QUALITY CONSORTIUM

THE AVOCA GROUP

2016 SUMMIT USA

Integrating Quality, Innovation, and Collaboration for Clinical Trial Transformation

PRINCETON, NEW JERSEY

May 10-11, 2016

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THE AVOCA GROUP
2016 SUMMIT USA

Thank You to Our Consortium Sponsors

Sponsored by Eli Lilly and Pfizer and led by The Avoca Group, the Avoca Quality Consortium (AQC) provides leading practices for the optimization of proactive approaches to achieving quality and mitigating risk in clinical trials and programs. The AQC brings together pharma, biotech, and clinical service companies that share a commitment to collaboratively improving the execution and management of outsourced trials.

Welcome

On behalf of The Avoca Group and event chair, Dr. Robert Metcalf, Vice President, Global Regulatory Affairs – NA and Clinical Quality, Lilly, I am pleased to welcome you to the fifth annual Avoca Quality Consortium (AQC) Summit USA. We genuinely appreciate the ongoing support of our corporate sponsors, Pfizer and Lilly. This year, inVentiv Health is the Platinum Sponsor of our event. Their sponsorship has helped to make the Summit possible, and I would like to extend a special thank you to Jeffrey McMullen, Chairman, inVentiv Health Clinical and Vice Chairman, inVentiv Health, Inc., and our colleagues at inVentiv for their ongoing support and commitment to the AQC. Robert Metcalf, Summit co-chair, will be partnering with us throughout the Summit to ensure that you not only engage in thought provoking, pushing-the-envelope debates but also leave with ideas on what we can do differently going forward. We are also excited to be hosting our inaugural AQC Summit in Europe, June 6-7, which promises to be a tremendous success.

When we launched the Quality Consortium in 2011, Avoca's vision was to create a vehicle for sponsors and CROs to work in collaboration with Avoca to improve quality and mitigate risk in clinical research, while at the same time, to shorten timelines and increase efficiency in the clinical trial process. Since its inception, the Quality landscape has evolved to see new and emerging goals, processes, companies, and technologies. As a collective team, we have continued to move the Quality needle, and in a short period of time, have had a successful collaboration that has seen the launch of over 250 guidelines, leading practices, tools, templates, and in some cases, standards for the proactive management of quality and risk in clinical trial execution.

Our annual face-to-face meetings, coupled with plenty of formal and informal discussions and brainstorming sessions have led to a potent partnership that is growing in strength from year to year. Our Members continue to leverage and optimize the AQC as a key enabler to ensure that lofty goals and strategies can be turned into actionable process changes that lead to advancing quality and improving efficiency in the conduct of clinical trials.

Given the rapidly evolving healthcare landscape that has seen a plethora of mergers and acquisitions, amazing technological advancement, and the emergence of the educated, empowered patient, the need for open, honest debates and dialogue among AQC members is crucial.

Our Summit is an integral component of this dialogue since this is where we convene as a collective, committed body to listen to the latest trends, celebrate our progress, and take on new challenges to deliver on things that were unfathomable a few years ago. The AQC Summit invigorates meaningful progress through sharing and collaboration.

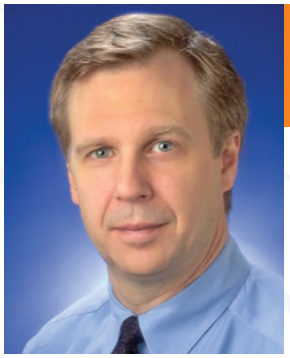
The 2016 Summit theme is **Integrating Quality, Innovation, and Collaboration for Clinical Trial Transformation**. This year, based on your advice and guidance, we will straddle between new, exciting areas of innovation and very tactical tools/methods discussions to enhance your value from the AQC. Our Keynote Speaker, Dr. Roni Zeiger, Former Chief Health Strategist at Google and current CEO of Smart Patients, will speak on *Patients as Micro-Experts: Enhancing Clinical Research by Seeing Patients as Collaborators*. You will also have the option to participate in a hands-on workshop, which will use Design Thinking to incorporate patient input into clinical trials.

I want to take a moment here to thank each of our AQC Members. The Consortium is successful because of all we collectively do to push the Quality agenda forward. In addition to our Platinum Sponsor, inVentiv Health, our Silver Sponsors are Acurian and ICON. I would like to extend a special thanks to each of these companies. And thank you to our Summit Media Partners: Outsourcing Pharma and Life Science Leader.

We hope you walk away feeling energized by new ideas and thoughts, and raring to go to implement changes that will continue to focus on bringing medicines to patients in a more efficient manner.

PATRICIA LEUCHTEN
President & CEO, The Avoca Group

SUMMIT CHAIR



Robert Metcalf, PhD
Eli Lilly and Co.

Robert is Vice President of Global Regulatory Affairs – NA and Clinical Quality. He is responsible for interactions with the FDA supporting new drug development and marketed products, including US product labeling, advertising and promotion, and regulatory policy. Robert also has responsibility for global label management, global submission management, and global Chemistry, Manufacturing, and Control for Lilly. He also has responsibility for the Quality organizations supporting clinical development, regulatory, and product safety.

After completing his PhD in Pharmacology and Toxicology at Queen's University in Canada, Robert joined Eli Lilly Canada in the Regulatory Affairs organization where he led successful approval efforts for neuroscience and anti-infective new chemical entities. His next opportunity led him to the Lilly Corporate Center in Indianapolis where, as a member of the Global Project Management organization, he led cross-functional teams in the global development and registration of new molecular entities in Lilly's diabetes and osteoporosis portfolios. Following this opportunity, Robert returned to Lilly Canada where he had leadership responsibility for Regulatory Affairs, Health Outcomes, and Quality. In 1998, Robert was transferred to Japan where he led the Project Management and Pharmaceutical Development organizations for Lilly Research Laboratories, Japan. Robert returned to Indianapolis in 2002 as a Director in Project Management with responsibility for the Project Management organizations supporting early and late stage drug development. In 2005, Robert was named Executive Director of Global Patient Safety with worldwide responsibility for adverse event case management, pharmacovigilance, and quality systems in support of product safety. In June of 2009, Robert was named Vice President of Global Ethics and Compliance where he had responsibility for providing Ethics and Compliance leadership to functional and geographic areas across Eli Lilly, including implementation of an effective compliance program. In February of 2011, Robert was named Vice President of Global Regulatory Affairs – US and Global Medical Quality, responsible for the organization and activities noted above.

KEYNOTE SPEAKER

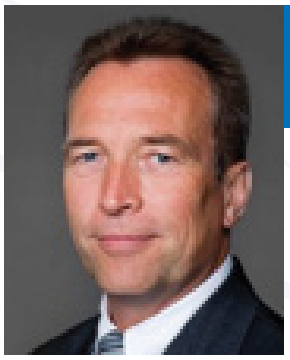
Roni Zeiger, MD
Smart Patients

Dr. Zeiger is the former Chief Health Strategist at Google. He is a practicing physician, technologist, and medical innovator. He has a solid understanding and vision of technology's potential in healthcare.

At Google, Dr. Zeiger was in charge of how the company shared all health-related information, including Symptom Search, making emergency information such as poison control and suicide hotlines prominent, Flu Trends, which provided information on wellness with as much accuracy as the CDC, in real time and at a fraction of the cost, and Google's personal health records project.

Dr. Zeiger has also worked to connect patients with each other to form communities of experts. He enabled connections among researchers to facilitate and improve medical research, and explored the future of medical education as impacted by technology. With knowledge of technological capabilities, as well as medical and institutional realities, Dr. Zeiger has a vision for how technology will transform healthcare. He is a broad thinker with true insight and a passion for the work. He sees the present time as one of great opportunity.

EXECUTIVE ROUNDTABLE PANELISTS AND PRESENTERS



Peter Aurup, MD
Pharmacyclics

Peter Aurup joined Pharmacyclics, Inc. (PCYC) in early 2015 as Head of Global Development Operations (GDO). In this role, he is responsible for all aspects of clinical trial execution including Project and Alliance Management, Vendor strategy and management, Clinical Quality Management, Systems Support, and Trial Management for all clinical phases.

Dr. Aurup has spent more than 28 years in Pharmaceutical Medicine with more than 9 years in Continental Europe and the UK and the last 19 years in the US. Before joining PCYC he was Vice President and Head of Global Clinical Trial Operations at Merck with approximately 3800+ staff globally. Here, he was overall responsible for clinical trial programs phases IB-IV in all therapy areas involving more than 250,000 patients randomized from across the Globe. In 2014, Dr. Aurup was responsible for all development operational activities leading to the approval of 5 NDAs, including PD-1 for the treatment of malignant melanoma. Other therapeutic areas have been Cardiovascular, Endocrine/Metabolism including Diabetes, Women's Health/Infertility, CNS, and Allergy. Prior to Merck, he worked in similar senior key management roles for companies like Pharmacia, Pfizer, Novo Nordisk, and Schering-Plough.

Dr. Aurup received his medical degree from the Medical School at University of Copenhagen, Denmark, in 1984 and trained in internal medicine and cardiology before joining the pharmaceutical industry in 1989. He has published several scientific papers and is a member of various academic and professional societies.

Courtney L. Bryant
Shire

Courtney Bryant is Director of a Clinical Due Diligence & Integration Team at Shire Pharmaceuticals. In this role, she and her team evaluate the clinical components assets that Shire may acquire. Prior to joining Shire, Courtney worked at Novartis Vaccines & Diagnostics and Quintiles in various process improvement and clinical operations roles.

Courtney received her BS in Nutrition and is a Registered Dietitian. She also holds an MBA from Simmons College and is a Six-Sigma Green Belt.

EXECUTIVE ROUNDTABLE PANELISTS AND PRESENTERS

Jennifer Byrne
PMG Research

Jennifer Byrne is Chief Executive Officer of PMG Research, Inc. (PMG) and serves on its Board of Directors. In this role, Jennifer is responsible for driving the company's growth as a leader of one of the largest wholly owned and operated Integrated Site Networks in the US. PMG Research delivers a standardized clinical research infrastructure to large physician practices and mid-market organized systems of care with a commitment to deliver improved care, decreased costs, and improved patient satisfaction through clinical trial participation as a care option. Jennifer spends much of her time with health care providers learning more about the challenges they face in connecting the right patients to the right trials. This understanding leads to better solutions for both the health care system and the Pharma and CRO clients of PMG.

Jennifer has concentrated her career in the clinical research site sector for over 25 years. During her long-term tenure at PMG she and her team have completed over 7,200 Phase I-IV clinical trials, which have included over 100,000 research volunteers. Jennifer was recognized as a CenterWatch Top 25 Innovator and currently serves as an Advisory Board member to CISCRP and the Wake Forest Institute of Regenerative Medicine and Board member of the Hospice Foundation and The Greater Gift Initiative.

Jennifer earned her Bachelor of Science in Nutrition at Texas A&M University.

Elspeth Carnan, PhD
Sunovion

A global biopharmaceutical industry executive with a strong technology background in clinical operations, Elspeth Carnan is adept at driving strategic transformation of the clinical trial execution platform, capitalizing on more than 25 years of both domestic and international accountability. Elspeth currently serves as Head of R&D Operational Excellence at Sunovion.

In 2005, Elspeth was recruited by Amgen, following 16 years at GlaxoSmithKline. Elspeth held several notable positions during her 9 years of tenure. Her first role was as a European Regional Director, responsible for European feasibility and study delivery based in the UK. In 2007, she was promoted to Executive Director, moving with her family to Thousand Oaks. In this role, Elspeth was accountable for site management activities globally. Responsibilities were significant and included: feasibility, study placement, subject recruitment, pharmacy oversight, and monitoring functions within GDO across all phases of Amgen-sponsored clinical trials. Elspeth was instrumental in shaping the Amgen clinical monitoring platform; first successfully driving the global implementation of the Functional Service Provider, with 12 providers and across 56 countries. More recently, with Elspeth's wealth of clinical operations experience, she was instrumental in the design and support of the centralized monitoring initiative. While at Amgen, she made a significant impact in shaping Amgen's approach to innovation. Through her commitment to driving Operational Efficiency and supporting the scoping of the Streamline Clinical Trials initiative, Elspeth ensured a focus on transforming the approach of clinical trial execution, most notably in study design and study start-up. Her dedication to the establishment of the R&D Global Network framework to enhance end-to-end process development has added value to Amgen's approach to knowledge sharing. A key industry contributor to Linking Leaders Risk Based Monitoring working group (paper published), Partners in Innovation, Tufts Medical School, Avoca, and most recently the Society of Clinical Research Sites, and over the past 4 years, Elspeth has had many panel and speaker engagements at DIA, Disruptive Innovation (EU), Partnerships, been interviewed for articles in CenterWatch, and published in Applied Clinical Trials.

Elspeth holds a PhD in Physiology from University Newcastle Medical School and a Bachelor of Science (Physiology) from University of Glasgow.

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Anthony J. Costello
Mytrus

Anthony Costello is Co-Founder and CEO of Mytrus and a leader in the area of clinical trials technology. For over 20 years, he has been developing disruptive innovations that can simplify clinical trials for patients, sites, and sponsors. After beginning his clinical career in clinical data management at Genentech, Anthony has gone on to co-found several clinical and high technology start-up companies in California including Nextrials, Bazu Media (now Chronotrack), and Mytrus - a clinical research technology company building web and mobile applications for patients on clinical trials. He has been selected as one of the PharmaVoice Top 100 Most Inspiring People in Clinical Research, served as Chairman of the Board for the Society for Clinical Data Management, on the Founding committee for the CDISC CDASH initiative, and is currently a member of the editorial advisory board for Applied Clinical Trials magazine. He is a frequent author and presenter on topics related to the efficient use of technology in clinical research. He has a degree in Sociology from UC Berkeley. inVentiv Health is an investor in Mytrus and integrates its pioneering technology to help clients improve clinical trial execution, speed time to market, and reduce product development costs.

Grace Crawford
MedImmune

Grace joined MedImmune in April 2015 as head of the Clinical Quality & Compliance function responsible for the Quality Management Framework that supports Clinical Biologics. Prior to joining MedImmune, Grace spent over 21 years at ICON where her main focus was leading the Clinical Quality Assurance Department. She is active in the industry, participating in forums such as the Society for Quality Assurance, the Avoca Quality Consortium, and Linking Leaders Clinical "Quality" Roundtable. Before joining ICON, Grace was a medical technologist in the Clinical Laboratory (Special Chemistry and Immunology) at Bryn Mawr Hospital in Pennsylvania. She earned a Master of Science Degree in Clinical Microbiology at The Medical College of Pennsylvania.

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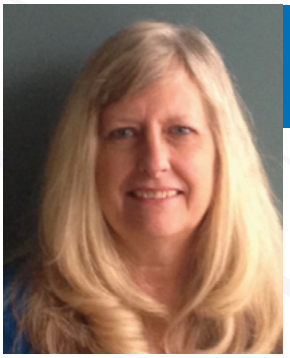

Marta Fields
Seattle Genetics

Marta Fields joined Seattle Genetics in 2008 as Senior Director of Research and Development Quality after 21 years at Amgen, where she served in a variety of roles, most recently Director of Clinical Compliance. At Seattle Genetics, Marta is responsible for GCP and GLP Compliance and serves on the management team for the Quality Organization. She has presented on protocol complexity and inspection management at the Drug Information Association Annual Meetings and was co-chair of the 2001 and 2003 Good Electronic Records Management (GERM) conferences sponsored by the Parenteral Drug Association. She is currently partnering with Quorum IRB to explore alternatives in obtaining informed consent from clinical research participants. Marta holds a Bachelor of Science in Speech from Northwestern University and received her Master's Degree in Healthcare Management from California Lutheran University.

With 25+ years in biopharma, Marta has an in-depth knowledge of GCP regulations and extensive experience with conducting clinical trials in a global setting.

Kathleen Griffin
INC Research

Kathleen Griffin currently serves as an Executive Director in the INC Research Corporate Strategy group. In that role, she identifies opportunities to harness data and technology that will help innovate in the important areas of Sites and Patients. In addition, she monitors the digital health environment and advises on critical areas of the company's business, such as strategic planning and business intelligence. She supports the Clinical Innovations and Site and Patient Access teams to ensure that INC Research utilizes data to innovate with the right partners and the right trials, at the right time.

Prior to her strategic business role, she served as an Executive Director in the INC Research IT department and was responsible for IT Strategy, Communication, and Business Relationship management teams. Ms. Griffin is a founder of AVOS Life Sciences, a management consulting firm in the biopharmaceutical industry. Her industry experience includes 3 years at Quintiles Transnational in a host of strategic development roles. Additionally, she spent time at IBM's Wilkerson Group, focusing on pharmaceutical practice initiatives.

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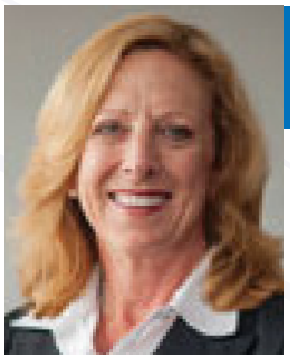

Amy Y. Grahn, MS
Horizon Pharma

Amy Grahn has more than 30 years of pharmaceutical industry experience spanning pre-clinical research to commercial roles, with a primary focus on clinical development and operations. She has been responsible for the clinical portion of the New Drug Applications (NDAs) for two approved drugs, DUEXIS® (ibuprofen/famotidine) for OA and RA, and RAYOS® (delayed-release prednisone) for a variety of indications primarily focused in rheumatologic diseases. She has led clinical trial teams for many registration trials, both Ex-US and US based, as well as trials for post marketing requirements for RAVICTI in a rare orphan disease. Previously, she was Vice President of Clinical Operations at MedGenesis Therapeutix, Inc. in British Columbia, Canada, and prior to that, Vice President of Clinical Operations at NeoPharm, developing unique therapies targeting primary brain cancer, other cancers, and Parkinson's disease. During her career, Ms. Grahn has also held various senior level positions at Takeda Pharmaceuticals North America, Inc., Searle, and Abbott, developing drugs for HIV, asthma, diabetes, and chemotherapy-induced neutropenia. During her career, Ms. Grahn has authored and co-authored over 20 peer-reviewed publications of clinical trial results

Paul Gilbert
MedAvante

Mr. Gilbert has 30 years of leadership, strategy, and innovation experience at best-practice organizations including Johnson & Johnson, Arm & Hammer, Booz Allen, and Gillette. He has successfully scaled up companies in both consumer and business markets with emphasis on innovating new markets.

One of three co-founders of MedAvante in 2002, he has led the building of a global team that now delivers signal detection services for clinical trials in more than 40 countries worldwide. His leadership focus has been on placing exceptional talent, capital and resources behind pioneering powerful methodological innovations to address the high rate of failed central nervous system (CNS) clinical trials, including remote Central Ratings and electronic source documents (eSource), always ensuring that MedAvante's culture, organizational design, business model and strategy reinforce service excellence. Mr. Gilbert led MedAvante's acquisition of $49 million in growth capital, including an initial $14 million round from 82 organizational leaders from pharma, Wall Street, and innovative growth company CEOs who continue to provide expertise and insights.

Prior to MedAvante, Mr. Gilbert was Vice President of Marketing and Strategy for Princeton eCom, which was awarded New Jersey Technology Council's 2001 Technology Company of the Year, overseeing the development and execution of all marketing and strategy initiatives. He has served most recently on the boards of Derma Sciences, a publicly traded tissue regeneration company, and the prestigious non-profit International Longevity Centre Global Alliance (acquired by Columbia University). He's been invited to present on innovation multiple times at Princeton and Wharton and is a strategic advisor to young innovative companies. In 2012, Mr. Gilbert was awarded the Ernst & Young Lifesciences Entrepreneur of the Year.

Paul graduated magna cum laude from Bowdoin College where he was named a James Bowdoin Scholar, and received his MBA from Harvard University.

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Mitchell Katz, PhD
Purdue Pharma

Dr. Mitchell Katz is Head of Medical Research and Drug Safety Operations at Purdue Pharma L.P. In this position, he is responsible for leading all operational activities across Purdue's multinational clinical programs.

Dr. Katz has 27 years' experience in the pharmaceutical and biotechnology industries, including preclinical research, pharmaceutical operations, and regulatory affairs. Prior to joining Purdue, he served as Vice President of Global Clinical Operations & Data Management at Eisai Medical Research. Dr. Katz has experience working in start-up biotechnology companies, including Acorda Therapeutics, InterMune, Connetics, and NABI. He also held management positions at Ortho Biotech and Schering-Plough and participated in six successful NDA applications in his professional career.

Dr. Katz holds a BA in Biology, a PhD in microbiology, and served as a postdoctoral research fellow at Downstate Medical Center in New York.

Joseph Kim, MBA
Eli Lilly and Co.

Joseph Kim serves as a Senior Advisor in Clinical Innovation at Lilly, focusing on developing and implementing innovative patient engagement solutions. He has spent over 17 years in the Pharma industry utilizing a unique approach that integrates his experiences working for Sponsors such as Shire and Merck, CROs, and technology vendors. He has a robust combination of experience that includes early and late phase clinical research, and a well known history of innovation in the clinical research industry, 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 in 2013. He holds a BS in Molecular Biology from Lehigh University and an MBA from Villanova. He tweets from: @JoPeKim

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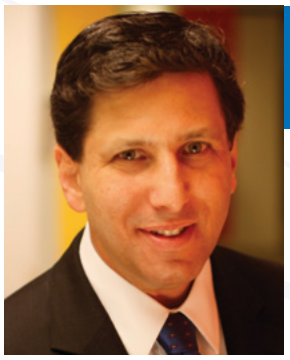
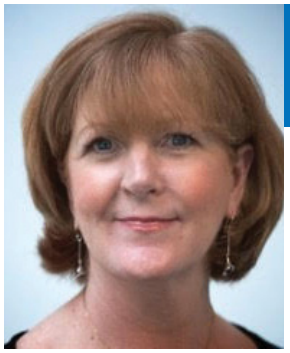


Craig Lipset
Pfizer

Craig H. Lipset is Head of Clinical Innovation within Worldwide Research & Development at Pfizer. Craig's team is responsible for impacting clinical research through digital tools, innovative research approaches, and unprecedented collaborations. He serves on the Board of Directors for the Foundation for Sarcoidosis Research, the Board of Directors for the MedStar Health Research Institute, the Operations Committee for TransCelerate BioPharma, and as a Mentor at health tech accelerator Blueprint Health. Craig also serves on the Editorial Board for Therapeutic Innovation & Regulatory Science.

Craig previously served as Venture Partner in Pfizer Venture Investments as well as Senior Director in Molecular Medicine within Pfizer R&D. Prior to Pfizer, he served as Associate Vice President of Program Management at Adnexus Therapeutics (acquired by Bristol-Myers Squibb) and on the founding management team for Perceptive Informatics (now part of PAREXEL International).



Karen McIntyre
Longboat

Karen is Head of Clinical Compliance and Site Engagement at Longboat Clinical and has held this role since August 2015. Prior to this role, Karen worked at Firecrest Clinical where her responsibilities included clinical compliance, supporting operations, and client relationship. Karen also spent two years (2004/5) at Leiden University Clinical Trials Unit implementing quality systems in compliance with Directive 2001/20/EC and GCP/ICH. With 25 years experience in the clinical trials industry, she has held a variety of positions of increasing responsibility from study site coordinator to Head of a Site Management Organization. Karen's main focus is to improve quality and compliance by introducing study management systems to revolutionize the organization and successful delivery of today's clinical trials.

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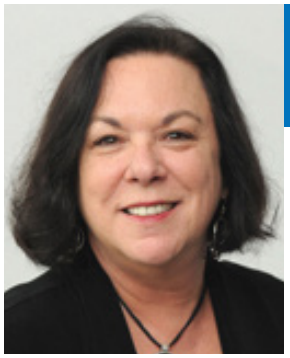
Neil McCullough, PhD, MSc
ICON

As Executive Vice President of Quality and Compliance, Dr. Neil McCullough provides strategic direction for quality management, quality assurance, and corporate compliance across all ICON lines of business. As a member of the Executive Leadership Team, he brings full development expertise to corporate risk decision-making and provides expert input to the strategic management of the company. Neil also provides guidance and regulatory intelligence to the various operational, medical, and scientific groups across ICON.

Neil brings to ICON over 25 years of experience leading global quality functions for pharmaceutical and clinical research organizations. Prior to ICON, Neil led the global quality and compliance division of PPD, before which he spent nine years at Pfizer as a member of the Pfizer Global Medical Quality Assurance Leadership team. Prior to Pfizer, Neil served as a quality consultant to GlaxoSmithKline's division of manufacturing and began his career in Beecham Pharmaceuticals in Worthing, UK as a quality control technician in penicillin manufacturing.

Neil earned his doctorate in chemistry from the University of Kent at Canterbury in the UK, and his master's degree in pharmaceutical medicine from Hibernia College, Dublin, in partnership with Harvard University and the Royal College of Physicians, Ireland. Neil serves as the Chairman of the ACRO Ethics & Regulatory Compliance Committee, working closely with key industry advocacy groups and regulatory agencies.



Nancy Meyerson-Hess, BA, MPhil
Grünenthal

Nancy Meyerson-Hess, a native New Yorker, has studied in the US and England. She has over 30 years of experience in clinical research including working for large, medium, and small pharma and contract research organizations in the US and Europe. She has been responsible for establishing and leading global clinical research teams, including emerging regions. In 2011, she joined Grünenthal GmbH, a pharmaceutical company located in Aachen, Germany, where she is currently Head Clinical Operations & Compliance.

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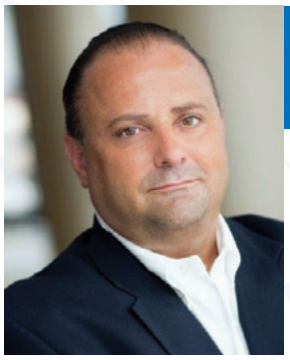

Paulo Moreira
EMD Serono

Paulo Moreira is a Clinical Development executive with 25 years of experience in Clinical R&D. He has been with EMD Serono for the last 15 years in diverse positions within Clinical Development and presently serves as the Head of Global Clinical Operations External Innovation. In this capacity, Paulo is responsible for Clinical Innovation, as well for Patient Centricity in Clinical Development and Operations where he has had a preponderant role in establishing EMD Serono as an industry leader in patient centricity around clinical trials.

Paulo is also a Visiting Scholar at Boston College where he teaches at the Essentials of Clinical Research and Project Management Program. Paulo is very active in several industry-wide organizations. He dedicates some of his time to the Steering Committee of the Clinical Trial Transformation Initiative (CTTI). He represents EMD Serono on TransCelerate's Operations Committee, PhRMA's Clinical Trial Advocacy Group and fulfills the role as the Global Impact Partner of the Society for Clinical Research Sites (SCRS). Paulo also serves on the Advisory Board of a couple of companies that provide services to the Pharma/Biotech industries. Lastly, Paulo was named this past August to PharmaVoice's 100 Most Inspirational Leaders of 2015 recognizing his industry leadership around patient centricity.

Armelde Pitre
Pfizer

Armelde Pitre has more than 25 years of experience spanning many aspects of drug development. She led clinical projects from feasibility to regulatory submission in all phases and in multiple disease areas. Her experience includes functional line management in biometrics, information technology, benchmarking and metrics, quality assurance, vendor management, and SOPs and training. Currently, Armelde is the Senior Director of Quality Performance and Risk Management and Analytics at Pfizer. She provides leadership and expertise in analysis, interpretation and presentation of performance intelligence to drive decision-making, process improvement and delivery in clinical trials.

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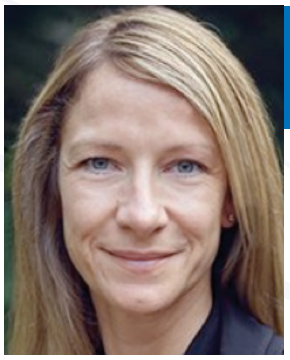

Jane Rhodes, PhD, MBA
Biogen

Jane [Relton] Rhodes is Senior Director of New Initiatives in the Value Based Medicine group at Biogen. Dr. Rhodes leads a number of initiatives that employ digital solutions to help transform the care of patients with neurological diseases and create value for the business.

Dr. Rhodes began her scientific career in the field of neurology drug discovery research, and worked on novel therapies for stroke, MS, ALS, Parkinson's disease, and Alzheimer's disease.

Elizabeth Robinson
Horizon Pharma

Beth Robinson is the Executive Director, Clinical Compliance and Operations at Horizon Pharma, plc. Since 2002, Beth has also been an instructor in the Certificate in Clinical Trials Management program at University of Chicago's Graham School. She teaches the Fundamentals of Clinical Monitoring course and the regulatory portions of the Drug Development Process course. In her 20+ years of industry experience, Beth has worked and consulted in data management, clinical operations (monitoring and study management), medical writing, quality (SOPs, training, auditing, risk evaluation), GCP consulting, and regulatory affairs. Prior to her industry experience, Beth worked as a study nurse coordinator among other clinical roles.

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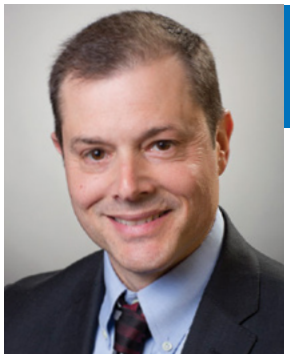
Susan Romberg
Chiltern

Susan Romberg has been with Chiltern International since early 2014 where she is currently responsible for the Global Clinical Operations.

Susan started her career as a cardiac critical care nurse and left the hospital to begin her industry career at the University of Pennsylvania in the Cognitive Neurology and Geriatric Psychiatry departments as a Study Coordinator. From there she moved to Astra Merck working with their CV compounds and eventually moving to the CRO side of the industry. She has worked for PPD, Clinsys, PRA, and now Chiltern.

Over her 20+ year career, Susan has held a wide variety of roles within the industry. Susan specializes in Clinical Operations, and her responsibilities have included oversight of global departments including project management, study start-up, records management, clinical training, clinical quality operations, and contracts & budgets. She also sits on numerous governance teams, industry executive committees, is involved in change management initiatives, innovation development, and developed & hosted Chiltern's first ever hackathon.

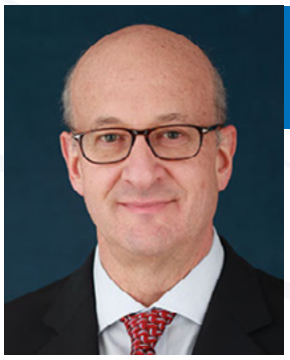
Currently, Susan is passionate about our evolving industry and the impact it will have on our future workforce. In light of technology advancements, change in site make-up, and new drug development partners emerging, she is interested where new talent comes from, the type of background that will be required, and how we can begin now to pull them into the industry.



Jonathan Rowe, PhD
Pfizer

Since 1996, Jonathan Rowe has been working within and supporting large and small pharmaceutical companies to develop medical therapies from the clinical, operational, and business perspectives. Currently, Jonathan holds the position of Executive Director, Head of Clinical Development Quality Performance and Risk Management at Pfizer where his responsibilities include monitoring, modeling and predicting the Pfizer GCP Quality Management System, leading the analysis of Pfizer's Clinical Trial Quality Performance, and ensuring clinical trial quality risk management is built into all trials. At Pfizer, he has held a number of roles of increasing responsibility including Clinical Director, Cardiovascular Risk Factors Group with responsibility for the phase IIIb and IV Lipitor program; Director, Intellectual Property Strategy Management; and Senior Director Process and Performance. Jonathan spent a number of years supporting the growth of small pharmaceutical companies. From 2009-2014, he was the Head of Intellectual Property and Portfolio Strategy for both Amarin and Dignity Sciences, and was a member of the team that raised more than $70M to support the Phase III clinical program and eventual approval of Vascepa. 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. He has published a number of articles in peer-reviewed journals, is an inventor on a number of patents and has served as a consultant on the topics of Innovation and Strategy Implementation.

EXECUTIVE ROUNDTABLE PANELISTS AND PRESENTERS

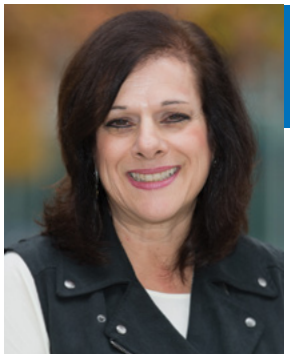


Kenneth A. Somberg, MD, MBA
Covance

Dr. Kenneth (Ken) Somberg is the Chief Medical Officer at Covance. He has served in this capacity since joining Covance in 2009. In the role of Chief Medical Officer, Dr. Somberg oversees the physicians from phases 1-4, as well as Global Regulatory Affairs, which includes regulatory strategy, regulatory submissions, and medical writing. As a member of the Covance Global Operating Committee, he contributes to business unit and corporate strategy and senior client relationships. Since 2012, he has chaired the company-wide Covance Scientific Council.

Dr. Somberg joined Covance after nearly twelve years at Novartis, where he progressed through numerous roles of increasing responsibility. Most recently, he held the position of Vice President and Global Franchise Head, drug regulatory affairs for Immunology and Infectious Diseases. He previously served as global head of clinical development for Transplantation and Infectious Diseases.

He received his medical degree from Baylor College of Medicine, completed his residency in Internal Medicine at Harbor-UCLA Medical Center, and his fellowship in Gastroenterology at the University of California, San Francisco (UCSF). He served as Assistant Professor and Associate Medical Director of the Liver Transplantation Program at UCSF for 5 years prior to joining Novartis. Dr. Somberg also holds a Master of Business Administration degree from Duke University and a Bachelor of Arts degree in human biology from Stanford University. He lives in Florham Park, New Jersey, with his wife and has two grown sons.



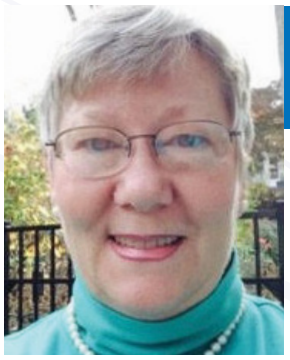
Joanne Spallone
Novartis

Joanne is Global Head Clinical Development Quality Assurance at Novartis Pharmaceuticals Corporation. She has worked for over 35 years in the pharmaceutical industry, and over half of her career has been in the clinical and pharmacovigilance quality assurance field. The majority of her career has been with Novartis (and formerly Ciba-Geigy Corporation) where she has worked a total of 35 years. In her current position, Joanne leads the Clinical Quality Assurance function for Novartis Pharma Division, supporting General Medicines and early human clinical trials conducted by Novartis Institute for Biomedical Research (NIBR). The Clinical QA function provides regulatory, compliance, and quality consultation/advice to clinical teams and line functions, manages health authority inspections for global clinical trials, performs investigations, and supports process improvement initiatives.

Prior to re-joining Novartis in December 2006, Joanne worked at Schering-Plough Corporation where she was responsible for setting up a corporate Pharmacovigilance audit group. She also worked at ALTANA Pharma from May 2003 until February 2005, where she set up a US Clinical and PV quality assurance program.

Joanne has participated in the several GCP conferences and training programs including ExL Pharma, the Pharmaceutical Education and Research Institute, Inc. (PERI), and DIA. She spent several years on the former PhRMA Bioresearch Monitoring Steering Committee (BRMC) in positions of Chairperson, Vice-Chair and Past Chair, and member-at-large.

EXECUTIVE ROUNDTABLE PANELISTS AND PRESENTERS



Susan Stasiorowski
Inovio

Susan Stasiorowski has a degree in Biology from Chestnut Hill College and has 25 years of experience in Clinical Research. She held various positions at Merck and Co., Inc. for over 17 years, supporting the advancement of both biological and drug research programs. While at Merck, she was also the Business Process Lead for the initial project which resulted in digitization of the Trial Master File (eTMF). Susan has served as Regulatory Director at Thomas Jefferson University Kimmel Cancer Center and as a Senior Project Manager at Covance. Susan is currently a Senior Clinical Program Manager with Inovio Pharmaceuticals and is contributing to the HPV immunotherapy programs.

Wendy Taylor
PPD

Wendy Taylor currently holds the role of Director of Quality Governance at PPD. In this role, she oversees both internal and client-facing quality governance activities. Her responsibilities include providing strategic direction to her team, implementing improvements to the quality governance processes, leading quality governance meetings and initiatives, and developing best practices.

Wendy started her career in clinical research as a CRA in 1999 before moving into Quality Assurance as an auditor in 2003. She has subsequently held various quality management positions where her responsibilities have included management of audits/auditors, quality issues, and SOP systems.

EXECUTIVE ROUNDTABLE PANELISTS AND PRESENTERS

Reb Tayyabkhan
Bristol-Myers Squibb

Reb Tayyabkhan is the Head of Central Clinical Services in Global Clinical Operations at Bristol-Myers Squibb based out of Lawrenceville, NJ. He has responsibility for the oversight of clinical operations resource and portfolio planning, process improvement (for full development registrational studies), and contractual and relationship oversight for the outsourcing of full development trials with CROs, Labs, Imaging vendors, and other functional service providers.

Reb began his career at Merck in 1991 in API manufacturing and process scale up. In 1998, he left Merck to pursue a career in management consulting with PricewaterhouseCoopers focused on the pharmaceutical and medical device sector. He joined Bristol-Myers Squibb in 2003 and has had various positions in Pharmaceutical Development Informatics and Global Development Operations leading to his current role. He has an undergraduate degree in Chemistry from New York University, a Masters in Chemical Engineering from Cornell University, and an MBA in Finance from New York University.

Eric Terhaerdt
Astellas

Eric Terhaerdt currently serves as the Senior Vice President of Development Operations at Astellas. In this role, Terhaerdt brings a breadth of diverse experience spanning drug development, strategic planning, and change management to this role working closely with Japan Development Operations to ensure operational effectiveness and efficiency worldwide.

Prior to joining Astellas, Terhaerdt spent 24 years with AstraZeneca Pharmaceuticals in several global leadership roles surrounding clinical research and development, quality assurance, and strategy. During his time at AstraZeneca, he led the transformation of the Clinical Development organization in achieving increased global productivity, a more flexible cost base and enhanced capabilities in design and interpretation. Terhaerdt was also awarded the AstraZeneca CEO Award for defining the first end-to-end outsource of data management in the industry, bringing an innovative approach to improving the business.

Terhaerdt attended the University of Waterloo in Canada, where he received a Bachelor of Science in Kinesiology. Terhaerdt continued his education by receiving a Master of Business Administration from the University of Warwick in the United Kingdom.

GUEST SPEAKERS

Marc Foster
Transparency Life Sciences

Marc Foster brings 16 years of biotech and 15 years of high-tech experience to TLS. Prior to Transparency, he worked in business development for FoldRx Pharmaceuticals, where he helped craft and implement the business development strategy of the company's protein misfolding pipeline and discovery platform, leading to an acquisition by Pfizer in 2010. Marc began his biotech career working on behalf of Schrodinger in product development. Subsequently he co-founded and built Reify Corporation, developer of high-content assay systems for pre-clinical discovery and toxicology. During his high-tech career, Mr. Foster held operating, co-founding, and advisory roles with numerous firms that created substantial shareholder value through acquisition or public offering, including NETBot, Apropos, and InTouch Systems. Mr. Foster holds a BS in Electrical Engineering and a BA in English from Brown University, and an MBA in Finance from The University of Chicago Booth School of Business. He served as a Research Fellow at BIDMC/Harvard Medical School in Endocrinology.

Kenneth Getz
Tufts CSDD

Kenneth A. Getz is the chairman of CISCRP – a nonprofit organization that he founded to educate and raise public and patient awareness of the clinical research enterprise. He is also the Director of Sponsored Research and an associate professor at the Tufts Center for the Study of Drug Development, Tufts University School of Medicine where he conducts research programs on drug development management strategies and tactics, outsourcing, global investigative site and patient recruitment practices and policies. Ken is also the founder and owner of CenterWatch, a leading publisher in the clinical trials industry and an owner and board member of the Metrics Champion Consortium, LLC.

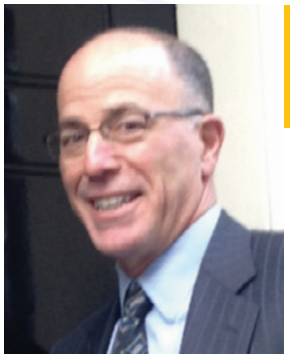
A well-known speaker at conferences, symposia, universities, investor meetings, and corporations, Ken has published extensively in peer-review journals, books, and in the trade press. He is the author of two nationally recognized books for patients and their advocates entitled Informed Consent: A Guide to the Risks and Benefits of Volunteering for Clinical Trials and The Gift of Participation, and the recipient of several awards for innovation and scholarship. Ken has held a number of board appointments in the private and public sectors including serving on the Institute of Medicine's Clinical Research Roundtable, the DIA Foundation, the Consortium to Examine Clinical Research Ethics, and the Clinical Trials Transformation Initiative. He is on the editorial boards of Pharmaceutical Medicine and Therapeutic Innovation and Regulatory Science, writes a bi-monthly column nominated for a Neal Award in Applied Clinical Trials, and has twice been nominated for a Distinguished Faculty award at Tufts University.

Ken holds an MBA from the J.L. Kellogg Graduate School of Management at Northwestern University and a bachelor's degree, Phi Beta Kappa, from Brandeis University. Prior to founding CenterWatch in 1994, Ken worked for over seven years in management consulting where he assisted biopharmaceutical companies develop and implement business strategies to improve clinical development performance.

GUEST SPEAKERS

Jeremy Gilbert, MBA
PatientsLikeMe

Jeremy Gilbert leads product strategy and development efforts at PatientsLikeMe. Prior to joining the company, he was an Engagement Manager at McKinsey & Company's healthcare practice, where he led strategy and execution projects for Fortune 500 clients. Jeremy has co-founded four technology startups and has invented and launched notable products in e-commerce, mobile, and discovery bioinformatics.



Jeffrey S. Kasher, PhD
Patients Can't Wait

Jeffrey Kasher is a known pharmaceutical development change expert with 28 years of experience at Eli Lilly. He is passionate for improving outcomes, bringing patients and research sites into the development process, and dramatically decreasing time to market. His expertise includes novel product development from bench through market launch, research and clinical trial leadership, innovation center start-up, as well as new industry paradigm creation.

Jeff is President of Patients Can't Wait, Chairman/member of Advisory Boards for DrugDev, TrialReach, Be The Partner, and GoBalto. He sits on the DPharma steering committee and faculty, and is a member of Linking Leaders. In 2013, CenterWatch named Jeff one of the "20 Innovators Changing the Face of the Clinical Trials Industry". He received a BS in Chemistry from Franklin & Marshall College, a PhD in Pharmacology from the State University of New York, and a Post-Doctoral Fellowship in Physiology at Yale University School of Medicine.

GUEST SPEAKERS

Drew Marshall
Primed Associates

Drew is the CEO and Principal of Primed Consulting, LLC. His primary focus is on helping his clients' leadership teams map a strategic path to success so they can deliver game-changing value to their customers (be they internal or external) as quickly as possible. In working on the development of an innovation-capable culture within his clients Drew helps them articulate their strategic intent, define how to achieve their goals through breakthrough human performance management, and deliver results through the application of design thinking to critical enterprise challenges.

Drew has consulting and management experience in process consulting, project management, human resources management, product development methodologies, and strategy formulation and execution. He also possesses broad industry knowledge and experience having worked with such clients as: Visa, Morgan Stanley, Port of Seattle, Unified Port District of San Diego, Exploratorium, US Special Operations Command, Cisco, Microsoft, Oracle, HP, Boston Scientific, Verizon and Bayer AG among others.

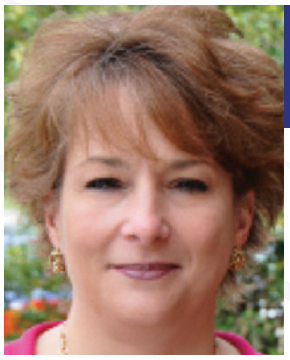
Prior to founding Primed Consulting, LLC, Drew spent ten years with Princeton-based boutique consulting firm Kepner-Tregoe where he rose to become a Partner and the Chief Innovation Officer. Before that he spent five years in the software industry with Adobe Systems, Inc., where he held a variety of management positions in global Support Services.

Drew received his Bachelor of Arts and Graduate Diploma of Education from the University of Western Sydney in Australia. He holds a Master of Arts in Whole Systems Design from Antioch University in Seattle, Washington, is a certified Project Management Professional and a member of the Academy of Management, the Organization Development Network and Product Development and Management Association. He is a past Chair of the Project Management Institute's (PMI) Consulting Specific Interest Group and Community of Practice. He also sits on the Board of Advisors for Princeton Innovation Center.

Drew is adjunct faculty for Philadelphia University's Strategic Design MBA Program and delivers programs at such business schools and executive education programs as University of Pennsylvania Wharton, UCLA Anderson, Duke and the Australian Graduate School of Management at UNSW.

A frequent presenter and speaker, Drew's writing currently appears widely and most regularly both on the Forbes Entrepreneur and Business Insider blog sites, as well as on the Washington Post small business blog. In 2012 he was named one of "10 Consultants Who Avoid the BS" at Forbes.com.

SUMMIT MODERATORS, FACILITATORS, AND FACULTY



Debbie Briffa
The Avoca Group

Debbie Briffa is Senior Project Manager of The Avoca Group. In this key role, Debbie manages and oversees a variety of relationship programs for both Pharma and CRO clients. In addition, Debbie is an active member of the Avoca Quality Consortium leadership team, working on a variety of projects including the Prequalification initiative, as well as managing the Quality Oversight Portal and overseeing logistics for the Summit and other Consortium meetings. Prior to joining Avoca, Debbie had over 16 years of executive and management experience. She was former Vice President, Corporate Services and Marketing at Morgan Stanley, managing all of the Firm's Corporate Service functions including Procurement, Contingent Labor, Global Media Production, Business Services and Marketing, and the Global Events Planning group.

Karin Daun
The Avoca Group

Karin Daun has over 30 years of experience in the pharmaceutical industry with a focus on Clinical Development and in the disciplines of Project Management, Alliance Management, and Strategic Sourcing. She has led and worked on international teams and with various sourcing models and sourcing partners. She leverages her global perspective, strong leadership skills and innovative thinking in every project.

Karin retired from Eli Lilly and Company in April of 2015 where she had been very involved in a number of outsourcing activities and partnerships. Karin held several roles across the Drug Development Process, but her passion lies in Clinical Development and the interface between the Sponsor and CRO. While at Lilly, she led the Clinical Sourcing Organization which partnered with senior leadership to develop and execute the sourcing strategy and worked with the development teams, functions, and CROs to develop numerous clinical candidates. While at Lilly, she was ranked in the 99th percentile of leaders with the highest attributes including integrity, excellence, respect for people, and teamwork.

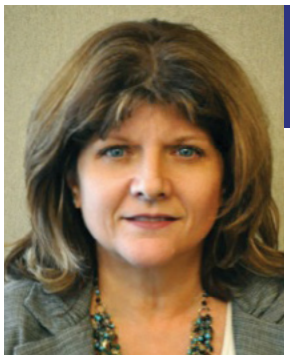
Karin continues professional development activities to maintain her Alliance Management Certification and Project Management Professional Certification. She is also certified as a Six Sigma Black Belt. In addition to being a Senior Consultant at Avoca, she volunteers her consulting expertise for Global Mission Organizations.

SUMMIT MODERATORS, FACILITATORS, AND FACULTY

Denise Calaprice, PhD
The Avoca Group

Dr. Denise Calaprice has extensive experience in directing clinical research programs in a variety of settings, including academia, a CRO, a large global pharmaceutical company, and a small biotechnology company. After receiving her Bachelor's degree in Biology from Harvard University and her MS and PhD from Princeton, Dr. Calaprice entered the world of clinical research as an NIH fellow at Columbia University's College of Physicians and Surgeons. She subsequently joined Quintiles as a Clinical Research Project and Program Director, where she directed full-service international research programs, including studies in Phases I through IV, and including NDA and IND preparation, submission, and support. As Senior Director of Clinical Research at Altana Pharma, Dr. Calaprice developed the infrastructure of the US clinical research department and contributed to infrastructure development internationally, including training of personnel, SOP and guideline development, and KOL relationship development, while simultaneously overseeing the performance of both outsourced and sponsor-performed international clinical trials. As Director of Clinical Sciences at Regeneron Pharmaceuticals, Dr. Calaprice played a similar role, overseeing programs in Phases I through III.

As a consultant for the last 11 years, Dr. Calaprice has provided support to pharmaceutical companies, clinical service providers, university investigators, and government agencies engaged in clinical research, with a focus on the areas of partnering strategies, relationship management, metric development, protocol quality, and business data analysis.



Janis Hall
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. While at Johnson & Johnson Pharmaceutical Research & Development (J&JPRD) she was responsible for R&D sourcing, contracting, and supplier alliance management. As the primary point of contact to health authorities for inspection readiness for strategic sourcing, she developed and successfully implemented an end-to-end process for inspection readiness of the sourcing organization.

Janis is a Certified Outsourcing Professional and 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.

SUMMIT MODERATORS, FACILITATORS, AND FACULTY

Caryn Laermer
The Avoca Group

Caryn Laermer is Associate Director of The Avoca Quality Consortium. In this key role, Caryn manages and oversees all Consortium strategies and initiatives, member engagement, member recruitment, member and industry communications, and the annual Summit and other Consortium meetings.

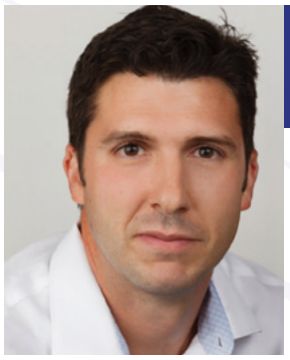
Prior to joining Avoca, Caryn had several years of executive and management experience. She was formerly Vice President, Derivatives Group at Donaldson, Lufkin & Jenrette (now Credit Suisse) specializing in the sales and trading of stock options, foreign currency derivatives, and futures.

Ms. Laermer graduated from Tufts University with a BA in Economics. She is a member of Omicron Delta Epsilon, Economics Honor Society and holds an MBA in Finance from New York University.

Patricia Leuchten
The Avoca Group

Patricia Leuchten has more than 25 years of experience in the pharmaceutical industry and is a leading authority on global clinical outsourcing and strategic alliances. In 1999, Ms. Leuchten founded The Avoca Group, a consulting and research firm specializing in clinical outsourcing, alliance management and quality management in outsourced clinical trials. Avoca 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. Ms. Leuchten launched the Avoca Quality Consortium in 2011 to encourage the sharing of leading practices and to bring sponsors and CROs into greater alignment. Since its inception, the rapidly growing Consortium community has advanced collaboration on improving quality, mitigating risk and increasing efficiency in outsourced clinical trials.

SUMMIT MODERATORS, FACILITATORS, AND FACULTY



Dennis Salotti
The Avoca Group

Dennis Salotti has 15 years of experience in the pharmaceutical industry with positions of increasing responsibility in clinical research, business operations, and strategic management. Prior to joining The Avoca Group, Mr. Salotti was Head of Operations for a boutique clinical data solutions provider specializing in electronic clinical outcome assessments (eCOA) and was responsible for global deployment and support of technology across 40+ countries and hundreds of investigator sites. He has experience as Sponsor, CRO, and Consultant executing clinical trials, enhancing clinical operations, and developing and implementing new technologies for clinical research.

Dennis is a certified Clinical Research Associate, and holds an MS in Clinical Research Organization Management from Drexel University, an MBA from the New Jersey Institute of Technology, and a BS in Biology from Sacred Heart University.

Lakshmi Sundar
The Avoca Group

Lakshmi Sundar is a global business leader who brings together data, technology, and story telling to creatively address business challenges and move strategy forward. In the two decades she has spent in the pharmaceutical industry, Lakshmi has led teams across sponsors and CROs in multiple functional areas to spark innovation, manage risk, and lead change with a sense of purpose and fun. At Avoca, Lakshmi will partner with members of the Avoca Quality Consortium and industry innovators to deepen the dialogue on building a quality culture within and across organizations to mitigate risk, advance drug development, and bring treatments to patients in a more effective manner.

SUMMIT MODERATORS, FACILITATORS, AND FACULTY

Steve Whittaker
The Avoca Group

Steven B. Whittaker is Executive Director for The Avoca Quality Consortium and Senior Consultant for the Avoca Group, where he conducts Quality Workshops, Executive Level Consulting for Pharmaceutical Quality, Clinical Development, Project Management, Sourcing, Alliance, and Relationship Management.

Steve is an independent consultant for the pharmaceutical, biotech, and CRO industries, providing expertise in project management, pharmaceutical development, clinical development, outsourcing strategies and execution plans. His wealth of experience through years of drug development leadership roles and his established network with professionals across these industries provide a unique and valuable combination of insights for organizational leaders. Whittaker has served for 12 consecutive years on the Advisory Board for the annual Partnerships in Clinical Trials program, chairing the board for 2 years. In addition, Whittaker has moderated numerous quarterly Clinical Research Consortium forums, developing strategic agendas and facilitating the exchange of leadership concepts between clinical development executives across several top-tier pharmaceutical and biotech organizations.

Whittaker retired from Eli Lilly and Company in December 2009 where he served as Chief Operating Officer/ Sr. Director of Operations and Project Management for the Cardiovascular/Acute Care Platform. As the leader of the Global Clinical Research Sourcing Office, Whittaker established Lilly's first corporate strategy and operational design for outsourcing global clinical development to CRO preferred partners. This included the selection and initial implementation of the preferred partner approach for global, full-service CRO capabilities. Whittaker also led Lilly's Project Management Center of Excellence, establishing standards for leaders of project development.

UPCOMING AQC EVENTS

QUALITY CONSORTIUM
THE AVOCA GROUP
2016 SUMMIT EUROPE

AQC 2016 Summit Europe

June 6-7
Basel, Switzerland

Has your company registered your two complimentary attendees for the upcoming Summit Europe? Please contact Caryn Laermer at Caryn.Laermer@TheAvocaGroup.com or visit our site at theavocagroup.com/2016summiteurope to register.

Location: June 6
Schloss Bottmingen Castle
Schlossgasse, Bottmingen, Switzerland

Location: June 7
Radisson Blu Hotel
Steinentorstrasse, Basel, Switzerland

June 28, 2016

AQC Regional Networking Breakfast at DIA
2016 Annual DIA Conference
Philadelphia, Pennsylvania
(Restaurant To Be Confirmed)

November 3, 2016

Fall Member Meeting
Princeton Marriott at Forrestal
Princeton, New Jersey

December 6, 2016

Executive Forum
Liberty View Ballroom
Philadelphia, Pennsylvania

CONSULTING AND RESEARCH SERVICES
THE AVOCA GROUP

The Avoca Group Consulting & Research Services

Avoca has conducted research and provided consulting services to Sponsors and Clinical Service Providers for nearly two decades

RESEARCH

Avoca works closely with sponsors, CROs, sites, and patients to conduct customized qualitative and quantitative research to help organizations understand and proactively manage perceptions, performance, issues, and challenges to drive successful outsourcing strategies and optimized partnering.

CONSULTING

Avoca is a leader in analyzing, creating, and driving the evolution of leading practices in clinical outsourcing. We have worked closely with sponsors and clinical service providers, gathered and authored more than 250 leading practices as part of the AQC, defined a taxonomy for quality metrics, and enabled organizations to evolve to a risk-based approach for quality management.

TRAINING AND DEVELOPMENT

As former leaders from the bio-pharmaceutical industry, Avoca's consultants come with deep, hands on experience in Quality Management, Sponsor-CRO Collaboration, Effective Outsourcing, Risk Identification/Management, and more. The marriage of in-depth industry knowledge with insights from a broad "outside consulting perspective" enables Avoca to provide training that moves your team towards enhanced collaborative relationships across the outsourcing spectrum.

To learn more about specific consulting and research programs, please visit www.theavocagroup.com. For more information or a quote, please contact Danya Burakoff at Danya.Burakoff@TheAvocaGroup.com or (609) 759-2856.

CONSULTING AND RESEARCH SERVICES
THE AVOCA GROUP

Here are a few recent examples of how Avoca has enabled our clients:

- **Breaking down organizational siloes in drug development:** Avoca facilitated a full-day Strategy Session with a major Pharma company to help them refine their approach to outsourcing across multiple functions. Avoca built an effective implementation roadmap and provided "fit to purpose" AQC tools to facilitate adoption.

- **Incorporating the patient perspective in protocol development:** Avoca launched an extensive patient survey to gather intelligence to assist with the Protocol Quality initiative. This included building an alliance with multiple partners to help broaden the outreach.

- **Creating and capturing actionable metrics:** For the past 10 years, Avoca has partnered with a top five CRO to build customized relationship metrics to increase market share. This Program included extensive qualitative and quantitative research across global projects.

- **Reshaped the way metrics are used to signal risk:** Avoca partnered with a leading global Pharmaceutical company to develop a customized taxonomy focused on Quality Management.

- **Enabling organizations to move to lean sourcing:** In this instance, the Avoca team served as an extension of the clinical development organization to conduct partner research, investigative site research, training, and consulting to move to lean sourcing.

DILIGENT
PREQUALIFICATION
PLATFORM
THE AVOCA GROUP

Diligent Prequalification Platform

As part of the Avoca Quality Consortium's ongoing commitment to bring innovative solutions to enable outsourced clinical trials, we are pleased to bring you Diligent. Diligent is a centralized repository of completed RFIs that will help Sponsors and CROs to shave off time, cost, and effort associated with completing RFIs to prequalify Technical Service Providers.

Diligent brings the right level of rigor to drive quality and compliance, while accelerating the connections between Technical Service Providers and clinical researchers that need those services. The table (below) lists RFI materials that are available. To request this information, email Diligent@TheAvocaGroup.com and specify the Provider(s) and Service(s) in which you are interested.

RFIs Currently Available

Company	Core*	Bioanalytical Lab	Biomarker Lab	Central Lab	COA	ECG	IxRS	Imaging	Total
Almac	✓						✓		2
Broad Institute	✓		✓						2
Covance	✓	✓	✓	✓					4
Clinical Reference Laboratories (CRL)	✓			✓					2
Eurofins	✓			✓					2
ICON	✓			✓					2
Intrinsic	✓							✓	2
IXICO	✓							✓	2
New York Genome Center	✓		✓						2
PPD	✓	✓	✓	✓			✓		5
Q2 Solutions	✓		✓	✓					3
Worldwide Clinical Trials	✓	✓	✓						3
Total RFIs	12	3	6	6	0	0	2	2	31

*Core RFI addresses industry standards that apply across all technical service providers.

THANK YOU TO OUR 2016 SUMMIT PLATINUM SPONSOR

inVentiv Health is a leading global provider of outsourced clinical development and commercialization services to biopharmaceutical companies. Our combined Clinical Research Organization (CRO) and Contract Commercial Organization (CCO) is made up of more than 14,000 employees that have the ability to service clients in more than 90 countries. We offer clients a differentiated set of solutions designed to enhance operational and financial efficiencies across the clinical development and commercialization continuum. For more information, visit inVentivHealth.com.

THANK YOU TO OUR 2016 SUMMIT SILVER SPONSORS

ICON plc is a global provider of drug development solutions and services to the pharmaceutical, biotechnology, and medical device industries. The company specialises in the strategic development, management, and analysis of programs that support clinical development – from compound selection to Phase I-IV clinical studies. With headquarters in Dublin, Ireland, ICON currently operates from 90 locations in 37 countries and has approximately 11,900 employees. Further information is available at www.iconplc.com

Acurian, a subsidiary of PPD, is the leading global full-service provider of clinical trial patient enrollment and retention solutions for the life sciences industry. With over 1 million study candidates referred to over 7,000 sites in 70+ countries, the company increases the enrollment performance of investigator sites worldwide by identifying, contacting, rescreening and referring people who live in the local community but are unknown to a research site. As a result, trial sponsors complete enrollment without incurring the unexpected expense of adding sites or time. When you can't afford a delay in patient enrollment, only Acurian delivers the patients you need, when and where you need them. For more information, visit www.acurian.com.

THANK YOU TO OUR 2016 SUMMIT MEDIA PARTNERS

QUALITY CONSORTIUM
THE AVOCA GROUP
2016 SUMMIT USA

About The Avoca Group

The Avoca Group is a driving force behind the continuous improvement of outsourced clinical research.

As a developer of progressive solutions to challenges faced in clinical research, Avoca makes a tangible difference to the operations of pharmaceutical companies and clinical service providers.

A pioneer in clinical outsourcing research and consulting, Avoca has for years both tracked and influenced the progression of the sector, making it the ideal partner for companies seeking to better understand the dynamics of their business relationships today, and establish structures to improve the management of those relationships tomorrow. Avoca's clients include top five pharmaceutical companies and global contract research organizations, as well as small companies within the pharmaceutical industry.

Contact Us

The Avoca Group
179 Nassau St.
Suite 3A
Princeton, NJ 08542

Phone (609) 252-9020
Fax (609) 252-9022

For information regarding new Membership for Avoca's Quality Consortium, please contact Danya Burakoff at Danya.Burakoff@TheAvocaGroup.com or (609) 759-2856.

Existing Members, please contact Caryn Laermer at Caryn.Laermer@TheAvocaGroup.com or (609) 799-0511.

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