Avoca Quality Consortium

Improving Proactive Quality Management in Outsourced Clinical Trials
The Avoca Quality Consortium brings together quality, outsourcing and operational professionals from member pharma, biotech, niche clinical service providers, and CRO organizations to accelerate and streamline clinical trial execution and improve quality through industry collaboration.
2016 AQC Members: Pharma and Biotech
2016 AQC Members: CROs and Associate Members
Member Testimonials

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

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

“This is a place of action to change behaviors to move the industry for both sponsors and providers, because we need both sides of that coin.”

Colleen Glessner
Vice President, R&D Quality and Compliance, Alexion Pharmaceuticals

“What I’m really pleased about with the Avoca Quality Consortium is that they’ve actually brought forward tangible improvements and allowed us to implement these and improve quality in the industry.”

Stephen Cutler, PhD
Chief Operating Office, ICON plc

“This Consortium enables me to listen to the lessons learned and best practices from other companies, both small and large. The value here is to speak and define it, and come to agreement on some key areas around quality.”

Mitchell Katz, PhD
Executive Director, Medical Research Operations, Purdue Pharma LP
Avoca Quality Consortium

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.

- **Avoca Research**: Gathering of quantitative and qualitative data from Members; provision of aggregate data and individual benchmarking reports.
- **Leading Practices**: Development of guidelines, tools, approaches, standards, and templates focused on proactive quality management.
**AQC Timeline, History, and Deliverables**

**2011**
- Meeting with FDA to discuss 2011 industry research on quality of outsourced trials
- Formation of Avoca Quality Consortium, sponsored by Eli Lilly and Pfizer

**2012**
- Quality Agreement template
- Launch of Quality Metrics work – Identification of gaps, insight
- Report of Consortium Member quality practices and approaches

**2013**
- Quality Metrics Taxonomy and Framework
- Eight-element framework for Proactive Quality Management and Effective Oversight
- AQC Research on Risk Management
- Industry approaches to prequalification and routine systems audits of full-service CROs and niche providers

**2014**
- Quality Oversight Guidelines & Tools
- Standards for Prequalification of Technical Service Providers
- Proactive Risk Identification Tools and QbD Principles
- Study-level Quality Metrics
- Research of Members’ Quality Management Practices
- Research with investigative sites focused on quality and clinical trial execution (in collaboration with SCRS)

**2015**
- Collaboration through creation of AQC Online Community, Aha!
- Standards for Prequalification of Technical Service Providers – Inclusion of additional services
- Quality Management Framework
- Protocol Quality Principles
- Study-level Quality Metrics
- Benchmarking research on Quality Management Systems
AQC Proactive Quality Management Framework

Quality Agreement Templates and Concepts

Metrics Taxonomy and Outcomes-based Quality Metrics

Leading-practice Quality Oversight Guidelines and Tools

Quality by Design (QbD) Principles

Risk Assessment and Management

Core and Technical Industry Standards for Provider Prequalification

AQC Research

AQC Collaboration Opportunities
Quality Oversight Framework – Continuation in 2016

Documents continuously updated to stay current with industry changes and to incorporate Member feedback.
Quality Oversight Framework, Guidelines and Tools - Background

Accomplishments to Date

• Development of Eight Component construct for Effective Quality Oversight for Outsourced Programs with over 190 leading practice guidelines and tools with a particular focus on:
  - Quality Oversight Guidelines and tools
  - Quality Agreement template
  - Quality Metrics and Taxonomy; provision of Quality Metrics mapped to Taxonomy
  - QbD Principles and tools
  - Risk Management Framework and tools
• In depth discussion and exploration of leading practices via Case Studies and Webinars
• Collaboration regarding oversight practices on Aha, the AQC online community
• Review by and discussions with EMA in preparation for 2014 DIA session focused on effective oversight
• Recent (October 2015) review by and discussions with FDA
• Acknowledgement by Member company representatives through consistent positive feedback regarding the richness of the content and quality of the guidelines and tools
Quality Oversight Framework, Guidelines and Tools - Background

During the October 21, 2015 AQC Members’ Working Session in Princeton, NJ, Ravi Patel, RPh, PharmD, MBA, Sr. Director, Head of Global Pharmacovigilance & Drug Safety Operations, Alexion Pharmaceuticals, Inc. quoted a comment from an FDA inspector that followed an inspection of their pharmacovigilance program where AQC tools had been used to oversee outsourced programs...

FDA Inspector Quote: “This was the most comprehensive Oversight plan we have seen so far for patient support programs.”
The AQC selected Quality Metrics as an initial initiative because research showed that sponsors and CROs were reporting low levels of satisfaction with their own approaches to measuring quality. The work the AQC conducted started with an analysis of how the industry approaches quality metrics. Ultimately, the AQC developed a taxonomy and framework for Quality Metrics with an emphasis on quality outcomes.
**Approach to Quality Metrics Framework**

**Quality Outcomes – 7 Major Categories**

**DOCUMENTATION**

**Technical Attributes**
- Scientifically valid/achievable/clear protocol
- Execution of study per protocol
- Integrity of data (accurate reflection of results)
- Appropriate and accurate analysis and reporting (leads to scientifically appropriate conclusions)

**Ethical Attributes**
- Protection of subjects’ rights
- Protection of subjects’ safety/welfare
AQC Prequalification Initiative

The Industry Challenge:
Prequalification is an area of dysfunction in the industry. Providers and Sponsors suffer negative cost and resource implications due to duplicative efforts, and realize an opportunity cost in the absence of a better model.

The AQC Prequalification initiative is designed to transform the way the industry prequalifies their technical providers to improve quality and efficiency in clinical trials.

- Introduce a more cost, time and resource efficient model
- Deliver a more transparent, consistent message to Providers for standards of quality in order to shorten timeframes of onboarding niche suppliers
- Dispel common notions that liability and legal risk shroud a smarter, more efficient approach
- Provide industry leadership recognizing that prequalification is not a source of competitive advantage and
- Reduce risk in the conduct of clinical trials
Vision for Prequalification Initiative

- **Reduced costs** for sponsors, CROs and niche providers
- **Shortened timeframes** for onboarding niche suppliers
- **Greater efficiency** through sharing of information
- **Reduced risk** in the conduct of clinical trials

In 2016, the AQC Prequalification Initiative will include AQC Member access to centralized RFI information.
Consortium Members can access all completed guidelines, templates, and tools through Avoca’s user-friendly technology platform which permits Members to extract the components and sections of documents that they need for their respective organizations.
Quality Consortium 2016: Benefits

- 2016 Research on quality-promoting practices
- 2015 Research focus on Quality Management Systems and Protocol Quality
- 2014 Research of Consortium Members’ quality management practices
- 2014 Research with investigative sites focused on quality and clinical trial execution (in collaboration with the Society for Clinical Research Sites)
- 2013 AQC research on Risk Management
- 2013 Industry approaches to prequalification and routine systems audits of full-service CROs and niche providers
- 2012 Report of Consortium Member quality practices and approaches
Quality Consortium 2016: Benefits

- **Participation in AQC educational webinar series**, designed to address areas of dysfunction in proactive quality management. Topics include:
  - Culture, People, Process, Technology: Operationalizing Integrated Approaches to Clinical Trial Execution
  - Design Thinking Methodology to promote integration across components of a quality management framework and collaboration across sourcing partners
  - Traits that embody the “Clinical Operations Professional of the Future”

- **Aha! Online Community**: Members can ask questions of each other and of Avoca through an online platform used to orient Members to existing leading-practice documents, research and, to introduce new ideas and approaches.

- **Participation** at the following 2016 meetings:
  - US Summit: May 10-11, in Princeton, NJ
  - Inaugural AQC European Summit: June 6-7, in Basel, Switzerland
  - Fall Members Working Session
  - Opportunities for executive engagement via regional networking meetings
Thank you

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