QUALITY CONSORTIUM
THE AVOCA GROUP
2017 SUMMIT

Summit USA: May 10 & 11, 2017
Summit Europe: June 7 & 8, 2017

Executive Summary

CHANGING LANDSCAPES

SHAPE THE FUTURE

Since the Avoca Quality Consortium (AQC) launched five years ago, its mission and purpose has been to create greater alignment between key stakeholders and to improve the quality of clinical trials.

Today, as one of the earliest consortiums in the clinical trial space, the AQC has grown to 70+ Member companies, which include pharmaceutical/biotech firms, CROs and specialty service providers.

In New York City in May and Dublin in June, industry experts, change makers and thought leaders from Member companies and beyond convened to engage in provocative exchanges on the changing landscape of clinical trials and to celebrate five years of the AQC. Over the course of four days and across two continents, they shared ideas and engaged in energetic debates around their personal and collective ambitions to transform clinical trials and bring medicines to patients faster. As one participant articulated, "I normally feel good if I come home with one pearl of wisdom gleaned from a meeting. With this meeting, I came back with a treasure chest of ideas."

Below is a recap of the Summits. It captures the pulse of what's top of mind for the leaders who attanded from around the clinical trials ecosystem.

Risk

Risk is top of mind, especially in light of the recent launch of ICH E6 R2. From trying to understand risk to quantifying its impact, from having the right teams in place to complying with new guidelines, multiple facets of risk permeated the discussions at both AQC Summits.

"We often miss first filters. How do we build a good first filtering mechanism to assess and quantify risk?"

"We tend to overestimate our ability to influence outcomes and underestimate the potential range of impact/outcomes."

"We live in a complicated world, but how do we simplify it? We make medicines that go into biological systems – humans. This is complex, but we should be able to break this process down and simplify it."

"As quality professionals, we are seeing a shift in the marketplace of risk coming away from legal. If we can just mine quality data, interpret from tipping points and inform where risks are most likely and impactful, that would have impact."

Large and small organizations are struggling with defining, assessing and managing risk. Since risk is, by definition, the possibility that something bad may happen, teams need short, concise stories that resonate to educate management about issues.

Human Capital Management

Leaders are thinking through multiple questions and tactics to ensure that employees have the right mindset to approach decisions from a risk perspective. Executives are looking for clarity around human capital management, particularly in the context of risk mitigation.

> *"There are other regulated industries that have done this (risk management) well. How can we learn and adopt from these industries and let go of our own antiquated practices?"*

> *"How do you culturally get to the point where the risk questions asked are patient-focused?"*

Getting to the right mindset calls for changing some current ways of thinking.

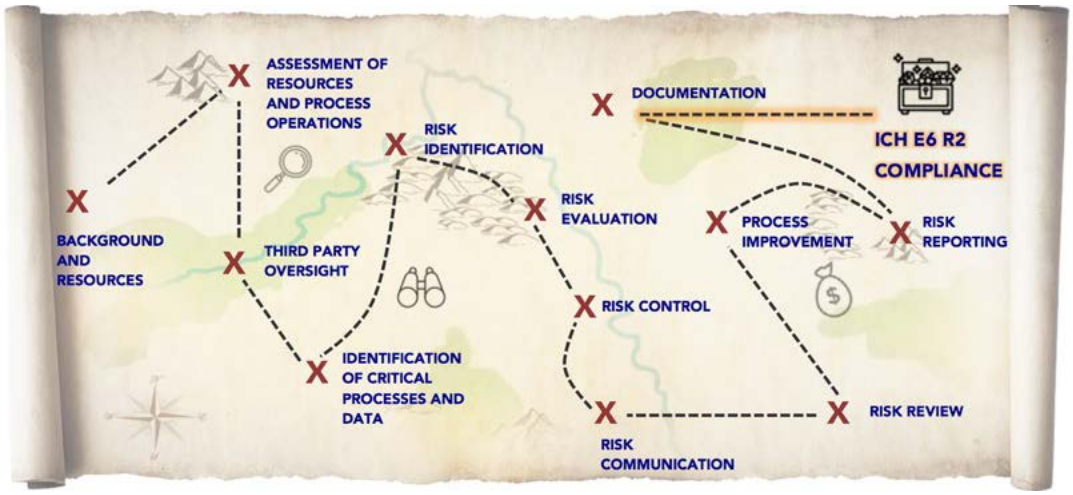
> *"A 'can do attitude' is the antithesis of risk management. We have to neutralize the biases. We get to where we are by using our expertise to formulate our opinion. We stick to the narrative even when it's wrong. The paradox – we think fast and make a decision based on being experts. The flipside is to think slow, which is too arduous for the payoff."*

> *"We all have the experience in this industry that we need the A-team for things to go well. What can we do with the level of detail, process and precision so that you don't have to have the A-team?"*

WATCH THE RECAP OF THE 2017 SUMMITS

ICH E6 R2

The majority of participants did not feel well prepared to comply with the requirements of ICH E6 R2. Since the AQC has been working diligently for years on many facets of these guidelines, including oversight and risk, we launched a guide map to empower companies to navigate this changing world.



The guide map provides a visual overview of the key elements of ICH E6 R2. Each topic on the map is clickable. The topics link to a series of leading practices, tools and templates that Members can download and use right away. The launch of the guide map was met with much enthusiasm. It is already one of the most visited parts of our Knowledge Center.

Given the AQC's laser-focus on quality, it was not surprising that the role of proactive quality management in risk mitigation was frequently mentioned.

> *"Quality – build it up-front; make it right the first time. Have adequate controls in place so the results are not devastating."*

> *"We need to standardize – we don't have unlimited resources, we don't have ebb and flow in the market – this is what you have to work with. We need to work out how to build the quality and then work out the risks."*



Inspections

The topic of inspections has generated much interest among our Members. The progress update on the build-out of the Inspection Readiness Knowledge Center was met with enthusiasm and inspired dialogue.

There was general consensus that Inspection Readiness should not be retrospective or reactive. Rather, it should be a process that is part of the "quality by design" approach from the very beginning.

Inspection Readiness Knowledge Center three-component construct:

- Sharing global approaches, tips and experiences
- Setting leading processes and tools for Inspection Readiness (0-9 month prior to inspection)
- Empowering Inspection Preparedness (proactive, ongoing Inspection Readiness built in, with special consideration given to ICH E6 R2)

> ***"This is excellent. There is a difference that needs to be understood between inspection readiness and inspection preparedness. You should be prepared, always in a state of readiness."***

At the Summits, Members showed significant interest in sharing their inspection experiences with others, especially when done anonymously.

Both in the US and Europe, the area of Inspection Readiness drew much interest from those engaged in pharmacovigilance (PV). Attendees requested that concepts in this space and patient centricity be adopted into tools that can be readily used in the PV area.

Collaboration and Partnerships

Since the inception of The Avoca Group, we have been dedicated to gaining better alignment between sponsors and providers to streamline and optimize clinical trials. While shifts in the industry have led to a growing reliance on traditional and non-traditional partners, collaboration (especially across sponsors and providers) continues to draw attention. Attendees agreed that more can be done to improve the effectiveness of existing partnerships. They also agreed that an open mindset is key to successfully attracting and growing the partners of the future.

"Regardless of the type of partnership, it is important to define what win-win looks like. We do RFPs, discuss prices and agree on scope of work, but don't talk about culture, value and partnering."

"Standardization" was mentioned multiple times as a key foundational element to not only improve the effectiveness of partnerships but also as a springboard for innovation.

"With multiple CROs/partners involved even in a single clinical trial, standardization, especially in the areas of SOPs along with clear documentation and transparent communication is key in staying aligned and coordinated."

"We switch CROs like we change shirts. Standardization and continuity are key to our success. For those of you switching out every five minutes and using 20 different CROs, that doesn't maintain standards."

"In order to innovate, you need to have standard approaches."

"We are working like crazy with a mission-driven purpose to reach each patient. We are not innovative about our processes and our people. We have to train, train, train."

"Start with quality. It's non-negotiable. You have to meet a certain standard, and from there you have to build reliability (do it over and over again). Then build in speed. And then you go to flexibility and innovation."

Members acknowledged the enabling role of the AQC in furthering this standardization.

"What you have done at Avoca is remarkable. What's in the Knowledge Center is phenomenal."

Oversight

Oversight continues to be a top priority for sponsors, especially in light of ICH E6 R2. Surveys conducted by The Avoca Group show that while sponsor and provider expectations are getting more closely aligned, gaps still exist.

"We are getting increasingly concerned about mergers and acquisitions. We have partnerships and relationships in place, but when these huge organizations are created, what will happen? How does that impact the work, the partnering, the relationships?"

"The ability to create trust and collaborate is pivotal in getting closer."

"I'm concerned that ICH E6 R2 is more focused on oversight. As an industry, we don't need more oversight. We need the right levels of well-defined oversight."

Members shared their oversight experiences and were excited about the launch of the new Oversight Capability Maturity Model (OCMM), a tool that enables organizations to assess and advance their oversight levels.

Not surprisingly, open communication and trust play pivotal roles in successful partnerships.

"Debriefs – we should do them after a less important event so it is not a life-and-death situation. Do them regularly so you are improving."

"You need to solve problems and not blame. Focus on building trust through earning it."

Regulatory Agencies

Better knowledge of regulatory agency input and thinking was an oft-heard request. Many stakeholders are overwhelmed by the guidance put out by agencies, which tends to be subject to interpretation.

For example, even if each agency puts out guidance around inspections, inspectors interpret the guidelines differently leading to dramatically different interactions and outcomes. These experiences lead to greater struggles with predicting and managing risk.

Member companies would love the AQC to play a role in this space, bringing regulatory perspectives to these meetings. Given the wealth of data we are bringing together from our latest industry survey and our work on Inspection Readiness, we plan to revisit the FDA to bring our Member requests/challenges to the agency.

Technology

The availability of transformative technologies in the clinical trial space is of great interest to stakeholders across the board. Leaders agree that the industry has a moral imperative to do clinical research more effectively and efficiently, and that technology can play a key enabling role.

> *"We, as an industry, have an ethical and moral obligation to be more efficient in clinical trials."*

> *"The long-term NPV of big pharma is heading in the wrong direction. We have to change that."*

Panelists suggested that a major barrier to technological transformation is the industry's continuous search for the "next shiny object." It leads to the exploration of interesting concepts, but getting investment approval is tough.

> *"Culture is the biggest impediment in the adoption of new technology. Pharma is usually a laggard. Decision-making is siloed and technology is tougher to evaluate that way."*

> *"The first question you get asked is, 'How much cost can I cut?' We have to think about this more strategically. For example, we have to ask, 'How can technology support me with information to make better decisions?' rather than ask, 'How many heads can I cut?'"*

A contrarian point of view came from another panelist who offered the opinion that pharma's investments in technology have not yielded strong results. The pervasive presence of legacy systems makes technology replacements expensive, risk-laden propositions with very long-term ROI. Smaller companies wait to watch what larger firms do. For the latter, technology investments take place among multiple competing priorities. For CROs, the job of serving multiple companies with a variety of technologies presents challenges in investment and integration.

There was general agreement that pharma's core competency is drug development and any innovation in digitizing the R&D world would come from partners outside of the native ecosystem. This represents an opportunity. As some panelists also noted, though, it is also the way the clinical trials industry is most likely to be disrupted. Disruption, that is, is likely to come from the outside.

Patient Engagement

Panel discussions and executive roundtables with extensive audience participation addressed the topic of patient engagement. Participants agreed that, as an industry, we lack a common definition of what it means to "engage patients" or be "patient-centric." Across both New York and Dublin, attendees concurred that much work remains to be done in patient engagement.

> ***"Everywhere else, when you design a user experience journey, you involve an end user. The pharma industry has been slow to involve patients in the design of their clinical trial journey."***

Panelists articulated that we make patient engagement more complicated than it needs to be. Opportunities to ask questions, engage patients and tap into advocacy groups abound. But they remain largely untapped.

> ***"Ask questions of the patient. Have a mechanism to collect those insights. Don't underestimate the power and value of these insights, and incorporate these into the research study."***

"Look at things from the patient perspective. As a breast cancer survivor, I can recall transportation being a hurdle to get to and from chemo. Don't underestimate how one little detail can help a patient and make it easier for them."

"Really change and maintain engagement in a meaningful way."

"Patients are not interested in helping pharma sell more drugs. They are interested in helping them make better drugs. Ask them to be collaborators."

And, what is the one thing that we can do beginning tomorrow to make a difference?

"I think it is to really sit down and be honest with what we mean by "patient-centric." Don't make it lip service. Find the intersections where we can honestly say what we're doing is good for the patient and good for the pharma company."

"Try to use appropriate language. Even with the same protocol, how you communicate with an investigator is vastly different than how you would communicate with a patient. Pay attention to this."

Frequently, the absence of tangible ROI or ROE is given as a reason for not doing more in the patient engagement space. Our panelists stated that if one does the right things for patients, they will stay committed for the duration of the clinical trial and beyond.

"How do you put an ROI on patient engagement? It is the right thing to do. If you do it right once, you engage the patient early on, you will keep them all the way through. Design studies that patients are interested in, provide transportation, make parking easy, enable blood draws and testing to be easier… your patients will stay."

"Pick a topic area and commit to doing some kind of learning over a period of time. Commit to something more of a one-off with a couple cycles. Learn what kind of questions to ask. Make a bet small enough you can tolerate it, but do something that is more than a one-off."

While the content and energy from the meetings will shape the work of the AQC during the rest of 2017 and beyond, we could not be more grateful for the overwhelming response from our Members to the recently concluded Summits.

"I loved the interactive sessions, so unlike any meeting I have ever attended."

"The networking was wonderful as usual – you hit the industry sweet spot with the new materials presented. I loved the combination of strategic and tactical topics presented."

"I specifically benefit from the wonderful opportunity of idea exchange with peers, realizing how strong the community actually is and that most of us are working through the same challenges and issues. AQC's incredible leadership and drive to support us on our journey to a more successful, highly quality, partner and patient oriented future are amazing."

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