QUALITY CONSORTIUM®
THE AVOCA GROUP

7TH ANNUAL AQC GLOBAL QUALITY SUMMIT

Executive Summary

EMBRACE THE PRESENT | OWN THE FUTURE

13-14 June 2018
Dublin, Ireland

SUMMIT EXECUTIVE SUMMARY

Interactive panel discussions. Poignant presentations. Productive workshops. The 7th Annual AQC® Global Quality Summit featured two engaging days of high-quality analyses and discussions that addressed topics ranging from key industry challenges, such as risk mitigation, ICH E6 (R2)'s impact on the industry, to creating a culture of quality within virtual teams.

The theme for the event – *Embrace the Present. Own the Future.* – focused on today's most innovative solutions for driving efficiency, improving quality, and mitigating risk in the execution of clinical trials.

As in years past, the Summit provided a unique opportunity to network, dialogue, debate, and collaborate on issues transformative to the industry. The collaborative component of the event allowed for the free flow of ideas required to influence global change and to view the important work of clinical research through a different lens.

The event was attended by more than 100 representatives across 10 countries, including C-level executives and industry professionals from clinical operations, quality, regulatory, and procurement.

The speaker lineup included over 20 panelists and presenters from the top sponsor companies, CROs, and clinical service providers. The influential list included co-Chairs Neil McCullough, PhD, MSc, Executive Vice President Quality & Compliance for ICON Clinical Research and Jonathan Rowe, PhD, MS, MA, Executive Director, Head of Clinical Development Quality Performance and Risk Management for Pfizer.

The keynote address was delivered by Lucien Engelen, Director Radboud University Medical Center's REshape Center for Innovation; Global Strategist Digital Health Deloitte Center for the Edge, Faculty Singularity University Silicon Valley and The Netherlands. Engelen has helped to shape innovation in healthcare for more than a decade. He spoke to the intersection of technology and patient empowerment in the changing clinical trial landscape. Engelen has his 'finger on the pulse' of how technology will shape the future of healthcare and the impact it will have on clinical trials.

Patient-turned-advocate, Imogen Cheese, who was diagnosed in 2013 with melanoma, gave an inspirational personal account of her journey with cancer. She shared her experiences and perspectives on diagnosis, treatment, and clinical trials. Her presentation highlighted that, for many patients, access to trials is often a matter of life or death. Cheese also moderated a panel discussion focused on increasing awareness of and access to clinical trials and making trials more patient-focused.

SUMMIT EXECUTIVE SUMMARY (CONTINUED)

In the Summit's opening remarks, Patricia Leuchten, Founder and CEO of The Avoca Group, spoke about how NASA engineers, scientists, and astronauts had to work together as a cohesive team to do what was previously unthinkable: achieve a soft landing on a moving target hurtling through space a quarter of a million miles away from Earth. Like those astronauts, AQC Member companies are also pioneers of their field, and it is through the innovation, teamwork, and collaborative nature of the AQC that the industry as a whole will reach new heights.

Two new innovations were introduced at the Summit by The Avoca Group – the Diligent® Qualification Platform, the industry's first centralized platform for provider qualification, as well as eLuminate™, an online learning platform focused on clinical research quality, compliance, inspection readiness, and oversight. Both are logical extensions of work completed through the AQC over many years and are representative of our continued efforts to drive improvements to quality and compliance in an increasingly complex and rapidly-evolving clinical trials landscape.

In the following pages, we capture the ideas and key takeaways of this year's Summit – let it serve as launchpad to support the goals we, as an industry, seek to achieve.

The Avoca Group wishes to thank Platinum-level sponsor ICON, Gold-level sponsor Purdue Pharma, and Silver level sponsors Appian Corporation and Longboat Clinical for their support of the 7th Annual AQC Global Quality Summit.

SUMMIT DEMOGRAPHICS

92 attendees represented leadership positions from manager to C-Level.

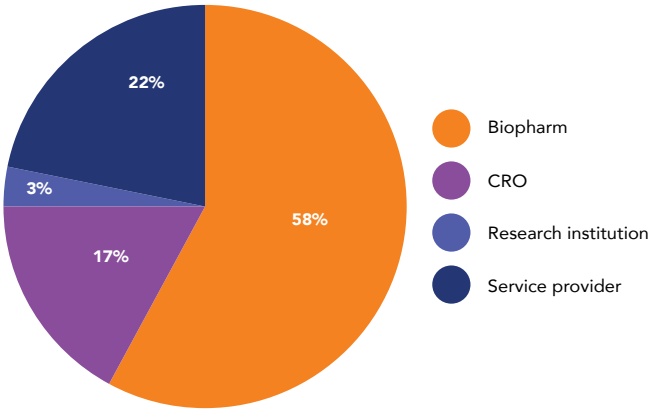

Figure 1.
The majority of attendees represented biopharm companies, followed by service providers, CROs, and research institutions.

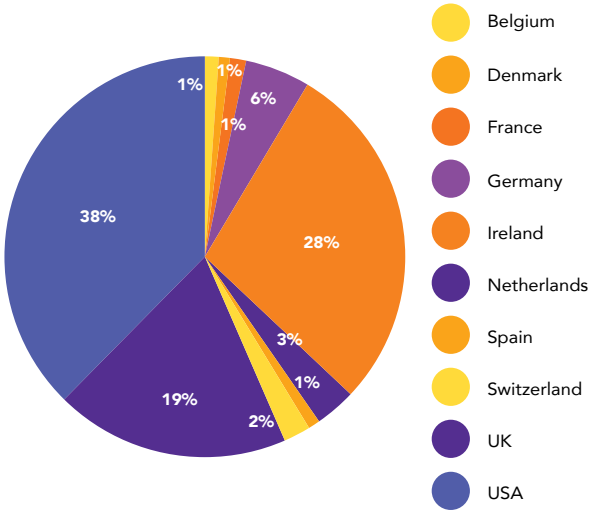

Figure 2.
Attendees represented 10 countries across Europe and North America.

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During the pre-conference workshop on Day 1 of the Summit, the presenters and workshop attendees discussed and reviewed additions, improvements, and changes to the AQC.

In 2011, The Avoca Group formed the Avoca Quality Consortium, (AQC). The AQC is a member-based, pre-competitive collaborative comprised of clinical operations, quality, and outsourcing professionals from pharma, biotech, CROs, and clinical service providers. The AQC was founded based on a commitment to improve quality, drive efficiency and mitigate risk in clinical trial execution. Each Member organization receives company-wide access to a comprehensive and proprietary Knowledge Center of over 400 leading practices, guidelines, tools, templates, and process documents, as well as AQC research and archived webinars. (Figure 3).

Figure 3. Areas of need identified and addressed by the Avoca Quality Consortium by incorporating industry best practices and experiences into leading practices and tools.

Although tools and templates have already been developed in a number of areas, with the ever-changing nature of the clinical trials industry, there are always new needs. Based on Member feedback, **Inspection Readiness** is a focus area for 2018, with requests for additional knowledge sharing about real-world experiences and tools to support an inspection preparedness mindset within organizations. The AQC has already increased the number of inspection experiences documented within the AQC Inspection Readiness Grid for the FDA, MHRA, EMA, Health Canada, PMDA, and CFDA and has compared the experiences pre- and post-ICH E6 (R2) implementation. Next, additional resources will be added to supplement the AQC's suite of inspection tools.

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Another AQC focus for 2018 is **Site Centricity**, with priorities being the development of components of a proactive quality management system specifically for investigative sites as well as inspection readiness and preparation tools for sponsors and CROs to provide to sites.

The AQC is also continuing to look to **the future of clinical trials,** with consideration of artificial intelligence, big data, direct-from-patient data (e.g., wearables), social data (Figure 4), administrative changes regarding communications and visualization, and operational and administrative reporting from multiple channels.

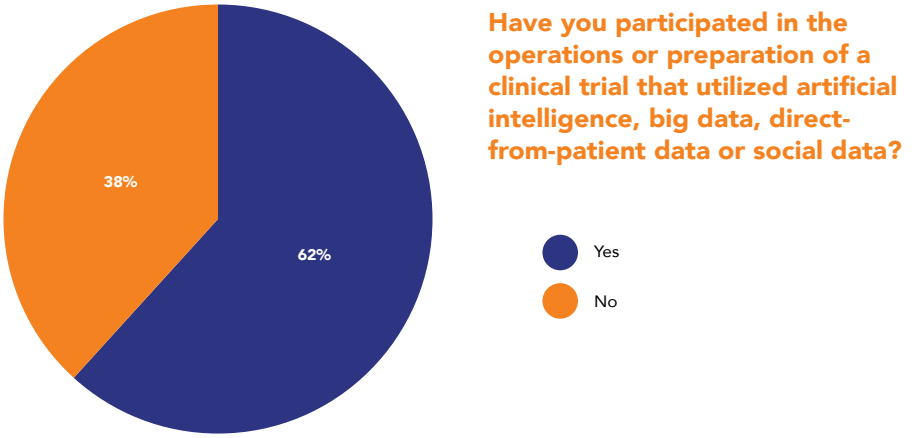

Figure 4. The majority of attendees have already had exposure to alternative forms of data collection.

With these new forms of data collection come new sources of risk that must be reviewed, considered, and incorporated into quality management systems. The AQC is working on new tools to help effectively manage these risks.

Presenters:

Steve Whittaker, *Senior Consultant, The Avoca Group; Executive Director, Avoca Quality Consortium, 2011-2018*

Crissy MacDonald, *Executive Director, The Avoca Group*

Irene Catherine Michas, *Senior Consultant, The Avoca Group*

"Loved the interaction."

"The Avoca Group's Diligent Qualification Platform is reimagining how qualifying vendors will look in the future and is transforming the vendor selection timeline and process."

"Great overview."

THE FUTURE OF ENGAGEMENT

This session offered a review of the concept of virtual distance and how new technologies and lack of facetime with the treating physician may impact the industry. To identify ways that project teams can improve communication and efficiency, as well as how to communicate with patients virtually, Dr. Karen Lojeski shared how to create a culture of quality within virtual teams. Dr. Lojeski stressed the importance of patient centricity and clean data to enhance virtual distance predictive analytics, while reducing risk and cost.

Presenter:

Dr. Karen Lojeski, *Founder and CEO, Virtual Distance International*

"Interesting viewpoints."

"Applicable to many types of industries and organizations."

"Good way to stimulate thinking."

TODAY'S DECISIONS, TOMORROW'S OUTCOMES

During this workshop, participants discussed risk mitigation and the impact of ICH E6 (R2) on pharma's definition of "business as usual." Following a brief presentation about quality processes and quality tolerance limits (QTLs) framed by The Avoca Group's 2017 research, as well as a case study from Pfizer about how they were able to move to a risk-based quality management system, the participants, in small groups, practiced applying the criteria for defining a QTL.

The key takeaways were:

- **The definition of a QTL:** A QTL is a trial-level (not patient-level) parameter that, when a deviation is detected, should trigger an evaluation to determine if there is a possible systemic issue. They are critical to basic trial integrity, patient safety, and primary endpoint.
- **How to determine your QTLs:** Limit to 3-5 parameters that impact subject safety and the reliability of trial results and proactively define the plans to address any deviations to those parameters before the trial begins. Consider the unit, expectation, tolerance limit(s), and justification for each parameter.
- **A few QTLs that each organization should consider adopting:** Some examples include the #/% of entered subjects that do not meet ≥1 of the protocol entry criteria, #/% of subjects with premature drug discontinuation (both arms), and #/% of subjects classified as lost to follow up.

Presenters:

Jonathan Rowe, *Executive Director, Head of Clinical Development, Quality Performance, and Risk Management, Pfizer*

Steve Whittaker, *Senior Consultant, The Avoca Group; Executive Director, Avoca Quality Consortium, 2011-2018*

QUALIFYING THE FUTURE

Based on AQC Member feedback regarding the challenges they are facing, The Avoca Group and the AQC developed a new offering specifically for vendor qualification, as described in this presentation by Jeffrey Kasher and Dennis Salotti. The Diligent® Qualification Platform supports vendor qualification decisions and was built based on The Avoca Group's 20+ years of experience in clinical outsourcing as well as our fluency in global regulatory requirements. Inherent within the Diligent Qualification Platform is a rigorous set of industry standards and tools developed and vetted by Member companies of the AQC (Figure 5).

Figure 5. The robust standards and tools are built around regulatory guidance, industry leading practices, and industry current practices/expectations. The standards and tools are maintained and updated, as necessary, by the AQC. Providers complete the standards-based RFI questionnaires, which are then stored in the centralized Diligent Qualification Platform.

The platform supports five functional categories (clinical monitoring, data management, medical writing, biostatistics, Phase I units) and seven endpoint-generating categories (central laboratories, IxRS, central ECG, medical imaging, biomarker laboratories, bioanalytical laboratories, clinical outcome assessment providers) as well as a core sent of requirements applicable to all providers and services. Based on Member feedback, additional categories will be considered for development.

Presenters:

Jeffrey Kasher, *Executive Chair, Avoca Quality Consortium*

Dennis Salotti, *Chief Operating Officer, The Avoca Group*

A SOFT LANDING INTO THE FUTURE

In his keynote session, Lucien Engelen discussed the challenges that healthcare is facing in almost every aspect of its processes. With technology pushing innovative advancements, patients demanding inclusion, and sustainability under pressure, change is imminent, and as a result, we will begin to see the healthcare delivered in non-traditional settings. Within 10 years, the mobilization of healthcare is estimated to move 67% of "good" healthcare from the home, hospital, or doctor's office, to "everywhere," as we enter into a phase of Augmented Health(care)™.

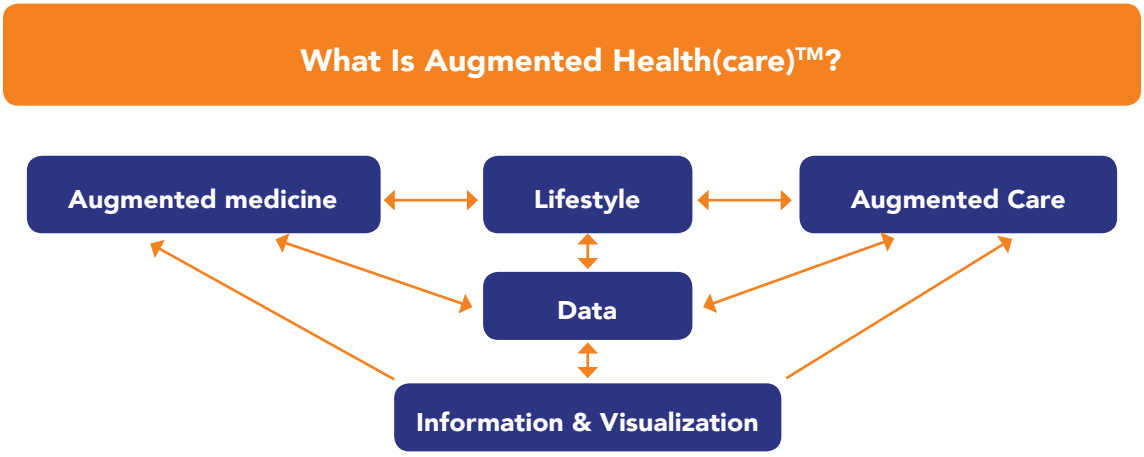

Figure 6. Augmented Health(care)™ represents a system in which a variety of factors, including lifestyle, data, and information and visualization, work together to impact patient care.

Presenter:

Lucien Engelen, *Director Radboud University Medical Center's REshape Center for Innovation; Global Strategist Digital Health Deloitte Center for the Edge, Faculty Singularity University Silicon Valley and The Netherlands.*

PLANNING FOR QUALITY WITH AN UNCERTAIN FUTURE

Following the keynote, audience members were encouraged to participate in an engaging discussion during this senior executive keynote panel. Panel members discussed the diagnosis of current gaps in the industry and their perspectives on regulatory constraints, clinical trial complexity, and the current industry approach to conducting clinical trials.

A combination of views from both panelists and audience members included a balance of concern and caution vs. hope and optimism. The session provided for great insights into the future of healthcare and ultimately what role these new technologies can play in improving clinical research.

Moderator:

Jeffrey Kasher, *Executive Chair, Avoca Quality Consortium*

Panel Members:

Lucien Engelen, *Director Radboud University Medical Center's REshape Center for Innovation; Global Strategist Digital Health Deloitte Center for the Edge, Faculty Singularity University Silicon Valley and The Netherlands*

Tanja Keiper, *Director, GCO External Innovation/Clinical Applications & Innovation, Biopharma, Merck KGaA (EMD Serono)*

Neil McCullough, *Executive Vice President, Quality & Compliance, ICON*

Jonathan Rowe, *Executive Director, Head of Clinical Development Quality Performance and Risk Management, Pfizer*

"Fantastic way to start the Summit."

"Excellent content. It's great there was so much interaction with the audience."

THE GROWING COMPLEXITY OF THE CLINICAL TRIAL ECOSYSTEM

Gauging the pulse in the industry and identifying gaps, the audience was polled during this panel discussion, finding that process methodology is the lead contributor to reducing clinical trial complexity and sustaining operational excellence (Figure 7), and inertia limiting change was considered the most dominant industry barrier to adopting technology and effectively incorporating technology into research and development (Figure 8).

Figure 7. Process methodology is viewed as the lead contributor to clinical trial complexity and sustaining operational excellence.

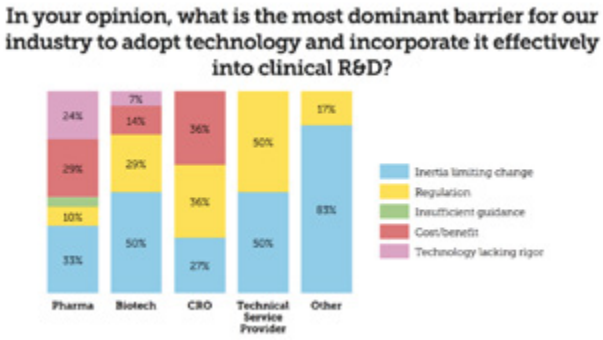

Figure 8. Inertia limiting change is viewed as the most dominant industry barrier to adopting technology and effectively incorporating technology into research and development.

Moderator:

Steve Whittaker, *Senior Consultant, The Avoca Group; Executive Director, Avoca Quality Consortium, 2011-2018*

Panel Members:

Evjatar (Evi) Cohen, *Vice President, Global Life Sciences - Pharma/Biotech & Medical Devices, Appian Corporation*

Nona Dokuzova, *Head, Global Quality Compliance, Biopharma, Global Research and Development Quality (RDQ), Merck KGaA (EMD Serono)*

Patty Donnelly, *Vice President, Research and Development Quality, Eli Lilly and Company*

Rose Kidd, *Senior Vice President, Global Clinical Operations, ICON*

Jim Kremidas, *Executive Director, The Association of Clinical Research Professionals (ACRP)*

EMBRACE THE PRESENT, DESIGN THE FUTURE

After lunch, attendees were prompted to think about their organization and determine how to make the ideas of the future of the clinical trial landscape that were discussed in the morning into ideas that can be implemented today. Recognizing that various communication styles and personality types are represented throughout project teams, Merrick Rosenberg linked the DISC style of communication to birds in his discussion on behaviors of innovative cultures. Following an interactive exercise, Merrick detailed how the differences on the individual level can inform assembling better project teams, improve team dynamics, and shared how any individual or company can take ideas of the future and make them goals for today.

"Great energy and presentation style."

"Very helpful to understand difference between creativity vs innovation."

"Very engaging, close to reality and lots to take away."

"Very informative discussions with great questions and insights into the future of healthcare and clinical research and what role technology can play."

CLINICAL STUDY CONDUCT TRENDS

After speaking of the future of medicine, Kenneth Getz provided insights into the types of industry disruption occurring today. Examining the complexities in clinical trials, Getz provided an outline of key trends driving the clinical research landscape. He detailed how the industry must prepare for a new paradigm in clinical trial execution and expect to see:

New Models

- Patient-informed and engaged design and execution
- Embedded within large clinical care settings
- Optimized for convenience, open innovation and transparency

New Skills and Competencies

- Roving, flexible clinical research professionals
- Patient and professional navigators
- Data scientists
- Recognized/certified capabilities and support
- HCP trained/enabled

New Infrastructure

- Portable, mobile solutions
- Data-oriented vs. process-oriented
- Open, cloud-based
- Unified, integrated datasets
- Interrogative and predictive analytics; AI and machine learning
- Remote, risk-assessment based analytics

The key takeaway from Getz's presentation was that, despite the increase in technology, the duration of clinical trials (the time from initial drug development to regulatory approval) is stagnant.

Presenter:

Kenneth Getz, *Director, Sponsored Research Programs, Associate Professor, Tufts CSDD, Tufts University School of Medicine*

PATIENTS WITH POWER

A focus on patient centricity, improving engagement, and informing patients was a key theme throughout the sessions, with a strong message delivered by Imogen Cheese. During her presentation, Patients with Power, Cheese shared her experience as a Stage 2c Melanoma patient in a clinical trial, highlighting the challenges she faced, such as:

- Knowledge
- Funding/Sponsorship
- Patient health
- Time management as a mother, professional, and friend

With the evolving role of patients, Cheese detailed the valuable elements to consider in the design and conduct of clinical trials:

- Increasing face-to-face time between patients and members of clinical care team
- Easing the discrepancies of the health system
- Encouraging patient knowledge
- Emphasizing inclusion, not exclusion

Presenter:

Imogen Cheese, *European Director, Business Development, Imperial Clinical Research Support*

EMBRACING THE EVOLVING ROLE OF THE PATIENT

The follow up panel discussion, **Embracing the Evolving Role of the Patient,** moderated by Cheese, explored how the future of clinical trials will be affected by patients who have access to better technologies and information in their search for a treatment or cure.

Presenter:

Imogen Cheese, *European Director, Business Development, Imperial Clinical Research Support*

Presenters:

Kenneth Getz, *Director, Sponsored Research Programs, Associate Professor, Tufts CSDD, Tufts University School of Medicine*

Jim Lane, *Chief Business Officer, Longboat*

Suzanne Murray, *Vice President, Quality, Agios Pharmaceuticals*

Dennis Salotti, Chief Operating Officer, *The Avoca Group*

"Excellent panel discussion. Nice to hear mixture of views."

"A privilege to listen to this debate."

"I cannot thank everyone enough for their attendance and participation in the 2018 Summit. It was my honor to be surrounded by leaders in clinical development working hard toward breaking down barriers and discussing solutions on how to move our industry forward in order to get patients the medicines that they need faster. Our mission at The Avoca Group is to make a positive impact on the quality of all clinical trials and having all of these leaders in the room discussing pain points and solutions was certainly a step in the right direction for our mission and for the industry."

Crissy MacDonald, PhD, Executive Director, Client Delivery, *The Avoca Group*

"It has been an absolute privilege and pleasure to witness how leaders within clinical development and quality have collaborated through membership in the Avoca Quality Consortium to share leading practices and contribute to value for the industry, organizations, partnerships and ultimately patients. The Dublin AQC Summit was a premier example of that value as creative minds assembled and shared in interactive discussions and activities that embrace the present while creating vision and possibilities to own future enhancements for quality."

Steven B. Whittaker, Senior Consultant; *The Avoca Group*, Executive Director, *Avoca Quality Consortium, 2011-2018*

"It was my privilege to connect with attendees from AQC Member companies, along with additional industry colleagues, at this year's AQC Summit. It was extremely gratifying to receive consistent feedback that networking opportunities provided during the two-day event were unparalleled. The environment of transparency and inspiration which the Consortium creates encourages collaboration and discussions that lead forward-thinking leading practice initiatives."

Caryn Laermer, Executive Director, Client Engagement, *The Avoca Group*

THANK YOU TO OUR SUMMIT SPONSORS!

PLATINUM SPONSOR

ICON is a global provider of outsourced development services to the pharmaceutical, biotechnology and medical device industries. We specialise in the strategic development, management and analysis of programmes that support Clinical Development - from compound selection to Phase I-IV clinical studies. In a highly fragmented industry, we are one of a small group of organisations with the capability and expertise to conduct clinical trials and development projects on either a local or global basis. We have the operational flexibility to provide development services on a stand-alone basis or as part of an integrated "full service" solution. We are also an 'end-to-end' Pharmacovigilance service provider and this includes Post Marketing Surveillance activities too.

GOLD SPONSOR

Purdue Pharma L.P. is a privately held pharmaceutical company founded by physicians more than 60 years ago. We are committed to advancing the care of patients with innovative, quality products that make a positive impact on healthcare — and on lives. Purdue Pharma is part of a global network of independent associated companies that is known for pioneering research in chronic pain and opioids with abuse deterrent properties. The Company is engaged in the research, development, production, and marketing of prescription medicines and over-the-counter healthcare products. We are pursuing a promising pipeline of new medications through internal research & development and strategic industry partnerships. At Purdue, we embrace our mission to find, develop, and introduce innovative medicines that meet the evolving needs of healthcare professionals, patients and caregivers.

SILVER SPONSORS

Appian provides a low-code software development platform that enables organizations to rapidly develop powerful and unique applications. The applications created on Appian's platform help companies drive digital transformation and competitive differentiation. For more information, visit www.appian.com.

In the complex world of global clinical trials, the Longboat team believes that well-designed and practical technology solutions are vital in tackling the challenges of site engagement, patient engagement, and protocol compliance. Through our user-friendly and fully-mobile solutions, Longboat is dedicated to generating better study outcomes by creating a complete support structure for site staff, patients, monitors, and study teams - where protocol compliance becomes easy and instinctive.

Learn how AQC Membership provides your organization the opportunity to network and share leading practices with other Members.

About The Avoca Group®

The Avoca Group is a life sciences consulting firm dedicated to improving quality and compliance in the clinical trial execution process. Integrating deep subject matter expertise with industry-leading approaches and technology, The Avoca Group tailors solutions that help companies build quality management, inspection readiness, and effective oversight systems into existing processes.

About The Avoca Quality Consortium®

Founded in 2011, the Avoca Quality Consortium (AQC) is a collaborative comprised of nearly 100 pharma, biotech, CRO, and clinical service provider companies with the shared objective of elevating clinical trial quality and bringing key stakeholders in the clinical trials process into greater alignment. Each AQC Member organization receives company-wide access to a comprehensive and proprietary Knowledge Center of over 400 leading practices, guidelines, tools, templates, and process documents, as well as AQC research and archived webinars. The AQC provided the foundation for the launch of the Diligent® Qualification Platform, a suite of tech-enabled services that streamlines, centralizes, and improves the process for clinical service provider qualification.

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