## Agendas

### Sunday, September 16

**6:00 p.m. – 8:00 p.m.**

Welcome Reception

### 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 Braindate

#### BREAKOUT SESSIONS

<table>
<thead>
<tr>
<th>Time</th>
<th>Clinical Operations</th>
<th>Clinical Data Management</th>
<th>Quality</th>
<th>Regulatory</th>
<th>Vault Platform</th>
</tr>
</thead>
</table>
| 10:45 a.m. – 11:30 a.m. | Janssen, Synexus Health, IACT Health: Collaboration in Clinical Trials
Jeff Kingsley, IACT Health
Dawn Fury, Janssen
Clare Grace, Synensus Health | Cara Therapeutics: Vault EDC Early Adopter Journey
Evelyn Dorsey, Cara Therapeutics | BMS: Modernizing Quality Management
Raghunandan Satyanarayana, 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. | Janssen, Synexus Health, IACT Health: Collaboration in Clinical Trials
Jeff Kingsley, IACT Health
Dawn Fury, Janssen
Clare Grace, Synensus Health | Cara Therapeutics: Vault EDC Early Adopter Journey
Evelyn Dorsey, Cara Therapeutics | BMS: Modernizing Quality Management
Raghunandan Satyanarayana, 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 |
| 12:45 p.m. – 1:30 p.m. | Alloskios: Best Practices for Surviving Inspections
Brent Sorrells, Alloskios | 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 |
| 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 | 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 | Ultragenyx: Scalable and Compliant Release Management
Gudrun Finn, Ultragenyx |

**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 | 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 | Ultragenyx: Scalable and Compliant Release Management
Gudrun Finn, Ultragenyx |

**2:30 p.m. – 3:00 p.m.**

Break and Braindate
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<tbody>
<tr>
<td><strong>3:15 p.m. – 4:00 p.m.</strong></td>
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<tr>
<td>Hunter Walker, ARG</td>
<td>Lisa Rakebrand, J&amp;J</td>
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<td>David Katzoff, Valiance</td>
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<td>Andrew Tummon, Integra</td>
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<td>EJ \leftin, Ora</td>
<td>Ultranexy: Streamlining Quality Processes and Configuring Vault QMS</td>
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<td>Joe Vigil, Ultragenyx</td>
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<td><strong>4:15 p.m. – 5:00 p.m.</strong></td>
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<td>Karen McCarthy-Schau, CGI</td>
<td>Christine Pierre, SCRS</td>
<td>Tracy Dahi, Manager, Upsher-Smith</td>
<td>Steve Gens, Gens &amp; Associates</td>
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<td>Stephen Wilson, FDA</td>
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<td>Jeanne Strain, Clinitec</td>
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<td>Scott Fisher, BioEnterprise</td>
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<td>Trial Pirotopsis, ICON</td>
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<td>Deloitte: Building a Collaborative Clinical Landscape</td>
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<td>Dawn Anderson, Deloitte</td>
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<td><strong>5:15 p.m. – 6:00 p.m.</strong></td>
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<td>Amy Edwards, Seattle Genetic</td>
<td>Christine Pierre, SCRS</td>
<td>Wendy Gorecki, Gilead Data Socks, Veeva Systems</td>
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<td>AbbVie: Optimizing eTMF to Tell the Story of a Trial</td>
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<td>Karen Whitson, AbbVie</td>
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<td><strong>Evening Event</strong></td>
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**Agenda subject to change**

Amazon Web Services: Managing Compliance in the Cloud for Life Sciences

Accenture: Bringing Automation to Regulatory Activities

Extending Vault with Vault SDK, APIs, and Objects

Radius, Regeneron, Tesaro: Advice for Successful Implementations

BMS: Planning and Tracking Submission Content

Gilead: Vault QualityDocs Implementation Best Practices

Seattle Genetics: Using Metrics to Stay Inspection Ready

AbbVie: Optimizing eTMF to Tell the Story of a Trial

BioEnterprise, Clinitec, ICON, SCRS: The Future of Clinical Data Management, Part 2

Christine Pierre, SCRS

Stephen Wilson, FDA

Jeanne Strain, Clinitec

Scott Fisher, BioEnterprise

Trial Pirotopsis, ICON
## Agenda

### Tuesday, September 18

<table>
<thead>
<tr>
<th>Time</th>
<th>Breakout Sessions</th>
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<tr>
<td>9:00 a.m. – 10:00 a.m.</td>
<td>Veeva Clinical Network Deep Dive and Demo</td>
<td>Veeva Systems</td>
<td>Roadmap and Vision: Vault Clinical Data Management</td>
<td>Roadmap and Vision: Vault QMS</td>
<td>Roadmap and Vision: Vault Registrations</td>
<td>Roadmap and Vision: Vault Platform</td>
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<td>Steve Harper, Sondra Pepe, Todd Tullis, Jeremy House</td>
<td>Ray Letulle, Richard Young, Drew Garty, Veeva Systems</td>
<td>Sandeep Chopra, Scott Mitreuter, Veeva Systems</td>
<td>Kate Wilber, Uri Reich, Veeva Systems</td>
<td>Peter Thorsen, Andy Han, Veeva Systems</td>
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<td>10:00 a.m. – 10:30 a.m.</td>
<td>Break and Braindate</td>
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<td>Deep Dive on Managing Vault Environments</td>
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<td>Henry Galo, Tom Dekkat, Kyle Stephenson, Veeva Systems</td>
<td>Sarah O'Hora, Yvonne Hsieh, Veeva Systems</td>
<td>Demi Niforos, eClinical Solutions, Dawn East, Eli Lilly, Brian Kelly, AG ModNet, Tina Pietropaolo, ICON plc</td>
<td>Joby George, Kent Mathros, Veeva Systems</td>
<td>Sandra Komadinic, Rolando Sa, Uri Reich, Veeva Systems</td>
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<td>Ashley Davidson, Brian Blakowski, Veeva Systems</td>
<td>Sarah O'Hora, Yvonne Hsieh, Veeva Systems</td>
<td>Henry Galo, Tom Dekkat, Kyle Stephenson, Veeva Systems</td>
<td>Sandeep Chopra, Chris Bosch, Veeva Systems</td>
<td>Rolando Sa, Rich Merrick, Veeva Systems</td>
<td>Mike Jovanis, Scott Mitreuter, Uri Reich, Veeva Systems</td>
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<td>1:00 p.m. – 2:00 p.m.</td>
<td>Networking Lunch and Braindate</td>
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<td>1:00 p.m. – 3:00 p.m.</td>
<td>Workshops and Customer Community Meetings</td>
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