



8:30 – 9:00

Registration and Continental Breakfast

9:00 – 9:15

Welcome and Opening Remarks

- Crissy MacDonald, *Executive Director, Client Delivery, The Avoca Group*

9:15 – 10:15

Session 1: Review of Current and Future AQC Initiatives

- Kristen Bennett, *Associate Director, Client Delivery, The Avoca Group*
- Janis Hall, *Senior Consultant, The Avoca Group*

10:15 – 10:45

Networking Break

10:45 – 11:30

Session 2: Inspection Readiness – Proactive Risk Management and Lessons Learned

This session will explore the challenges that organizations face when preparing for regulatory inspections and identify opportunities for support. Through a series of activities and discussions, participants will identify the highs and lows of the inspection process, identify critical stages where the AQC Inspection Readiness workstream could offer strategic insights, and define the contours of an effective inspection intelligence platform. Participants will have a chance to share and learn from peers about inspection preparation and collaboratively shape a solution.

- Julie Guinn, *Principal Consultant, Executive Design Thinking Facilitation*
- Dennis Salotti, *Chief Operating Officer, The Avoca Group*

11:30 – 12:15

Session 3: Key Findings from the Tufts CSDD-Avoca Study on Vendor Qualification

A report-out of key insights into industry trends, resource expenditure, and approaches for vendor qualification in clinical trials derived from an industry-wide research study conducted by Tufts CSDD in collaboration with The Avoca Group.

- Dennis Salotti, *Chief Operating Officer, The Avoca Group*

12:15 – 1:30

Networking Lunch

Moderated roundtable lunch discussions (*optional*)

Table 1: The Future of Clinical Trials: Are you ready to engage with new technologies and services for Decentralized and Virtual Clinical Trials?

- Janis Hall, *Senior Consultant, The Avoca Group*

Table 2: Managing risk while implementing decentralized clinical trials: Patients and the data validity, does decentralized clinical trials put them at risk?

- Elvin Thalund, *Director, Industry Strategy, Oracle Health Sciences*

Table 3: Connecting to Site-Based eISFs to maintain inspection readiness: Benefits and Challenges

- Blake Adams, *Head of Marketing, Florence Healthcare*
- Ryan Jones, *CEO, Florence Healthcare*

Table 4: Integration of Clinical Trial Risk Management and Risk-Based Monitoring

- Theresa Mason, *Senior Consultant, The Avoca Group*
- Elizabeth Woodson, *Director, Client Delivery, The Avoca Group*

1:30 – 1:40

Post-Lunch Energizer

Video of AQC Member Interview with Merck & Co.

- Caryn Laermer, *Executive Director, Client Engagement, The Avoca Group*

1:40 – 3:30

Session 4: Master Workshop – Managing Risk While Implementing Decentralized Clinical Trials

The advantages of decentralized clinical trials and the process to outline and mitigate risks through a variety of operational and logistical lenses will be explored through table exercises.

- Theresa Mason, *Senior Consultant, The Avoca Group*
- Elizabeth Woodson, *Director, Client Delivery, The Avoca Group*

3:30 – 4:00

Networking Break

4:00 – 4:30

Session 5: Speed and Quality – A Biotech Perspective

AQC Member, Seattle Genetics, will present a case study on the balance between speed and quality in a rapidly growing organization.

- Kamran Ansari, *Vice President, Clinical Development Operations, Seattle Genetics*
- Bryce Mansfield, *Director, R&D Quality, Seattle Genetics*

4:30 – 4:45

Session 6: Strategies and Focus – A Second Take

A review of what 2020 will hold for AQC Members.

- Crissy MacDonald, *Executive Director, Client Delivery, The Avoca Group*

4:45 – 5:00

Close of Event