Bethesda North Marriott Hotel and Conference Center

Feb 08, 2027 10:00 AM - Feb 10, 2027 12:45 PM

5701 Marinelli Road, North Bethesda, MD 20852

Regulatory Submissions, Information, and Data Management Forum

Don't miss the latest trends, innovations, and best practices in regulatory submissions, information, and document and data management (RSIDM)!

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Early Bird Ends In



Print Agenda

Day 1 Feb 08, 2027

10:00 AM — 5:05 PM	Ballroom Foyer (Upper Level)

Forum Registration

11:30 AM — 12:30 PM	Ballroom A-E

Networking Luncheon in the Exhibit Hall

12:30 PM — 1:00 PM Ballroom E-H

Welcoming Remarks and Presentation of the Excellence in Service Award

1:00 PM — 1:45 PM Ballroom E-H

Session 1 Opening Plenary: Turn Collaboration into Better Evidence: Use Digital Endpoints and Biomarkers to Improve Development Decisions

Pharma and biotech companies increasingly rely on external partners to generate new types of evidence, from digital endpoints and wearable data to biomarkers and shared development tools. The challenge is not simply generating the data, but ensuring it is credible, meaningful to patients, and able to influence trial design and development decisions. This session will bring together perspectives from industry, technology, collaborative science, and regulators to examine what makes these partnerships work, where they fall short, and what organizations need to change internally to realize their value. Real-world examples will show how collaboration can accelerate science while improving the quality and relevance of evidence used in development.
Learning Objective : At the conclusion of this session, participants should be able to:

- Identify at least three factors that enable external partnerships to generate decision-relevant digital endpoint or biomarker data
- Assess how patient-centered measures can influence trial design, endpoint selection, and development strategy
- Apply lessons from industry, collaborative science, and regulatory examples to improve adoption of new evidence approaches within their own organizations

Track: General Session

Session Chair(s)



Chris Gorini

Vice President, Global Science Research Programs
DIA, United States

Dr. Gorini, Vice President of Global Science Research Programs at DIA, leads global scientific initiatives, strategic partnerships, and multi-stakeholder collaborations to advance regulatory science and drug development. Dr. Gorini has 15+ years in biomedical research, regulatory science,

clinical development, and scientific program leadership. Previously he oversaw therapeutic development portfolios for the Cystic Fibrosis Foundation and as a contractor supporting the U.S. Department of Defense, leadership roles at Koneksa Health, and regulatory review of medical devices at the FDA. He holds a PhD in Molecular Medicine from George Washington University and completed postdoctoral training in Bioengineering at Stanford University.



Nimesh Patel

Senior Director of Global Regulatory Systems
Eisai Co., Ltd., United States

Senior Director of Global Regulatory Systems, overseeing the implementation, support and development Eisai's Regulatory technology strategy. Active member of IRISS and Committee Member in PhRMA's Regulatory IT Workstream. Prior to Eisai, performing similar roles in supporting the Regulatory functions at Big Pharma, Consultancies and mid-size biotech's for the past 20+ years.

Speaker(s)



Speaker

Zhengrong Ma

Digital Health Specialist
FDA, United States



Speaker

Laura Taraboanta

Director, Digital Medicine & Translational Imaging
Pfizer, United States



Speaker

Representative Invited

Critical Path Institute, United States

Klaus Romero MD, MS, FCP is a clinical pharmacologist and epidemiologist by training, with 15 years combined experience in academic clinical research. Dr. Romero has been with C-Path since December of 2007, and during his tenure, he has helped lead clinical pharmacology, pharmacoepidemiology and modeling and simulation projects in Alzheimer's disease, polycystic kidney disease, tuberculosis, type 1 diabetes, Parkinson's disease, Duchenne muscular dystrophy, kidney transplantation and Huntington's disease, achieving major milestones such as the first regulatory endorsement by FDA and EMA of a clinical trial simulation tool for mild and moderate Alzheimer's Disease and the qualification of an imaging prognostic biomarker for PKD.

1:50 PM — 3:05 PM

Ballroom E-H

Session 2: Stay Submission-Ready: The Latest on eCTD Standards and FDA Electronic Submission Portals

This session will provide information related to electronic submissions. Topics include an update on FDA's implementation of eCTD v4.0 with a focus on Forward Compatibility, general eCTD validations and metrics, recent updates to CDER's NextGen portal, and ESG NextGen portal.
Learning Objective : At the conclusion of this session, participants should be able to:

- Discuss updates to FDA's eCTD program including eCTD v4.0 and updates to specification and guidance
- Follow updates to the FDA eCTD web pages and learn about most common validation issues
- Identify latest updates to CDER's NextGen Portal
- Share latest improvements and metrics under the modernized ESG NextGen Portal

Track: General Session

Session Chair(s)



Jonathan Resnick, PMP

Advisor, Office of Digital Transformation
FDA, United States

Jonathan Resnick is an advisor for FDA's Office of Digital Transformation, with a focus on eCTD and has been with FDA since 2011. In addition to eCTD, Jonathan is the FDA Topic Lead on the ICH M8 Expert Working Group and FDA's Chair for the PDUFA Information Management Working Group. Prior to joining FDA, Jonathan spent 18 years working in IT project management supporting federal and private sector clients.

Speaker(s)



Speaker

Representative Invited

FDA, United States

Heather Crandall has been with the FDA since 2012, working in the Office of Business Informatics. She currently focuses on standards and processes around electronic submissions.



Speaker

Seyoum Senay, MS

Advisor, Office of Data Platform Engineering
FDA, United States

Mr. Senay is a strategic leader specializing in healthcare informatics innovation and regulatory science advancement. He focuses on implementing transformative informatics solutions that accelerate the development and approval of safe, effective medicines for patients. His work directly supports the FDA's mission to protect and promote public health through evidence-based regulatory decision-making. As a U.S. Excellence in Government Leadership Fellow, Mr. Senay has demonstrated exceptional capability in leading complex initiatives that deliver measurable outcomes for public health. He holds a Master's degree from The Johns Hopkins University and maintains certification as a Program Manager, bringing both academic rigor and practical exp



Speaker

Jessica Bernhardt, MS

Advisor, Office of Data Platform Engineering
FDA, United States

Jessica Bernhardt currently is the Program Manager for the Electronic Submissions Gateway (ESG) and AdminApps programs at the Food and Drug Administration (FDA). She took on the role of ESG Program Manager at the start of 2023 and oversaw the successful completion of the ESG AWS Migration. Jessica joined the FDA in 2020 as the AdminApps Program Manager, which she has successfully managed for the past three years. Jessica started her career in Government nine years ago when she joined the Social Security Administration (SSA) as an IT Specialist. After a year working as an IT Specialist for a year, was assigned to lead and manage an IT Modernization project, promoting the use of the Agile development lifecycle. In 2016 she was promoted

3:05 PM — 3:50 PM Ballroom A-D

Refreshment and Networking Break in the Exhibit Hall

3:50 PM — 5:00 PM Ballroom E-H

Session 3: FDA – Ask the Regulators

Dedicated to sharing the latest information on new guidance's, this session will allow open discussion between the audience and an esteemed panel of regulatory experts. This session provides attendees the opportunity to ask regulators questions directly regarding topic areas covered in Session 2.

Please note: due to the high volume of questions, not all will be answered live at the forum. We encourage participants to consider the regulators' backgrounds and expertise when directing their questions to ensure a more tailored and focused discussion.

Track: General Session

Session Chair(s)



Jonathan Resnick, PMP

Advisor, Office of Digital Transformation
FDA, United States

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5:00 PM — 6:00 PM Ballroom A-D

Networking Reception in the Exhibit Hall

Day 2 Feb 09, 2027

7:45 AM — 4:30 PM Ballroom Foyer (Upper Level)

Forum Registration

7:45 AM — 8:15 AM Ballroom A-D

Networking Breakfast in the Exhibit Hall

8:15 AM — 8:30 AM Ballroom E-H

Welcome to Day Two

8:30 AM — 10:00 AM Ballroom E-H

Session 4: Modernizing FDA-Industry Communication: How PDUFA VII Cloud Initiatives Can Improve Regulatory Collaboration

The session would provide an overview of FDA demonstration projects (proof of concepts to test out feasibility) under PDUFA VII to leverage cloud technologies to improve FDA – Industry communication

Track: General Session

Session Chair(s)



Seyoum Senay, MS

Advisor, Office of Data Platform Engineering
FDA, United States

Mr. Senay is a strategic leader specializing in healthcare informatics innovation and regulatory science advancement. He focuses on implementing transformative informatics solutions that accelerate the development and approval of safe, effective medicines for patients. His work directly supports the FDA's mission to protect and promote public health through evidence-based regulatory decision-making. As a U.S. Excellence in Government Leadership Fellow, Mr. Senay has demonstrated exceptional capability in leading complex initiatives that deliver measurable outcomes for public health. He holds a Master's degree from The Johns Hopkins University and maintains certification as a Program Manager, bringing both academic rigor and practical exp

10:00 AM — 10:45 AM Ballroom A-D

Refreshment and Networking Break in the Exhibit Hall

10:45 AM — 12:00 PM

Session 5, Track 1: Structured Content, Smarter AI: Taming the Rising Cost of GenAI in Regulatory Operations

As enterprises scale Generative AI, rising costs, expanding context windows, and agentic workflows are creating new challenges for governance and sustainability. This panel explores how structured content and data standards such as SDTM, ICH M11, USDM, and FHIR can improve AI efficiency, reliability, and auditability in regulated environments. Industry experts will share practical implementation experiences and actionable strategies for responsible AI adoption.
Learning Objective : At the conclusion of this session, participants should be able to:

- Explain why unstructured content drives unsustainable GenAI token costs
- Describe how structured content and data improve AI cost, reliability, and governance
- Identify practical strategies for implementing responsible, AI-ready content within regulated organizations

Track: Establishing Robust Foundations for a Sustainable Regulatory Ecosystem

Session Chair(s)



Jennifer Dames

Director, RA Submission Management
United States

Jennifer Dames is Director, Regulatory Submissions at AbbVie. She has over 10 years experience in Regulatory. Jennifer has experience with implementation of Regulatory Information Management systems, Document Management, Submission Management, Publishing, and system support.

Speaker(s)



Structured Content, Smarter AI: Taming the Rising Cost of GenAI in Regulatory Operations

Santanu Sen

Solution Partner, Life Sciences
InteliNotion, a Tandym Company, United States



Speaker

Michael Jasper, PhD

Head, Content and Document Technologies
Takeda Pharmaceuticals International Co., United States

Michael received his BS in Electrical Engineering from Cornell University, an M.S. in Exercise Physiology and Anatomy from Boston University and his Ph.D. in Neurobiology, Physiology and Biophysics from Brown University, followed by a post-doctoral fellowship at Massachusetts General. He has held positions at Parexel, Genetics Institute, Millennium Pharmaceuticals, Genzyme, and Sanofi. In September 2015, Michael joined Shire's Clinical Writing group as Content Management Team Lead.



Speaker

Regina Lynn Preciado

Vice President, Content Strategy Solutions
Content Rules, Inc., United States

Regina Lynn Preciado is the Vice President of Content Strategy Solutions at Content Rules. She leads content strategy teams to help pharma and biotech organizations optimize content for automation and AI-readiness. She has 25+ years of experience in structured content strategy for pharma/biotech, med device, high tech, financial services, and manufacturing. Regina is an industry expert in structured content authoring, component content management, and content reuse and automation. She lives a dogspotting lifestyle.

10:45 AM — 11:59 AM

Session 5, Track 2: Measure What Matters: Build the Visibility Needed to Improve Regulatory Performance

Before organizations can improve a process, they need to understand whether it is actually working. This session explores how regulatory teams can build meaningful visibility into their operations through integrated data, reporting, dashboards, and performance metrics, while avoiding the trap of measuring activity instead of outcomes. Speakers will share practical approaches for identifying the metrics and behaviors that truly drive performance, enabling better decision-making, stronger oversight, and sustainable operational excellence. Attendees will leave with ideas for building measurement frameworks that not only track performance, but also support continuous improvement and lasting organizational change.
Learning Objective : At the conclusion of this session, participants should be able to:

- Identify metrics, dashboards, and data sources that provide meaningful visibility into regulatory operations
- Differentiate between performance indicators and behavioral indicators that drive sustainable operational excellence
- Apply practical approaches to improve oversight, decision-making, and continuous improvement through measurement frameworks

Track: Optimizing Processes and Procedures

Session Chair(s)



John Popp, PhD

Senior Manager - Regulatory Information Management
Celegence, Netherlands

John is a skilled and versatile life science professional with 6 years of industry experience and a robust scientific background, including over a decade of research in chemistry with conference presentations and journal publications. As a certified change practitioner with (agile) project management certifications, John combines strong analytical skills, a hands-on mentality, and a solution-focused

mindset helping regulatory teams manage data more effectively, drive digital transformation, and stay ahead in a changing industry.

Speaker(s)



Beyond KPIs: Measuring the Behaviors That Sustain Regulatory Operational Excellence

Rishma Ulrich

Associate Director, Global Regulatory Strategic Operations
Bristol Myers Squibb, United States



Integrated Data Management – Using Reporting, Metrics, and Dashboards to Enhance Quality Oversight

Eric Randel, MBA, PMP

Associate Director, CCDS & Labeling Lead
Astellas Pharmaceuticals, United States

Regulatory Labeling professional with over 20 years of experience in Biotech and Pharma. Skilled project manager who has led cross-functional and cross-cultural teams and global labeling activities across major markets. Experienced in automation and validation engineering, having designed and implemented automated solutions, including GxP-validated systems, that improve efficiency and consistency across global processes. Named AI Adoption Champion for the RAPV function at Astellas, with hands-on experience designing and delivering multiple AI agents now in production use, including solutions deployed enterprise-wide and an agent that generates workload metrics while meeting critical accuracy and quality standards.

10:45 AM — 12:00 PM

Session 5, Track 3: Selecting, Scaling, Measuring, and Governing Regulatory Artificial Intelligence

As regulatory organizations move beyond AI experimentation and into enterprise adoption, they face a common challenge: identifying high-value use cases, establishing the data and governance foundations needed for scale, and demonstrating both business impact and meaningful human oversight. This session presents practical approaches for selecting and implementing AI-enabled capabilities across regulatory workflows, including automation, knowledge management, drafting, and analytics. Through real-world case studies, participants will explore how organizations can build business cases, improve data readiness, measure value realization, and evaluate whether human review remains substantive as AI becomes increasingly integrated into regulatory decision-making. Attendees will leave with actionable frameworks for scaling AI responsibly while balancing efficiency, governance, and regulatory confidence.
Learning Objective : At the conclusion of this session, participants should be able to:

- Analyze regulatory processes and data readiness to prioritize scalable AI use cases.
- Develop a practical framework for AI-enabled regulatory capabilities using governance, structured content, metadata, and human oversight

- Evaluate AI workflows using performance, adoption, decision influence, override patterns, and reviewer rationale

Track: AI, Automation and Emerging Technologies

Session Chair(s)



Ashley Jones-Mitchell, MPH

Deputy Vice President, Science and Regulatory Advocacy
PhRMA, United States

Ashley Jones-Mitchell is Deputy Vice President, Science & Regulatory Advocacy at PhRMA. In this role, Ashley will supports PhRMA's regulatory policy and advocacy efforts, working collaboratively with member companies, regulators, policymakers, and other stakeholders to advance science-based regulatory modernization and innovation. Before joining PhRMA, Ashley served as Head of Global Regulatory Policy at Accumulus Synergy and spent more than 16 years at the U.S. Food and Drug Administration, serving in several policy roles within the Center for Drug Evaluation and Research. Ashley holds a Master of Public Health from the University of Maryland and a Bachelor of Science in Marketing from The Pennsylvania State University.

Speaker(s)



Getting to Yes: Turning Regulatory AI Ideas into Approved Investments and Measurable Business Value

Vladimir Penkrat, MBA

Associate Vice President – Regulatory Affairs
Indegene, United States

Vladimir Penkrat is AVP of Regulatory Affairs at Indegene. With an MBA in International Business, Vladimir has provided strategic leadership throughout his career across clinical development, biometrics, biostatistics, medical writing, pharmacovigilance, and regulatory affairs. Over the past three decades Vlad worked across top pharma, biotech startups, CROs, and consulting firms. Within the recent 10 yrs, Vlad's passion for regulatory excellence has established process leadership in Regulatory Writing, Submissions Management, Publishing, Labelling, CTT, Consulting, & GenAI innovation as a business. Vlad's leadership has enabled businesses to prepare for digital adeptness & as a business leader he has scaled R&D operations to >500 FTE.



Scaling AI Across the RTQ Lifecycle: Search, Drafting, Analytics, and Data Readiness for Regulatory Adoption

Sarah Skye, PhD

Head of Digital Enablement, CMC RA
Gilead Sciences, United States

Sarah Skye is Senior Director, CMC Regulatory Affairs at Gilead Sciences, focused on the evolution of regulatory ways of working through data, technology, and AI. Her work brings together regulatory content, data, processes, and decision-making to create more connected and scalable capabilities. She has a particular interest in responsible AI adoption and in translating emerging technologies into sustainable improvements in regulatory work.

Beyond Accuracy: Using Override Rates to Evaluate Human Oversight of AI



Jenna Zhang, MPA

Founder
MonitAI, United States

10:45 AM — 12:00 PM

Session 5, Track 4: Accelerating Regulatory Transformation: Leadership, Governance, and Organizational Readiness for Digital-First Execution

As digital infrastructure removes traditional barriers to regulatory collaboration, organizational readiness is emerging as the defining challenge in regulatory transformation. The ability to engage multiple health authorities simultaneously requires organizations to rethink leadership, governance, decision-making, and cross-functional alignment across Regulatory, Manufacturing, and Commercial functions. Drawing on lessons learned from the world's first end-to-end digital submission of a novel biologic with a Latin American regulatory authority, this session will explore practical strategies for securing leadership sponsorship, establishing effective governance, and preparing teams for digital-first regulatory execution. Attendees will gain insights into how organizations can evolve traditional operating models, accelerate regulatory collaboration, and ultimately enable faster patient access to innovative therapies.
Learning Objective : At the conclusion of this session, participants should be able to:

- Evaluate organizational readiness capabilities needed to enable digital-first regulatory execution
- Identify strategies for strengthening leadership, governance, and cross-functional alignment to support simultaneous regulatory engagement
- Apply lessons from a real-world digital submission to recommend actions for accelerating regulatory transformation

Track: Strategic Leadership and Organizational Readiness

Session Chair(s)



Katherine Novak, MS

Director
Epista Life Science, United States

Katherine Novak is a Director at Epista Life Sciences, specializing in regulatory affairs, clinical operations, and digital transformation. With experience across both industry and consulting, she helps life sciences organizations modernize business processes, implement technology solutions, and establish effective data governance strategies. Her expertise spans Regulatory Information Management (RIM), Clinical Trial Management Systems (CTMS), and electronic Trial Master Files (eTMF), with a focus on aligning technology, data, and operating models to support regulatory compliance and business objectives.

Speaker(s)



When Technology Stops Being the Constraint: Leadership and Organizational Readiness for the Next Era of Regulatory Execution

Dominique Lagrave, PharmD

Chief Regulatory Officer
Accumulus Technologies, United States

Dominique has over 25 years of International Regulatory Affairs experience with the last 20 years spent in Global Regulatory Operations leadership role. Past experiences include work at Galderma, Novo Nordisk, Liquent-Parexel and Dendreon. Dominique joined Accumulus as SVP of Regulatory Innovation in early 2022 coming from Amgen where he was heading Global Regulatory Operations. As part of his role at Accumulus, Dominique is supporting global Accumulus platform adoption from Health Authorities and Biopharmaceutical organizations. Dominique is also a Board Member of IRISS Forum since 2021. Dominique holds a Pharm D and a master's in International Regulatory Affairs from the University of Paris.

12:00 PM — 1:15 PM

Networking Luncheon in the Exhibit Hall

1:15 PM — 2:30 PM

Session 6, Track 1: Future-Proof AI-Generated Regulatory Content: Building Inspection-Ready Evidence, Traceability, and Governance

Most evaluations of AI authoring focus on speed and output quality, yet regulatory inspections ultimately require evidence of how a document was created and validated years after submission. This session examines four essential pillars of inspection readiness: traceability to source data, complete auditability, documented human oversight, and explainability captured at the time of generation. Through sponsor and technology perspectives, attendees will explore the evidence, metadata, and governance required to make AI-generated content submission-ready, including a biotech case study and an interactive inspection challenge that tests participants against real-world acceptance criteria.
Learning Objective : At the conclusion of this session, participants should be able to:

- Identify the four evidentiary criteria an inspector applies to an AI generated submission document
- Specify the metadata and audit trail a platform must capture at generation rather than reconstruct later
- Evaluate whether a candidate platform can reproduce a document's full provenance years after submission

Track: Establishing Robust Foundations for a Sustainable Regulatory Ecosystem

Session Chair(s)



Venkatraman Balasubramanian, MBA

Healthcare and Life Sciences Strategic Advisor
VB Insights, LLC, United States

Bala heads VB Insights, an advisory firm for the Healthcare and Life Sciences sector. Bala brings over 36 years of experience. During his long tenure, he has been responsible for the introduction of Web, document management, global team collaboration, and regulatory information management applications to large pharma. Until recently, Bala was Head of the Healthcare and Life Sciences at Orion Innovation. As an entrepreneur and a thought leader, he has been involved in initiatives to transform regulatory affairs from a document-centric function to a data-driven function. Bala has been associated with DIA for more than 17 years, leading DIA RIM Reference Model workstream and DIA AI Consortium Regulatory Frameworks and Terminology workstream.

Speaker(s)



Inspection-Ready by Design: What an AI-Authored Document Must Prove Three Years Later

Ravi Ramachandran, PhD

Co-Founder & CSRO
Peer AI, United States



Speaker

Representative Invited

Canal Row Advisors, United States

Donna Rivera, PharmD., MSc., FISPE is Executive Vice President, Clinical Evidence Modernization at Canal Row Advisors, sharing strategic guidance on the use of real-world data (RWD), real-world evidence (RWE), artificial intelligence (AI), and innovative trial designs for drugs, biologics, and devices to support regulatory objectives. She was the Former Associate Director for Pharmacoepidemiology and Founding Director of the Oncology RWE Program in the FDA Oncology Center of Excellence, leading national and international initiatives to transform RWD into RWE to accelerate innovation in oncology drug development. She also formed the FDA Oncology AI Program to guide the use of artificial intelligence applications in regulatory review, researc



Speaker

Representative Invited

Vertex Pharmaceuticals, United States

1:15 PM — 2:30 PM

Session 6, Track 2: Building Bridges, Not Bottlenecks: Advancing Regulatory Agility Through Coordination,

Dialogue, and Reliance

This session explores how stronger coordination among Sponsors, Partners, and Health Authorities can help reduce submission gaps, shorten review timelines, and enable more efficient implementation of global Post-Approval Changes (PACs). Through real-world examples and collaboration models, speakers will share practical approaches for improving transparency, reducing duplication, and creating more consistent regulatory pathways across regions. Attendees will gain insights into frameworks for aligning stakeholders around common goals, enhancing agency dialogue during review, and scaling Change Management process from pilot to practice. Participants will leave with actionable ideas for building more connected, efficient, and agile and scalable regulatory processes.
Learning Objective :

- Identify review delays and use coordination, transparency, and agency engagement to accelerate approvals
- Improve cross-functional alignment, stakeholder coordination, and Health Authority communication
- Assess collaborative and reliance-based CMC post-approval change models versus traditional approaches
- Create a scalable framework for post-approval change collaboration, governance, and success measurement

Track: Optimizing Processes and Procedures

Session Chair(s)



Alisa Amirova

Manager, Regulatory Information Management & Technology (RIMT)
Biomarin Pharmaceutical, United States

Alisa has 20+ years of experience spanning regulatory, quality, and technology consulting, she brings a pragmatic, execution driven perspective to complex regulatory and data challenges. She has successfully guided enterprise organizations through large scale system implementations, data harmonization initiatives, and process transformations, with a focus on enabling compliance, operational efficiency, and long term value realization. As Manager of Regulatory Information Management & Technology at BioMarin, Alisa supports regulatory teams through the optimization of Veeva based systems and enterprise technology initiatives. She is a Certified Veeva Associate Administrator, ScrumMaster and an active member of DIA.

Speaker(s)



Closing the Gap: Reducing Submission Delay and Clock-Stop Time Through Coordination and Agency Dialogue

Patricia Santos-Serrao, RAC

VP of AI Strategy & Enablement, Product Management
LORENZ Life Sciences, United States

Patricia entered the Life Sciences Industry in 1994 starting her career at Schering-Plough in Kenilworth, NJ and later joining Boehringer Ingelheim Pharmaceutical in Ridgefield, CT. Within both organizations she took a leading role in transitioning business processes, document management and submission compilation from a paper to electronic system. She is a member of Regulatory Affairs Professional Society (RAPS) and has also earned her Regulatory Affairs Certification (RAC) from RAPS and the Regulatory Affairs Certification Board (RACB). She is also a member of the Drug Information Association (DIA) and a member of the TMF Reference Model Working Group (sponsored by DIA).



From Pilot to Practice: A Reusable Framework for Global CMC Post-Approval Change Reliance and Collaboration

J Paul Kirwan, PhD, MS

Senior Manager, Regulatory Affairs
Amgen, United States

J. Paul Kirwan is a Senior Manager, Regulatory Affairs, with Amgen. He currently leads reliance activities associated with cloud-based regulatory submissions and manages the initial filing content for module 3 authoring in collaboration with RA CMC and Process Development. Paul has been a member of the advocacy and external engagement team with Amgen and is active with ISPE, IQ Consortium, CASSS, and BioPhorum. He previously served as a Global CMC Regulatory Lead and is also a former FDA product quality reviewer (CDER, Office of Biotechnology Products) and FDA Commissioner's Fellow. Paul holds a PhD in Biochemistry from the University of Colorado Anschutz Medical Campus.

1:15 PM — 2:30 PM

Session 6, Track 3: Operationalize AI Across the Clinical Data Lifecycle: Lessons from Biostatistics, Programming, and Data Management

AI pilots in clinical development are common, but few become controlled, everyday tools, and the stakes are highest for the data that becomes a regulatory submission. This session follows three AI implementations from a single pharmaceutical organization across the clinical data lifecycle:

- **Data Review:**An interactive application that surfaces anomalies, summarizes patient profiles, and speeds medical and statistical review.
- **Statistical Programming:**AI agents that automate SDTM/ADaM dataset generation, TFL production, and QC checks.
- **Data Querying:**A system that lets biostatisticians and data managers ask plain-language questions of clinical databases and receive validated, reproducible answers.

Along the way, presenters will share lessons on validating non-deterministic outputs, 21 CFR Part 11 compliance, traceability and human oversight, integration with EDC, CDMS, and submission platforms, build-versus-buy decisions, and measuring quality, speed, and adoption.

Learning Objective : At the conclusion of this session, participants should be able to:

- Identify practical use cases for AI across clinical data review, statistical programming, and regulatory query response
- Apply validation and governance frameworks for deploying AI in regulated environments while maintaining compliance and human oversight
- Evaluate build-vs-buy decisions and integration strategies for scaling AI pilots into sustainable operational workflows

Track: AI, Automation and Emerging Technologies

Session Chair(s)



Aliza Nathoo

Senior Director, Structured Component Management (SCM) Strategy, Operations & Go
GSK, Canada

Aliza began her career on molecular teams and leading complex regulatory submissions. Over her 20+ years in biopharmaceuticals, she has expanded her focus into automation-assisted content authoring, generation, and management. Today, she leverages her foundation to drive content innovation within Roche, transforming theoretical strategies into scalable, sustainable operations. Known for her collaborative leadership, Aliza partners across regulatory, technology, and business units to shape, standardize, and implement solutions that anticipate the future of work. She is passionate about building adaptive, compliant systems and processes that empower teams to deliver in an ever-evolving regulatory landscape.

Speaker(s)



From Pilots to Practice: AI-Enabled Clinical Data Workflows Across Biostatistics, Statistical Programming, and Data Manage

Nusrat Rabbee, PhD

Head of Statistical Innovation
Regeneron Pharmaceuticals, Inc., United States



Speaker

Representative Invited

HopeAI, United States

1:15 PM — 2:30 PM

Session 6, Track 4: Enabling Small & Mid-Sized Pharmaceutical Companies to Leverage Reliance Pathways, Data-Driven Decision Making, and AI

As health authorities embrace reliance pathways, structured data, and AI, small and mid-sized pharmaceutical companies face a widening innovation gap due to resource constraints, limited digital maturity, and heightened risk sensitivity. This panel of three sponsor organizations will examine the barriers, including technology adoption, fragmented data, limited access to proof-of-concept outcomes from large pharma, and uncertainty over regulatory expectations for AI, along with the cost, governance, validation, cybersecurity, and compliance considerations. Drawing on case-based examples, panelists will share pragmatic approaches such as scalable operating models, strategic partnerships, reliance-driven strategies, and phased implementation of data and AI capabilities, balancing innovation with risk management and return on investment. The session closes with recommendations for a more accessible regulatory innovation ecosystem so organizations of all sizes can benefit from reliance programs, data-driven practices, and AI-powered decision support.

Learning Objective : At the conclusion of this session, participants should be able to:

- Identify at least three barriers small and mid-sized pharma face adopting reliance pathways, data strategies, and AI
- Evaluate cost, governance, and compliance trade-offs of regulatory innovation using two panel case examples.
- Plan two scalable strategies (e.g., partnerships, phased AI rollout) to start in their own organization within 90 days

Track: Strategic Leadership and Organizational Readiness

Session Chair(s)



Kunal Lal, MBA

Consultant - Strategy & Change
Red Nucleus, United Kingdom

Kunal Lal is a UK-based Consultant with Red Nucleus and a subject matter expert in Regulatory Information Management and IDMP/XEVMPD. He has over 13 years of experience working across the Regulatory, Pharmacovigilance, Clinical and Supply Chain functions of pharmaceutical organizations, with robust knowledge of related regulations, processes, and systems. Kunal has led and contributed to many projects for regulatory readiness, process assessment, definition and optimization, data maturity assessment and governance and application support and maintenance.

Speaker(s)



Enabling Small & Mid-Sized Pharmaceutical Companies to Leverage Reliance Pathways, Data-Driven Decision Making, and AI

Brooke Casselberry, MS, RAC

Vice President, Advisory and Delivery
Epista Life Science, United States

Brooke is known for her pivotal roles in collaborating with Sponsor Companies, Health Authorities, and Technology Developers. She has maintained focus on leveraging cutting-edge technologies as a catalyst for regulatory advancements, optimization, and collaboration for global go-to-market strategies and data harmonization. She was named PharmaVoice's top 100 most inspiring individuals for Mentorship and Team Development and received the esteemed Excellence in Service award from DIA. Brooke has an integral role in shaping the discourse surrounding data and technology in regulatory affairs through her work with DIA as programming chair for the Data & Technology Track and as the co-chair of the DIA RA Community.

2:30 PM — 3:15 PM

Refreshment and Networking Break in the Exhibit Hall

3:15 PM — 4:45 PM

Session 7, Track 1: Beyond the PDF: How Digital Protocols, ICH M11, and USDM Can Accelerate Regulatory Review

Clinical protocols are scientific documents and operational trial specifications. In document-first workflows, approved protocols are finalized as DOCX or PDF and reinterpreted for data capture, monitoring, statistical planning, registry disclosure, SDTM mapping, and submission. This can introduce inconsistencies between approved content and downstream artifacts. M11 supports structured authoring approaches that minimize variability, shorten review times, and enable consistent comparisons. This session will present a use case evaluating whether M11-authored protocol content, represented through USDM, can be reused for review, eCRF generation, Source Data Extraction (SDE), and SDTM preparation.

The session will explore how structured, machine-readable protocols can support faster completeness checks, automated cross-referencing, and more consistent reviews across amendments and regions. Examples will demonstrate how digital protocols and USDM-based metadata could shorten review cycles, strengthen links to the Study Data Reviewer's Guide and define.xml, reduce manual reconciliation, and support analytics- and AI-assisted review tools.

Presenters will also discuss regulatory pilot opportunities, alignment with data-modernization initiatives, and the feedback needed from regulators to prioritize effective use cases.

Attendees will gain a clearer understanding of the future of digital protocol standards, their potential to improve regulatory review efficiency, and opportunities for greater industry-regulator collaboration.

Learning Objective : At the conclusion of this session, participants should be able to:

- Describe how ICH M11 and the CDISC USDM create a structured protocol that supports faster and more consistent regulatory review.
- Identify specific opportunities where digital protocol data could streamline protocol review, strengthen protocol-to-data traceability, and reduce manual reconciliation
- Explain the value of a structured, machine-readable protocol for both the sponsor and regulators

Track: Establishing Robust Foundations for a Sustainable Regulatory Ecosystem

Session Chair(s)



Rachel Bombara

Submissions Lead
WAYS Pharmaceutical Services, United States

Rachel has 14+ years of experience in regulatory operations and helping sponsors achieve their eCTD submission goals. She has led the eCTD submission publishing of a variety of application types for different regions, from small amendments to large-scale original marketing applications, as well as mentored and trained others in eCTD publishing and submission management. She has also spoken at industry conferences on topics pertinent to investigational and marketing related submissions and produced a variety of blogs, presentations, and other materials to share valuable industry insights.

Speaker(s)



Beyond the PDF: How Digital Protocols, ICH M11, and USDM Can Accelerate Regulatory Review

Chris Decker, MS

President and CEO
CDISC, United States

Chris Decker is President and CEO of CDISC. Widely recognized in the industry, Chris has decades of experience leveraging technology and standards to optimize processes and help industry drive innovation forward. He has extensive experience in executive roles across software development, clinical research, and consulting and his 20-year engagement with CDISC includes roles as a volunteer, implementer, and board member. Chris is passionate about leading CDISC towards a technology-based standards future and expanding the organization's global impact in clinical research standards.



The Computable Protocol: M11/USDM Authoring for Submission Readiness

Ron Fitzmartin, MBA

Principal Consultant
Decision Analytics, United States

Ron Fitzmartin is a Principal Consultant at Decision Analytics. Previously, Ron was Senior Advisor in the Data Standards Branch, Office of Regulatory Operations, Center for Biologics Evaluation and Research, FDA. He provided policy and strategy consultation on electronic regulatory submissions and standardized data. Ron served as Rapporteur for the ICH M11 Expert Working Group and as Co-chair of the Global IDMP Working Group. Prior to FDA, Ron held several leadership positions in industry: VP, Biostatistics and Data Management and VP, Informatics at Daiichi Medical Research and Daiichi Sankyo, respectively. Ron received his PhD in Statistics from the University of Maryland, College Park.

3:15 PM — 4:45 PM

Session 7, Track 2: The Edit Room: Make Regulatory Process Change Stick

Most regulatory process improvements do not fail because the idea was wrong; they fail because the organization was not ready, the measures were insufficient, or the change could not withstand real workloads. This facilitated roundtable brings together three pharmaceutical regulatory practitioners to examine what stalled earlier efforts, what was different when change finally worked, and how organizations determine whether improvement is holding. Participants will rotate through three expert-led tables focused on operating model, implementation, and performance at scale, using examples such as reliance processes, rolling submissions, structured content in Veeva, cycle-time improvement, and AI-enabled regulatory work. The session is designed as a candid practitioner conversation, not a presentation of polished best practices, and will leave attendees with practical questions to pressure-test their own change initiatives.
Learning Objective : At the conclusion of this session, participants should be able to:

- Recognize at least three organizational conditions that can cause regulatory process improvements to stall or reverse
- Compare the operating model, measurement, and change-management conditions of an implementation that succeeded with one that did not
- Apply a practical set of questions to pressure-test whether a current change effort can scale and remain sustainable under real workloads

Track: Optimizing Processes and Procedures

Session Chair(s)



Theresa Pinnell, MLS

Independent, United States

Theresa has over 20 years of experience in the life sciences industry, where she has developed and delivered innovative and user-friendly solutions for regulatory, clinical and QA processes. She currently is the Track 2 Chair for the RSIDM conference. She is passionate about empowering emerging life science groups to accelerate their research and development and bring their products to market faster and safer. She fosters a culture of inclusion and collaboration within teams, leveraging her diverse background in library and information science and her global experience with various pharmaceutical clients.



Vladimir Penkrat, MBA

Associate Vice President – Regulatory Affairs
Indegene, United States

Vladimir Penkrat is AVP of Regulatory Affairs at Indegene. With an MBA in International Business, Vladimir has provided strategic leadership throughout his career across clinical development, biometrics, biostatistics, medical writing, pharmacovigilance, and regulatory affairs. Over the past three decades Vlad worked across top pharma, biotech startups, CROs, and consulting firms. Within the recent 10 yrs, Vlad's passion for regulatory excellence has established process leadership in Regulatory Writing, Submissions Management, Publishing, Labelling, CTT, Consulting, & GenAI innovation as a business. Vlad's leadership has enabled businesses to prepare for digital adeptness & as a business leader he has scaled R&D operations to >500 FTE.

3:15 PM — 4:45 PM

Session 7, Track 3: Connect Regulatory Content from Source to Patient: Put FHIR and Structured Data Standards into Practice with Low-Cost Tools

Regulatory information remains fragmented across documents, systems, and functions, limiting content reuse, interoperability, and timely access to trusted information. This session explores how FHIR can provide a common structured data foundation for connecting and reusing pharmaceutical quality and electronic product information across submissions, labeling, and quality processes. Attendees will also see a practical, low-cost approach for transforming Word-based content into standards-based outputs using open-source scripting, metadata, APIs, and AI-assisted development. Finally, a German ePIL pilot demonstrates how FHIR-based product information can be delivered through health insurance apps, connecting authoritative regulatory content directly to patients.
Learning Objective : At the conclusion of this session, participants should be able to:

- Explain how FHIR can connect PQ/CMC and ePI content for reuse across submissions, labeling, and quality processes
- Apply a low-cost, open-source method to transform Word content into standards-based structured data
- Evaluate a FHIR-based ePIL pilot and identify patient benefits and regulatory or policy implications

Track: AI, Automation and Emerging Technologies

Session Chair(s)



Karin Schneider, MLIS, MS

Associate Director
Johnson & Johnson, United States

German citizen, who worked in Switzerland and now lives in the US. I have been in the Pharmaceutical Industry for my entire career. I looked at Content Management from many different angles: Information broker, information architect, solution engineer and end user in various business domains and regions. The time is now to prepare for fundamental change in RIM. We have done Document and Data Management in silos for decades. The past couple of years AI dominated the solution space with various success. It is time to fundamentally rethink how we work with content and design business centric solutions that actually deliver desired results.

Speaker(s)



FHIR for Pharmaceutical Quality and ePI: Building Interoperable, Reusable Regulatory Content

Joan Cheung, PharmD, RPh

Principal Consultant
Epista Life Science, United States

Joan Cheung is a Senior Consultant at Epista Life Science where she leverages new technologies for digital transformations in the life sciences. Since her Doctor of Pharmacy from St. John's University, she gained technical project and product management skills in Regulatory Affairs with projects spanning structured content authoring, IDMP compliance, and data standardization. She is excited to share Epista's successes in driving data standardization initiatives and future proofing companies for global health authorities' requirements. Outside of work, Joan is advocating for AANHPI civil rights across NYC as a board member of OCA-NY, a national 501(c) nonprofit. She is also pursuing a Master of Data Science from Brown University.



Mock Connectathon: Connecting Structured Content and Structured Data Using Industry Standards (USDM, EPI, Others)

John Jones, MBA

SVP, Consulting
Entitech, A Tandym Company, United States

John Jones is the Founder and CEO of Entitech Solutions, a system integrator focused on developing innovative technology solutions for unmet business needs in Life Sciences. John has more than 25 years experience in developing and delivering IT Solutions for various companies, and has extensive experience in the clinical, regulatory, and commercial areas. His technical specialties include: enterprise architecture planning and definition, long-term technology strategy development, knowledge and content management, information architecture and metadata definition, structured component authoring and data integration/business intelligence platform implementation



Integrating ePIL into Statutory Health Insurance Apps Using FHIR globally

Paul Kamm

Product Owner Patient Solutions

Rote Liste Service GmbH (cormeo GmbH), Germany

3:15 PM — 4:45 PM

Session 7, Track 4: Beyond Documents: Designing the Future of Regulatory Data Collaboration

The pharmaceutical industry has digitized dossier delivery, but regulatory collaboration remains document-centric and dependent on parallel legacy processes. This session examines why technology alone has not produced trusted, lifecycle-aware data exchange.

The session will include an interactive governance exercise. Using a cross-border data-exchange scenario, attendees will assign responsibilities, identify confidentiality and residency controls, define pilot success and transition criteria, and select a platform approach that preserves interoperability without dependence on one regulator or vendor.

Learning Objective : At the conclusion of this session, participants should be able to:

- Explain how governance, confidentiality, process, and culture constrain regulatory data collaboration
- Apply a layered architecture separating regulatory review, data/analytics, and interaction capabilities
- Evaluate certification, platform-neutral gateways, consent, provenance, and pilot-to-production controls

Track: Strategic Leadership and Organizational Readiness

Session Chair(s)



Noelia Plaza

Director of Process Excellence & Analytics
Daiichi Sankyo, United States

Noelia leads Daiichi Sankyo's Process Excellence & Analytics group for Global Regulatory Affairs. She is responsible for managing GRA's controlled procedural documents, optimizing global processes, ensuring compliance, and delivering metrics that support data-driven decision making in Regulatory. She began her career at Accenture and joined Daiichi Sankyo in December 2022. During her tenure at Accenture, Noelia partnered with a variety of sponsors on global transformation programs across Clinical and Regulatory, with a focus on improving processes with enabling technologies.

Speaker(s)



Beyond Documents: Designing the Future of Regulatory Data Collaboration

David S Ross, MBA, PMP, RAC

Senior Director, Global Regulatory Policy and Intelligence
AstraZeneca, United States

David Ross (Senior Director, Regulatory Data and Submissions, AZ) has undergraduate degrees in Chemical Engineering, and Biochemistry with an MBA and Engineering Management graduate degrees. He led global complex Business Transformation projects in the Pharmaceutical and Biologics industry. In his Global Regulatory Policy role, David is actively involved in Reliance and Collaboration efforts at AZ. David is Bio Representative in the ICH Task

Force for PQKM Feasibility Assessment. As the GSO IRISS Lead (2016 to present) David hosts monthly meetings on Regulatory Submission and Data innovation. As AZ Lead for PhRMA IT Group (2014 to 2023), David helped lead the PhRMA IT White Paper on Cloud based computing with global collaboration.



Speaker

David Isom

Senior Director, Global Regulatory Policy and Intelligence, Global Product Devel
Pfizer, United States

David Isom is Senior Director, Global Regulatory Policy at Pfizer where he leads policy and advocacy for priorities that include innovative use of technology and data to transform regulatory submission and review, and global regulator collaboration. Before his focus on policy, David led several Pfizer regulatory information management, real world data, and clinical trial data services. Prior to joining Pfizer in 1999, David served at the U.S. FDA as a regulatory project manager in CDER's Division of Antiviral Drug Products, and later as Head of CDER's Office of IT and e-submission programs. Before FDA, David worked in healthcare outpatient and surgical settings as a U.S. Navy Hospital Corpsman. David has a B.Sc from University of Maryland.

Day 3 Feb 10, 2027

7:15 AM — 12:45 PM

Forum Registration

7:15 AM — 8:00 AM Ballroom A-E

Networking Breakfast in the Exhibit Hall

8:00 AM — 9:15 AM

Session 8, Track 1: Global harmonization and Reality: Navigating eCTD v4 Pilots in Key Markets

The global transition to eCTD v4.0 is reshaping regulatory submissions from document-centric processes to structured, data-driven information exchange. As Japan advances production implementation and both the FDA and EMA continue their pilot and forward compatibility initiatives, companies are gaining valuable insights into how regional implementation approaches influence global submission strategies.

This session will explore lessons learned from eCTD v4.0 pilots and early adoption experiences across major regulatory regions, highlighting key challenges such as metadata harmonization, lifecycle management, interoperability, and balancing global standards with local requirements. Industry experts will share practical experiences from collaboration with health authorities and discuss how pilot findings are informing future implementation roadmaps.

Looking beyond technical compliance, the session will examine how eCTD v4.0 enables the vision of "Submit Once, Reference Many," supports distributed content management through trusted information ecosystems, and creates new opportunities for automation, metadata reuse, and AI-enabled regulatory processes. Participants will gain practical recommendations and readiness strategies to successfully navigate the transition while positioning their organizations for the next generation of global regulatory submissions.

Learning Objective : At the conclusion of this session, participants should be able to:

- Compare eCTD v4.0 implementation approaches adopted by the FDA, EMA and PMDA
- Evaluate lessons learned and common challenges from eCTD v4.0 pilot programs and early adoption activities
- Develop actionable readiness plans to support a successful transition from eCTD 3.2.2 to eCTD v4.0
- Assess how metadata-driven submissions, content reuse and AI may shape future regulatory operations

Track: Establishing Robust Foundations for a Sustainable Regulatory Ecosystem

Session Chair(s)



Shenqi (Handsome) Ji

Publishing Regional Director, Asia, Global Regulatory & International Operations
Pfizer, China

Handsome Ji is a recognized expert in regulatory operations and eCTD. Since 2015, Ji has chaired DIA China Annual Meeting sessions, including ICH Theme Day and CTD/eCTD workshops. He served as advisor to the DIA China Young Professionals Committee and co-lead of the RA Community Core Working Group. Ji co-led the RDPAC China Regulatory Requirements Working Group and lectures at the NMPA Institute of Executive Development. He also leads industry courses at Fudan University and contributes to global DIA programs. Ji holds a bachelor's degree in Computer Science and Technology from Fudan University.

Speaker(s)



Global Harmonization and Reality: Navigating eCTD v4 Pilots in Key Markets

Priya Krishnan, MBA

Regulatory Intelligence Specialist
EXTEDO GmbH, Germany

Priya Krishnan was a Scientific Editorial Advisor at Springer Nature and is now a Regulatory Intelligence Specialist at EXTEDO GmbH. Her work focuses on Regulatory Intelligence, regulatory publishing and translating evolving global regulations into actionable requirements that support product compliance and regulatory solutions. With a strong focus on eCTD v4, she delivers client training, regularly speaks at webinars and has presented on eCTD v4 at industry conferences. Priya is also active in professional and industry groups including IRISS, DIA and INPACT and contributes to the PMS subgroup supporting EMA initiatives.

Are You Really Ready for eCTD 4.0?

Diarmuid Waide

Senior RIM Consultant



Ennov, France



Experiences from the Ground Reality

Patrick Capella, MS

Regulatory Operations Lead
Argenx, United States

Patrick has worked in regulatory operations since 2009. In his career, he has managed submissions in a number of industries including consulting, generics, OTC, immunotherapy, and gene therapy. Currently, Patrick is the regulatory operations lead at argenx, where he manages a team of publishers overseeing worldwide submission activities. He holds a Bachelor of Science in Biomedical Engineering from Drexel University and a Master of Science in Biochemical Engineering from Villanova.

8:00 AM — 9:15 AM

Session 8, Track 2: Wake Up to Calmer Submissions: Bust Bottlenecks, Build Adoption, Strengthen Content Processes

Explore practical ways to remove submission bottlenecks, reduce manual effort, and strengthen regulatory content processes—without creating new headaches for your team. Through candid practitioner lessons and real-world examples, examine how content strategy, targeted automation, cross-functional coordination, and training work together to build adoption and improve execution. Learn to avoid common implementation pitfalls and measure whether process changes actually reduce rework rather than shift it elsewhere.
Learning Objective :

- Identify submission assembly bottlenecks and evaluate how automated consistency checks, validation, and readiness assessment can reduce manual effort
- Apply practitioner lessons in content strategy, implementation, training, and change management to strengthen content processes and build adoption
- Evaluate process improvements using measures that distinguish genuine reductions in rework from effort shifted to other teams or workflows

Track: Optimizing Processes and Procedures

Session Chair(s)

Theresa Pinnell, MLS

Independent, United States



Theresa has over 20 years of experience in the life sciences industry, where she has developed and delivered innovative and user-friendly solutions for regulatory, clinical and QA processes. She currently is the Track 2 Chair for the RSIDM conference. She is passionate about empowering emerging life science groups to accelerate their research and development and bring their products to market faster and safer. She fosters a culture of inclusion and collaboration within teams, leveraging her diverse background in library and information science and her global experience with various pharmaceutical clients.

Speaker(s)



Stop Hand-Assembling eCTD Packages: Scaling Submission Operations Without Scaling Headcount

Kristen Sauter, MBA

President & GM, Life Sciences
Adlib Software, United States

Kristen has 20 years of experience helping life sciences clients create modern and innovative regulatory practices and processes that leverage cutting-edge technology to satisfy both FDA requirements and their bottom line. She has built and led global regulatory operations and project management teams for top industry organizations using forward-facing strategy and business systems. Her experience includes comprehensive knowledge of electronic submissions requirements, connections into e-subs group, strong experience in pharmaceutical process and submission preparation through pre-market and NDA stages of development, and strong exposure and awareness of post-marketing and international filings.



Lessons from the Field: Optimizing Regulatory Content Processes from Strategy Through Implementation and Training

Murali Menon, MS

CRO
Docuvera, United States

Murali Menon is Chief Revenue Officer at Docuvera, where he leads business strategy and partnerships focused on transforming how life sciences organizations create, manage, and deliver clinical and regulatory content. With over 20 years of experience in technology and digital transformation, Murali is passionate about helping teams move from document-based to data-driven processes. His leadership combines deep domain expertise with a vision for interoperability, automation, and compliance across the clinical lifecycle.

8:00 AM — 9:15 AM

Session 8, Track 3: Choose the Right Regulatory AI: Evaluating Solutions That Deliver Real Business Value

AI options are rapidly increasing across organizations but the hard question now is where it fits and where it does not. This session brings together three perspectives on selecting fit-for-purpose technology for your organizational needs. Attendees will leave with practical frameworks for matching the right solution to the right problem, assessing vendors and tools, and preparing their organizations for the workforce and operating model changes that come with AI adoption.
Learning Objective : At the conclusion of this session, participants should be able to:

- Distinguish when rules-based automation, AI, or both is the right solution for a regulatory process, weighing accuracy, cost, oversight needs and ROI.
- Evaluate AI tools and vendors based on accuracy, reliability, security, data governance and workflow integration.
- Identify business value from AI and automation and the organizational and skills implications for regulatory teams.

Track: AI, Automation and Emerging Technologies

Session Chair(s)



Kevin Tompkins, MBA

Executive Director, Regulatory Information & Submission Management
Bristol Myers Squibb, United States

Kevin Tompkins is the Executive Director, Regulatory Information and Submission Management at Bristol Myers Squibb. He joined BMS in 2018 and has over 20 years of experience in different roles leading regulatory operations teams. In his current role, Kevin is responsible for the strategic direction and delivery of regulatory submissions, product data, and regulatory systems for BMS. He holds a B.S. in Information Systems and a M.B.A. from LaSalle University.

Speaker(s)



Regulatory Intelligence Automation and AI Organizational Impact

Steve Gens, MS

Managing Partner
Gens & Associates, United States

Steve Gens (MSOD) is the Managing Partner of Gens & Associates Inc., a global Life Science benchmarking and advisory firm specializing in performance improvement, strategy, industry analysis, benchmarking and organizational transition. His early career was spent at Johnson & Johnson in a variety of management positions and then transitioned to consulting where he lead global Life Science consulting practices for First Consulting Group and Booz Allen Hamilton. His organization is well known for their insightful industry benchmarks and World Class RIM thought leadership. Steve has a Bachelor's of Science in Business Computer Science and a Master in Organizational Development and Performance.



Evaluating AI for Medical Writing: Moving Beyond the Hype

Mati Kargren, MSc

MW Optimization Lead
GSK, Taiwan

8:00 AM — 9:15 AM

Session 8, Track 4: Achieving an Effective Regulatory KPI / Metrics Program

This session will review this standard list of KPI / Metrics, discuss how to rapidly evolve your KPI Performance Metrics program, and provide key process maps that highlight metrics placement and milestones.
Learning Objective :
At the conclusion of this session, participants should be able to:

- Improve your Regulatory KPI /Metrics Program,
- Understand what are standard metrics for regulatory effectiveness, submission quality, regulatory productivity, time to market, submission plan vs actual, regulatory compliance, labeling, CMC, and Regulatory intelligence

Track: Strategic Leadership and Organizational Readiness

Session Chair(s)



Lorelle Leonienco, PMP

Executive Lead Government & Regulatory Intelligence Product Management
LORENZ Life Sciences Group, United States

With over 20 years of experience spanning Commercial, Regulatory, Medical, Clinical, and IT functions across the pharmaceutical and software industries, Lorelle has led technology-driven initiatives that advance regulatory operations, digital transformation, and strategic objectives across both industry and health authority environments. Leveraging a unique perspective gained from working across the broader regulatory ecosystem, Lorelle now focuses on global regulatory intelligence, emerging technologies, and regulatory modernization initiatives. Her work centers on translating regulatory and market insights into strategic guidance that fosters innovation, collaboration, informed decision-making, and corporate growth.

Speaker(s)



Achieving an Effective Regulatory KPI / Metrics Program

Preeya Beczek

Managing Director and Co-Founder
BECZEK.COM, United Kingdom



Speaker

Representative Invited

Eli Lilly and Company, United States

Laura works at Eli Lilly and Company in Global Regulatory Affairs as RIM System Owner and Data Governance Lead. She has been in the Pharmaceutical Industry for over 26 years, having held positions in the laboratories, process improvement, and systems implementation across several organizations.

9:25 AM — 10:40 AM

Session 9, Track 1: Building an AI-Ready Regulatory Data Foundation: How Data Products, Dimensional Models, and Semantic Layers Enable Trusted Data

Session 9, Track 1: Building an AI-Ready Regulatory Data Foundation: How Data Products, Dimensional Models, and Semantic Layers Enable Trusted Data
Track: Establishing Robust Foundations for a Sustainable Regulatory Ecosystem

Session Chair(s)



Nimesh Patel

Senior Director of Global Regulatory Systems
Eisai Co., Ltd., United States

Senior Director of Global Regulatory Systems, overseeing the implementation, support and development Eisai's Regulatory technology strategy. Active member of IRISS and Committee Member in PhRMA's Regulatory IT Workstream. Prior to Eisai, performing similar roles in supporting the Regulatory functions at Big Pharma, Consultancies and mid-size biotech's for the past 20+ years.

Speaker(s)



Building an AI-Ready Regulatory Data Foundation: How Data Products, Dimensional Models, and Semantic Layers Enable Trusted Data

Donna Yosua

Director, Global Regulatory Data Management
Merck & Co., Inc., United States

Donna Yosua leads the Merck Data Harmonization & Interoperability program which includes the implementation of a regulatory data hub and canonical data model with reusable data publications, reporting and analytics dimensional data model, and corresponding regulatory data governance framework. Donna is a seasoned Life Sciences Strategist/Business Architect and an expert in Regulatory Information Management with 25 years of experience guiding organizations toward improved business performance by leading the development and deployment of new strategies, processes, and enabling technologies. She has global experience in the pharmaceutical, technology development, and consulting industries.



Scaling Regulatory Data Readiness Through Automation and Business Ownership

David Gwyn, MBA

Vice President, Strategy and Solutions

fme Life Sciences, United States

With more than 25 years of experience in the Life Sciences industry, David is a seasoned executive with extensive experience delivering solutions to customers, with a particular focus in the areas of regulatory information management (RIM), content management and collaboration. His main focus is aligning customer needs with the capabilities of the company's Life Sciences Suite and ensure that the solution meets the needs of the customer. David also leads the DIA EDM Submission Reference Model team that developed a document architecture for use when designing and building content management solutions.

9:25 AM — 10:40 AM

Session 9, Track 2: From Fire Drills to Frameworks: Realizing the Value of Regulatory Investments

The true transformation of a regulatory organization occurs when emergency heroics turn into routine infrastructure and technology investments deliver verifiable business value. As the culmination of Track 2's journey, this session brings together biopharma operational leadership and platform strategy experts to show what operational maturity looks like after the initial dust settles.

Attendees will hear firsthand how Novavax transitioned submission planning from reactive fire drills into seamless, embedded infrastructure using Veeva RIM Submission Content Plans, anchored by change-management strategies that drove genuine user adoption rather than passive compliance. Building on that foundation, Implement Consulting Group will present a practical value-realization framework designed to answer the question every regulatory leader faces post-implementation: When and how does the investment actually pay off? Together, these presentations equip regulatory leaders to assess where their organization sits on the operational maturity curve, close the gap between software go-live and everyday execution, and prove sustained return on investment across global portfolios.

Learning Objective :

- Standardize submissions using structured, repeatable content plans that improve visibility, consistency, and planning
- Drive stakeholder adoption with practical strategies that encourage engagement and sustained system use
- Identify and close gaps between system implementation and everyday business processes
- Measure and communicate system ROI through meaningful metrics and business outcomes

Track: Optimizing Processes and Procedures

Session Chair(s)



Lindsay Fitzgerald

Delivery Manager
Astrix, United States

Experienced Regulatory Affairs Delivery Manager & Business Solutions Expert with a strong background in project management, advisory services, business analysis, and departmental support within the pharmaceutical industry. Certified Veeva Vault Platform Associate Administrator and recognized Regulatory Operations Subject Matter Expert (SME). Skilled in managing and optimizing multiple electronic document management systems (eDMS), with a focus on business administration, cross-functional alignment, and industry best practices. Adept at stakeholder engagement across all organizational levels, consistently maintaining a a customer-centric approach and high attention to detail.

Speaker(s)



From Fire Drill to Afterthought: Optimizing Submission Planning and Process

Jared Lantzy, PMP

Executive Director, Global Regulatory Affairs Operations
Novavax, Inc., United States

Mr. Lantzy has over 20 years experience solving technology and people problems in government, vendor, consulting, and industry environments. He is a former member of CDER's Electronic Submission Support Team at the US FDA and currently leads the Global Regulatory Affairs Operations team at Novavax, Inc. His current interest is on improving the exchange and review of data between industry and regulatory health authorities, to ultimately provide safer and more effective products to patients and for public health.



Beyond Go-Live: Realizing Measurable Value from Regulatory Platform Investments

Rune Bergendorff, MSc

Partner, International Life Sciences
Implement Consulting Group, Denmark

Rune Bergendorff, Partner at Implement Consulting, boasts two decades of consultancy experience spanning Europe and the US. Educated in IT and business, his focus is centered on delivering sustainable digital transformations that drive business impact and value. Over the past 15 years, he has honed his expertise within Life Sciences, initially in RA and Quality, then expanding into Clinical and Safety. Rune has spearheaded initiatives such as digitalizing regulatory product submissions and implementing AI in safety and clinical data intake. He actively contributed to industry standards, including development of IDMP with ISO and as member of the EMA SPOR task force. Committed to community advancement, he champions improved digital workflows

9:25 AM — 10:40 AM

Session 9, Track 3: Unlock Trusted, Reusable Data from Regulatory Content: Preparing for Digital Data Exchange

Biopharmaceutical organizations need to convert information embedded in legacy documents into data that can be reused, exchanged, and trusted across an increasingly digital regulatory ecosystem. This session examines practical approaches for extracting structured data from unstructured regulatory and product-quality content; preserving a verifiable record of how data is transformed and transferred; and enabling interoperable exchange through standards-based architectures and governed AI workflows. Real-world examples will demonstrate how FAIR data can be applied across clinical, labeling, and CMC domains.
Learning Objective : At the conclusion of this session, participants should be able to:

- Describe unique approaches for converting unstructured regulatory content into FAIR, standards-aligned data
- Distinguish data provenance from source-data validation in cross-organizational regulatory workflows

- Identify opportunities to apply interoperable data standards and governed AI within their regulatory operations

Track: AI, Automation and Emerging Technologies

Session Chair(s)



Rita Algorri, PhD, MS

Associate Director, Global Regulatory Affairs
Amgen, United States

Rita Algorri, PhD is an Associate Director, Regulatory Affairs at Amgen Inc. in Thousand Oaks, CA. In this role, she leads and orchestrates internal and external activities relating to regulatory modernization, digitization, automation, and emerging technologies. She also supports Amgen's Advocacy and External Engagement function which fosters collaboration with multiple internal and external cross-functional teams to coordinate and progress company and industry initiatives. Rita is a microbiologist by training and holds a PhD in Clinical and Experimental Therapeutics and M.S. in Regulatory Science from the University of Southern California.

Speaker(s)



Unlocking Unstructured Legacy Data at Scale: A Semantic Analytics Approach to ISO IDMP-Compliant FAIR Data Extraction

Daniela Rosa, MBA

Director, Structured Data Submissions & Product Master Data
Abbvie, United Kingdom

Daniela Rosa is a Director for Structured Data Submissions & Product Master Data at AbbVie. With over 20 years in biopharma, she leads global data governance and structured submissions programs, specializing in ISO IDMP, XEVMPD, HL7 FHIR, and PQI, pioneering AI tools for regulatory data extraction. She holds a BSc in Pharmaceutical Sciences and an MBA from the University of Sao Paulo.



Portable Trust Across Organizational Boundaries: A Verifiable Chain of Custody for AI-Enabled Regulatory Data Pipelines

Tina M. Morrison, PhD

VP, Scientific Strategy
EQTYLab, United States

Tina Morrison, PhD, Vice President of Scientific Strategy at EQTYLab, was previously a Senior Executive at the U.S. Food and Drug Administration. Throughout her career, she has led cross-agency initiatives on computational and in silico alternative methods, credibility assessment of complex model approaches, including computational modeling, AI and complex in vitro test methods. Tina is a mechanical engineer and applied mathematician with 25 years of simulation experience and 17 years in regulatory science, specializing in the intersection of engineering, computation, and policy.

9:25 AM — 10:40 AM

Session 9, Track 4: Navigate Regulatory Operations Transformation: From Digital Strategy to Actionable Intelligence

Regulatory Operations is evolving beyond submission execution into a strategic partner in enterprise data, digital transformation, and regulatory decision-making. This session brings together perspectives on the future of AI-enabled operations, structured data and collaborative review; the governance, operating models, and workforce capabilities needed to implement change; and practical ways to turn regulatory monitoring into prioritized, actionable intelligence. Speakers will discuss how Regulatory teams can connect technology investments to business and regulatory priorities, strengthen cross-functional alignment, and build scalable capabilities—even in resource-constrained environments.
Learning Objective : At the conclusion of this session, participants should be able to:

- Identify key digital, data, AI, and workforce trends reshaping Regulatory Operations
- Apply a practical framework to prioritize regulatory intelligence and communicate decision-ready insights
- Assess governance, operating-model, and capability needs for future-ready Regulatory Operations

Track: Strategic Leadership and Organizational Readiness

Session Chair(s)



Jasmine Gupta

Global Regulatory Affairs Lead
Synthekine, United States

Speaker(s)



Evolution in Action: Regulatory Operations as the Bridge to Data and Digital Transformation

Sandra Krogulski, MA

Senior Director, Regulatory Digital Strategy and External Engagement
Bristol-Myers Squibb Company, United States

Sandy Krogulski is an experienced and solution-oriented individual with over 10 years of submission and regulatory experience. Sandy joined BMS in 2018, working on global submissions and process evolution. In her current role, Sandy leads regulatory digital strategy and external engagement for Global Regulatory Sciences at BMS, where she sets the vision and roadmap for how the organization modernizes the way it authors, manages, and delivers regulatory submissions. She helps identify, prioritize, and scale high-value digital and AI use cases, from content authoring automation to knowledge reuse and regulatory intelligence, while keeping regulatory rigor front and center.

Regulatory Operations 2030



Brian Williams

Advisory Managing Director, Life Sciences
KPMG, United States

Brian is a leader in KPMG's Life Sciences Consulting practice, with a focus on Regulatory Affairs. He has extensive experience helping clients improve efficiency and enable compliance by implementing process and technology changes. His experience includes leading programs related to global RIM deployments, RA operating model and process redesign, data cleansing/harmonization and adoption of emerging digital technologies.



From Alerts to Action: Building a Strategic Regulatory Intelligence Function

Kim Gallop

Sr. Global Regulatory Analyst
Florence Healthcare, United States

Kimberly Gallop is the Sr. Global Regulatory Analyst at Florence Healthcare, bringing 13 years of clinical research experience with a strong foundation in global regulatory affairs and clinical trial start-up operations at a major CRO. In her role, she oversees the Regulatory Compliance Library, ensuring alignment with international standards such as ICH GCP E6(R2), FDA 21 CFR Part 11, EMA Annex 11, and MHRA guidance. Kimberly provides regulatory insight and consultation to software development teams, guiding product compliance with both internal policies and external regulations. She collaborates with subject matter experts to research and interpret global clinical research requirements, and plays a critical role in internal audits.

10:40 AM — 11:15 AM Ballroom A-D

Refreshment and Networking Break in the Exhibit Hall

11:15 AM — 12:30 PM Ballroom A-D

Session 10: Stay Ahead of Global Regulatory Change: Agency Modernization, Digital Transformation, and Future Regulatory Priorities

Receive the latest updates from international regulators about recent and future developments. This session provides attendees the opportunity to ask regulators questions directly. Please note: due to the high volume of questions, not all will be answered live at the forum. We encourage audience members to submit questions in advance via the DIA mobile app.
Learning Objective : At the conclusion of this session, participants should be able to:

- Discuss how regulatory agencies are transforming their operating models to adapt to emerging industry needs

- Explain modernization efforts within regulatory infrastructure, focusing on how digital tools, data capabilities, and streamlined processes support more efficient review and submission management

Track: General Session

Session Chair(s)



Tamei Elliott, MS

Director, Global Scientific Content
DIA, United States

Tamei Elliott, MS, is the Director of Global Scientific Content at the Drug Information Association (DIA). She leads DIA's global scientific content strategy, ensuring alignment with regulatory priorities, industry trends, and evolving stakeholder needs across regions. She also established and leads DIA's Global Science Content Center of Excellence, driving harmonization of content development and strategy across Europe, Asia, North Africa, and the Middle East. With expertise in regulatory science, she brings stakeholders together to address the life sciences industry's most pressing challenges, driving outcomes that move toward solutions.



Lorelle Leonienco, PMP

Executive Lead Government & Regulatory Intelligence Product Management
LORENZ Life Sciences Group, United States

With over 20 years of experience spanning Commercial, Regulatory, Medical, Clinical, and IT functions across the pharmaceutical and software industries, Lorelle has led technology-driven initiatives that advance regulatory operations, digital transformation, and strategic objectives across both industry and health authority environments. Leveraging a unique perspective gained from working across the broader regulatory ecosystem, Lorelle now focuses on global regulatory intelligence, emerging technologies, and regulatory modernization initiatives. Her work centers on translating regulatory and market insights into strategic guidance that fosters innovation, collaboration, informed decision-making, and corporate growth.

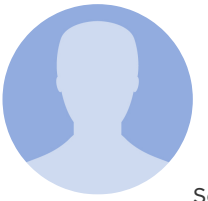
Speaker(s)



Speaker

Representative Invited

Medicines and Healthcare products Regulatory Agency (MHRA), United Kingdom



Speaker

Representative Invited

Health Canada, Canada

Seema Verma-Pharasi is an Executive Director at Health Canada and a leader in digital transformation, artificial intelligence, information management, and regulatory modernization. With experience across both the public and private sectors, she specializes in translating complex business and technology challenges into practical strategies that drive organizational performance and public value. A collaborative and results-oriented executive, Seema is passionate about leveraging data, technology, and AI to

improve decision-making, modernize services, and support regulatory excellence. She is recognized for building partnerships, leading change, and delivering enterprise-wide initiatives that create meaningful impact for Canadians.



Speaker

Representative Invited

European Medicines Agency, Netherlands

Kristiina joined the European Medicines Agency in January 2002 and is responsible for the implementation, coordination and maintenance of the eSubmission systems and processes at the agency. Kristiina is a Product Owner and a subject matter expert for eCTD v3.2.2, eCDT v4.0, the electronic Application Forms (eAFs), the eSubmission Gateway and Web Client, the Common Repository, the PSUR Repository and the business processes related to the eSubmissions. Kristiina works closely with the EMA business and technical colleagues and the development teams, the colleagues from the European Medicines Network (EMRN) and pharmaceutical industry. Kristiina represents the EMA in eSubmissions related stakeholder groups and is a co-chair of the ICH M8.

12:30 PM — 12:45 PM Ballroom A-D

Closing Remarks

12:45 PM — 12:45 PM

FORUM ADJOURNS