QUALITY CONSORTIUM

THE AVOCA GROUP

2016 SUMMIT EUROPE

Integrating Quality, Innovation, and Collaboration for Clinical Trial Transformation

SWITZERLAND

6-7 June 2016

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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.

Pfizer

Lilly

Welcome

On behalf of The Avoca Group and event chair, Paula Gildert, Global Head of Procurement, Clinical Development, Global Head Diversity & Inclusion, Novartis, I am pleased to welcome you to the inaugural Avoca Quality Consortium (AQC) Summit Europe. 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. Paula Gildert, 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 excited to be hosting our inaugural AQC Summit in Europe, expanding our global presence and giving us the opportunity to collaborate face-to-face with more representatives from our Member companies and beyond. We welcome those of you who are joining us for the first time and look forward to your input and participation. 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 in the US and now in Europe, 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.

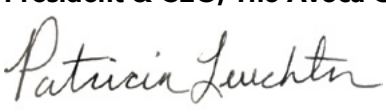
Our Summit is an integral component of this dialogue since this is where we convene as a collective, committed body to listen to the latest trends, celebrate our progress, and take on new challenges to deliver on things that were unfathomable a few years ago. The AQC Summit invigorates meaningful progress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

The 2016 Summit theme is Integrating Quality, Innovation, and Collaboration for Clinical Trial Transformation. This year, based on industry trends and our Members' input, we will straddle between new, exciting areas of innovation and very tactical tools/methods discussions to enable you to learn and implement. We have a special focus this year on the theme of Patient Centricity, as we tackle the question of how to keep patients central to the design and conduct of clinical trials. We have multiple sessions dedicated to this topic.

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 Supporting Sponsor is PA Consulting. 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

Paula Gildert
Novartis

Paula is Global Head of Clinical Development Procurement and is Fellow and Past President of the Chartered Institute of Purchasing and Supply. She is responsible for driving total value in all activity with external providers in the clinical development of new medicines for Novartis Group: Pharma, Sandoz, NIBR, and Alcon. She is a physicist and chartered control and electrical engineer with over 25 years experience in the Fine Chemical and Pharmaceutical Industry in a wide range of roles; engineering, manufacturing, supply chain, R&D and procurement.

EXECUTIVE PANELISTS AND PRESENTERS

Rolf Banholzer, PhD
Novartis

Rolf Banholzer is the global head of eClinical QA at Novartis. He started as a Safety System Administrator and then moved to a Business Analyst role in the Pharmacovigilance area before he took over a global team of QA IT Systems and Process Experts. For two years Rolf's team has provided QA oversight over Clinical Data Management and Biostats processes.

Rolf is a member of the DIA Advisory Committee Region Europe and is actively supporting the organization committee of the DIA EU Clinical Forum. Rolf was also co-leading the DIA/ISPE CSV workshop held in Basel in 2014.

EXECUTIVE PANELISTS AND PRESENTERS

Anne C. Beal, MD, MPH
Sanofi

Dr. Anne C. Beal, MD, MPH, is the Chief Patient Officer for Sanofi, a global healthcare leader that discovers, develops, and distributes therapeutic solutions for patients. In that role, she is responsible for integrating the patient voice and priorities into all aspects of Sanofi's work to facilitate development of healthcare solutions that truly meet patients' needs. She is currently based in Paris.

Dr. Beal joined Sanofi from PCORI (Patient-Centered Outcomes Research Institute), where she was the Deputy Executive Director, Chief Officer for Engagement, and the inaugural COO. PCORI is a US-based independent organization that supports comparative effectiveness research guided by patients, caregivers, and others to help people make informed decisions and improve healthcare delivery and outcomes. Prior to PCORI, Dr. Beal was president of The Aetna Foundation, the charitable arm of Aetna, and previous to that she directed programs on Quality of Care for Underserved Populations at the Commonwealth Fund.

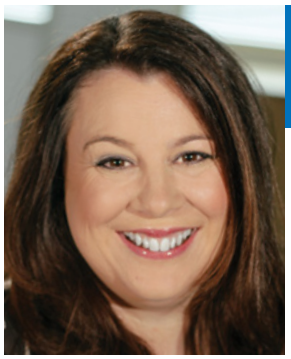
Pauline Carr, MA, MBL, MRQA
Boehringer-Ingelheim

After spending more than 20 years in Clinical Research, Pauline has recently moved into the Quality Medicine organisation of Boehringer Ingelheim. She brings with her experiences from working in multiple countries throughout the African continent and Eastern Europe. Her key areas of interest are in Vendor oversight and Vendor management.

EXECUTIVE PANELISTS AND PRESENTERS

Anthony J. Costello
Mytrus

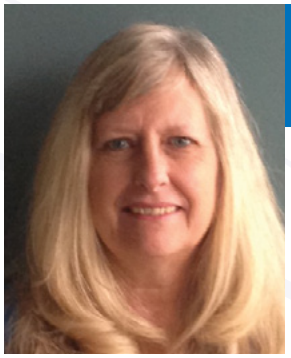
Anthony Costello is Co-Founder and CEO of Mytrus and a leader in the area of clinical trials technology. For over 20 years, he has been developing disruptive innovations that can simplify clinical trials for patients, sites, and sponsors. After beginning his clinical career in clinical data management 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.



Holly Dixon, BSc (Hons), MQRA
Chiltern

Holly Dixon is the Executive Director, QA Compliance at Chiltern. Holly's career at Chiltern spans 19 years, initially with roles in clinical monitoring and project management, before she moved to a QA role in 2003. In her current role, Holly oversees a global team of compliance personnel with oversight responsibilities for hosting and management of regulatory inspections and client audits, document control, CAPA processes, GCP compliance, quality metrics, customer feedback and quality improvement initiatives. Holly also represents Chiltern's Quality function in executive governance relationships and forums with Sponsor companies.

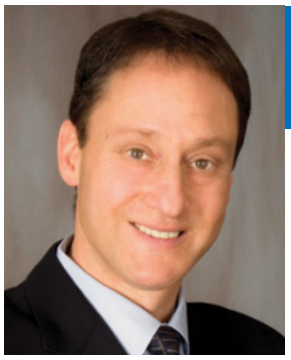
EXECUTIVE PANELISTS AND PRESENTERS



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.



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.

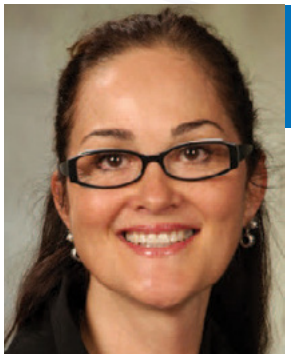
Ken holds an MBA from the J. L. Kellogg Graduate School of Management at Northwestern University and a bachelor's degree, Phi Beta Kappa, from Brandeis University. Prior to founding CenterWatch in 1994, Ken worked for over seven years in management consulting where he assisted biopharmaceutical companies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

EXECUTIVE PANELISTS AND PRESENTERS

Tilo Hache
Novartis

In his 18 years of professional experience, Tilo held various leadership positions in IT, Procurement, and Development. In every position he had, his main interest was continuous improvement of business processes and innovation.

Since 2013, Tilo has worked in an innovation program in Novartis to identify and implement new ways of running clinical trials. He leads project teams identifying and implementing mobile technologies to capture data directly from the patient more seamlessly.



Donna Hellsten
PPD

As vice president of quality risk management, Donna Hellsten provides strategic direction for PPD's global quality and compliance functions, including client and regulatory inspections, issue management, internal audits, and vendor audit management. Hellsten leads the company's corrective action and preventative action (CAPA) program, and oversees quality services for Phase I / early development as well as pharmacovigilance / medical communications.

In her previous role as vice president of clinical operations, Hellsten led the clinical development functions within PPD's Phase II–IV business in North America. Hellsten was responsible for ensuring that all clinical projects were executed in accordance with contractual timelines, quality measures, and financial commitments. She also served as co-leader of a cross-functional team responsible for the governance strategy and global implementation of the Preclarus™ data analytics platform.

Before joining PPD, Hellsten served as vice president of product development for a technology organization specializing in the evolution of electronic data capture and e-business solutions for pharmaceutical life science companies. Hellsten's experience includes a term as the director of American Phase II-IV operations for an international drug development company, as well as several years as a project manager and CRA in the CRO industry.

Prior to her transition to the private sector, Hellsten was an academic research nurse for the University of California at Irvine, working with an international team on islet cell transplants and implantable insulin pumps.

Hellsten earned a bachelor's degree in nursing from the University of Texas. She has been invited to present at numerous conferences, and has published several articles in the industry journal Applied Clinical Trials.

EXECUTIVE PANELISTS AND PRESENTERS

Andreas Koester, MD, PhD
Janssen

Andreas Koester has more than 20 years of R&D experience working for pharmaceutical companies and contract research organizations. As Head of Clinical Trial Innovation at Janssen Research & Development, Andreas is leading the company's efforts to enhance and optimize the pharmaceutical clinical trial process through novel tools, technologies, and industry collaborations. He also leads a cross-disciplinary early development team, which utilizes a biotech-like approach to bring drug candidates to Proof-of-Concept faster and cheaper.

His background is in drug development, spanning first in human, proof of concept, and large registration trials. He worked in leadership roles for trials that led to approvals of Prezista®, Intelence®, and Reminyl®. Andreas is a graduate of Leipzig Medical School and earned his PhD in Clinical Pharmacology from Humboldt University in Berlin.

Adalbert Lackhoff, DVM
Alexion

Adalbert Lackhoff is Senior Director Clinical Operations EMEA at Alexion Pharma International since October 2012 and is located in Zürich.

Before joining Alexion, he was Head of Clinical Trial Management Full Development at Merck Serono in Geneva. Previously, he held positions of increasing responsibility at Eli Lilly in Germany and Switzerland in animal health, clinical operations, regulatory affairs, and pharmacovigilance.

He received a doctorate in Veterinary Medicine and a Diploma in Pharmaceutical Medicine from SwAPP (Swiss Association of Pharmaceutical Professionals). He has been working in the pharmaceutical industry for over 30 years.

EXECUTIVE PANELISTS AND PRESENTERS

Alistair Macdonald
INC Research (UK)

As President and Chief Operating Officer, Alistair Macdonald leads global operations at INC Research. He joined the Company in 2002 and has been responsible for leading the data management, data services, and ultimately global services teams, driving the implementation of new technologies and processes and the expansion of those services on a global scale. Additionally, he led the business development, marketing, and alliances teams to establish strategic partnerships to improve the speed, efficiency, and quality of drug development. A 20-year pharmaceutical industry veteran, he has held management positions across manufacturing, consultancy, business and corporate development, data management, and clinical operations.

Wilhelm Muehlhausen, DVM
ICON

Willie developed his entrepreneurial spirits early in his career and started his first venture when he was still in training at the Free University of Berlin School of Veterinary Medicine. He provided technical research services for a number of pharmaceutical and chemical clients at a time when information could not be accessed via Google and the Internet. His clients were seeking environmental data of chemical and pharmaceutical compounds. After he graduated from vet school, he provided veterinary research services to veterinary pharmaceutical sponsors who studied the environmental impact of their drugs.

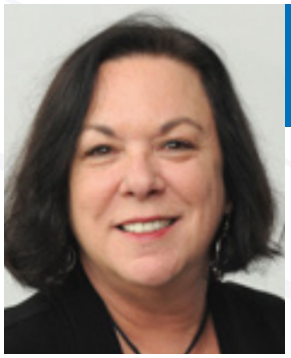
Eventually Willie moved into big corporate organizations and turned to being a successful Intrapreneur and for the last 2 decades he consistently identified opportunities and turned them into profitable ventures. He takes great satisfaction out of developing new solutions that enable us to get better treatments to patients quicker.

During his career, he oversaw a variety of new developments, including a dedicated Late Phase EDC system, a Patient Portal, a "Single Sign On solution", several medical devices in the Patient Reported Outcomes services area and analytical modules that support decisions in the lifecycle of a clinical trial.

As ICON´s Head of Innovation he built a highly skilled team of global experts that provides support and guidance to every employee at ICON who wants to progress an idea. His team developed an Innovation process that utilizes a Crowdsourcing platform to benefit from the combined wisdom and experience of the whole of ICONs global workforce.

In recent years his team has conducted extensive original research in the fields of machine learning, BYOD in eCOA, Actigraphy and Wearable devices, Gamification and drug adherence systems to support decentralized Clinical Trial scenarios. He and his team have regularly published and presented scientific findings at industry conferences to inspire others and to challenge the status quo. In 2015 these efforts have been honored by his peers in the Clinical Trial industry, when Willie was recognized as a PharmaVoice100 Global Innovation Leader.

EXECUTIVE PANELISTS AND PRESENTERS



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.

Natalia Misciattelli, PhD
PA Consulting

Natalia is a management consulting partner focused on the life sciences industry. She specialises in business transformation and analytics. She joined PA from General Electric's Healthcare Business with a Strategy and Analytics background. In the 11 years that Natalia has been at PA she has delivered a diverse portfolio of programs. These programs range from highly technical and financial due diligence of acquisition targets to multi-million dollar business transformation projects. Natalia is known by her clients for her dedication to delivering practical long term insightful solutions. Natalia is a scientist by training and holds a PhD in microbiology.

EXECUTIVE PANELISTS AND PRESENTERS

Jane Restorick
Synexus

Jane Restorick joined Synexus in 2001 as the Director of Quality Systems. From 2002 until 2010, Jane held various roles including Vice President, International Projects, Vice President, International Client Services and Chief Operating Officer, becoming Chief, Business Operations in January 2016. Jane has a strong background in Clinical Operations and Quality Management having held senior positions at Pfizer, Fujisawa Limited, and Vernalis Ltd. (formerly Vanguard Medica Limited). Jane began her career in Urological Research at Guy's Hospital.

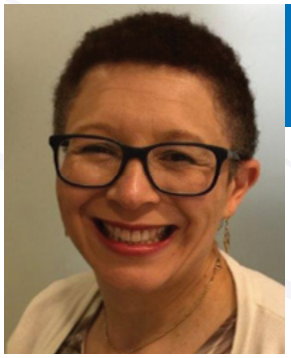
Christopher J. Rull
Merck Biopharma

Christopher Rull is presently the Global Head of Service Provider Management within Global Clinical Operations at EMD Serono (A business of Merck KGaA, Darmstadt, Germany). In this role, which was created in June 2015, his focus has been on developing and launching a new singular global team that brings together several disparate functions across the company that focused on various aspects of outsourcing for Clinical Development projects to manage the strategy around how we source, the day to day management of E2E business operations, and Alliance Management of the external providers. The mission, vision, and objectives of this relatively new team are all built around the focus to deliver exceptional internal & external service, performance, and value in the business of sourcing with external providers (strategy, contracting, budgeting, oversight, and continuous improvement) that will enable R&D functions the ability and a framework to execute their programs and projects.

Before this role, Chris held two other positions within EMD Serono. Most recently as the Head of Alliance Management for CRO Partnerships within Global Business Development & Alliance Management, Chris focused on implementing, driving and optimizing relationships with strategic CRO partners to provide value across the entirety of the healthcare business within the Merck Group, globally. Originally, Chris joined the company in February of 2014 within the Strategic Partnership Unit (SPU) of Global Clinical Operations with an eye towards evolving the Alliance Management approach for the then recently created Global Partnership with Quintiles. His present role brings together the learnings of these other two positions and better aligned the company for integrated approach and success.

Prior to joining EMD, Chris spent 15+ years in various roles within the healthcare spectrum, the last 13 of which were in different roles of increasing responsibility on both the buy and sell sides of drug development. This has enabled him to see and participate in the evolution of Strategic Partnership & Alliance Management in the industry. In these roles, Chris has had the opportunity to collaborate on a global basis with CROs, large biotech companies, all the way through the largest pharmaceutical companies in the world to support initiatives focused around change management, oversight, business & commercial management, portfolio delivery, and innovation.

EXECUTIVE PANELISTS AND PRESENTERS



Rebecca Stanbrook
Novartis

Rebecca Stanbrook is Senior Compliance Professional at Novartis Pharma based in Basel. She has a role spanning GCP, Pharmacovigilance, and GMP.

Prior to joining Novartis in 2014, Rebecca was Group Manager, Inspections (GLP/GCP/PV) at the Medicines and Healthcare products Regulatory Agency (MHRA). She joined the Agency in January 2003 as a GCP inspector. She was part of one of the teams which conducted the first statutory GCP inspections in the UK and played an active role in determining the statutory GCP inspection programme.

Rebecca was promoted to Operations Manager for Pharmacovigilance in 2004 and in 2006 became Group Manager Inspections (GCP/GLP/PV).

Rebecca's group at the Agency wrote the Good Clinical Practice Guide and the Good Pharmacovigilance Guide.

Rebecca has been in the Pharmaceutical Industry in various roles, which include Clinical Trial Supplies, Clinical Quality Assurance Auditing, and Training and Development.

She is a pharmacist by profession and holds a Diploma in Research Quality Assurance. She currently sits on the Credentialing Panel of the Faculty of the Royal Pharmaceutical Society.

Susan C. Stansfield, PhD
inVentiv Health

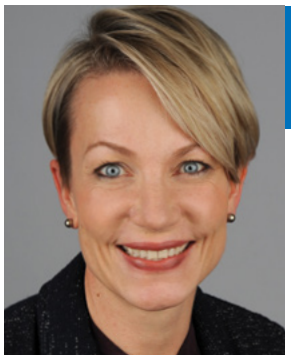
Dr. Susan C. (Sue) Stansfield, PhD, is Executive Vice President of Global Clinical Operations for Phase II-IV with inVentiv Health. In this role, currently Sue has a specific focus on Site Centricity with a remit to develop and enhance strong site relationships. Sue represents inVentiv on a number of industry committees including CRO Forum, the ACRO body interfacing with Transcelerate. Prior to inVentiv, Dr. Stansfield served as Executive Vice President of Clinical Development at Premier Research Group, Ltd. and Executive Vice President of Product Registration for Europe, Asia-Pacific and Africa at PRA International, Inc. She has held senior leadership positions at other global clinical research organizations including Quintiles and PPD. Dr. Stansfield has more than 25 years of experience in the clinical research industry beginning her career in Pharma with Wellcome Research Foundation, Janssen Research Foundation and Parke Davis. Dr. Stansfield has a BSc in Physiology and Biochemistry from Nottingham University and a PhD in Neuropharmacology from Reading University.

EXECUTIVE PANELISTS AND PRESENTERS

Barbara Valenta-Singer, MD
Baxalta

Barbara Valenta-Singer currently serves as Vice President, Global Clinical Development Operations at Baxalta, building on a nine-year career at Baxalta in several areas, starting with a role as Medical Director Technical Assessment focused in rare diseases and contributions. During her tenure at Baxalta, she has also provided strategic support in Clinical Research throughout the evolution of clinical trial design, execution, and completion, providing medical and technical support.

She has worked in Medical, Clinical, Regulatory, Pharmacovigilance, and Compliance roles, giving her a broad perspective of the industry. Prior to joining Baxalta, she held senior positions at Wyeth Pharmaceuticals, Pfizer, Pharmacia Austria, and Serono Austria.



Carla Wandt, PhD
The Roche Group

Carla is the Global Head of Product Development Quality (PDQ) in F-Hoffmann-La Roche Ltd./Genentech, Inc. since January 2016. She is responsible for developing and delivering an integrated Quality Management strategy across the company to support the conduct of non-clinical and clinical trials and Pharmacovigilance activities. She leads a global function responsible for enterprise risk management; inspection management; quality assurance oversight including risk based audit planning; CAPA management; and the strategies for controlled document management and training. The scope of responsibilities for this function covers early and late phase product development, and the affiliates.

As a quality executive with about 20 years of experience, Carla served in several strategic global quality roles with increasing responsibility in Quality Project Management, Quality Control, Qualified Person, GCP and Pharmacovigilance Auditing, GMP Auditing, Head of Management, Corporate Head of GMP Auditing & Compliance, Global Head of Affiliate GxP QA in global companies, such as Institute Fresenius, Dupont/Bristol-Myers-Squibb, Otsuka, Novartis, and most recently F. Hoffmann-La Roche Ltd/Genentech, Inc.

EXECUTIVE PANELISTS AND PRESENTERS

David Wright
Amgen

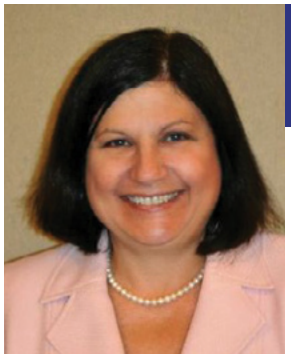
David is currently leading a new global initiative at Amgen which has the objective of assessing mHealth and wearable patient engagement technologies with a view to establishing new technology platform capabilities within Amgen's clinical development processes. David is a global clinical operations professional with over 22 years of biopharmaceutical and medical device industry experience. His broad experience ranges from leading global drug development clinical operations teams across diverse therapeutic areas to the management of large global clinical operations functional departments. David has a strong interest in business process transformation and change management and is active in industry consortia including Transcelerate, IMI, and CTTI. David holds a BSc in Computer Science from the University of New South Wales, an MSc in Clinical Research from the University of Wales and an MBA from the Imperial College London.

SUMMIT MODERATORS, FACILITATORS, AND FACULTY

Janice Hutt
The Avoca Group

In addition to her role overseeing Avoca project teams, Janice Hutt consults with senior teams within pharmaceutical companies to develop effective strategies focused on strengthening relationships with their service providers. Janice also works in-depth with service providers focusing on effective partnering practices to optimize outsourced relationships. Janice's expertise enables her clients, both sponsors and service providers, to foster an environment of mutual understanding, enhanced collaboration, and increased commitment, resulting in improved program outcomes.

Janice brings over thirty years experience in the pharmaceutical and pharmaceutical services industries. Prior to joining Avoca, Janice worked in clinical research at Merck for 10 years before working for 8 years with several CROs, as Director of Business Development. Janice holds a Masters Degree in Education from Acadia University and a BS degree in Biology and Chemistry from Rider University.



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.

SUMMIT MODERATORS, FACILITATORS, AND FACULTY

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. The Quality Consortium is focused on improving quality and increasing efficiency in outsourced clinical trials.

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

June 28, 2016

AQC Regional Networking Breakfast at DIA
2016 Annual DIA Conference
Fork Restaurant
Philadelphia, Pennsylvania

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 +1 (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
Agreement Pending**	✓						✓		2
Agreement Pending**	✓		✓						2
Covance	✓	✓	✓	✓					4
Clinical Research Laboratory (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 SUPPORTING SPONSOR

PA is an independent consulting, technology, and innovation firm of over 2,600 technologists, innovators, go-getters, strategists, leaders, developers… We operate globally from offices across the Americas, Europe, the Nordics, the Gulf, and Asia Pacific. We are experts in life sciences, healthcare, consumer and manufacturing, defence and security, energy and utilities, financial services, government, transport, travel, and logistics. Our deep industry knowledge together with skills in management consulting, technology, and innovation allows us to challenge conventional thinking and deliver exceptional results that have a lasting impact on businesses, governments, and communities worldwide. Our clients choose us because we find the solutions that really work – in practice, not just on paper. Then we roll up our sleeves and get the job done. At PA we don't just believe in making a difference. We believe in making the difference.

THANK YOU TO OUR 2016 SUMMIT MEDIA PARTNERS

QUALITY CONSORTIUM
THE AVOCA GROUP
2016 SUMMIT EUROPE

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.

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