

Sunday, September 16

Agenda subject to change

6:00 p.m. – 8:00 p.m.	Welcome Reception
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Monday, September 17

7:30 a.m. – 8:30 a.m.	Registration					
9:00 a.m. – 10:15 a.m.	General Session					
10:15 a.m. – 10:45 a.m.	Break and Braintdate					
BREAKOUT SESSIONS	Clinical Operations	Clinical Data Management	Quality	Regulatory		Vault Platform
10:45 a.m. – 11:30 a.m.	Janssen, Syneos Health, IACT Health: Collaboration in Clinical Trials Jeff Kingsley, IACT Health Dawn Furey, Janssen Clare Grace, Syneos Health	Cara Therapeutics: Vault EDC Early Adopter Journey Evelyn Dorsey, Cara Therapeutics	BMS: Modernizing Quality Management Raghunandan Satyanarayan, Priya Durvasula, Bristol-Myers Squibb	Lilly: Taking a Process-centric Approach to RIM Transformation Nancy Allen, Paula Hudson, Lilly		Roadmap and Vision: Vault Platform Peter Thorson, Andy Han, Veeva Systems
11:30 a.m. – 12:30 p.m.	Birds of a Feather Lunches and Braintdate					
12:45 p.m. – 1:30 p.m.	Allakos: Best Practices for Surviving Inspections Brent Sorrells, Allakos	Regeneron: Improving CRO Oversight with CTMS Angela Todd, Vinay Dheer, Regeneron	Intersect ENT: Implementing a New Clinical Systems Strategy David Templeton, Intersect ENT	Sysmex: Efficient Document Control is Essential to Positive Audit Outcomes Kim Duffy, Rachael Garcia, Sysmex	GSK: Our Journey of Regulatory Transformation Eckart Schwarz, MD, and Adrian Cottrell, GSK	Daiichi Sankyo: A Winning IT and Business Partnership – From Implementation to Governance Jamie Toth, Sobe Good, Daiichi Sankyo
	or Roadmap and Vision: Vault Safety ■ Andrew Mitchell, Marius Mortensen, Veeva Systems					
1:45 p.m. – 2:30 p.m.	Incyte: Best Practices for Driving Study Start-up Speed and Quality Jennifer Heckman, Incyte	Syneos: The Journey to Strategic TMF Management Gareth Sully, Syneos	Tufts Research: Challenges and Opportunities in Data Management Beth Harper, Tufts Center for the Study of Drug Development Richard Young, Veeva Systems	Alkermes: Harmonizing a Global Change Control Process Angela Murphy, Alkermes	BMS: End-to-end Visibility for Global Variations John Meyers, BMS	IONIS, Agios: Redesigning Regulatory Processes with Vault RIM Christie Hamel, IONIS Jamie Scialdone, Agios
2:30 p.m. – 3:00 p.m.	or Best Practices for Vault Lifecycles and Workflows ■ George Lee, Adam McMillan, Veeva Systems					
	Break and Braintdate					

Monday, September 17 CONTINUED

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BREAKOUT SESSIONS	Clinical Operations	Clinical Data Management	Quality	Regulatory	Vault Platform		
3:15 p.m. – 4:00 p.m.	<p>ARG, Integra, Ora: Improving Clinical Trial Performance with Vault CTMS Hunter Walker, ARG Andrew Tummon, Integra Ed Leftin, Ora</p>	<p>J&J: Transforming Study Start-up in a Global Environment Lisa Rakebrand, J&J</p>	<p>Customer Session: Driving to Complete and Concurrent Data Shelley Padgett, Eli Lilly</p>	<p>Valiance: Planning Successful Migrations David Katzoff, Valiance</p> <p>or</p> <p>Ultragenyx: Streamlining Quality Processes and Configuring Vault QMS Joe Vigil, Ultragenyx</p>	<p>Daiichi Sankyo: Making Organizational Change Management Successful Cheryl Resland, Sobe Good, Daiichi Sankyo</p>	<p>Melinta, REGENXBIO: Implementation Insights of Vault Submissions Publishing Shelly Plapp, Melinta Maryanne DiMarco, REGENXBIO Bhupesh Joshi, Veeva Systems</p>	<p>Vault Platform Security and Access Control Best Practices ■■4 Jean-Christophe Meriaux, Melissa Aron, Veeva Systems</p>
4:15 p.m. – 5:00 p.m.	<p>CGI: Externalizing TMF to Study Partners Karen McCarthy-Schau, CGI</p>	<p>Deloitte: Building a Collaborative Clinical Landscape Dawn Anderson, Deloitte</p>	<p>BioEnterprise, Clintec, ICON, SCRS: The Future of Clinical Data Management, Part 1 Christine Pierre, SCRS Stephen Wilson, FDA Jeanne Strain, Clintec Scott Fisher, BioEnterprise Tina Pietropaolo, ICON</p>	<p>Upsher-Smith: Big, Bold, and Unified Manufacturing, Quality, and Regulatory Tracy Dahl, Manager, Upsher-Smith</p>	<p>Gens & Associates: Improving Regulatory's Role in Cross-functional Processes Steve Gens, Gens & Associates</p>	<p>Accenture: Bringing Automation to Regulatory Activities Heather E. McIntire, Ph.D., Accenture</p>	<p>Amazon Web Services: Managing Compliance in the Cloud for Life Sciences ■■4 Matt Nagle, Amazon Web Services</p> <p>or</p> <p>Enabling Data-Driven Decisions with Vault Reporting and Dashboards Jason Weinstein, Regeneron Graham Gelwicks, Mark Gallagher, Veeva Systems</p>
5:15 p.m. – 6:00 p.m.	<p>Seattle Genetics: Using Metrics to Stay Inspection Ready Amy Edwards, Seattle Genetic</p>	<p>AbbVie: Optimizing eTMF to Tell the Story of a Trial Karen Whitson, AbbVie</p>	<p>BioEnterprise, Clintec, ICON, SCRS: The Future of Clinical Data Management, Part 2 Christine Pierre, SCRS Stephen Wilson, FDA Jeanne Strain, Clintec Scott Fisher, BioEnterprise Tina Pietropaolo, ICON</p>	<p>Gilead: Vault QualityDocs Implementation Best Practices Wendy Goretski, Gilead Dana Sook, Veeva Systems</p>	<p>BMS: Planning and Tracking Submission Content Danielle Beaulieu, BMS</p>	<p>Radius, Regeneron, Tesaro: Advice for Successful Implementations Rich Fredericks, Tesaro Rob Pers, Regeneron Patty Paulete, Radius</p>	<p>Extending Vault with Vault SDK, APIs, and Objects Todd Taylor, Bob Ng, Veeva Systems</p>
6:30 p.m. – 9:30 p.m.	Evening Event						

Tuesday, September 18

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BREAKOUT SESSIONS	Clinical Operations	Clinical Data Management	Quality	Regulatory	Vault Platform	
9:00 a.m. – 10:00 a.m.	Veeva Clinical Network Deep Dive and Demo ▶ Steve Harper, Sondra Pepe, Todd Tullis, Jeremy House, Veeva Systems	Roadmap and Vision: Vault Clinical Data Management Ray Letulle, Richard Young, Drew Garty, Veeva Systems	Roadmap and Vision: Vault QMS Sandeep Chopra, Scott Mitreuter, Veeva Systems	Roadmap and Vision: Vault Registrations Kate Wilber, Uri Reich, Veeva Systems	Roadmap and Vision: Vault Platform Peter Thorson, Andy Han, Veeva Systems or Deep Dive on Managing Vault Environments ▶ David Mills, Kimberly Wehger, Veeva Systems	
10:00 a.m. – 10:30 a.m.	Break and Braindate					
10:45 a.m. – 11:45 a.m.	Roadmap and Vision: Vault CTMS Henry Galio, Tom Dekker, Kyle Stephenson, Veeva Systems	Roadmap and Vision: Vault eTMF Sarah O'Hora, Yvonne Hsieh, Veeva Systems	ICON, Eli Lilly, eClinical Solutions: Collaboration Through Data Demi Niforos, eClinical Solutions Dawn East, Eli Lilly Brian Kelly, AG MedNet Tina Pietropaolo, ICON plc	Roadmap and Vision: Vault Training Joby George, Kent Malmros, Veeva Systems	Roadmap and Vision: Vault Submissions and Vault Submissions Archive Sandra Komadinic, Rolando Sa, Uri Reich, Veeva Systems	Implementation Considerations and Best Practices for Governing Multiple Vaults ▶ Eric Makovsky, Veeva Systems
	or Roadmap and Vision: Vault Safety ▶ Andrew Mitchell, Veeva Systems					
12:00 p.m. – 1:00 p.m.	Roadmap and Vision: Vault Study Startup Ashley Davidson, Brian Bialkowski, Veeva Systems or Roadmap and Vision: Vault CTMS Henry Galio, Tom Dekker, Kyle Stephenson, Veeva Systems	Roadmap and Vision: Vault eTMF Sarah O'Hora, Yvonne Hsieh, Veeva Systems	Roadmap and Vision: Vault Clinical Data Management Ray Letulle, Richard Young, Drew Garty, Veeva Systems	Roadmap and Vision: Vault QualityDocs Sandeep Chopra, Chris Boschen, Veeva Systems	Roadmap and Vision: Vault Submissions Publishing Rolando Sa, Rich Merrick, Veeva Systems	Vision: Connecting Change Control and Variation Management Mike Jovanis, Scott Mitreuter, Uri Reich, Veeva Systems
1:00 p.m. – 2:00 p.m.	Networking Lunch and Braindate					
1:00 p.m. – 3:00 p.m.	Workshops and Customer Community Meetings					