The Spirit of Radical Integration

Since 2011, The Avoca Group's Quality Consortium has brought together industry experts from pharma, biotech, and CROs to collaborate on innovative solutions to mitigate risks and improve the quality of clinical trials

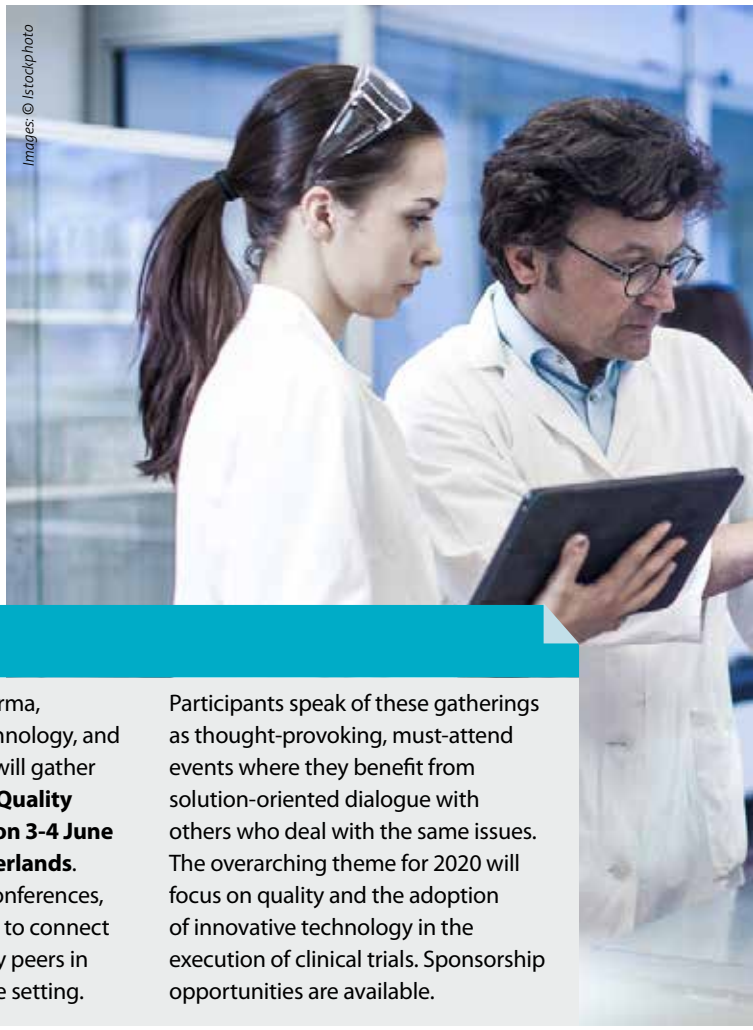
Patricia Leuchten, Founder and CEO of The Avoca Group, asked people at a recent pharmaceutical industry conference to raise their hands if they felt their company was 'pretty good' – not great, just pretty good – at dealing with the risks inherent in the clinical trial process.

Not a single hand went up.

Her goal is to one day ask again and see every hand raised. Leuchten's passion, and Avoca's mission, is for an industry that now struggles to manage risks and design quality into clinical trials to develop a more proactive mindset and overcome communication gaps in bringing life-changing products to patients. As she puts it, "It's the difference between putting out fires and preventing fires".

Clinical trials are, of course, never free of risks, especially with increasingly complex therapies, trial designs, and operating models. They all contain elements of the unknown that no amount of preparation can completely erase. However, risks can be proactively identified, managed, and mitigated, and that's where Avoca comes in.

"Many companies reinvent the wheel in areas where they should be collaborative," Leuchten observes. "As an industry, businesses have had to switch from being very reactive to being extremely proactive – taking a long-view approach to



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Save the Date

Leaders from biotech, pharma, technology/emerging technology, and AQC member companies will gather at the global **2020 Avoca Quality and Innovation Summit on 3-4 June in Amsterdam, The Netherlands**. Like Avoca's previous 10 conferences, this will be an opportunity to connect with Avoca and its industry peers in an informal yet substantive setting.

Participants speak of these gatherings as thought-provoking, must-attend events where they benefit from solution-oriented dialogue with others who deal with the same issues. The overarching theme for 2020 will focus on quality and the adoption of innovative technology in the execution of clinical trials. Sponsorship opportunities are available.

quality and risk management. The latter approach requires a different mindset and a different skillset, and it requires senior executives to endorse and support the shift that is required to adopt proactive and holistic approaches to risk and quality management."

The Outsider's Vantage Point

The Avoca Group occupies a unique and advantageous position in that it works closely with industry insiders but doesn't have a stake in clinical trials, enabling it to act as an external catalyst to drive change.

Leuchten started Avoca in 1999 after working for several large CROs and a major pharma company in clinical research. Problems she saw included disconnects around expectations between sponsors and CROs, a lack of clarity in roles and responsibilities, and inefficiencies in the clinical trial process. The ever-changing regulations and increasing complexity in the clinical trial ecosystem created further challenges. She believed that if some of the silos came down and various stakeholders worked together more effectively, the quality of clinical trial execution would improve.

"I saw the need to bring sponsors and clinical service providers into greater alignment for the purpose of executing high-quality clinical trials," she says, "and I felt compelled to put forward new solutions".

That vision led Avoca to become a powerful force in leading the industry to elevate quality in all aspects of clinical trials, helping others work better and smarter. Avoca's consulting, research, and consortium have brought about something of an industry transformation, where quality is seen as something to plan ahead for rather than 'police' after the fact.

Avoca drives quality, proactive risk management, and collaboration, against a backdrop of immense industry change over two decades – whether from increased outsourcing of trials and new regulations such as ICH E6 (R2), or digital biomarkers and decentralised trial approaches. One constant is that the success of every clinical trial hinges on quality. Another is the continued need for a more evolved approach to partnering.

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Research Roots, Practical Solutions

The firm, based in Princeton, US, and embedded in New Jersey's life science corridor, began with a focus on research and consulting projects for pharma, biotech, and CROs. Initially, Avoca specialised in clinical outsourcing, alliance management, and quality management in outsourced clinical trials. As so often happens when dedication and curiosity combine, one thing led to another. Soon, Avoca began conducting yearly research on the health of industry relationships. A 2011 study proved to be a turning point for the company. The research uncovered a huge divergence in the perception of quality in outsourced clinical trials, which cried out for action and led to the creation of the Avoca Quality Consortium® (AQC). Today, this pre-competitive

collaborative of sponsors, CROs, and clinical service providers consists of more than 100 active member companies sharing experiences, challenges, and – most importantly – solutions. It serves as both a platform for collaboration and an advocate for the industry, and it brought about a growth spurt for Avoca. Since the AQC was introduced eight years ago, Avoca's full-time staff and consultant base have more than quadrupled.

Avoca and the AQC are at the epicentre of the complex clinical trials ecosystem, poised to help the transition to better adoption of emerging technology and novel data sources without losing the focus on quality.

At the request of AQC members, Avoca engaged in the process of addressing industry dysfunction and inefficiency inherent in the qualification of clinical service providers. This work has included the development of robust standards mapped to regulatory guidance, and associated tools such as 'request for information' templates, scorecards, and visit checklists. From there, the next step became clear: centralise the various business activities involved in clinical trials into a single technology platform.

The Avoca Group Introduces Diligent® Pharma

Avoca's latest groundbreaking venture, the Diligent® Qualification Platform, unites Avoca's deep domain knowledge with technology to enable more efficient and higher-quality execution of clinical trials. One example is the capability to reduce the time it takes to identify and qualify vendors by up to 90%.

Analogous to clinical trials themselves, the Diligent Platform benefited from a methodical launch approach that started with a successful pilot, engaging 13 pharma and biotech companies and 50 clinical service providers. The value to sponsors and providers was clear – centralisation helps:

- Reduce ICH E6 (R2) compliance risk
- Enable data-driven, higher-quality decisions for provider selection
- Bring onboard new providers and capabilities in shorter timeframes
- Use a more cost-, time-, and resource-efficient model
- Lower administrative expenses

"We are very excited about the potential to drive cost savings with Diligent, and, importantly, to shorten timelines for the launch of clinical trials," Leuchten says.

More to Come

What's the next step in Avoca's cutting-edge quest for greater collaboration? Following the groundbreaking path of the AQC, The Avoca Innovation Alliance™, a multi-stakeholder initiative, will bring together sponsors, CROs, and non-CRO providers to facilitate the widespread adoption of technology into clinical trials.

Avoca will continue surveying the industry, digging into data, and offering innovative solutions in an ever-changing environment. "It's helpful for individual companies to see the aggregate trend data because many are trying to find their own way, thinking they're the only ones struggling," Leuchten says. "It can be cathartic to see that there are common challenges, especially since technology adoption is advancing very quickly." Leuchten added, "The clinical trial industry's ability to adopt and integrate new technology isn't keeping pace with other industries. I'd like to see a spirit of 'radical integration', where there's better cooperation between the key stakeholders of clinical trials, fewer silos within companies, and better connection with sites – and with patients in the center of the process. At the end of the day, the work we do in this industry is all about the patients".

As clinical trials keep evolving, they will grow more complex, and in the future, the concept of decentralised and direct-to-patient trials will become the norm. The speed, cost, and quality tension will only intensify. The Avoca Group will remain at the forefront of helping companies increase quality, mitigate risk, and improve efficiency in the execution of clinical trials.

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The Avoca Group is a life science consulting firm dedicated to improving quality and compliance in clinical trial execution. Since 2011, the AQC, a collaborative of over 100 pharma, biotech, CRO, and clinical service provider companies, has led the industry in developing practical solutions for improving quality and execution in clinical trials. Companies benefit from Avoca's insightful research, deep subject matter expertise, industry-leading approaches, and technology. Avoca offers platforms and tailored solutions to help clinical research companies increase quality, ensure compliance, and improve efficiency so that medicines can reach patients faster.
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