



THE AVOCA GROUP

# QUALITY CONSORTIUM SUMMIT 2015

SPONSORED BY



May 13<sup>th</sup>- 14<sup>th</sup> 2015  
Princeton, New Jersey

## BRIDGING CLINICAL TRIAL INNOVATION AND QUALITY

The Avoca Quality Consortium **Summit 2015** brought together more than 150 senior clinical leaders from sponsors, CROs, and clinical service provider organizations in Princeton, NJ to discuss clinical trial innovation and quality.

Having worked for three years to develop leading practices, the AQC focused the two days on how to implement and operationalize these approaches. Coleen Glessner, Vice President, Head of Clinical Trial Process & Quality at Pfizer, set the tone for what followed in her opening remarks. "You have to change the mental model," Glessner said. She was talking about how the industry thinks about quality management, but the mental evolution she advocates applies to many topics discussed at the Summit.

To encourage more expansive thinking and the spread of leading practices, the **AQC launched Aha!**, a first-of-its-kind online community, at the Summit. Members are using Aha! to share ideas and exchange insights in a secure, private environment. AQC Members see such sharing as vital to the improvement of clinical trials. "We are in this together. And we need to figure it out together," John W. Hubbard, PhD, FCP, CEO and Member of the Board of Directors of BioClinica, said. This process entails establishing what is important, looking for ways to improve in these key areas, and operationalizing innovative methods to do so.

→ [See the Full Agenda Here](#)  
→ [2015 Summit Bio Booklet](#)



[Watch the 2015 Summit Video](#)



**Event MC Craig Lipset**  
**Head of Clinical Innovation, Pfizer Inc.**  
spoke on the Intersection of Innovation and Quality

“What sets Avoca apart is Avoca gets things done. They are efficient in the execution and implementation of ideas that we all bring and they develop tools that we can all use and are of value.”

**Jeffrey McMullen, Chairman, inVentiv Health Clinical and Vice Chairman, inVentiv Health Inc.**

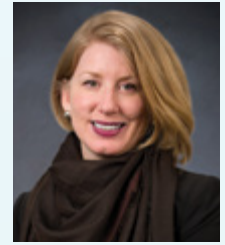
## OPENING REMARKS SET THE TONE



**Robert Metcalf, PhD**  
Vice President, Global Regulatory Affairs- U.S. and Medical Quality Organization, Eli Lilly and Company



**Jeffrey P. McMullen**  
Chairman, inVentiv Health Clinical and Vice Chairman, inVentiv Health, Inc



**Coleen Glessner**  
Vice President, Head of Clinical Trial Process and Quality, Pfizer Inc.

## #WhatMattersMost

All successful clinical trials are built on a shared understanding of what is expected, a process that should include the establishment of clear definitions of quality so the end objective is known from the start. Attendees at the Summit agreed that such a basis and foundation can simplify contracting and improve performance. The benefits of laying such a groundwork ripple outward. High quality trials are inherently compliant and proceed faster because they require fewer change orders and other sources of delays.

Similar themes emerged in the roundtable discussions, in which attendees stressed the importance of having an agreed upon set of shared standards and of identifying metrics and mapping them to outcomes. Other speakers mooted a rule to live by: “If you do what is right for the patient, then you will do what is right.” Following this line of thinking can lead to multiple opportunities to improve clinical trials, from the easing of enrollment through engaging with patients, to the streamlining of future studies by polling participants about their experiences.

## The Avoca Group Launches Aha! An Online Community to Facilitate Clinical Trial Quality Cooperation



Aha!, the online community of the Avoca Quality Consortium, officially launched at the 2015 Summit. So far, over 175 Members have registered and over 100 conversations have been started. Aha! is off to a great start! Read the press release [here](#).

### Current Trending Conversations on Aha!



#### PREQUALIFICATIONS

[Does anyone delegate technical service vendor qualification to CROs?](#)



#### PROACTIVE QUALITY MANAGEMENT

[Does anyone know of available benchmarking data regarding duplicate enrollment of trial subjects?](#)



#### PROACTIVE QUALITY MANAGEMENT

[During an inspection, would you provide copies of your audit reports?](#)

### Aha! Features

- Various different formats to share and receive information: discussions, podcasts, slideshares and video
- Integration with The Avoca Quality Consortium SharePoint Portal for seamless access to tools and templates
- Web-based and mobile-compatible for use on laptops, smartphones and tablets
- Email notifications that allow effortless connectivity to topics that matter most
- Active moderation by AQC subject-matter experts

“Too often, we passively provide ideas that do not translate to innovation. The CRO industry needs to step up.”

Stephen Cutler, PhD, Chief Operating Officer, ICON plc

## #ImprovementOpportunities



Everyone agrees there are plenty of opportunities to improve clinical trials. The challenge, for CROs and sponsors, is to adapt their practices to capitalize on these openings. “Too often, we passively provide ideas that do not translate to innovation. The CRO industry needs to step up,” Stephen Cutler, PhD, Chief Operating Officer at ICON, said. Attendees discussed how CROs have the opportunity to serve as innovation laboratories. On the sponsor side, the need to develop the important skills that facilitate strong partnerships and to engage CROs in the most effective way featured prominently at the Summit. Roundtable discussions also brought up better use of the skills and knowledge of investigator sites as an opportunity to improve the quality of the process and deliverables.



## Avoca 2015 Research

**74%**  
of sponsors

**92%**  
of service providers



**Believe their company recognizes and adopts innovative approaches to clinical development that are shown to be successful.**

**But less than half...**



**...of respondents felt their company invests an appropriate amount of money and resources into innovative approaches to clinical development.**

“Innovation is taking two things that already exist and putting them together in a new way.”

**TOM FRESTON**



## **KEYNOTE SPEAKER NICK WEBB**

**Innovation Consultant &  
Corporate Strategist,  
Best-Selling Author, Senior  
Partner, Lassen Innovation**

## **BRIDGING CLINICAL TRIAL INNOVATION AND QUALITY**

Keynote speaker, Nick Webb, provided a balanced perspective of an innovator’s view and a quality leader’s view of how both of these may be integrated and used to collaborate with patients, investigators and other customers to deliver better value and innovation for all.

## #Innovation

In many cases, improvement opportunities will only be realized through innovation. However, new approaches create new challenges. “How do we innovate without destabilizing our infrastructure?” John Barry, Head of Vendor Strategy and Management, Global Clinical Development, Merck & Co., said. More fundamentally, sponsors and CROs need to overcome their conservatism and establish a model to cover the upfront costs innovation often incurs. Nick Webb, Innovation Consultant and Keynote Speaker, gave some practical tips on how to encourage innovation.

Webb’s suggestions included setting aside time and space to focus on innovation exclusively and giving people the freedom to experiment without fear of punishment. Pairing this shift in philosophy to innovation pathways that are aligned with an appetite for risk can help organizations move away from the tendency to stagnate. Other strategies offered by Webb include the creation of digital connection architecture, the embracing of patient-centricity, and the encouragement of collaboration with all stakeholders.

“Where do we go from here? Do we move slowly and incrementally or do we seize the challenge of our time and tackle the great issues of our day?”

**THOMAS VILSACK**

## #TheFuture

Now, having spent two days sharing ideas about how to collectively improve clinical trials, the focus turns to implementing these suggestions into day-to-day operations. AQC Members are on hand to help each other through this process on the Aha! online community. Similarly, Avoca will continue to develop ways to support sponsors and CROs through the mental and operational evolutions that lie ahead.

“What sets Avoca apart is *Avoca gets things done*. They are efficient in the execution and implementation of ideas that we all bring and they develop tools that we can all use and are of value,” Jeffrey McMullen, Chairman, inVentiv Health Clinical and Vice Chairman, inVentiv Health Inc, said.

# THANK YOU TO OUR PLATINUM SUMMIT 2015 SPONSOR



**inVentiv Health** is a global provider of best-in-class clinical development and comprehensive commercialization services, seamlessly linking the capabilities of a leading, global Clinical Research Organization (CRO) with a unique Contract Commercial Organization (CCO). inVentiv Health helps clients improve performance, reduce risk and speed much-needed therapies to market. With 13,000 employees providing services to clients in 70 countries, our global scale and broad expertise make us an attractive strategic partner for companies developing and delivering medicines in a complex operating, regulatory and reimbursement environment. Our clients include more than 550 life sciences companies, including all 20 of the largest biopharmaceutical companies in the world.

## SILVER SPONSORS:



## MEDIA PARTNERS:



## ABOUT THE AVOCA QUALITY CONSORTIUM

Led by **The Avoca Group** and sponsored by Eli Lilly and Company and Pfizer, Inc., **The Avoca Quality Consortium** brings together quality, outsourcing and operational professionals from member pharma, biotech, niche clinical service providers, and CRO organizations to accelerate the development of leading practices and industry standards for proactive quality management and risk mitigation in clinical research. The Consortium currently has over 45 Member companies.

For more information on membership please contact **Danya Burakoff**  
Danya.Burakoff@TheAvocaGroup.com or (609) 759-2856

## CURRENT CONSORTIUM MEMBERS JUNE 2015

