Regulatory Submissions, Information, and Document Management Forum

North Bethesda, MD | February 3-5, 2025

PROGRAM COMMITTEE CO-CHAIRS

Jillian Carinci, MS
Senior Director, Head of Submission Sciences
Biogen

Cindy Chiu
Senior Director, Regulatory Affairs Operations and Quality Management
Merck & Co., Inc.

Sandra Krogulski, MA
Director, GRSO Innovation and Business Operations Lead
Bristol-Myers Squibb Company

Jonathan Resnick, PMP
Project Management Officer, OBI, OSP, CDER
FDA

Cary Smithson, MBA
Managing Partner
LeapAhead Solutions, Inc.

PROGRAM COMMITTEE

Rita Algorri, PhD, MS
Senior Manager, Global Regulatory Affairs (CMC)
Amgen

Jennifer Dames
Director, RA Submission Management
AbbVie

Lindsay Fitzgerald
Delivery Manager
Astrix Inc.

Dominik Gigli
Management Consultant & Regulatory Consulting Lead
Main5 GmbH & Co. KGaA, Germany

Shenqi (Handsome) Ji
Regional Publishing Lead, Asia, Global Regulatory Operations
Pfizer, China

Jared Lantzy, PMP
Executive Director, Global Regulatory Operations
Novavax, Inc.

Kunal Lal, MBA
Consultant - Strategy & Change
Red Nucleus, United Kingdom

Aliza Nathoo
Senior Director, Content Strategy
F. Hoffmann-La Roche Ltd., Canada

Daniel Offringa
Principal Consultant
eSub Solutions

Nimesh Patel
Director of Global Regulatory Systems
Eisai Pharmaceuticals

Vladimir Penkrat, MBA
Associate Vice President of Regulatory Affairs
Indegene

Noelia Plaza
Director of Process Excellence & Analytics
Daiichi Sankyo

Theresa Pinnell, MLS
Director of Regulatory Solutions
Kivo

Maria Johnette Barhams Sagoua, MHA
Director of Regulatory Innovation
Accumulus Synergy

Seyoum Senay, MS
Supervisory Operations Research Analyst, CDER/OBI
FDA

Matthias Sijtstra
Senior Consultant
Main5 GmbH & Co. KGaA, Netherlands

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.

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

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. 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. 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.

Track Key:
Track 1: Building and Sustaining Successful RSIDM Foundations | Track 2: Optimizing Processes and Procedures
Track 3: Adopting Innovative Technologies | Track 4: Achieving Regulatory Excellence

Schedule At-A-Glance

All times listed in Eastern Time

DAY ONE | MONDAY, FEBRUARY 3		ROOM
10:00AM-5:00PM	Forum Registration	Ballroom Foyer (Upper Level)
11:30AM-12:30PM	Networking Luncheon in the Exhibit Hall	Ballroom A-E
12:30-12:55PM	Welcoming Remarks and Presentation of the Excellence in Service Award	Ballroom E-H
12:55-1:40PM	Session 1: Opening Plenary - Managing Change in a Time of Regulatory Transformation	Ballroom E-H
1:45-3:00PM	Session 2: Global IDMP Implementation – Getting Closer to the Goal	Ballroom E-H
3:00-3:45PM	Refreshment and Networking Break in the Exhibit Hall	Ballroom A-D
3:05-3:35PM	Hosted Session: Case Study Sponsored by DNAnexus: Fostering Dynamic Submission Management (DSM) Innovation	Forest Glen (Lower Level)

3:45-4:45PM	Session 3: A Year in Review: FDA Updates	Ballroom E-H
4:45-5:45PM	Networking Reception in the Exhibit Hall	Ballroom A-D
DAY TWO | TUESDAY, FEBRUARY 4		**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
8:30-9:45AM	Session 4: eCTD 3.2.2 & 4.0: EMA Updates & Industry Insights on Global Regulatory Efforts	Ballroom E-H
9:45-10:45AM	Refreshment and Networking Break in the Exhibit Hall	Ballroom A-D
10:05-10:35AM	Hosted Session: Case Study Sponsored by Weave AI: Evaluating Time Savings in Regulatory Writing	Forest Glen
10:45AM-12:00PM	Session 5: BREAKOUT SESSIONS	
	Track 1: A Framework for Decision-making for Regulatory Information Management and Operations Leaders	White Oak (Lower Level)
	Track 2: Igniting Seamless Data Flow: Enhancing Business Processes and Governance with FHIR and ICH Innovations	Brookside AB (Lower Level)
	Track 3: How to Avoid AI Overload: Navigating Impactful Applications Today and Tomorrow	Ballroom FGH
	Track 4: Enhancing Regulatory Submissions and Interactive Communication: Insights from PRISM	Brookside C (Lower Level) (formerly White Flint Amphitheater)
12:00-1:15PM	Networking Luncheon in the Exhibit Hall	Ballroom A-E
1:15-2:30PM	Session 6: BREAKOUT SESSIONS	
	Track 1: DIA RIM Reference Model V2.0 Catches FHIR!	White Oak (Lower Level)
	Track 2: Driving Value from Regulatory Intelligence – A Multi-disciplinary Approach	Brookside AB (Lower Level)
	Track 3: How to Make the Most of an Evolving Tech Landscape Crowded with Competing Solutions: Survival of the Fittest vs Symbiosis?	Ballroom FGH
	Track 4: Is a Single Dossier Really Possible? Attainable Technological and Regulatory Advancements Toward Global Dossier Harmonization	Brookside C (Lower Level) (formerly White Flint Amphitheater)
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 InteliNotion: Harnessing GenAI in a Global Biopharmaceuticals Company	Forest Glen

3:15-4:30PM	Session 7: BREAKOUT SESSIONS	
	Track 1: Common Pain Points Surrounding Regulatory Submissions	White Oak (Lower Level)
	Track 2: Towards Instantaneous Approvals in 5 Years: What Would it Take to Get There?	Brookside AB (Lower Level)
	Track 3: ICH PQKM Task Force to Enable Regulatory Collaboration on Post Approval CMC Through Technology Approaches	Ballroom FGH
	Track 4: The Next Frontier in Regulatory Submissions: Powering Industry Growth with Structured Data to Deliver Value Through Connected Global Use Cases	Brookside C (Lower Level) (formerly White Flint Amphitheater)

DAY THREE | WEDNESDAY, FEBRUARY 5		ROOM
7:30AM-12:45PM	Registration	Ballroom Foyer
7:30-8:00AM	Networking Breakfast in the Exhibit Hall	Ballroom A-E
8:00-9:15AM	Session 8: BREAKOUT SESSIONS	
	Track 1: Regulatory Submission Revolution: Insights into eCTD 4.0, Agile Governance and AI-Driven Document Migration	White Oak (Lower Level)
	Track 2: Automated Authoring: The Perfect Harmony of SCA and Gen AI	Brookside AB (Lower Level)
	Track 3: How to Be Data-Centric: A Practical Approach for Data-Driven Regulatory Authoring and Exchange	Ballroom FGH
	Track 4: Future-proofing Regulatory Affairs: Redesigning Operational Models in a Transformative Era	Brookside C (Lower Level) (formerly White Flint Amphitheater)
9:25-10:40AM	Session 9: BREAKOUT SESSIONS	
	Track 1: Gaining Efficiency: Using Automation across Writing, Hyperlinking, and Rendering	White Oak (Lower Level)
	Track 2: Optimizing Marketing Application Timelines: Insights and Strategies for Transitioning to eCTD 4.0	Brookside AB (Lower Level)
	Track 3: Strategic Innovation in Regulatory: Advancing Technology and Its Impact on Submissions	Ballroom FGH
	Track 4: Not Business as Usual: How to Modernize your Regulatory Operations for Today's Venture Capital and AI-fueled Pharma Market	Brookside C (Lower Level) (formerly White Flint Amphitheater)
10:40-11:20AM	Refreshment and Networking Break in the Exhibit Hall	Ballroom A-D
10:45-11:15AM	Hosted Session: Case Study Sponsored by Astrix: Optimizing Change Management for Collaborative Success	Forest Glen
11:20AM-12:35PM	Session 10: International Regulatory Authority Updates	Ballroom E-H
12:35-12:45PM	Closing Remarks	Ballroom E-H

Continuing Education Credit Allocation

This program is eligible for Attendance Credit. No Continuing Education will be offered.

DIA Disclosure Policy

It is DIA policy that anyone in a position to control the content of a continuing education activity must disclose to the program audience (1) any relevant financial relationships related to the content of their presentation and/or the educational activity, and (2) discussions of unlabeled or unapproved uses of drugs or medical devices. Disclosures will be included in the handout materials. This educational activity may include references to the use of products for indications not approved by the FDA. Opinions expressed with regard to unapproved uses of products are solely those of the faculty and are not endorsed by the DIA or any of the manufacturers of products mentioned herein. Faculty for this educational activity was asked to disclose any discussion of unlabeled or unapproved uses of drugs or medical devices.
Disclosure statements are included with each speaker's biographical sketch.

Planning Committee

DIA staff members have no relevant financial relationships to disclose.

TO ACCESS MY TRANSCRIPT:

- Visit **DIAglobal.org**
- **Sign In** with your DIA User ID and Password
- Select the **Welcome Menu** in the upper right hand corner (where your name appears)
- Select **My Account** from the menu
- Select **My Transcripts** then **Manage My Transcripts**

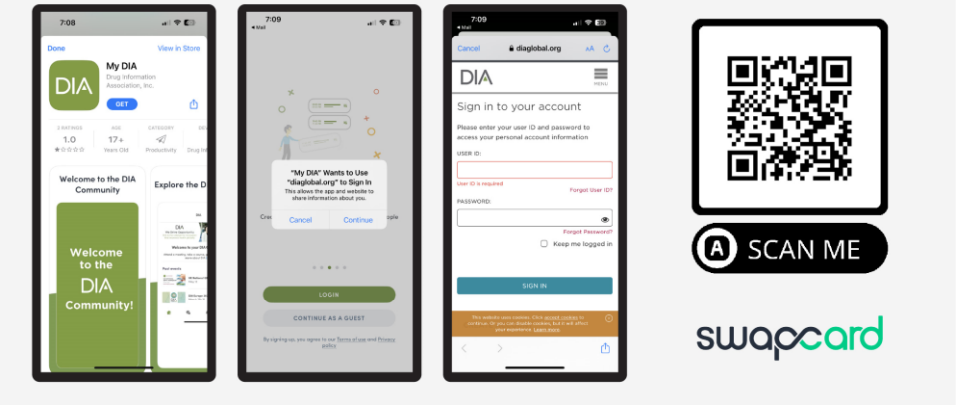
ACCESS PRESENTATIONS:

- Visit **DIAglobal.org**
- **Sign In** with your DIA User ID and Password
- Select the **Welcome Menu** in the upper right hand corner (where your name appears)
- Select **My Account** from the menu
- Choose **My Presentation**

Please Note: DIA User ID and Password are needed to access presentations. If you have forgotten your DIA User ID and Password, or this is your first time logging into the DIA website, please use our Login Reminder. **Presentations will be available for six months post conference.*

Want to view the detailed agenda? Download DIA's Mobile App!

- Agenda at your fingertips
- Network with Attendees, Speakers, Exhibitors
- Ask questions live during sessions through the session chat function



You will be directed to login to our My DIA Account in order to access the mobile app.

Follow the instructions on screen, or please see the registration desk/contact NAEvents@DIAglobal.org if you need additional assistance.

DIA 2025 is the premier gathering for industry leaders, regulatory authorities, governmental representatives, academia, innovators, and patients. Set against the vibrant backdrop of Washington, DC, DIA 2025 will beckon stakeholders from around the world to converge, collaborate, and catalyze transformative change within the life sciences realm.

At DIA 2025, 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.

Thank you to our Wi-Fi Sponsor, IQVIA

IQVIA™

Network: MarriottBonvoy_Conference

Password: RSIDM25