



QUALITY  
CONSORTIUM®  
THE AVOCA GROUP

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## 2018 Quality Congress

### Meeting Agenda

Friday, April 27, 2018  
Gaylord National Resort & Convention Center  
National Harbor, MD

## Key Topics

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- Patient-centered clinical trials: progress, gaps and opportunities
- Creating a quality culture and the benefits of implementing holistic Quality Management Systems (QMS)
- Operationalizing risk-based approaches in light of regulatory mandates and inspection preparedness
- The growing complexity of the clinical trial ecosystem and consequences of effective oversight
- Improving quality through effective partnerships

## Schedule

8:30 - 9:00

### **Registration and Continental Breakfast**

9:00 - 9:45

### **Session 1: Welcome and Review of AQC and ACRP Initiatives and Partnership Goals**

- **Jim Kremidas, Executive Director, ACRP**
- **Patricia Leuchten, Founder and CEO, The Avoca Group**

9:45 - 10:45

### **Session 2: Clinical Trials, The Growing Complexity of the Clinical Trial Ecosystem**

9:45 - 10:05

This session will begin with a data-driven discussion of the disconnect within the key players of the clinical trial ecosystem. The disconnect between sponsors, providers, and sites as well as within departments of each of these organizations proves that there is a need to stabilize the industry understandings across the rapidly changing ecosystem. The role that is critically involved with all of these players is the Clinical Research Associate. ACRP has developed a set of core competencies that will help to address the variability of an important role within clinical research.

- **Dennis Salotti, COO, The Avoca Group**

10:05 - 10:45

The session will progress through a panel of site, sponsor, and CRO representatives that discuss how we bridge the learning gaps in a rapidly changing environment across multiple roles in clinical trial execution. Questions for the panelists may be entered through the Conference I/O System.

**Moderator: Dennis Salotti, COO, The Avoca Group**

#### **Panelists:**

- **Beth Harper, BS, MBA, Workforce Innovation Officer, ACRP**
- **Andy Lee, SVP, Head Global Clinical Trial Operations, Merck**
- **Susan Romberg, Senior Vice President, Global Clinical Operations, Premier Research**
- **Chris Hoyle, MBA, Executive Director, Elite Research Network**

10:45 - 11:15

### **Networking Break**

11:15 - 12:30

**Session 3: Operationalizing Risk-Based Approaches in Light of ICH E6 (R2) and a Focus on Inspection Preparedness Across the Entire Clinical Trial Ecosystem**

11:15 - 11:35

This session will begin with an overview of ICH E6 (R2) and how it impacts sponsors, CROs, and sites.

- **Ellen Kelso, Senior Consultant, The Avoca Group**
- **Steve Whittaker, Executive Director, The Avoca Quality Consortium**

11:35 - 12:00

This interactive session will breakout into table sessions to review ongoing efforts to expand and enhance the content and robustness of the AQC Inspection Readiness and Preparedness Knowledge Center to include site-centric leading practices, tools, and inspection site experiences. Each table will discuss the opportunities for improvement surrounding the topic they were provided.

**Topics of Discussion:**

- Site inspection preparation tools
- Site inspection experiences
- Differences between risk-based approaches at site vs. sponsor/CRO level

12:00 - 12:30

A panel of sponsor, CRO, and site executives will respond to the highest ranked suggestions captured within Conference I/O from interactive table sessions.

**Moderator: Steve Whittaker, Executive Director, The Avoca Quality Consortium**

**Panelists:**

- **Grace Crawford, Vice President, Clinical Quality and Compliance, MedImmune**
- **Dawn Sauro, President, Sarah Cannon Development Innovations**
- **Erika Stevens, MA (ACRP)**

12:30 - 1:45

**Networking Lunch & Presentations by Workforce Innovation Finalists**

1:45 - 2:30

### **Session 4: Improving Quality Through Effective Partnerships**

The Avoca Group has focused on increasing the quality and efficiency of clinical trials while decreasing the risk by focusing on sponsor/CRO partnerships. This panel will discuss how quality is impacted through partnerships between sites and sponsors/CROs and what we can do as an industry to improve these partnerships.

**Moderator: Steve Whittaker, Executive Director, The Avoca Quality Consortium**

#### **Panelists:**

- **Jeff Kingsley, DO, CPI, FACRP, Founder and CEO, IACT Health**
- **E.B. McLindon, SVP, Site & Patient Recruitment, ICON Clinical Research Services**
- **Virginia Nido, MS, Global Head, Industry Collaborations, Genentech, a Member of the Roche Group**
- **David Vulcano, LCSW, MBA, CIP, RAC, Vice President, Research Compliance & Integrity, HCA**

2:30 - 3:30

### **Session 5: Creating a Quality Culture and the Challenges of Implementing Holistic Quality Management Systems (QMS)**

2:30 - 2:50

This session will discuss the key components that the Avoca Quality Consortium has identified as necessary to having a holistic Quality Management System (QMS).

- **Steve Whittaker, Executive Director, The Avoca Quality Consortium**
- **Liz Wool, RN, BSN, CCRA, CMT, Senior Consultant, The Avoca Group**

2:50 - 3:30

This session will include an interactive activity at the tables where each table is assigned a component of the proposed holistic site quality management system. The groups will then define the rationale behind that component as well as helpful concepts for guidelines, templates, and tools that could be developed as part of the site holistic quality management system. Toward the end of the exercise, moderators will share the insights of each of the tables to the larger group for discussion.

#### **Facilitators:**

- **Kira Drummond, Vice President, Research & Development Quality (RDQ), Alexion**
- **Jay Turpen, Senior Consultant, The Avoca Group**

3:30 - 4:00

**Networking Break**

4:00 - 4:45

**Session 6: Clinical Trials, The Patient Perspective**

The session will progress through a panel of patient, sponsor, CRO, and site which focuses on how patients and their support system experiences in clinical trials have progressed, gaps that should be closed with consideration to the patient experience and, lastly, opportunities where the pharma and CRO players can take the investigative site experiences and advice to create a greater focus on the patient experience.

**Moderator: Crissy MacDonald, PhD, Executive Director, Client Delivery, The Avoca Group**

**Panelists:**

- **Jennifer Byrne, Co-Founder, Greater Gift Initiative**
- **Robert M. Goldberg, PhD, Vice President and Co-Founder, Center for Medicine in the Public Interest**
- **Fabian Sandoval, MD, CEO & Research Director, Emerson Clinical Research Institute**
- **Jamie Troil, patient (ACRP)**

4:45 - 5:00

**Close of Event**

5:00 - 6:30

**Opening Reception**

6:45 - 8:30

**ACRP/Avoca Awards & Recognition Ceremony**