



**OWN THE
FUTURE** 8TH ANNUAL AVOCA
GLOBAL SUMMIT

June 5-6, 2019
BOSTON, MA

A NOTE FROM THE AVOCA GROUP

I'm pleased to welcome you to the Avoca Global Summit. 2019 marks the eighth year of the Avoca Quality Consortium® and the holding of our annual event. And, it is a special year for our company: The Avoca Group is celebrating the 20th Anniversary of our founding in 1999.

I have been reflecting on how Avoca has evolved over the past two decades concurrent with the changes in our industry. We are now at an interesting inflection point: the clinical trial ecosystem has become more complex, approaches to engaging patients have evolved, the lines between clinical trials and healthcare are blurring, and traditional ways of working are shifting due to the advent of new technologies. In short, the clinical trials industry is undergoing a transformation. And, to navigate these changes successfully, we need to adopt new ways of working while remaining grounded in the fundamentals of quality and risk management in clinical trial execution. This is what we will focus on in the workshops, presentations, and interactive sessions at this year's event.

The theme for the meeting is Own the Future. Our objective is to support our AQC Members with proactive approaches to address current challenges while helping them to maximize opportunities for the future. This includes driving efficiency and incorporating new technology while maintaining a focus on managing quality and mitigating risk.

I would like to express my sincere appreciation to our AQC Member companies for their ongoing engagement and participation. Pfizer and Lilly were our very first Members and corporate sponsors and their continued support has helped to fuel the success of the AQC.

I also want to thank our sponsors, Verizon Media, Sanofi, Seattle Genetics, Longboat, and Oracle Health Sciences. This year we have added a new opportunity for companies to showcase their products and services at the Summit. I encourage you to visit the exhibit tables outside the conference area and speak with company representatives.

Avoca's role over the past twenty years has been to shed light on areas for improvement, to offer creative solutions, and to serve as a catalyst for change. While we have grown and changed as the industry has evolved, one thing has stayed the same: we are as passionate about making a difference and having a positive impact on clinical trials as we were when the company was formed in early 1999. We hope you share that same passion and will approach the next two days with an open mind and a renewed sense of purpose.

Thank you for joining us at this year's meeting.



PATRICIA LEUCHTEN
Founder & CEO, The Avoca Group

A handwritten signature in black ink that reads "Patricia Leuchten".

Day 1 - Wednesday, June 5

9:45 am - 10:30 am	REGISTRATION AND NETWORKING BREAKFAST
10:30 am - 12:00 pm	PRE-CONFERENCE WORKSHOP AQC Workstream Updates
12:00 pm - 1:00 pm	WELCOME LUNCHEON Sponsored by Longboat
1:00 pm - 1:45 pm	OPENING REMARKS AND INTERACTIVE DISCUSSION
1:45 pm - 2:00 pm	ACRP/AQC WORKFORCE COMPETENCY INITIATIVES
2:00 pm - 2:10 pm	TRANSITION TO WORKSHOPS
2:10 pm - 3:20 pm	WORKSHOPS Unraveling the Mystery of Quality Tolerance Limits OR Risk-Based Inspection Readiness
3:20 pm - 3:45 pm	NETWORKING BREAK
3:45 pm - 4:55 pm	WORKSHOPS Enhancing Site Quality OR De-mystifying Decentralized Clinical Trial Provider Qualification
4:55 pm - 5:00 pm	CLOSING REMARKS
6:00 pm - 6:30 pm	SHUTTLE DEPARTS FROM BOSTON HARBOR HOTEL TO LEGAL HARBORSIDE
6:30 pm - 9:00 pm	THE AVOCA GROUP'S 20TH ANNIVERSARY CELEBRATION Legal Harborside
8:30 pm - 9:00 pm	SHUTTLE DEPARTS FROM LEGAL HARBORSIDE TO BOSTON HARBOR HOTEL

Day 2 - Thursday, June 6

7:45 am - 8:30 am	REGISTRATION AND NETWORKING BREAKFAST Sponsored by Oracle Health Sciences
8:30 am - 9:00 am	WELCOME AND OPENING REMARKS
9:00 am - 9:10 am	KEYNOTE INTRODUCTION
9:10 am - 10:00 am	KEYNOTE ADDRESS BY DAVID SHING ("SHINGY"), DIGITAL PROPHET, VERIZON MEDIA Current and future trends in the evolving digital landscape will be discussed, including how the rapid adoption of technology will advance the work of the clinical trials industry. Includes insight into what the industry's most valued stakeholder, the patient, will expect from clinical trials.
10:00 am - 10:30 am	RUNNING A DIGITAL CLINICAL TRIAL: THE FUTURE IS NOW A look at how clinical trials are changing in light of new technologies and what we can anticipate as an industry.
10:30 am - 11:00 am	NETWORKING BREAK
11:00 am - 12:00 pm	PANEL DISCUSSION: OWNING THE FUTURE What were once considered "Clinical Trials of the Future" are now the clinical trials of today. What are we learning about risk management and mitigation as this new wave of technologies implement themselves into clinical trial execution?
12:00 pm - 1:30 pm	LUNCH Sponsored by Verizon Media
1:30 pm - 2:00 pm	THOUGHT LEADER SPOTLIGHT A one-on-one interview with Tom Pike, Former CEO, Quintiles, on the state of clinical trials.
2:00 pm - 2:40 pm	INDUSTRY CHALLENGES WITH PROVIDER QUALIFICATION: WHAT'S AT STAKE? A review of the Tufts-Avoca working group study design and interactive discussion.
2:40 pm - 3:10 pm	NETWORKING BREAK
3:10 pm - 3:30 pm	THOUGHT LEADER SPOTLIGHT A one-on-one interview with Jennifer Byrne, CEO and Board Chair, Javara, on the intersection between clinical trials and patient care.
3:30 pm - 4:20 pm	PANEL DISCUSSION: FUTURE OF CLINICAL TRIAL PATIENT EXPERIENCE WITH USE OF DIGITAL TECHNOLOGY Experts discuss how far we have come as an industry in terms of clinical research merging with patient care and how technology is impacting the patient experience today.
4:20 pm - 4:30 pm	CLOSING REMARKS

The background features a city skyline with several buildings, including a prominent one with a grid-like facade. A green semi-transparent overlay covers the upper portion of the image, and a blue semi-transparent overlay covers the lower portion. A network diagram with nodes and connecting lines is visible in the green area.

2019 Presenters and Panelists

KEYNOTE SPEAKER



David Shing

Digital Prophet
VERIZON MEDIA

David Shing, aka Shingy, is Verizon Media's Digital Prophet. He spends most of his time watching the future take shape across the vast online landscape. The rest he spends talking to people about where things are headed, and how we can get the most out of it. Shing has spent most of his adult life in the digital world working for both large and small creative companies globally, while also co-authoring several technology related patents. He served as AOL's European Head of Media and Marketing before taking on his current mantle in New York City.

2019 PRESENTERS AND PANELISTS



Chen Admati

Head of Intel Pharma Analytics Platform
INTEL CORPORATION

Chen Admati is the Head of Intel® Pharma Analytics Platform at Intel. Prior to leading Intel Pharma Analytics Platform, Chen managed various artificial intelligence solutions and services in various domains. She is an AI professional with a vast understanding in the healthcare domain, including how to successfully digitize clinical trials.



Beatrice Anduze-Faris, MD

Executive Director, Head of Global Clinical Compliance and Continuous Improvement, Global Clinical Operations
BRISTOL-MYERS SQUIBB

Beatrice Anduze-Faris has 20 years of pharmaceutical experience with Bristol-Myers Squibb in various roles in commercial, regulatory compliance and strategy, and Medical Affairs. She has worked in France and Belgium and has been in the US for the last 16 years in US and Global roles of increasing responsibility. She joined Global Clinical Operations in early 2018 and now leads the Global Clinical Compliance organization. She earned her medical degree from the Pierre and Marie Curie University Medical School in Paris, France, and spent several years in the Infectious Disease Unit of the Pitié-Salpêtrière Hospital as a clinician, clinical investigator, and clinical monitor.

2019 PRESENTERS AND PANELISTS

Kristen Jonathan Bennett

Associate Director, Client Delivery
THE AVOCA GROUP



A member of the Avoca Group's integrated consulting and Avoca Quality Consortium workstreams, Kristen Bennett provides consulting services to top pharmaceutical, biotech, and contract research organizations, and oversees client deliverables, systems, and processes across The Avoca Group. Kristen has 12 years of clinical trial experience with expertise in clinical trial execution, process development, and strategic management. Her previous professional roles include project, data, and site management.

Brian Burk

*Life Science & Healthcare Innovation
Practice Leader*
VERIZON MEDIA



Brian Burk's life science career has entailed "carrying the bag" running US operations and as a marketer of global brands. He has led healthcare data, analytics, and compliance service providers. Additionally, he founded and successfully sold an e-prescribing and pharmacy routing company. Currently, Brian is the Practice Leader of Verizon's Business Outcomes Team for Life Science and Healthcare. Brian, his wife, and children live in central NJ. He has a passion for health & wellness which he applies by cooking, calisthenics, and competing in the USATF.

Bree Burks

*Senior Director, Vanderbilt Institute for
Clinical and Translational Research*
VANDERBILT UNIVERSITY
MEDICAL CENTER



As the Senior Director of the Vanderbilt Coordinating Center (VCC), Bree Burks works to advance global health. The VCC provides flexible, comprehensive clinical and translational research support to faculty at Vanderbilt University Medical Center. Prior to joining Vanderbilt, Bree coordinated various neurological trials at The University of Florida and worked as a neurosurgical ICU nurse. She also worked in The University of Colorado Denver's (UCD) Department of Radiology where her focus included interventional and general Radiology projects as well as establishing methods for providing Radiology support for trials across the UCD campus with specific research needs.

2019 PRESENTERS AND PANELISTS



Jennifer Byrne

CEO and Board Chair
JAVARA

Jennifer Byrne is CEO and Board Chair of Javara, an Integrated Research Organization (IRO) that offers comprehensive site services to better align population health initiatives across value-oriented healthcare systems. Her career has centered on advancing the clinical research enterprise; namely to better connect patients and providers to clinical trials. Jennifer's involvement in the clinical research enterprise includes collaborations with pharma, device, Contract Research Organizations (CROs), technology, site organizations, and other research service providers. Jennifer is the former CEO of PMG Research and Founder of Greater Gift (501(c)3).



Patty Donnelly, PhD

Vice President, Global Quality - Research and Development
ELI LILLY AND COMPANY

Patty Donnelly has a breadth of experience in drug discovery and development. She has held a variety of roles within the pharmaceutical industry over her 20-year career and currently is the Vice President of Global Quality for Research and Development at Eli Lilly and Company. Patty's experience includes leadership of drug development programs, senior management roles in Clinical Development and Quality, and key roles in in-/out-licensing of investigational drugs, strategic biotech acquisitions, and partnerships with CROs. She earned her doctorate in Pharmacology and Toxicology from Queen's University in Ontario, Canada.



Joseph Fortunato

Senior Director, Client Delivery
THE AVOCA GROUP

Joseph (Joe) Fortunato has 40 years of experience in clinical research including 17 years in large pharma and 19 years at CROs supporting trials at clinical sites. His background includes quality assurance and compliance; quality management systems and quality metrics; developing and implementing a quality culture; inspection readiness support and preparation; organizational change management and staff development; and delivering excellent customer satisfaction.

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2019 PRESENTERS AND PANELISTS

Aidan Gannon

Head of Client Services and Innovation
LONGBOAT



Aidan Gannon has over 20 years of clinical research experience in both pharmaceutical and CRO environments. He has managed early phase through to large global oncology and cardiovascular studies. Aidan is passionate about developing software solutions to make clinical trials easier for study teams, CRAs, sites, and patients, thereby giving new compounds the best chance for success. Aidan has completed an MSc in Biomedical Sciences at the University of Ulster and a BSc in Biotechnology at Dublin City University.

Kenneth A. Getz

Director, Sponsored Research; Principal Investigator CSDD
TUFTS UNIVERSITY SCHOOL
OF MEDICINE



Kenneth (Ken) Getz is the Director of Sponsored Research and an associate professor at the Tufts Center for the Study of Drug Development, Tufts University School of Medicine. He is also the chairman of CISCRRP – a nonprofit organization that he founded to educate and raise public and patient awareness of the clinical research enterprise. Ken is a speaker and published author, and founder of CenterWatch. He holds board appointments in the private and public sectors and serves on the editorial boards of Pharmaceutical Medicine and Therapeutic Innovation and Regulatory Science. Ken received an MBA from the J.L. Kellogg Graduate School of Management at Northwestern University.

Alexis Nichols Gorden

*Community Health Systems Infrastructure
Project Manager*
IDR Inc. and Clinical Trial Patient



Alexis Gorden is a business and technology manager with 18 years of experience providing cradle-to-grave management over large scale IT implementations as well as executive project management oversight. Alexis has sickle thalassemia beta zero and serves as a patient in a multi-center clinical trial. Her unique attributes of being a clinical trial patient and also a developer of technology solutions allow her to provide an important perspective for patients and technology.



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2019 PRESENTERS AND PANELISTS



Janis Hall

Senior Consultant
THE AVOCA GROUP

Janis Hall has over 25 years of experience in the healthcare industry with leadership roles in pharmaceutical, biotechnology, CRO, and medical diagnostic companies. As Senior Consultant for The Avoca Group, Janis developed many of the quality oversight tools within the Avoca Quality Consortium Knowledge Center including the Oversight Capability and Maturity Model® (OCMM) and Provider Qualification workstreams. Janis has been a chair, invited speaker, and panelist at numerous conferences. She holds an MBA from the University of Delaware and a BS in Chemistry from Towson University.



Joseph Kim

Senior Advisor, Clinical Operations
Transformational Technology and Innovation
ELI LILLY AND COMPANY

Joseph Kim serves as a Senior Advisor in Translational Technology and Innovation at Lilly, focusing on developing digital health solutions for patients. He has spent over 20 years in pharma research integrating his experiences working for Sponsors, such as Shire and Merck, CROs, and technology vendors. Joseph's experience includes early- and late-phase clinical research. He has been recognized as one of the Top 100 individuals on the 2015 MedicineMakers Power List, and 20 Innovators Changing the Face of the Clinical Trials Industry by CenterWatch (2013). He holds a BS in Molecular Biology from Lehigh University and an MBA from Villanova.



Lenna Kimball

Vice President, Clinical Operations
LYELL IMMUNOPHARMA

Lenna Kimball has over 25 years of drug development and clinical trial management expertise. Prior to Lyell, she served as VP, Clinical Operations at Five Prime Therapeutics where she built the clinical operations, data management, clinical outsourcing, and biosample management functions to run late stage clinical trials. Lenna served as VP, Clinical Operations at 3-V Biosciences and was a member of the executive leadership team. She spent over 10 years at Genentech, most recently heading the Research and Early Development Oncology Clinical Operations group where her team managed 60 trials across 28 assets. She also held roles at Cell Genesys, Intermune, and Roche.

2019 PRESENTERS AND PANELISTS

Jim Kremidas

Executive Director
ASSOCIATION OF CLINICAL RESEARCH
PROFESSIONALS (ACRP)



Jim Kremidas is Executive Director for ACRP, a not-for-profit association that represents the clinical research enterprise. Prior to ACRP, Jim consulted for a variety of clients such as investigator sites, academic institutions, sponsors, and suppliers. He was Senior Vice President, Patient Recruitment, at two different large CROs for over six years where he and his team were responsible for developing and implementing patient enrollment strategies for global clinical trials. Prior to that, Jim spent 24 years with Eli Lilly and Company. From 1999 to 2008, he led their clinical trial patient recruitment and retention efforts. In this role, he focused on predicting and accelerating the enrollment rates for all corporate studies. Jim is on the advisory board of CISCPR (a non-profit organization focused on enhancing patient participation in clinical trials) and is a volunteer for the Clinical Trial Transformation Initiative (CTTI) with Duke and the NIH. He is a frequent presenter at industry conferences and has written articles and papers that have been published in a wide variety of trade journals.

Patricia Leuchten

Founder and CEO
THE AVOCA GROUP



Patricia Leuchten has more than 30 years of experience in the pharmaceutical industry and is a leading authority on global clinical outsourcing and strategic alliances. In 1999, Patricia founded The Avoca Group, which has played an important role in the industry as the first consulting firm to track trends in clinical outsourcing and to measure the health of relationships between sponsors and CROs. Patricia is a frequent speaker and writer on topics surrounding clinical outsourcing, strategic alliances, quality management, and relationship management in the pharmaceutical industry.

Elizabeth Luczak

Vice President, Vertex Quality Assurance
VERTEX PHARMACEUTICALS



As Head of Quality Assurance for Vertex Pharmaceuticals, Elizabeth Luczak provides strategic oversight and direction for the deployment of the Quality Management System R&D, Manufacturing, Distribution, and Patient Safety operations and systems. Elizabeth has previously held positions of increasing responsibility across quality and compliance functions for clinical development, pharmacovigilance, and interrelated disciplines within biopharmaceutical companies, including 18 years at Pfizer, Inc. Elizabeth has more than 28 years of experience in quality model design and implementation across GxP disciplines in both sponsor and CRO organizations, with focus on culture, change management, and leadership for quality outcomes and effectiveness.

2019 PRESENTERS AND PANELISTS



Irene Michas, PhD

Senior Consultant
THE AVOCA GROUP

Irene Michas consults on pharmaceutical quality for The Avoca Group and provides subject matter expertise for the Avoca Quality Consortium. With a background in the pharmaceutical, biotech, and CRO industries, Irene brings extensive experience to diverse pharmaceutical development activities, including: regulated business process development; business process and systems training; audits and regulatory inspections; product licensing agreements; clinical research and development; data management; personnel and contractor recruitment and onboarding; and the management and implementation of global projects and initiatives. Previously, Irene was a senior leader within Pfizer's pharmacovigilance organization where she held the role of Regional Safety Lead.



Tom Pike

Former CEO
QUINTILES

Tom Pike is former CEO of Quintiles, a Fortune 500 pharmaceutical services firm which included the largest global Contract Research Organization. Under Tom's leadership, Quintiles grew and went public in 2013, innovating and winning a variety of awards including Fortune Magazine's World's Most Admired Company, Great Place to Work, and World's Most Ethical Companies. Tom is currently an advisor to and board member of a number of small, innovative services and technology firms. Prior to Quintiles, the majority of Tom's 35-year career was with Accenture where he was part of the leadership team. Tom has worked with over 200 companies as a consultant and executive throughout his career including with McKinsey & Co.



Steven Rosenberg

Senior Vice President & General Manager, Health Sciences Global Business Unit
ORACLE HEALTH SCIENCES

Steve Rosenberg has more than 30 years of experience leading development, services, support, and consulting, in addition to significant industry experience in life sciences and healthcare. Some of Rosenberg's key contributions to the industry include cloud-based solutions including an integrated approach to clinical trial management, new methodologies for patient-reported outcomes, and the introduction of advanced analytics for at-risk healthcare payers and providers.

2019 PRESENTERS AND PANELISTS

Jonathan Rowe, PhD, MS, MA

Executive Director, Head of Clinical Development Quality Performance and Risk Management, PFIZER



For more than 20 years, Jonathan Rowe has been working within large and small pharmaceutical companies to develop medical therapies from the clinical, operational, and business perspectives. As Executive Director, Head of Clinical Development Quality Performance and Risk Management at Pfizer, his responsibilities include monitoring, modeling, and predicting the Pfizer GCP Quality Management System, leading the analysis of Pfizer's Clinical Development Quality Performance, and ensuring clinical trial quality risk management is built into all trials. Jonathan earned his PhD and MS from the Department of Biochemistry at the Albert Einstein College of Medicine and his MA in reproductive endocrinology from the State University of New York at Binghamton.

Jay Turpen

Senior Consultant
THE AVOCA GROUP



Jay Turpen has held various leadership roles in the pharmaceutical industry over the span of his career. His background includes GMP, GLP, and GCP, as well as real-life experience developing numerous new drug candidates. He has been involved in leading clinical teams responsible for the clinical development and NDA preparation for multiple molecules. Jay retired from Eli Lilly and Company in 2017 where he was Senior Director, Clinical Project Management, Biomedicines.

Steven B. Whittaker


Senior Consultant
THE AVOCA GROUP



Steve Whittaker is lead consultant with The Avoca Group, providing expertise in project management, pharmaceutical development, clinical development, outsourcing strategies and execution plans. He served as Executive Director of the Avoca Quality Consortium from 2011-2018. Steve retired from Eli Lilly and Company in 2009, where he served as Chief Operating Officer/Sr. Director of Operations and Project Management for the Cardiovascular/Acute Care Platform.



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The background features a city skyline with several tall buildings. A large green rectangular overlay is positioned in the center, containing the title text. The top half of the image has a green tint, while the bottom half has a blue tint. Faint, light-colored network graphics, consisting of dots connected by lines, are visible in the background.

The Avoca Group Faculty and Staff

THE AVOCA GROUP FACULTY AND STAFF



Christine Albano

Vice President, Finance and Business Administration



Dawn Auerbach

Executive Director, Client Development



Michael Cruz

Senior Director



Rose Hunsicker

Senior Manager, Client Development



Janice Hutt

Vice President, Client Engagement

THE AVOCA GROUP FACULTY AND STAFF

Caryn Laermer

Executive Director, Client Engagement



Beth Listhaus, PhD

Manager, Client Development



Jenn Loaiza

Marketing Coordinator



Lisa McKay

Executive Director, Client Engagement



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GOLD SPONSORS



Sanofi is dedicated to supporting people through their health challenges. We are a global biopharmaceutical company focused on human health. We prevent illness with vaccines, provide innovative treatments to fight pain and ease suffering. We stand by the few who suffer from rare diseases and the millions with long-term chronic conditions. With more than 100,000 people in 100 countries, Sanofi is transforming scientific innovation into healthcare solutions around the globe.



Seattle Genetics, Inc. is an emerging multi-product, global biotechnology company that develops and commercializes transformative therapies targeting cancer to make a meaningful difference in people's lives. ADCETRIS® (brentuximab vedotin) is currently approved for the treatment of multiple CD30-expressing lymphomas. The company has also established a pipeline of novel targeted therapies at various stages of clinical testing, including three in ongoing pivotal trials for solid tumors. Tucatinib, a small molecule tyrosine kinase inhibitor, is in a pivotal trial for HER2-positive metastatic breast cancer. In addition, we are leveraging our expertise in empowered antibodies to build a portfolio of proprietary immuno-oncology agents in clinical trials targeting hematologic malignancies and solid tumors.

SILVER SPONSORS



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.



Oracle Health Sciences, now including goBalto, provides the only eClinical platform made up of best-of-breed solutions powered by the number one data and cloud technology in the world. With Oracle Health Sciences, life sciences organizations can unify all elements of the clinical development life cycle in a safe, secure, and compliant manner.

DILIGENT SPONSORS



DILIGENT PHARMA LEADERSHIP

John Jordan

Senior Vice President – Product Development



Michael O'Brien

Chief Strategy Officer

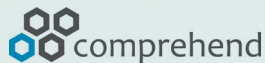


ASSOCIATE MEMBER COMPANIES



BIOCLINICA
SEE MORE CLEARLY

Bioclinica is a global life science provider that utilizes science and technology to bring clarity to clinical trials – helping companies to develop new life-improving therapies more efficiently and safely. Successful clinical trials require the ability to see key details and uncover hidden insights, and Bioclinica's hundreds of experienced scientific, medical, and domain experts bring unmatched insight across the development lifecycle, from the initial protocol to post-approval.



Comprehend provides a suite of cloud applications and consulting services that dramatically improve the clinical trial process. Our solutions deliver actionable risk and performance insights across studies, systems, sites, and vendors. By using elements of our Clinical Intelligence Platform to unify, monitor, and analyze data across all sources, sponsors and CROs alike are able to reduce risk, achieve milestones on time, and stay within budget. As a trusted partner, Comprehend helps speed the time to quality results.



Greater Gift's mission is to express gratitude for the heroic work of clinical trial contributors and to raise awareness for clinical research by saying Thank You to every clinical trial volunteer and every clinical research professional through a donation of a life-enhancing gift to a child. Through this "greater gift" of a vaccine or meal donation, we can immediately recognize the sacrifices made by clinical research participants while the benefits of their contribution to research will live on for years. By celebrating these volunteers and increasing patient engagement in clinical trials there is an opportunity to make a bigger impact on global health.



KPS Life is a functional service provider (FSP) that's redefining what "FSP" means by focusing on the one thing that matters above all else: Quality. At KPS, we deliver functional services through a progressive model - one that taps the best clinical ops professionals in the industry, supports them to do their best work, deploys state-of-the-art technologies, and enables full system integration with Sponsors.



Oracle Health Sciences, now including goBalto, provides the only eClinical platform made up of best-of-breed solutions powered by the number one data and cloud technology in the world. With Oracle Health Sciences, life sciences organizations can unify all elements of the clinical development life cycle in a safe, secure, and compliant manner.



Complion's mission is to revolutionize clinical research site regulatory and document management through the elimination of human error and redundant work to achieve maximum efficiency and compliance. That's why Complion is the first and largest eRegulatory and document management software vendor for sites, health systems, academic medical centers and cancer centers.



Florence advances clinical trials through software for managing document and data flow between research sites and sponsors. Florence eBinders is trusted by 4,000+ Investigators to manage eRegulatory/eSource for over 1,000 studies. Florence eTMF is the most flexible eTMF on the market with a wide range of innovative features, and Florence eHub is revolutionizing site-sponsor connectivity in a virtual site workspace for site oversight, monitoring, startup, and quality control.



Javara is an Integrated Research Organization (IRO) that provides first-rate clinical research services to healthcare organizations; bringing a turnkey site-based clinical trials infrastructure to enable more physicians and patients to participate in clinical trials. Recognizing the administrative and resource burden associated with the complexities of clinical trial conduct at the site level, we aim to make research more efficient and accessible.



In the complex world of global clinical trials, we believe that well-designed and practical technology solutions are vital in tackling the challenges of site engagement, patient engagement, and protocol compliance. Through 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.



Phlexglobal provides a unique Trial Master File solution by leveraging dedicated and authoritative TMF technologies and expert services to bring order, stability, and control to your Trial Master File – helping you achieve the highest standards for completeness, timeliness, and quality. Phlexglobal is headquartered in the UK, with offices in Malvern, PA and Lublin, Poland.

ASSOCIATE MEMBER COMPANIES



Strategic Development Solutions (SDS Clinical) is a specialized service provider for clinical operations with expertise in providing staff for clinical site monitoring, site management, and clinical trial management using a client-oriented model. We provide highly experienced clinical research associates (CRAs), regional monitors (RMs), clinical trial managers (CTMs), along with consultancy services in clinical operations execution and design.

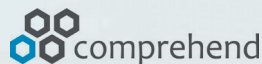


TRIO is a not-for-profit academic clinical research organization that is dedicated to advancing translational cancer research by bringing forward innovative and targeted therapeutic concepts into the clinical trial setting. TRIO offices are based in Canada, France and Uruguay. With an international network of 2000 investigators and 450 cancer centers in over 45 different countries, TRIO has conducted a number of new and innovative global studies evaluating systemic therapy for cancer.



University of Utah Health Care combines excellent patient care, medical research, and teaching to provide leading-edge medicine. We are the only academic healthcare system in the Intermountain West and serve burn patients, stroke victims, critically ill newborns and pediatrics, organ transplant recipients, and cancer patients. Nine-hundred board-certified physicians staff University Hospital, University Neuropsychiatric Institute, 12 Community Health Centers, Moran Eye Center, Huntsman Cancer Institute, University Orthopedic Center, and Utah Diabetes Center. Intermountain Healthcare's Primary Children's Hospital, located on the University Medical Campus, is the pediatric teaching hospital for the University of Utah. The Craig H. Nelson Rehabilitation Hospital construction will be completed in 2020.

EXHIBITORS



Comprehend provides a suite of cloud applications and consulting services that dramatically improve the clinical trial process. Our solutions deliver actionable risk and performance insights across studies, systems, sites, and vendors. By using elements of our Clinical Intelligence Platform to unify, monitor, and analyze data across all sources, sponsors and CROs alike are able to reduce risk, achieve milestones on time, and stay within budget. As a trusted partner, Comprehend helps speed the time to quality results.



KPS Life is a functional service provider (FSP) that's redefining what "FSP" means by focusing on the one thing that matters above all else: Quality. At KPS, we deliver functional services through a progressive model - one that taps the best clinical ops professionals in the industry, supports them to do their best work, deploys state-of-the-art technologies, and enables full system integration with Sponsors.



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Rho, a contract research organization (CRO) located in Chapel Hill, NC, provides a full range of services across the entire drug development process. For more than 30 years, Rho has been a trusted partner to leading pharmaceutical, biotechnology, and medical device companies as well as academic and government organizations. Our commitment to excellence, innovative technologies, and therapeutic expertise accelerate time to market, maximize returns on investment, and lead to an exceptional customer experience.



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Boost Site Quality with Longboat's Guided Compliance



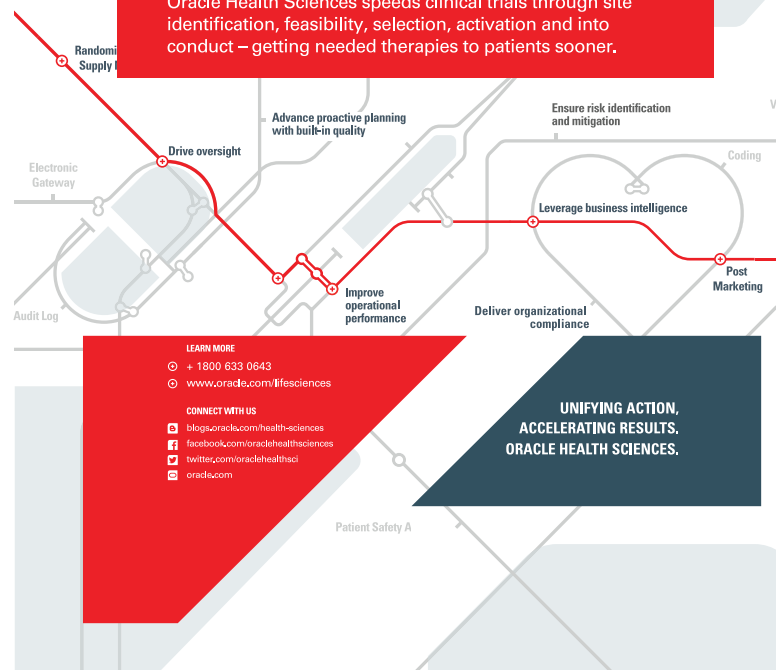
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of the Avoca Quality
Consortium since 2015

www.longboat.com

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Oracle Health Sciences speeds clinical trials through site
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conduct – getting needed therapies to patients sooner.



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ORACLE HEALTH SCIENCES.



**QUALITY
CONSORTIUM®**
THE AVOCA GROUP

Current AQC Members

The Avoca Quality Consortium consists of nearly 100 Member companies with over 8,000 Member representatives.





8TH ANNUAL AQC FALL MEMBER MEETING

**Please join us for the next AQC Fall Member Meeting,
Thursday, November 7, 2019**

AT THE SEATTLE RENAISSANCE HOTEL IN SEATTLE, WASHINGTON.

Since its inception in 2011, the AQC has been committed to furthering education, expanding awareness, and fostering engagement among Sponsors, CROs, and Clinical Service Providers.

The AQC Fall Member Meeting is an opportunity for ClinOps, Quality, Pharmacovigilance, Clinical Research and Development, and Outsourcing professionals to connect with Avoca and industry thought leaders in a fun, casual, and interactive learning environment.

The program consists of working sessions and is designed for participants to gain practical knowledge and experience that can be incorporated and communicated across their organization.

Attendance at the annual Fall Member Meeting is one of many benefits of Membership of the Avoca Quality Consortium. Two representatives from each Member company receive complimentary passes. To register your attendees, contact Caryn.Laermer@TheAvocaGroup.com.

PLAN NOW TO ATTEND!

About The Avoca Group

The Avoca Group leads the industry in GCP quality and compliance solutions. With 20 years of experience providing research and consulting services, Avoca merges deep institutional knowledge in the foundations of good clinical practice with future-forward leadership in regulatory compliance, quality management, and clinical operations across the evolving clinical trials landscape. The Avoca Quality Consortium, Avoca's cross-functional collaborative, unites sponsors, CROs, and clinical service providers to address challenges and maximize opportunities to mitigate risk and improve both quality and execution in clinical trials.

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