QUALITY CONSORTIUM
THE AVOCA GROUP
2016 SUMMIT

Integrating Quality, Innovation, and Collaboration for Clinical Trial Transformation

EXECUTIVE SUMMARY

USA | May 10-11, 2016 **EUROPE** | June 6-7, 2016

At the fifth annual AQC Summit USA and the inaugural AQC Summit Europe, over 250 of the brightest minds involved in many facets of the drug development process gathered to learn, collaborate, and demystify how process innovation can be applied to bring medicines to patients faster. From Heads of Quality to Leaders in Innovation, from academia to industry, stalwarts and upstarts voiced their thoughts on how the world of streamlined clinical trial execution can be a reality today.

Why is streamlining and process innovation so critical?

- *Multiple companies are rushing to bring competitive treatments to market*
- *It takes $2.6 billion in capitalized costs to develop a new drug*
- *Only one in 10 new drug applications is approved and cycle times are not faster compared to the mid-90s*
- *Rework makes up 27% of clinical trial costs*
- *Regulatory requirements and guidelines are continually evolving*
- *The battle for resources is fierce and the need to get the job done with less is a reality*
- *Patient engagement and loyalty is crucial but nascent*

From the opening session of the 2016 AQC Summit USA in Princeton, New Jersey, to the closing remarks at the AQC Summit Europe, in Basel, Switzerland, every discussion was an impassioned one – where issues were debated, needs were identified, and sparks of innovative practices were shared. The value of being "present" at these sessions is best expressed in the words of attendees.

"Networking opportunities and also learning how other companies are approaching key industry issues."

"Many ideas to take back to the mother ship."

"I thought the speakers were very well prepared including the panel chairs. They were engaging and their topics were relevant to the challenges we are facing in our industry."

"Great topics, great speakers, great time keeping (which is not always easy), excellent atmosphere of collaboration. The place, excellent as well."

"The topics and interaction were some of the best I have encountered. Also appreciated the use of technology for the questions and ability to help rank."

"Loved the energy generated from round table discussions."

It's hard to capture all the energy experienced at the Summits in words, but here's a microcosm of what we heard.

Making changes or championing innovation in a highly regulated global environment where quality is paramount is not easy.

From understanding the expectations of multiple regulatory bodies for inspections to the inability to streamline protocols, Sponsors and CROs struggle with comprehending and balancing regulatory requirements with innovative approaches.

"This environment is so complex and changing. Most companies are not good with complexity."

"How do different regulatory requirements (MHRA/ EMA/ FDA) influence the advancement of clinical research? Different individuals have different interpretations of the same guidelines."

"There is a lot of talk about innovation and improving processes, but in actual terms, change in the industry is slow…an environment of the way we do things."

Many agreed that innovation in this highly-regulated space requires out-of-the-box, out-of-this-space thinking.

"The lightbulb was not invented by improving the candle."

"Think of ourselves like Uber. Take what exists and apply it in a new way."

Many attendees commented on the need to better understand what the "right amount of quality" is in this highly regulated space.

"Do we always need to achieve the highest level of quality?"

"Is good quality achievable given the constraints?"

"We overestimate what regulators expect from us."

"People spend all their energy in being perfect. How do we stop the insanity? Get to 80/20."

"Quality is not what you can't do. It is enabling what you can do."

A shift in mindset was suggested as a key to propelling innovation.

"We need to focus on the 'things that really matter' in terms of quality outcomes."

"Why do we need different levels of quality for common regulatory agencies?"

"We need to be thinking of clinical research as a consumer product/service. Many companies don't have policies and procedures to do that."

In this continually evolving landscape, "resources" are seen to be the biggest challenge and the number one impediment to innovation.

The ongoing spate of mergers and acquisitions, staff cut backs, and siloed environments have all created a "resource" roadblock in the drug development journey.

"The mindset with 'lean organizations' is go-go-go…a habit that needs to be broken."

"We have the habit of just pushing through to get thing done in a time-constricted environment."

"We need to understand how to recruit and retain millennials so they can drive our industry's move to the future."

With nearly $20 billion of outsourced drug development activity, seamless partnering across players is crucial to optimizing effectiveness.

"We are still struggling with the limited partnerships we have. This is going to be a challenge."

"The ambivalence of who owns something creates confusion and a lack of ownership."

"Collaboration is more than just Sponsors and CROs; it has to include regulators, investigators, patients, and all providers that contribute to the industry."

"Sponsors don't want deviation among CROs. They want standardization."

Open dialogues, early investment in planning and trial design, redefining strategic partnerships, and better clarity on roles are some examples of solutions being used for better collaboration and resource optimization.

Process improvement is a universally-voiced need and many companies are forging creative solutions in this space.

Executives feel good about the collaborative progress made, but continue to discuss the merits of working together in pre-competitive areas focused on process innovation. This allows valuable resources to be redirected from "reinventing the wheel" on processes and procedures to activities related to ensuring high quality and mitigating risk.

"In five short years, the AQC's accomplishments are tremendous around thinking, tools, and common principles."

"Simplification of our processes is key. If we can't simplify, we can't communicate. Standardization and simplification does not stifle innovation."

Taking time upfront to ask the right questions and design the right processes is invaluable for successful drug development.

"Our focus as an industry has been on execution. We cannot underestimate the impact of design – it influences execution, efficiency, and bringing in the patient perspective."

"We (as an industry) don't allow ourselves enough time upstream to ask the right question".

"If you don't get design right, execution struggles."

"To influence change requires not only senior executive support but multiple stakeholders buy-in outside of clinical operations."

Among the many needs expressed, an open one was the need for an industry "playbook" on clinical trial design and conduct. It was acknowledged by many that the development of more standards, guidelines, and tools focused on "the how" of clinical trial design and execution would add great value and should be considered pre-competitive. Executives supported the role Avoca could play in this journey.

Several examples of process innovation were shared over the two days including crowdsourcing of protocol input, centralizing of RFI's and audits, platform for sharing preclinical data, evolving inspection readiness to submission readiness, moving from lagging metrics to predictive metrics, and marrying Big Data with Small Data.

Developing innovative medicines is a priority, and keeping patients at the heart of drug development is key but represents a challenge for our industry.

Patient centricity was a significant area of discussion at the meetings. Patients want doctors and nurses to show greater empathy and understanding of "what it is like to be a patient with our condition". They want to feel engaged before, during, and after a clinical trial.

Drug development stakeholders recognize the disconnect between patient expectations and industry operations, yet struggle with coming up with the "optimal" way to engage patients in this journey.

"Science is taking us more and more away from the patient. How do you make it easier for the patient?"

"The placebo-controlled trial is not a 'patient-centric' one."

"In a year, a patient with four doctor visits spends an hour with a physician and the remaining 8,759 hours managing their condition. How do you empower them to manage?"

The good news? This collective group is committed to improving the patient experience and shared multiple areas of innovation in this journey.

According to Tufts Center for the Study of Drug Development, in 2012, 48 percent of 95 companies surveyed had patient-centric initiatives or were planning to embark on this journey. In 2015, this number had jumped to 67 percent.

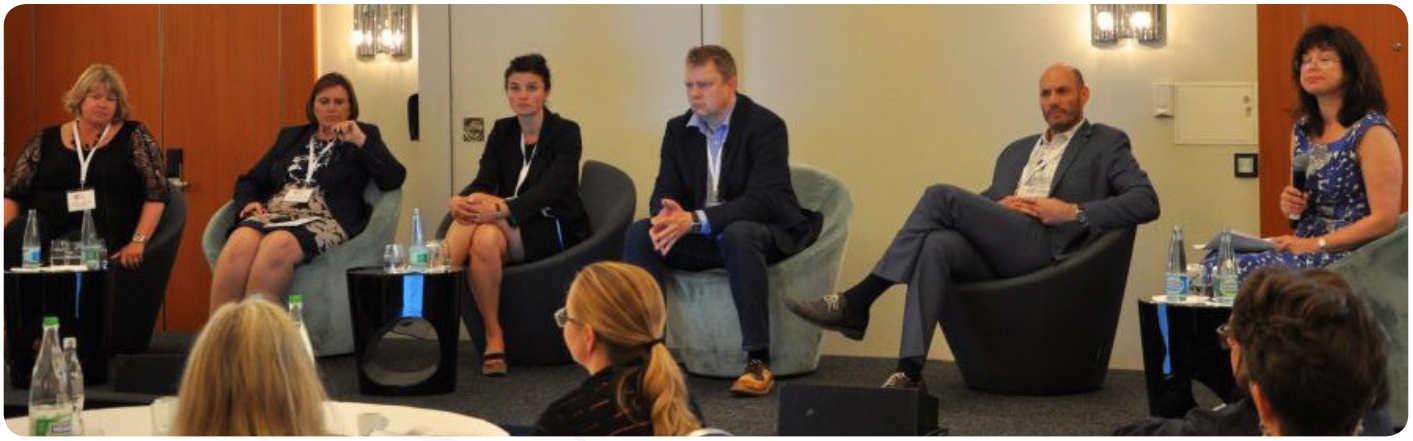
"I'm working on converting the 30-page 'mortgage form' informed consent to a few-page 'People Magazine' version. The feedback has been very positive."

"We designed an end-to-end offline/online experience that considered all aspects of the use of wearable devices."

"We are learning patient needs and insights from bloggers with health conditions. These bloggers are very influential."

"We are using ad boards; bringing patients into focus group facilities and getting them to talk to us about their condition. We've done it in the US and now we're taking it to Latin America."

"We are making it up as we go – fail, fail fast, learn, and go."



“ If quality is everyone’s job, then why can’t innovation be everyone’s job? ”

Proponents of patient centricity feel that the time to engage patients is here and now. The mantra “What have you learned from patients today?” needs to be part of every drug development executive’s vocabulary.

Data from the Tufts Center for the Study of Drug Development show some impressive returns on patient engagement.

67% of 63 companies report reducing number of amendments; 53% see a reduction in site work effort to administer protocol; 44% note improvement in study conduct cycle time.

There is an open opportunity to collaborate and create an ‘engagement model’ for moving forward. Many challenges were cited:

“While there is a lot of activity around patient centricity, the approaches are inconsistent.”

“Pharma companies see patients as subjects instead of patients as collaborators.”

“We have a cultural challenge in relating to patients in a way that is meaningful to them.”

“Patient engagement is not hard or expensive; we just need to begin.”

Despite the glaring need for change, many organizations would like to have better metrics to go down this path.

“ROR – return on relationship – different than ROI. Not always quantitative.”

“We need to get more metrics on the ROI of patient engagement.”

The two 2016 Summits revealed that our industry is often at the frontier of invention: executives admit that while innovation is easy for some forward-thinking companies, proliferating new practices is hard for most, if not all companies.

> *"A robust Consortium, engaged members, and a jolt of courage, may just be the right combination to accomplish the necessary paradigm shift."*

Since CROs handle a large volume of trials, there was a call to action issued to them to drive and share innovation based on the large volume of data, patients, and investigators handled.

"CROs have tremendous data of inspection findings…if there is a way to create a shared platform for these findings it will have a significant positive impact."

The final call to action to drug development leaders is best captured in these simple, yet powerful quotes.

"If someone in your organization has a good idea, don't try to kill it. Recognize the expertise at your fingertips."

"Give yourself a two-month test period to test interesting initiatives within your company."

"We associate innovation with high-tech stuff, but it doesn't have to be."

"Tech is not the issue. Outdated processes are."

As one executive put it, "*a robust Consortium, engaged members, and a jolt of courage, may just be the right combination to accomplish the necessary paradigm shift.*"

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