DIA

Regulatory Submissions, Information, and Document Management Forum

February 8-10 | Virtual in Eastern Standard Time

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)

THURSDAY | FEBRUARY 4

10:00AM–5:00PM ET	**Regulatory Content and Submissions Primer:** Content from Authoring Through Archive **Primer requires an additional registration fee. You do not need to be registered for the Forum to attend**

FRIDAY | FEBRUARY 5

12:30-4:00PM ET	**Short Course 1:** Regulatory Considerations for Blockchain in Clinical Research and Drug Development **Short Courses require an additional registration fee. You do not need to be registered for the Forum to attend**
12:30-4:00PM ET	**Short Course 2:** TBD

MONDAY | FEBRUARY 8

10:00-10:25AM ET	**Welcoming Remarks and Presentation of the Excellence in Service Award**
10:25-11:00AM ET	**Session 1**: Keynote Address
11:00-11:30AM ET	Break / Visit the Virtual Exhibit Hall
11:30AM-12:30PM ET	**Session 2:** FDA Plenary – Driving Data and Information Technology
12:30-1:30PM ET	Break / Visit the Virtual Exhibit Hall
1:30-2:45PM ET	**Session 3:** BREAKOUT SESSIONS **Session 3 Track 1:** Accelerating RIM Performance: Learning from Top Performers of the 2020 Industry World Class RIM Benchmark Survey **Session 3 Track 4:** Evolution from the "Global Dossier Concept" to Joint Dossier Co-Creation *OR You can view from our On-Demand Library at any time throughout the forum!*
2:45-3:15PM ET	Break / Visit the Virtual Exhibit Hall
3:15-4:30PM ET	**Session 4:** BREAKOUT SESSIONS **Session 4 Track 2:** Connecting Regulatory, Clinical, and Quality Information **Session 4 Track 3:** EDM Track eTMF Collaboration in Outsourced Studies *OR You can view from our On-Demand Library at any time throughout the forum!*

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TUESDAY | FEBRUARY 9

10:00-11:15AM ET	**Session 5:** FDA Electronic Submissions
11:15-11:45AM ET	Break / Visit the Virtual Exhibit Hall
11:45AM-1:00PM ET	**Session 6:** BREAKOUT SESSIONS **Session 6 Track 1:** The Crossroads Between Regulatory and Safety **Session 6 Track 4:** Submission Planning *OR You can view from our On-Demand Library at any time throughout the forum!*
1:00-1:30PM ET	Break / Visit the Virtual Exhibit Hall
1:30-2:45PM ET	**Session 7:** BREAKOUT SESSIONS **Session 7 Track 2:** Emerging Technologies and Data Driven Initiatives within the Regulatory Environment **Session 7 Track 3:** Merge and Go! Learning Opportunities from the AbbVie/Allergan Experience *OR You can view from our On-Demand Library at any time throughout the forum!*
2:45-3:15PM ET	Break / Visit the Virtual Exhibit Hall
3:15-4:30PM ET	**Session 8:** BREAKOUT SESSIONS **Session 8 Track 1:** Three Perspectives on Achieving Medicinal Product (Data) Quality **Session 8 Track 4:** Ad Promo *OR You can view from our On-Demand Library at any time throughout the forum!*
4:30-5:30PM ET	Virtual "Happy Hour" in the Exhibit Hall

WEDNESDAY | FEBRUARY 10

10:00-11:15AM ET	**Session 9:** BREAKOUT SESSIONS **Session 9 Track 2:** Enabling Regulatory Strategy Through Automation and Analytics **Session 9 Track 3:** NextGEN TMF Management Panel – Data is the Key *OR You can view from our On-Demand Library at any time throughout the forum!*
11:15-11:45AM ET	Break / Visit the Virtual Exhibit Hall
11:45AM-1:00PM ET	**Session 10:** BREAKOUT SESSIONS **Session 10 Track 2:** Introducing DIA RIM Reference Model 1.0 **Session 10 Track 3:** From Question to Answer: How Automation Can Improve Health Authority Communication *OR You can view from our On-Demand Library at any time throughout the forum!*
1:00-1:30PM ET	Break / Visit the Virtual Exhibit Hall
1:30-2:45PM ET	**Session 11:** Emerging Technologies Panel
2:45-3:15PM ET	Break / Closing Mingle in the Exhibit Hall
3:15-4:00PM ET	**Session 12:** Ask the Regulators
4:00-4:15PM ET	**Closing Remarks**
4:15PM ET	**Forum Adjourns**

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ON DEMAND LIBRARY

Take advantage and view any sessions in the On-Demand Library at any time throughout the Forum!

On Demand 1 Track 1: IRISS Forum Hot Topics

On Demand 2 Track 1: IDMP – To Iteration 1 and Beyond

On Demand 3 Track 2: Using Intelligent Automation and Advanced Technology to Enhance Regulatory Performance

On Demand 4 Track 3: Transformation of the Documentation World: What's Here and What's to Come

On Demand 5 Track 4: Global eCTD Specs

On Demand 6 Track 4: ERS: Sourcing

On Demand 7: International Update Panel