	Track 4: Achieving a Global Dossier: How Can Industry Encourage Convergence and Collaboration to Revolutionize Regulatory Review?	**White Flint Amphitheater (Lower Level)**
3:00-3:45PM	**Refreshment and Networking Break in the Exhibit Hall**	**Ballroom A-D**
3:10-3:40PM	**Hosted Session: Case Study Spotlight hosted by Astrix:** Evolving a Sponsor RIM Organization – Supporting Regulatory Excellence Leveraging COEs and Centralized Capabilities	**Forest Glen**
3:45-5:00PM	**Session 9: BREAKOUT SESSIONS**	
	Track 1: Shaping and Overseeing Regulatory Strategy, Operations, and Vendor Relationships	**Brookside (Lower Level)**
	Track 2: Developing and Implementing the International CMC Data Standards to Improve the Post-Approval Change Process	**White Oak (Lower Level)**
	Track 3: Taking Advantage of Generative AI to Optimize Regulatory & Medical Writing – Uses, Benefits and Risk Management	**Ballroom FGH**
	Track 4: The Transformational Impact of FHIR on Regulatory Affairs Now and in the Future	**White Flint Amphitheater (Lower Level)**
5:00-5:30PM	**RIM Working Group Open House and Team Meeting**	**Forest Glen**

DAY THREE | WEDNESDAY, FEBRUARY 14

8:00AM-2:30PM	**Registration**	**Ballroom Foyer**
8:00-8:30AM	**Networking Breakfast in the Exhibit Hall**	**Ballroom A-D**
8:30-9:45AM	**Session 10: BREAKOUT SESSIONS**	
	Track 1: Leveraging Structured Content Authoring in Regulatory Submissions: Real World Experience, Industry Insights and Tools	**Brookside (Lower Level)**
	Track 2: Complying with EU CTR, Managing Business Change and Submissions in CTIS	**White Oak (lower Level)**
	Track 3: So, You Think Technology Solutions are Failing your Content Transformation? Did You Set Them up for Success?	**Ballroom FGH**
	Track 4: Electronic Product Information (ePI): A Digital Passport for Therapeutic Product Information	**White Flint Amphitheater (Lower Level)**
9:45-10:30AM	**Refreshment and Networking Break in the Exhibit Hall**	**Ballroom A-D**
9:55-10:25AM	**Hosted Session: Non-CE: Case Study Spotlight hosted by Genpact, LLC** AI was Meant to Have all the Answers. But is Regulatory Asking the Right Questions?	**Forest Glen**
10:30-11:45AM	**Session 11: BREAKOUT SESSIONS**	
	Track 1: Improving Regulatory Processes Through Data-Driven Metrics, Generative AI, and Effective Change Management	**Brookside (Lower Level)**
	Track 2: Optimizing Submission Filings: Understanding the Challenges and Developing Strategies Accelerating Submission Delivery to Health Authorities	**White Oak (Lower Level)**
	Track 3: Exploring Opportunities and Challenges of Cloud Technology for Industry and Regulators	**Ballroom FGH**
	Track 4: New Trends and Challenges in Combination Products, Companion Diagnostics, and Digital Health Technologies	**White Flint Amphitheater (Lower Level)**
11:45AM-1:00PM	**Networking Luncheon in the Exhibit Hall**	**Ballroom A-D**
1:00-2:15PM	**Session 12:** International Regulatory Updates and Insights	**Ballroom E-H**
2:15-2:30PM	**Closing Remarks**	**Ballroom E-H**
2:30PM	**Forum Adjourns**	

Learning Objectives

At the conclusion of this conference, participants should be able to:

- Develop insights into effective strategies for establishing and sustaining robust regulatory submission, information, and document management foundations
- Explore techniques to enhance organizational processes and procedures, fostering a culture of innovation and forward-thinking
- Gain thought-provoking insights on effectively adopting innovative technologies, such as artificial intelligence and automation, into your organization
- Develop a comprehensive understanding of the elements required for achieving regulatory excellence in the life sciences industry
- Discuss current global regulatory authority updates and key initiatives as it relates to data standards, analytics, electronic submissions, and IT programs

Continuing Education Credits

Drug Information Association (DIA) is accredited by the International Accreditors for Continuing Education and Training (IACET) and offers IACET CEUs for its learning events that comply with the ANSI/IACET Continuing Education and Training Standard. IACET is recognized internationally as a standard development organization and accrediting body that promotes quality of continuing education and training.

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***IACET CEUs are only available for virtual Short Courses.**

IACET CEUs will be offered if you attend the live virtual Short Courses on February 6 & 8.

Credit will not be awarded for attending the Forum sessions.

Continuing Education Credit Allocation

- **February 6 – Virtual Short Course:**
  Driving IDMP Readiness and Compliance: Impact, Business Benefits, Strategies, and Application of AI: .4 IACET CEUs
- **February 8 – Virtual Short Course:**
  Mapping Common Regulatory Data Standards to FHIR: .4 IACET CEUs
- **February 12-14**
  Regulatory Submissions, Information, and Document Management Primer & Forum: No CEUs

Continuing Education Credit and My Transcript

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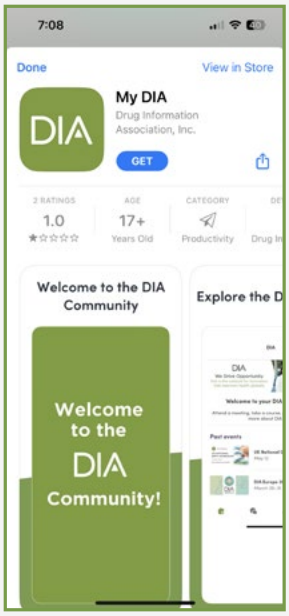

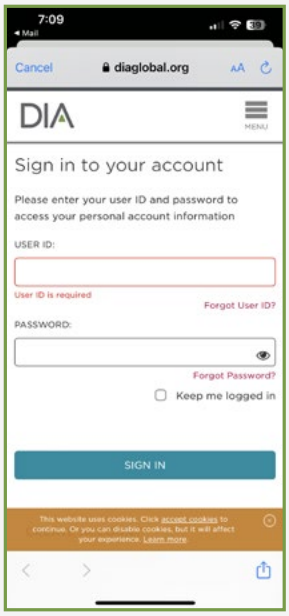

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We want to thank you with a 10% off discount code for DIA's Global Annual Meeting!

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