DIA

Regulatory Submissions, Information, and Document Management Forum

Short Courses: February 8 and February 9 – Virtual Only | Primer: February 13 – In-Person Only
Forum: February 14-16 | Hybrid Event

PROGRAM CO-CHAIRS

V. "Bala" Balasubramanian, PhD, MBA
Senior Vice President, and Global Head, Healthcare, and, Life Sciences
Orion Innovation

Karen McCarthy Schau
Director, Global Clinical Operations
Vertex Pharmaceuticals

Peter Terbeek, MBA
Senior Director, Publishing and Submission
Astellas

PROGRAM COMMITTEE

Danielle Beaulieu, PhD
Senior Director, Global Regulatory Business Capabilities
Bristol-Myers Squibb

Ethan Chen, MBA
Director, Division of Data Management Services and Solutions, OBI, OSP
CDER FDA

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

Jake Doran
Head of Global R&D IT
Bausch Health

Jo English
Vice President, Regulatory Information Management
Calyx, United Kingdom

Divya Gangaramani PhD, RAC
Senior Regulatory Specialist
VIR Biotech

Vahé Ghahraman, PhD
Senior Director, Global Regulatory Operations
Apellis Pharmaceuticals, Inc.

Sandra Krogulski, MA
Associate Director, Submission Management
Bristol-Myers Squibb

Rob Labriola, MS
Senior. Director, Regulatory Operations
Synchrogenix

Demetra Macheras, MBA
Director, Regulatory Policy and Intelligence, Regulatory Affairs
AbbVie, Inc.

Joanne Malia, MS, MSc
Director, Clinical Documentation Management
Regeneron Pharmaceuticals

Jamie O'Keefe
Vice President, Business & Technology
Just In Time GCP

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

Kristen Sauter, MBA
Director, Global Regulatory Informatics & Analytics
Takeda Pharmaceuticals

Michiel Stam
Head of Data Management and Regulatory Information Scientist
Qdossier, The Netherlands

Stacy Tegan
Associate Director, Program Management
Transcelerate Biopharma, Inc.

Overview

The last few years has 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 systems. The Forum presents four tracks: Regulatory Informatics Business, Regulatory Informatics Technology, Electronic Document Management, and Electronic Regulatory Submissions. Cross-track sessions provide the opportunity to discuss key connection points across major components of regulatory information, and plenary sessions featuring regulatory intelligence updates by FDA and other regulatory authorities are offered each day.

This Forum provides multiple opportunities for networking, knowledge sharing, and education for both business and technology-focused attendees.

Social distancing measures may be in place at the time of the event. Therefore, **we encourage you to register and make your housing arrangements early due to potential limited capacity**. If the capacity limit is reached, we will only be able to offer the virtual option. Don't miss out on your chance to meet live again with your friends and colleagues!

DIA has made the decision that all participants at in-person DIA Meetings, Workshops, Forums and Conferences, whether a presenter, attendee, exhibitor, staff, guest, or vendor, will be required to be fully vaccinated.

Who Should Attend?

Professionals involved in:

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

Schedule-At-A-Glance

Track Key: Track 1: Regulatory Informatics – Business **Track 2:** Regulatory Informatics – Technology
Track 3: Electronic Document Management (EDM) **Track 4:** Electronic Regulatory Submissions (ERS)

SHORT COURSE | TUESDAY, FEBRUARY 8

Sessions are held in ET

10:00AM-1:30PM	**Virtual Short Course:** The Future of Documents: Deep-Dive into Structured Content **Short Course requires an additional registration fee. You do not need to be registered for the Forum to attend**	

SHORT COURSE | WEDNESDAY, FEBRUARY 9

10:30AM-1:30PM	**Virtual Short Course:** Structured Data: IDMP is Not the Goal **Short Courses requires an additional registration fee. You do not need to be registered for the Forum to attend**	

PRIMER | SUNDAY, FEBRUARY 13

		ROOM
9:30-10:00AM	**Regulatory Content and Submission Primer: Content from Authoring to Archive Registration *(In-Person Exclusive)*** **This Primer Course requires an additional registration fee. You do not need to be registered for the Forum to attend**	Forest Glen Foyer (Lower Level)
10:00AM-5:00PM	**Regulatory Content and Submission Primer: Content from Authoring to Archive Registration *(In-Person Exclusive)*** **This Primer Course requires an additional registration fee. You do not need to be registered for the Forum to attend**	Forest Glen Foyer (Lower Level)

DAY ONE | MONDAY, FEBRUARY 14

		ROOM
8:30-9:00AM	**BONUS Session Registration** **No additional fee or separate registration is required. This Workshop is open to all*	Ballroom Foyer (Upper Level)
9:00AM-12:00PM	**BONUS Session:** RIM Reference Model 1.0 – Validation Workshop *(In-Person Exclusive)*	Brookside (Lower Level)
11:00AM-5:25PM	Forum Registration	Ballroom Foyer (Upper Level)
1:00-1:25PM	**Welcoming Remarks and Presentation of the Excellence in Service Award**	Ballroom E-H
1:25-2:00PM	**Session 1:** Keynote Address - How To Think Like an Innovator in a World of Uncertainty	
2:00-2:45PM	Refreshment and Networking Break in the Exhibit Hall 1	Ballroom A-D
2:15-2:45PM	**Exhibitor Event:** Regulatory Execution of Mergers, Acquisitions, and Divestitures *(Virtual Exclusive)*	
2:45-4:00PM	**Session 2:** FDA Strategy on Data and Technology Modernization	Ballroom E-H
4:10-5:25PM	**Session 3:** Progress Towards Structured Submission Documents: ICH M11 and the Clinical Electronic Structured Harmonized Protocol (CeSHarP)	Ballroom E-H
5:25-6:30PM	Networking Reception in the Exhibit Hall	Ballroom A-D

DAY TWO | TUESDAY, FEBRUARY 15		ROOM
7:30AM-5:30PM	Registration	Ballroom Foyer
7:30AM-8:30AM	Networking Breakfast in the Exhibit Hall	Ballroom A-D
8:30-9:45AM	**Session 4:** FDA Electronic Submissions	Ballroom E-H
9:55-10:45AM	**Session 5:** FDA - Ask the Regulators	Ballroom E-H
10:45-11:15AM	Refreshment and Networking Break in the Exhibit Hall	Ballroom A-D
11:15AM-12:30PM	**Session 6:** BREAKOUT SESSIONS	
	Track 1: Application of RIM in Medical Devices – Challenges and Opportunities for Automation	Ballroom FGH
	Track 2: Driving Data Integration, Data Governance, and Data Quality Monitoring Through Data Standards	White Oak (Lower Level)
	Track 3: Inspection Readiness: Different Approaches to Inspection Readiness with Real-World Case Studies and Inspection Outcomes from Sponsors	Brookside (Lower Level)
	Track 4: Structured Content: Where Are We Now, Where Are We Going, and Practical Applications	White Flint (Lower Level)
12:30-2:00PM	Networking Luncheon in the Exhibit Hall	
2:00-3:15PM	**Session 7:** BREAKOUT SESSIONS	
	Track 1: Innovation Across the Regulatory Spectrum: A Call to Action for Industry	Ballroom FGH
	Track 2: Implementation Experience Sharing: Next-generationGlobal RIM Solutions	White Oak (Lower Level)
	Track 3: Rethinking Documents: The Digital Content Revolution	Brookside (Lower Level)
	Track 4: It's All About the Data! From Case Report Forms to Datasets, What Does FDA Need to Approve your Submission?	White Flint (Lower Level)
3:15-4:15PM	Refreshment and Networking Break in the Exhibit Hall	Ballroom A-D
4:15-5:30PM	**Session 8:** BREAKOUT SESSIONS	
	Track 1: Establishing Data Quality & Data Governance Frameworks	
	Track 2: Perspectives on IDMP	White Oak
	Track 3: Acquiring the Knowledge to Survive a Merger - Pregame and Post-game	Brookside (Lower Level)
	Track 4: eCTD Future	White Flint

DAY THREE | WEDNESDAY, FEBRUARY 16		ROOM
7:30AM-2:00PM	Registration	Ballroom Foyer
7:30-8:30AM	Networking Breakfast in the Exhibit Hall	Ballroom A-D
8:30-9:45AM	**Session 9:** BREAKOUT SESSIONS	
	Track 1: The Only Constant is Change; How Will Emerging Data Standards Affect Global Regulatory Processes	Ballroom FGH
	Track 2: Key Intelligent Automation and Advanced Technology Use Cases in Regulatory	White Oak
	Track 3: From Sites to Health Authorities – Lessons Learned on Document Preparation and Exchange	Brookside
	Track 4: Managing Chaos, Time and Submissions: Organizing and Executing Global Submission Strategy	White Flint

9:45-10:30AM	Refreshment and Networking Break in the Exhibit Hall	Ballroom A-D
10:30AM-11:45AM	**Session 10:** BREAKOUT SESSIONS	
	Track 1: Enhancing the Utilization of RIM with Emerging Use Cases	Ballroom FGH
	Track 2: Cross-industry Collaboration and Cross-functional Integration of Data	White Oak
	Track 3: CTD Structured Authoring and the Shift Away from Documents	Brookside
	Track 4: Making Digital Transformation Real	White Flint
11:45AM-1:15PM	Networking Luncheon in the Exhibit Hall	Ballroom A-D
1:15-2:00PM	**Session 11:** FDA - Ask the Regulators	Ballroom E-H
2:00-2:15PM	**Closing Remarks**	Ballroom E-H
2:15PM	**Forum Adjourns**	

Track Descriptions

Track 1: Regulatory Informatics Business - This track addresses processes for obtaining and managing regulatory information in the form of data through data management, governance, change control, organizational impact, standards, and key issues shaping the global regulatory and business environments.

Track 2: Regulatory Informatics Technology - This track focuses on technology and solutions for managing data, extrapolating, and developing analytics, and emerging technologies to support data control and enhancements.

Track 3: Electronic Document Management (EDM) - This track examines the processes, systems, and best practices for content management across the product lifecycle, including alignment with the RIM system for optimal use of regulatory information.

Track 4: Electronic Regulatory Submissions (ERS) - This track explores the submission planning and execution processes, considering regulatory requirements and new industry developments as well as internal reg ops best practices and alignment.

Continuing Education Credit

Drug Information Association (DIA) is accredited by the International Association for Continuing Education and Training (IACET) and is authorized to issue the IACET CEU.

As an IACET Accredited Provider, DIA offers CEUs for its programs that qualify under the ANSI/IACET Standard. DIA is authorized by IACET to offer up to .6* CEUs for this program.

***IACET CEUs are only available for Short Courses. Participants must attend the entire program in order to be able to receive an IACET statement of credit. No partial credit will be awarded.**

IACET CEUs will be offered if you attend the live virtual Short Courses on February 8 & 9, 2022. Credit will not be awarded for attending the Primer and Forum sessions.

Continuing Education Credit Allocation

February 8, 2022 – Short Course #1: The Future of Documents: Deep Dive into Structured Content; .3 CEUs

February 9, 2022 – Short Course #2: Structured Data: IDMP is Not the Goal; .3 CEUs

Continuing Education Credit and My Transcript

If you would like to receive a statement of credit for the days you attend the live virtual short courses, you must virtually attend the one or both short course(s), in their entirety, achieve a passing score of 80% or better on the post-assessment, and complete the program evaluation and request CE credit online through My Transcript (see instructions below). Participants will be able to download a statement of credit upon successful submission of the credit request. My Transcript will be available for credit requests beginning **Wednesday, March 2, 2022**.

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- Select **My Account** from the menu
- Select **My Transcripts** then **Manage My Transcripts**

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- 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.*

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.

DIA staff members have no relevant financial relationships to disclose.

To view DIA's Disclosure and Grievance Policies, visit **DIAglobal.org/CE**

Learning Objectives

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

- Explain the regulatory electronic submission process from the completion of its upload to the Electronic System Gateway (ESG) through the time the submission is made available to the review team
- Discuss the agency target time frames for the 1) expected submission upload duration(s) and 2) timeframe between key milestones and notifications
- Describe the current required data standards for regulatory submissions and the status of ongoing data standards initiatives
- Describe organizational processes and governance to ensure integrity, quality, and security of regulatory information (data, documents, records)
- Examine the scope and assess the future of data standards, including IDMP, with respect to systems, processes, and master data
- Discuss ways data can be harmonized, integrated, and viewed to provide an end-to-end view of the regulatory information value chain
- Discuss organizational implications related to increasing electronic interactions with stakeholders and health authorities
- Explain ways to improve processes and communication of regulatory activities including communications, end-to-end processes, and integration of systems for document, submission, and records management
- Interpret global health authority regulations and guidance's for systems and business processes
- Identify ways in which the integration of data, documents, and knowledge can be leveraged to develop insights and enable better business decisions
- Identify changes in submission-related regulations impacting Regulatory Informatics business processes

SHORT COURSE | TUESDAY, FEBRUARY 8

Sessions are held in ET

10:00AM-1:30PM

Virtual Short Course: The Future of Documents: Deep-Dive into Structured Content

Short Course requires an additional registration fee. You do not need to be registered for the Forum to attend

The Future of Documents is shaped by a fundamental change in how information is shared. This future sees a shift from traditional 'e-paper', formatted and optimized for reading by humans, towards semantically tagged information in an open digital format. This course is for anyone involved in regulatory or documentation processes in an organization that is implementing structured content or is exploring to do so.

Learning Objectives

- Define structured content and the various terms used: components, structure, semantics
- Analyze strategies for content reuse: what differentiates successful from unsuccessful practices
- Compare challenges in Life Sciences with those in other industries
- Formulate a feasible plan forward to the implementation of structured content, and complete some hands-on exercises

Instructor

Jan Benedictus, MSc, Chief Executive Officer, Fonto

SHORT COURSE | WEDNESDAY, FEBRUARY 9

10:30AM-1:30PM

Virtual Short Course: Structured Data: IDMP is Not the Goal

Short Courses requires an additional registration fee. You do not need to be registered for the Forum to attend

As the EMA has changed the implementation approach for IDMP, we take a step back to understand the business imperative for managing data at an enterprise level and how to translate internal processes into various structured formats. We will also give participants a status update on ongoing initiatives such as IDMP, PQ CMC, ePI and KASA among others and look at these standards under the lens of enterprise data management.

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

- Explain the benefits of enterprise information management and analyze how to deploy these in their organization
- Define the next steps for EMA IDMP, SPOR and DADI and FDA PQ-CMC data updates for the next 6-12 months
- Recognize additional data opportunities that arise with emerging standards and define approaches to address these in their organization

Instructors

Hans van Bruggen, MSc, Chief Executive Officer and Senior Regulatory Affairs Consultant, Qdossier, The Netherlands

Kate Wilber, Director, Regulatory Information Management, Vertex Pharmaceuticals

PRIMER | SUNDAY, FEBRUARY 13 — ROOM

9:30-10:00AM — **Regulatory Content and Submission Primer Registration** — Forest Glen Foyer (Lower Level)

This Primer Course requires an additional registration fee. You do not need to be registered for the Forum to attend

10:00AM-5:00PM — **Regulatory Content and Submission Primer:** Content from Authoring to Archive *(In-Person Exclusive)* — Forest Glen Foyer (Lower Level)

This Primer Course requires an additional registration fee. You do not need to be registered for the Forum to attend

This Primer is only offered in-person and will not be recorded. Live attendance is required.

These talks are designed to meet the needs of individuals who are either new to biopharmaceutical-based regulated document management, information management, and regulatory submission publishing for authorities or already experienced in one area looking to gain a broader understanding. This Primer will present the full spectrum of the regulatory submission, information, and document management arena. Understanding the various steps throughout the life of document components from their authoring, publishing to PDF, assembling into a submission, delivery to regulatory agencies, and ultimately company archival will yield "aha" moments for the attendees of this offering from all functions along the lifespan of regulatory content.

Hands-on exercises will provide the attendees the ability to apply material as the day progresses. Participation in anonymous interactive polling will allow for sharing your understanding of the material, experiences, and hear fellow attendees.

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

- Describe the benefits of understanding the complete life phases of regulatory content and the impact that decisions in one place along the life path will have at other stages of the process
- Identify key drivers within each of the life phases and potential pros and cons associated with solution choices
- Recognize the needs of the other organizations involved within the lifespan of the regulatory content and fairly assess their concerns in process and procedure decision-making
- Comprehend the newly released regulations, guidelines, and industry best practices and gain an awareness of their impact

Instructors

Betsy Fallen, RN, Consultant, BAFallen Consulting, LLC

Dan Orfe, MS, President, Regulatory eSubmissions, LLC

DAY ONE | MONDAY, FEBRUARY 14 — ROOM

8:30-9:00AM — **BONUS Session Registration** — Ballroom Foyer (Upper Level)

**No additional fee or separate registration is required. This Workshop is open to all*

9:00AM-12:00PM — **BONUS Session:** RIM Reference Model 1.0 – Validation Workshop *(In-Person Exclusive)*

Session Chair

V. "Bala" Balasubramanian, PhD, MBA, Senior Vice President and Global Head, Healthcare and Life Sciences, Orion Innovation

This optional workshop is only offered in-person and will not be recorded.

The RIM Reference Model Working Group core team was formed in February 2019 to begin work on defining and building a baseline data/information model in order to address common needs of sponsors

and support effective implementation of Regulatory Information Management (RIM) solutions. The objective has been to enable regulatory and other functional areas to have better line of sight of regulatory activities and related information by defining component objects/concepts and relationships as well as common terminology. Such common terminology will not only be the basis for a "starter kit" for organizations looking to bootstrap their RIM initiatives from a user requirements perspective but also form the basis for interoperability, a template for potential RFPs and data exchange in a mergers and acquisition scenario. An extended team was formed at the RSIDM 2020 roundtable session, with representation from drug sponsors, software vendors and service providers. A draft version of a Reference Model was developed and shared at RSIDM 2021. Since then, the RIM Working Group has further developed the model, shared with industry sponsors/vendors, and received feedback.

This complimentary workshop will feature a recap of the RIM Reference Model structure and content along with feedback received from the industry. A live demonstration of the model will show how "objects and data elements" relate to regulatory activities and regulatory objectives. The team will also present a validation exercise using CMC Variation as an example to validate the proposed reference model data elements. The intent of this session is to encourage industry and vendor participation to further validate the work done so far and uncover any opportunities for the use of intelligent automation in support of the CMC Variation process. At the end of this exercise, the team is looking to formally release Version 1.0 of the Reference Model for industry/vendor use.

In addition, there will be an update by the DIA RIM AI Working Group regarding progress made by the group around AI use cases and call for industry participation.

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

- Contribute to the establishment of a best practices framework for managing regulatory information and processes
- Understand the benefit and structure of the RIM Reference Model and apply the structure, content, and nomenclature to RIM planning, design, and implementation activities
- Provide input to DIA RIM AI Use Cases

Instructors

Vanessa Brewer-Yizar, Sr. Manager, Regulatory Affairs Consultant, Ipharmaquest Inc

Joel Finkle, Associate Director, Regulatory Information Management, BeiGene

Vahe Ghahraman, PhD, Senior Director, Global Regulatory Operations Head, Apellis Pharmaceuticals, Inc.

Donald Palmer, MA, Senior Regulatory Affairs Director; Business & Technology Transformation, IQVIA, Inc.

Patterson Shafer, Managing Director, FTI Consulting, Inc.

Cary Smithson, MBA, Director, Regulatory Solutions, PhelxGlobal

11:00AM-5:25PM **Forum Registration** Ballroom Foyer (Upper Level)

1:00-1:25PM **Welcoming Remarks and Presentation of the Excellence in Service Award** Ballroom E-H

Speakers

V. "Bala" Balasubramanian, PhD, MBA, Senior Vice President and Global Head, Healthcare and Life Sciences, Orion Innovation

Karen McCarthy Schau, Director, Adaptive Monitoring, Vertex Pharmaceuticals

Peter Terbeek, MBA, Senior Director, Regulatory Operations, Astellas

Ethan Chen, MBA, Director, Division of Data Management Services and Solutions, OBI, OSP, CDER, FDA

Congratulations to our 2022 Excellence in Service Awardee

Brooke Casselberry, MSRA, Senior Director, US Life Sciences Advisory and Consulting, NNIT, Inc.

1:25-2:00PM

Session 1: Keynote Address - How To Think Like an Innovator in a World of Uncertainty

Gautam Gulati, MD, MPH, MBA, Co-Founder and Chief Executive Officer, Well Played

Change is here. And the pandemic has only made it certain that we will resurface with new models of care and delivery. The question is, "Are you prepared and what will you do?" There are two types of people...those who resist change seeking to preserve the status quo, and those who embrace change forging a new path forward. This inspiring, humorous, and action-oriented talk will help prepare leaders to think like an innovator to help create the future they envision.

2:00-2:45PM

Refreshment and Networking Break in the Exhibit Hall Ballroom A-D

2:15-2:45PM

Exhibitor Event: Case Study Spotlight hosted by Genpact *(Virtual Exclusive)*

Regulatory Execution of Mergers, Acquisitions, and Divestitures

Execution of mergers, acquisitions, and divestitures – regardless of asset size or stage – create extra work, extra risk, and can be disruptive to the everyday activities of regulatory teams. Seamless integration across regulatory, quality, and supply is critical to the overall success of large transactions and is essential to realize their full value. Join Kyle Fliszar, M&A regulatory transformation lead, Genpact, to explore the tools and best practices to transform regulatory execution, easing manual time-intensive tasks to enable regulatory teams to focus on adding value. Together we'll uncover ways to deepen the connection between regulatory, quality, and supply to deliver a successful transaction end to end.

Featured Topics

- The tools and best practices to transform regulatory execution end to end
- Effective execution planning and delivery to mitigate risk and revenue loss
- Creating a deeper connection between regulatory, quality and supply
- Digitalization for integration and harmonization of regulatory, quality, and supply chain data

Kyle Fliszar, PhD, Vice President, M&A Regulatory Transformation, Genpact

Separate RSVP is required. ***Click here to RSVP.***

Separate RSVP is required for each event. These sponsored sessions are open to all, including those not registered for the full forum. These sponsored sessions are separate to the forum content included in registration. Upon completion of your RSVP a login link will be sent to you for the session. By registering for this sponsored session, you are agreeing to share full contact information with the Solution Provider. You also understand that the Solution Provider, and DIA, may contact you with messages regarding products and/or services.

2:45-4:00PM

Session 2: FDA Strategy on Data and Technology Modernization Ballroom E-H

Session Chair
Ethan Chen, MBA, Director, Division of Data Management Services and Solutions, OBI, OSP, CDER FDA

FDA is focused on a strategic approach not only to technology, but to data itself. Data is at the heart of FDA's work as a science-based Agency, and there is anticipation of ongoing, rapid increases in the amount and complexity of the data that will inform regulatory decision-making and its public health mission. Leaders from the FDA's Office of Information Management and Technology, CDER's Office of Strategic Programs and Office of Business Informatics, and CBER Office of Director will discuss data topics, for instance, standards, analytics, cloud utilization, and artificial intelligence.

Update of the FDA Data Modernization Action Plan
Ram Iyer, MS, Chief Data Officer, FDA

CDER's Progress in Cloud Utilization, Data Analytics, and Drug Supply Chain
Sridhar Mantha, MBA, MS, Director, Office of Business Informatics, CDER, FDA

CBER's Informatics Modernization Update
Christopher Joneckis, PhD, Associate Director for Review Management, CBER, FDA

CBER Data Standards Update
Virginia Hussong, Chief, Data Standards Program, CBER, FDA

4:10-5:25PM — **Session 3:** Progress Towards Structured Submission Documents: ICH M11 and the Clinical Electronic Structured Harmonized Protocol (CeSHarP) — Ballroom E-H

Session Chair
Stacy Tegan, Associate Director, Program Management, Transcelerate Biopharma Inc

All clinical content and data trace their origins to the clinical study protocol. Currently there is no internationally harmonized format or content standards for the protocol document. It's often submitted as essentially electronic paper (PDF) with limited ability to leverage the wealth of information with. The lack of a structured, electronic, harmonized protocol contributes to inefficiencies and difficulties in reviewing and assessing clinical protocols across stakeholders. This session will provide an depth overview of the ICH M11 Clinical electronic Structured Harmonized Protocol (CeSHarP) including the latest developments on an (1) international guideline, (2) protocol template, and (3) internationally accepted technical specification (implementation guide) to promote development of structured and unstructured protocol content, application of international data standards, and interoperable/compatible electronic exchange.

Speakers
Vivian Combs, MS, Advisor/Process Owner, Clinical Systems and Supply Planning, Eli Lilly and Company

Ronald Fitzmartin, PhD, MBA, Senior Informatics Advisor, Office of the Director, CBER, FDA

Mitzi Allred, PhD, Director, Clinical Operations, Merck & Co., Inc.

Panagiotis Telonis, Scientific Administrator, Data Standardization and Analytics Department, European Medicines Agency (EMA), The Netherlands

5:25-6:30PM — **Networking Reception in the Exhibit Hall** — Ballroom A-D

DAY TWO | TUESDAY, FEBRUARY 15 — ROOM

7:30AM-5:30PM — **Registration** — Ballroom Foyer

7:30AM-8:30AM — **Networking Breakfast in the Exhibit Hall** — Ballroom A-D

8:30-9:45AM — **Session 4:** FDA Electronic Submissions — Ballroom E-H

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

This session will cover the latest information on eCTD related guidance/specification CDER submission mechanisms for certain types of content not required in eCTD, and updates on PQ/CMC and KASA. The presentations topics include eCTD, CDER's NextGen Portal, CDER's new Research IND application submission mechanism in the CDER NextGen Portal FDA Forms, and PQ/CMC and KASA. FDA will provide an update on submission metrics, processing challenges, and best practices for successful submission.

Electronic Submission Update
Jonathan Resnick, PMP, Project Management Officer, OBI, OSP, CDER, FDA

CDER NextGen Portal and Research IND Application Builder
Seyoum Senay, Supervisory Operations Research Analyst, CDER/OBI, FDA

FDA Forms Update
Daniil Graborov, Computer Scientist, CDER/OBI, FDA

PQ/CMC and KASA
Norman Schmuff, PhD, Associate Director for Science, OPMA, OPQ, FDA

9:55-10:45AM **Session 5:** FDA - Ask the Regulators — Ballroom E-H

Session Chair
Ethan Chen, MBA, Director, Division of Data Management Services and Solutions, OBI, OSP, CDER, FDA

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.

Please note: due to the high volume of questions, not all will be answered live at the forum

Speakers
Virginia Hussong, Chief, Data Standards Program, CBER, FDA

Ram Iyer, MS, Chief Data Officer, FDA

Sridhar Mantha, MBA, MS, Director, Office of Business Informatics, CDER, FDA

Christopher Joneckis, PhD, Associate Director for Review Management, CBER, FDA

10:45-11:15AM **Refreshment and Networking Break in the Exhibit Hall** — Ballroom A-D

11:15AM-12:30PM **Session 6:** BREAKOUT SESSIONS

Track 1: Application of RIM in Medical Devices – Challenges and Opportunities for Automation — Ballroom FGH

Session Chair
Vahe Ghahraman, PhD, Senior Director, Global Regulatory Operations Head, Apellis Pharmaceuticals, Inc.

This session focuses on topics related to implementation of RIM in medical device settings. It presents unique challenges faced in such implementations and contrasts with those of the implementation for a biopharmaceutical company. A case study on process automation for a RIM business process in a life sciences company is also presented.

Digital Trends in Post Market Surveillance for Medical Devices (and IVDs)
Adam Price, Director of Product, Post Market, Rimsys

Addressing the Unique Challenges of RIM for Med Devices
Brian Williams, Managing Director, Life Sciences Consulting, KPMG

Case Study: Implementing RIM Business Process Automation at a Biopharmaceutical Company
James Nichols, Chief Product Officer, Phlexglobal

Track 2: Driving Data Integration, Data Governance, and Data Quality Monitoring Through Data Standards — White Oak (Lower Level)

Session Chair
V. "Bala" Balasubramanian, PhD, MBA, Senior Vice President and Global Head, Healthcare and Life Sciences, Orion Business Innovation

This session will focus on several aspects related to data unification, data integration, data governance, and data quality monitoring through emerging data standards such as IDMP:

1. We will start with a case study of a large OTC products company defining their core product data by adopting ISO IDMP as a global data framework to be used across regions and functions and to unify data across disconnected systems using standardized vocabularies. This core product data can be leveraged across multiple functions and systems to allow end-to-end traceability from R&D to sales.
2. We will see how cloud technologies are being leveraged at another large pharmaceutical company to support emerging requirements of IDMP, PQCMC, and structured data submissions. This is accomplished through data integration, data governance, and data quality monitoring approaches that result in unambiguous data. Techniques such as data quality scorecards and data quality tools will be reviewed.

3. We will explore how organizations can get ready to meet IDMP requirements through the assessment of data sources and data quality through the use of intelligent data mapping and reporting techniques. Automated data quality solutions can enable efficient data mapping, identification of data gaps in IT-systems and documents and provide reporting dashboards for data quality issues and corrections. These outputs can then be utilized to bridge process gaps and develop an implementation strategy with high degree of confidence regarding data quality.

Delivering Unified data with Disconnected Systems Through Adoption of ISO IDMP Data Standards
Stephen Blanchard, MS, IDMP Programme Lead, Johnson & Johnson Consumer Health, United Kingdom

Leveraging Cloud Technologies for Data Integration in Regulatory
Donna Yosua, Director, Master Data Management & Data Governance, Merck & Co., Inc.

Accelerating IDMP Readiness: Intelligent Data Mapping and Optimized Business Processes
Katherine Novak, MS, Advanced Advisory Consultant, NNIT

Track 3: Inspection Readiness: Different Approaches to Inspection Readiness with Real-World Case Studies and Inspection Outcomes from Sponsors

Brookside (Lower Level)

Session Chair
Jamie O'Keefe, Vice President, Business & Technology Consulting, Just in Time GCP

Discussion on the approaches to inspection readiness with real-world case studies and inspection outcomes from sponsors. We will discuss different approaches to study level inspection readiness:

1. Reactive: Based upon an anticipation of an audit or audit request, performing IR reviews, identifying gaps and issues, and taking a risk-based approach to remediation & storyboarding
2. Pro-active: Establishing Inspection Readiness processes and a culture of inspection readiness throughout clinical trial management, and implementing across all studies
3. Hybrid: Based upon an understanding that certain programs are not inspection ready, execute an IR review program, and leverage the findings to not only remediate the specific programs, but establish new processes and culture across the portfolio

Speakers
Donna Dorozinsky, Chief Executive Officer, Just in Time GCP

Jaclyn Verrow, Director, Head of TMF Compliance and Oversight, Vertex Pharmaceuticals, Inc.

Gabriela Stanescu, Lead Clinical Project Manager, Chiesi Canada Corporation

Representative Invited, Beigene

Track 4: Structured Content: Where Are We Now, Where Are We Going, and Practical Applications

White Flint

Session Chair
Demetra Macheras, MBA, Director, Regulatory Policy and Intelligence - Regulatory Affairs, AbbVie, Inc.

This session will provide a high-level overview of the benefits, and lessons learned of structured authoring/structured content management implementation through the use of interactive audient polling and feedback from industry interviews. Presenters will discuss the history of structured file formats and the requirements and submission formats in the U.S., Health Canada, and the EU, including:

- U.S. FDA implementation of SPL, XML, and REMS
- Health Canada's implementation of XML PM and the evolution of the Product Monograph to the 2020 format
- EMA SPOR implementation program and how to take advantage of early timelines

Structured Authoring/Structure Content Management – Industry Experience and Lessons Learned
Stacy Tegan, Associate Director, Program Management, TransCelerate Biopharma, Inc.

Practical Application of Electronic Labeling Adoption in US, Canada, and EU
Gary Saner, Senior Manager, Information Solutions - Life Sciences, Reed Tech

David Wilson, Senior Account Executive, Reed Tech

12:30-2:00PM **Networking Luncheon in the Exhibit Hall**

2:00-3:15PM **Session 7:** BREAKOUT SESSIONS

Track 1: Innovation Across the Regulatory Spectrum: A Call to Action for Industry Ballroom FGH

Session Chair
Jake Doran, Head of Global R&D IT, Bausch Health

While innovative technology in other areas of drug accelerate the capacity for organizations to do more with less or support larger product portfolios, limitations to regulatory process and technology have become an impediment. Further upstream, innovations and advanced analytics and artificial intelligence drive broader molecule evaluation through advanced modeling and simulation. How can we look to technology for similar advancements in the Regulatory environment? During this session we will have an interactive discussion around how the industry needs to embrace innovation and look to the future, while diving into details around a few important areas that can ignite and accelerate advancement.

Panelists
Meredith Sewell, Executive Director, Head of Global Regulatory Operations, Sarepta Therapeutics

Matthew Neal, MA, Senior Director, Regulatory Affairs Operations, Atara Biotherappeutics

Daniel Chen, PhD, Senor Consultant, Veeva Systems, Canada

Track 2: Implementation Experience Sharing: Next-generation Global RIM Solutions White Oak

Session Chair
Michiel Stam, Head of Data Management and Regulatory Information Scientist, Qdossier, The Netherlands

In this session the presenters will share their vision and experiences of implementing global next-generation RIM solutions. Installing a RIM solution may be near ready for use, in theory, especially when cloud-based and pre-configured. However, the effort required by the Company to gain knowledge about the software and make significant adaptions to align with business processes and roles and responsibilities is significant, especially when implementing on a global scale. The presenters will share lessons learned and practical challenges the team experienced. The presentation will highlight the importance of realistic project scoping, planning and organization (including managing expectations), configuration, data migration and remediation, business process implementation and change management. These experiences and lessons learned are valuable for anyone who is about to/currently experience a similar update.

Lessons Learned from Data Management and Data Migration Aspects of a Global RIM Implementation Program
Dominik Gigli, Principal Consultant, Main5 GmbH & Co. KGaA, Germany

A RIM Implementation Case Study; Can RIM be Simply Taken Out of a Box?
Michiel Stam, Head of Data Management and Regulatory Information Scientist, Qdossier, The Netherlands

The Journey to World-class RIM – AbbVie's Future State Vision for Implementation of Global RIM Systems and Processes
Eric Caldwell, MA, Director, Process Excellence Regulatory Affairs, Abbvie

Track 3: Rethinking Documents: The Digital Content Revolution — Brookside (Lower Level)

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

This session will challenge the audience to think about the evolution from paper documents to digital content. We will share a use case for an EDM implementation at National Institute of Allergy and Infectious Diseases (NIAID), then transition to discussing the future of Regulated Transactions. Finally, we will dive into structured content authoring and management and share examples from pharma and other industries.

Accelerating Compliant Digital Transformation and Optimizing EDM Workflows
Kimberly Sivanathan, MPH, Quality Management Analyst, NIAID

Matthew Eisenberg, Chief, Business Process and Information Management Branch, NIH

Operationalizing Regulatory Content: A Future of Regulated Transactions
Karen Jones, Head of Product, Accumulus Synergy

The Future of Documents: Structured Content and Integrated Data
Jan Benedictus, MSc, CEO, Fonto, The Netherlands

Track 4: It's All About the Data! From Case Report Forms to Datasets, What Does FDA Need to Approve your Submission? — White Flint (Lower Level)

Session Chair
Stacy Tegan, Associate Director, Program Management, TransCelerate Biopharma, Inc.

Years of product development, intricate planning of study execution, patients serving as study participants – it all comes down to the data. Electronic submissions bring the journey of the data to life for reviewers. It starts with recording the data. Learn how to overcome challenges of incorporating Case Report Forms into "reviewer friendly" submissions while balancing the need for efficiency. Study data then has to be tabulated and analyzed. With the best practices to be shared in this session, publishing CDISC compliant datasets will no longer be an intimidating process.

Once that data arrives at FDA, it must pass validation to make it to the reviewer. Learn about the new validation criteria put into effect in September 2021, common reasons for rejection, and tools to help avoid these errors. Once submitted, FDA must assure the quality and integrity of the data. Learn about CDER's Bioresearch Monitoring (BIMO) program's requirements for new marketing applications.

Let's Talk About Case Report Forms (CRFs)
Evan Richardson, RAC, Director, Regulatory Services, Certara Synchrogenix

Publishing Datasets: What You Need to Know (and What You Don't Need to Know)
Mckenzie Orchowski, MS, Associate Director of Regulatory Operations, Biologics Consulting

Study Data Technical Rejection Criteria
Heather Crandall, Operations Research Analyst, OBI, OSP, CDER, FDA

CDER's Bioresearch Monitoring (BIMO) Requirements for New Drug and Biologic Licensing Applications
Jean Mulinde, MD, Medical Officer, Policy Advisor, Division of Clinical Compliance Evaluation, OSI, CDER, FDA

3:15-4:15PM **Refreshment and Networking Break in the Exhibit Hall** — Ballroom A-D

4:15-5:30PM

Session 8: BREAKOUT SESSIONS

Track 1: Establishing Data Quality & Data Governance Frameworks

Session Chair
Kristen Sauter, MBA, Director, Global Regulatory Informatics & Analytics, Takeda Pharmaceuticals

As industry is advancing the approaches to regulatory information management and the systems that contain their data, there is a heightened focus on the need for comprehensive data governance frameworks and sustainable data quality programs. This session will address:

1. Data Quality: The degree to which data in an organization meets the needs of the users and expectations of consumers is often measured by accuracy, validity, completeness, and consistency. And, defining and implementing a comprehensive approach to data quality is a critical component of a success for any organizations RIM program.
2. Data Governance: Given the increased complexity of the and demand for transparency, managing registrations and sharing regulatory data is critical and necessitates the need for organizations to establish robust approaches to data governance

Data Quality Sustainability - Improving Data Governance
Steve Gens, MS, Managing Partner, Gens and Associates Inc.

Implementing a Data Governance Program for Your RIMS
Samuel Thompson, Managing Consultant, NNIT

Track 2: Perspectives on IDMP

White Oak

Session Chair
Danielle Beaulieu, PhD, Senior Director, Global Regulatory Business Capabilities, Bristol-Myers Squibb

It is well known that IDMP is more than a regulatory problem. This session will focus on two benefits of implementing this standard, no matter the size of your enterprise: 1) leveraging your IDMP program to implement enterprise-wide data governance and standards, and 2) leveraging your newly defined IDMP process to ensure your enterprise is moving toward structured data. We will cover the thought process needed to be successful, potential interim solutions you might need to consider, how to include automation (or not!), planning your process to cover the target operating model, gather the data at the beginning instead of the end, how to handle guidance changes and their impact to what you have already done, and what your deliverables should be to complete the project.

A Small Biotech/Small Company Perspective on IDMP Assessment and Implementation
Scott Cleve, Vice President Regulatory Operations and Compliance, Bluebird Bio

Case Study: Practical Approach to IDMP Implementation for Regulatory Teams
Thomas Denaro, Senior Business Analyst, Orion

Isabel Esteve Garcia, MSc, Associate Director, Global Regulatory Business Capabilities Strategist, Bristol-Myers Squibb

Track 3: Acquiring the Knowledge to Survive a Merger - Pregame and Post-game

Brookside (Lower Level)

Session Chair
Divya Gangaramani, PhD, RAC, Senior Regulatory Specialist, VIR Biotech

The acquisition of one large organization by another can bring unique challenges when both come with their own mature fully compliant regulatory process documentation. This session led by Rich Fredericks, Head of Regulatory Operations and Technology, will touch on many of the steps involved leading up to and during an acquisition from a RIM System Administrator perspective as well as hear from a sponsor with a rich history in the process. The session will cover how a RIM team can 'future ready' their system and process to ensure any future acquisition/merger activities run as simple as possible.

Often processes are common to both organizations, but there are always wild cards which are discovered and must be addressed. Betsy Fallen, Regulatory Consultant, will share details of the project planning and execution and how the wild cards were managed. Best Practices and considerations which may apply to mergers as well as any large-scale documentation renovation will be shared.

So You've Been Acquired - Now What? Navigating an Acquisition From a RIM Perspective
Richard Fredericks, Director, Regulatory Operations and Technology, Black Diamond Therapeutics

Merger Acquisition - Global Process Documentation Integration: Playing the Long Game
Betsy Fallen, RN, Consultant, BAFallen Consulting LLC

Track 4: eCTD Future — White Flint

Session Chair
Rob Labriola, MS, Senior Director, Regulatory Operations, Synchrogenix

It's been seven years since Health Level Seven (HL7) approved the Regulated Product Submissions (RPS) standard, and six since ICH approved it to Step 4 as the basis for eCTD 4.0. Various reasons, from software updates to COVID-19, have kept it from being implemented, with only Japan reaching the pilot stage. So, what are we missing out by not having it? We will share the value and benefits software vendors; health agencies and drug sponsors will gain by moving forward with eCTD 4.0.

eCTD 4.0 – We're Ready Already
Joel Finkle, Associate Director, Regulatory Information Management, BeiGene

eCTD 4.0 - No Need to be Afraid
Frank Dickert, Business Consultant, EXTEDO Gmbh, Germany

Looking Towards the Future of eCTD
Daniel Smith, Business Analyst, RIM, Calyx, United Kingdom

ICH Update: Progress on M4Q
Sarah Pope Miksinski, PhD, Senior Director, Global Regulatory Affairs, AstraZeneca

DAY THREE | WEDNESDAY, FEBRUARY 16 — ROOM

7:30AM-2:00PM — **Registration** — Ballroom Foyer

7:30-8:30AM — **Networking Breakfast in the Exhibit Hall** — Ballroom A-D

8:30-9:45AM — **Session 9:** BREAKOUT SESSIONS

Track 1: The Only Constant is Change; How Will Emerging Data Standards Affect Global Regulatory Processes — Ballroom FGH

Session Chair
Jo English, Vice President, Regulatory Information Management, Calyx, United Kingdom

Regulatory Operations is continually being challenged with new standards and data requirements from global health authorities. Join the panel of experts to understand how some of the latest standards (PQ-CMC, KASA) will impact your business processes and what you can do to start planning for their implementation. The panel will build on your knowledge of these emerging standards and take a deep dive to understand the true business implications.

PQ-CMC and Its Interaction with IDMP and Other Emerging Standards
Karen Harry, Director, Regulatory Information Management, Calyx, United Kingdom

Identifying the Business Impact of PQ-CMC
Rodrigo Palacios, MBA, Regulatory Policy Lead, F. Hoffmann-La Roche, Switzerland

Overview of KASA and Its Implications on Current Business Process
Vada Perkins, DrSc, MSc, Executive Director, Regulatory Policy and Intelligence, Bayer Pharmaceuticals

Track 2: Key Intelligent Automation and Advanced Technology Use Cases in Regulatory — White Oak

Session Chair
Jake Doran, Head of Global R&D IT, Bausch Health

This session provides an update on DIA RIM AI Team use case definition, AI effort prioritization recommendations, leading practices and shares how sponsors are using AI to streamline document classification and information retrieval, migration, and end-to-end label management.

DIA RIM Working Group Update on Intelligent Automation Use Cases in Regulatory
Cary Smithson, MBA, Director, Regulatory Solutions, PhlexGlobal

Using Structured Content Authoring to Optimize the Label Management Process
Jenny Shu-Hui Chang, MS, Director, Labeling Digital Enablement and Innovation Management, Merck Sharp & Dohme, Taiwan

AI Based Document Auto Classification and Entity Extraction
Nirjhar Sarkar, MS, Associate Director, Technology Transformation, Novartis, India

Track 3: From Sites to Health Authorities – Lessons Learned on Document Preparation and Exchange — Brookside

Session Chair
Karen McCarthy Schau, Director, Global Clinical Operations, Vertex Pharmaceuticals

An electronic document exchange system between clinical sites and a sponsor or CRO eTMF system has many benefits. There are also many challenges with regard to procedures, communications, training and user onboarding. The decision to deploy this technology to sites requires a long term commitment to building and maintaining integrations, streamlining user onboarding/offboarding and user support. The technology for electronic document exchange with clinical sites continues to evolve but is still not widely adapted. A sponsor company will describe their strategy and experience with electronic document exchange technologies with eTMF.

Regulatory submissions are one of the most critical milestones for Life Sciences organizations and can consist of thousands of documents. Submitting on time & in full compliance with regulatory agencies' requirements, remains a challenge due to the process of authoring, reviewing, updating & formatting in tools like MS Word to strict guidelines before conversion for inclusion in dossiers. Life Sciences organizations adopt cutting-edge technology, but the technology alone doesn't guarantee compliance & that timelines are met. Efficient processes combined with technology does.

Regardless of the vendor and technology selected, you will learn about the challenges, benefits and the commitment to organizational change management that is required to achieve a successful deployment of both streamlined document preparation processes and document exchange.

Electronic Document Exchange with Clinical Sites: Lessons Learned
Michael Agard, MS, RPh, Managing Consultant, NNIT

How to Auto Check & Fix Word + PDF Content to Reduce the Risk of Non-compliance
Paul Ireland, Vice President, Life Sciences, DocShifter, Belgium

Jennifer Arters, eClinical Manager eTMF and Collaboration, CSL Behring

Track 4: Managing Chaos, Time and Submissions: Organizing and Executing Global Submission Strategy — White Flint

Session Chair
Sandra Krogulski, MA, Associate Director, Submission Management, Bristol-Myers Squibb Company

Companies are looking to ensure patients across the globe benefit from new and innovative medicines they are developing. To operations and submission management organizations, this means searching for new and innovative ways to manage global submissions. Teams need to maximize agility, absorb changes in volume, and ensure continuous improvement all while working to support mutliple different specifications, information requests and often submission format. As we look towards to the future of

submissions and eCTD, companies must ensure that they are familiar with the requirements for new regions adopting eCTD and understand the impact to their submissions. This is about so much more than just technology; establishing your organizational maturity with a focus on people and processes will be key to your success.

Harmonizing and Building a Regulatory Operations Culture and Brand during a Global Pandemic
Jillian Carinci, MS, MSc, Director, Submission Sciences, Biogen

Global Submissions in a Global Company
Nichelle Sage, Associate Director, Bristol-Myers Squibb

Follow Up: Bayer's Global Submission Support
Qian Liu, MSc, Regulatory Submission Manager, Bayer Healthcare Company Limited, China

9:45-10:30AM **Refreshment and Networking Break in the Exhibit Hall** Ballroom A-D

10:30-11:45AM **Session 10:** BREAKOUT SESSIONS

Track 1: Enhancing the Utilization of RIM with Emerging Use Cases Ballroom FGH

Session Chair
Danielle Beaulieu, PhD, Senior Director, Global Regulatory Business Capabilities, Bristol-Myers Squibb

Company additional Risk Minimization Materials (aRMM) is typically tracked as a safety process related to Risk Management plans. Efficiently following the milestones associated with aRMM often starts with the label changes and includes tracking the HA submissions, the approval / endorsement as well as the distribution of the materials. Much of this information can be found in a RIM system. This session will discuss setting up your aRMM tracking to facilitate linking it to both regulatory submissions/approvals, distribution, and to label changes. The session will also include a use case for configuring a RIM system to track aRMM, including the risk management strategy for an asset and risk management plan submission tracking throughout the product lifecycle, thereby closing the loop on tracking.

Optimizing Additional Risk Minimization Measures (aRMMs) and the Direct Impact of End-to-End Labeling
Cham Williams, MS, Associate Director, Business Systems, IQVIA

Leveraging RIM to Monitor End to End Risk Management
Tracy Hernandez, Global Risk Management Lead, Publishing and Support, Bristol-Myers Squibb

Track 2: Cross-Industry Collaboration and Cross-Functional Integration of Data White Oak

Session Chair
V. "Bala" Balasubramanian, PhD, MBA, Senior Vice President and Global Head, Healthcare and Life Sciences, Orion Innovation

There is increasing demand for sharing of regulatory data and also integrating with various aspects of the drug development value chain. This session will address three major, emerging topics, namely:

1. Collaboration across the industry with the creation of a platform for Health Authorities to collaboratively review submissions. This presentation will focus on the initial Accumulus use case, derived requirements and enabling technologies, and will highlight challenges and opportunities in security, compliance, and data privacy on this industry-first collaboration platform.
2. Use of Reference Data Management (RDM) as a powerful approach to integrate data without the challenges that arise from extraction, transformation, and loading (ETL) of data. RDM enables automatically connecting data in one system to similar but not necessarily identical data in other systems, through the use of semantic equivalents.
3. Integration of regulatory data with manufacturing data for better impact analysis and decision making. This presentation will focus on practical approaches to integrate Regulatory Information Management (RIM) data with Quality Management System (QMS) data to bring in efficiencies across two functional areas.

Introduction to Accumulus: Building a First, Real-time Cloud SaaS Submission Review Collaboration Platform Shared Across HA's and Sponsor Organizations
Dominique Lagrave, PharmD, Head of Product Management, Accumulus Synergy

Reference Data Management for Semantic Interoperability and Data Sharing
Hans van Bruggen, MSc, Chief Executive Officer and Senior RA Consultant, Qdossier, The Netherlands

Linking Regulatory Data with Manufacturing Data for Better Impact Assessments
Raghu Nandan, Director, Global Delivery, R&D and Quality Domain Architect, Bristol-Myers Squibb

Track 3: CTD Structured Authoring and the Shift Away from Documents — Brookside

Session Chair
Joanne Malia, MS, MSc, Director, Clinical Documentation Management, Regeneron Pharmaceuticals

This session will discuss the paradigm shift which is needed in this industry to move away from documents to a data focus. The presenters will discuss the advantages and challenges with structured authoring and ways to provide this to business applications. Participants will be encouraged to engage into the discussion regarding the paradigm shift coming to our industry.

Shifting Focus from Document to Component Management: A New Regulatory Paradigm
Donald Palmer, MA, Senior Regulatory Affairs Director, Business & Technology Transformation, IQVIA, Inc.

Increasing Efficiencies Through Data Reuse in CTD Modules with Structured Content Authoring Integrated in Veeva
Manuela Bernhardt, MS, Business Unit Director for Technology Services, Fme US, LLC

Track 4: Making Digital Transformation Real — White Flint

Session Chair
Peter Terbeek, MBA, Senior Director, Publishing and Submission, Astellas

Can machine learning and voice assistants really help us build a regulatory intelligence system? This session will identify Digital Transformation opportunities in the submissions space and advise on how to position this type of business case within your organization. Representatives from prominent technology companies will join Regulatory Operations leads from leading Pharma companies to discuss opportunities, obstacles and how to get beyond the buzzwords to bring meaningful change.

Speakers
Olaf Schoepke, PhD, Vice President, Regulatory Solutions, Instem, United Kingdom

Susant Mallick, MBA, Leader and Evangelist, Healthcare and Life Sciences, Amazon Web Services, The Netherlands

Karin Schneider, MLIS, MS, Document Management Enablement Head, Janssen Pharmaceuticals, Inc.

Keith Schlaudecker, Associate Director, Information Integration and Label Management, Merck & Co., Inc

Jennifer Wemstrom, Life Sciences Cloud Strategist, Google

11:45AM-1:15PM — **Networking Luncheon in the Exhibit Hall** — Ballroom A-D

1:15-2:00PM — **Session 11:** FDA - Ask the Regulators — Ballroom E-H

Session Chair
Mark Gray, Senior Project Manager, DSS, CBER, FDA

Dedicated to sharing the latest information on new guidance, 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.

Please note: due to the high volume of questions, not all will be answered live at the forum

Speakers

Heather Crandall, MA, Operations Research Analyst, OBI, OSP, CDER, FDA

Jonathan Resnik, PMP, Project Management Officer, CDER/OBI, FDA

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

Ethan Chen, MBA, Director, Division of Data Management Services and Solutions, OBI, OSP, CDER, FDA

Daniil Graborov, Computer Scientist, CDER/OBI, FDA

Norman Schmuff, PhD, Associate Director for Science, OPMA, OPQ, FDA

2:00-2:15PM	**Closing Remarks**	Ballroom E-H
2:15PM	**Forum Adjourns**	