Looking Ahead to 2019:
Insights into Clinical Research Trends from Our Experts

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As we move into 2019, the leadership of WCG is thinking about 2018 and the changes, trends, regulations and priorities that shaped the direction of the clinical research and drug development fields. With this in mind, we look forward to the next year and beyond. In this paper, WCG experts share what they anticipate in 2019, and what everyone should be prepared for as we approach another year of change.

Regulatory Oversight and Regulatory Policies

David Forster, JD, MA, CIP,
Chief Compliance Officer, WCG

To me the most interesting development to watch in 2019 will be the implementation and interpretation of the General Data Protection Regulation (GDPR), which went into effect on May 25, 2018. The interpretation of key provisions as they relate to clinical research remains unclear. For instance, there is significant debate about the most appropriate legal basis for processing data in clinical research. Some agencies have argued that GDPR-specific consent for participation in clinical research is necessary to provide the legal basis. Other agencies have stated that GDPR-specific consent is not necessary when there is a research informed consent, and that a more appropriate legal basis is "legitimate interest,"[1] given that clinical research provides value to society through the generation of knowledge.

Another provision that is not yet clear in the context of clinical research is the right to be forgotten; that is, the right to have any data about oneself permanently removed from electronic records. Data controllers such

as sponsors must honor a data subject and individual's request to be forgotten if the personal data are no longer necessary in relation to the purposes for which they were collected or otherwise processed. Most assume that for an ongoing clinical research study, the retention of such data is still necessary based on the EMA requirements to retain study records, but for other types of research such as a retrospective records review, the claim may be weaker. Similarly, once a clinical study has been finalized and closed, perhaps the data are no longer necessary in relation to the purposes for which they were collected. These issues will be clarified over the next few years, but in the meantime, we must keep a close eye on developing interpretations.

Jeffrey A. Cooper, MD, MMM,
Vice President, Process and Strategic Improvement, WCG

The revised Common Rule goes into effect January 21, 2019[2]. Currently, IRBs must follow two sets of regulations: FDA regulations for FDA-regulated research and the Common Rule for research supported by the federal government. For clinical trials, the two rules are essentially identical, and IRBs largely use the Common Rule as a standard for all research. IRBs must apply the revised Common Rule to new federally-funded research, but research approved before January 20 can follow either the original or the revised Common Rule.

For biopharma industry-sponsored clinical trials, IRBs face a choice: When a new protocol is submitted, will IRBs apply the revised Common Rule to FDA-regulated research, or just apply FDA regulations, which is equivalent to applying the original Common Rule? The former option allows IRBs to have a consistent standard and claim that they are following the "new and improved" protections; but adds requirements to industry clinical trials that don't technically apply. The latter option is less burdensome for the biopharma sponsors as it continues the requirements they are already used to; but requires IRBs to apply different rules to research based on the funding source (federal vs. private), which some people will view as a double standard.

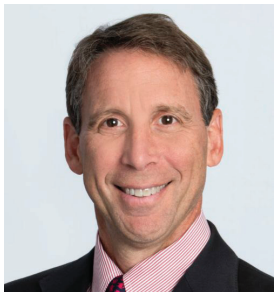
The WCG IRBs will continue to apply the appropriate and specific regulations to submitted protocols, based on whether the research is regulated by the Common Rule or FDA. But institutional IRBs will differ in their solutions to this question, and some IRBs are still struggling to choose what to do. As a result, sponsors can expect to see increased variability in requirements among institutional IRBs, especially around the content and format of consent documents.

David Borasky, MPH, CIP,
Vice President, IRB Compliance, WCG

The 21st Century Cures Act, signed into law on December 13, 2016[3], included a mandate to harmonize the human subject protection regulations between the FDA and the rest of the federal government within three years of implementation of the Act[4]. That timeline concludes in December 2019. If the FDA is held to that timeline, then 2019 will be a year of regulatory action from the FDA. (And it is worth noting that the revised Common Rule regulations will be effective starting January 21st, 2019).

The FDA's opening salvo may have come in November 2018 with the publication of a proposal to adopt the Common Rule criteria for waivers of informed consent[5]. I expect the FDA to continue harmonization efforts, looking for low-hanging fruit where they can. It would be logical for them to continue harmonization around consent. The revised Common Rule includes new required and optional elements of consent that should not be difficult to adopt, and while the key information requirement is completely new, it is reasonably straightforward.

That said, there are also aspects of the Common Rule that may be more difficult to harmonize, such as the requirement to make informed consent materials available to the general public through the posting of consent documents on government websites. Regardless, 2019 looks to be a year of regulatory change with the potential to impact sponsors, research sites, and IRBs.



Jonathan Seltzer, MD, MBA, MA,
President, WCG ACI Clinical

There are a couple of issues which I suspect will challenge us in the coming years. The first has to do with the incorporation of real world evidence (RWE) into the drug and development process. The 21st Century Cures Act specifically encourages the use of RWE as an efficiency measure for clinical development—for instance, at ACI Clinical, we are currently using RWE in an adjudication committee framework to establish a historical control group for a trial in which placebo-control is not possible. Because of the novelty of RWE, this is a highly complex process. I think we will see additional efforts with regulators, clinical scientists, and sponsors collaborating to establish the criteria by which

RWE will be able to support regulatory submissions. Another challenge we will likely face in 2019 is that of establishing accurate safety profiles. In the US, political pressure is forcing faster drug approvals; 2018 will have had a record number of drugs approved by the FDA. Rapid approval, however, requires an increase in oversight activities. A December 2015 FDA Guidance[6] suggests precisely this; it calls for Safety Assessment Committees (SAC) on every development program. However, SAC implementation has been an issue of great concern and debate. I suspect that we will see FDA clarification during 2019 and potentially a new paradigm for safety management.

Clinical Trials and Study Designs

Lindsay McNair, MD, MPH, MSB,
Chief Medical Officer, WCG

In 2018 we continued to see significant growth in the number of clinical trials with designs outside the "traditional" models, with evidence that the clinical research field continues to move away from the classic Phase 1/ Phase 2/ Phase 3 paradigm of development, especially in oncology. Sponsors are embracing these designs in part because they make sense for the new classes of therapies in development; a standard "3 + 3" design to identify a maximum tolerated drug dose does not make sense for most cancer immunotherapies. Sponsors are also moving toward these designs because they increase the efficiency of the drug development process. Adding expansion cohorts in a Phase 1 study or looking at multiple agents in one protocol without having to go through the process of shutting down a study and starting up the next one means that we can get to decision points, particularly those based on efficacy endpoints, more quickly. Sponsors are also increasingly looking at new operational models, including "virtual" trials, which

decentralize parts of the clinical research process and decrease the burden on research participants, which will hopefully improve study recruitment and retention, and will provide access to clinical research for a larger proportion of the patient population.

Mark G. A. Opler, PhD, MPH,
Chief Research Officer, WCG MedAvante-ProPhase

2019 will be an exciting year for psychiatry and neuroscience clinical trials on a number of fronts. The overall theme will be one of new frontiers—new mechanisms of action moving from early- to late-phase research, renewed progress and optimism for disorders that have thus far eluded successful pharmacotherapy, and new methods for assessment. Notably, several positive reports in 2018, including in rapid-acting antidepressants, combinations of therapies for PTSD, and new modalities for schizophrenia and associated conditions show that with the right study designs, technologies and assessment methods, we can achieve success.

While there were some notable late-stage failures in 2018, we are also seeing large organizations that have not been active in psychiatry re-entering the space. Coupled with the profusion of new technologies and new methods for executing neuroscience studies, from eCOA to eConsent, wearables and beyond, 2019 promises to be an exciting time.

Daniel Kavanagh, PhD,
Senior Scientific Advisor, Gene Therapy, WCG

As I write my thoughts for 2019, media sources that cover science and genetic issues are dominated by news out of China, that two infants born in 2018 are the product of deliberate germ-line CRISPR gene editing carried out by a Chinese researcher with some ties to an American research institute[7]. With few exceptions, the response from leading regulatory authorities and scientific societies has ranged from deep concern to unambiguous condemnation. Based on current information the research seems to be totally lacking in scientific and medical justification, and almost every ethical norm for human subjects research seems to have been violated. Although the scientific community and the public at large may eventually

embrace heritable human gene editing, this case is deeply concerning for the human subjects involved and for ethical genetic research in general. In the next year, we will likely see continuing updates on this story, and reactions in the scientific community in terms of guidelines and ethics policies.

Aside from these unfortunate events, 2019 still holds the promise of seeing gene transfer technology ethically implemented to meet real medical needs. I am especially watching out for new developments on a couple of fronts that have received less media attention. One area is the development of "universal donor" cells for cellular therapies. The human immune system is programmed to vigorously reject tissue transplants from any genetically distinct source, which makes it necessary for most cellular therapies to be "autologous"—meaning that the donor and recipient are the same person. New advances suggest that there may be ways to protect donor cells from immune rejection, creating the possibility of universal donor cells that can be used to manufacture therapeutic products for mass distribution. Another exciting area is passive immunization by gene transfer. Rather than using a vaccine to induce an immune response, researchers may use gene transfer agents encoding protective antibodies against a target pathogen or tumor. This approach allows for *in vivo* productions of antibodies engineered to have particular protective properties not normally achievable by vaccination.

Clinical Safety and Pharmacovigilance

James A Bannon,
President, Scientific and Regulatory Review, WCG

Developing a deep understanding of a new product's benefit to risk profile is critically important for regulatory approval. Ultimately, the goal is to provide patients and providers with the most up to date information with which to make informed clinical decisions. Building a medically valid and verified safety profile is an essential part of clinical development programs.

Increasingly, early stage product development has been and will continue to be conducted by the small to midsize biopharmaceutical companies. Funding for these companies has increased over the past few years. These companies press to meet their development milestones and must ensure that their resources are efficiently used to generate clinical and safety data of the highest quality. In addition to the regulatory reporting requirements, the safety data requires the proper interpretation and trending analysis. The importance of these activities increases as a product

proceeds through the clinical development program. These emerging companies are recognizing the need to engage drug safety and pharmacovigilance expertise early in the development process to provide the proper underpinning of the safety profile of their product.

Many of these companies, while recognizing the importance of product safety, are not in a position to commit internal resources to it. In 2019, service providers with the necessary depth and breadth of safety expertise will be an increasingly important resource for emerging biopharmaceutical companies to properly process, report, and analyze safety reports throughout the development program.

Steven Beales,
Senior Vice President, Safety Solutions, Scientific and Regulatory Review, WCG

For 2019, I am excited about the Global Safety Reporting Harmonization Working Group, which will release the Global Safety Reporting Reference Model (GSRM) this year. The lack of global harmonization has been the largest problem in safety reporting because there are more than 40 different regulatory frameworks for safety reporting worldwide. The noteworthy feature of GSRM is that it contains executable regulatory intelligence, which can be integrated into a safety distribution system. This enables precision distribution of safety reports to the right person at the right time anywhere in the world.

Another important initiative is the work being done on serious adverse event (SAE) intake systems. Currently, inbound SAE reporting involves the submission of potential SAEs by phone, fax, email, or PDF. These initial reports are often processed and tracked manually, and routed through Clinical Operations, Drug Safety, and Medical Writing departments that use different systems and find it difficult to collaborate. Covance is implementing a scalable, end-to-end, global workflow system to optimize triaging, tracking, processing and review of SAE reports to solve these problems. It is expected to generate higher case closure rates, improved compliance/on-time reporting, better quality, improved metrics reporting, collaboration and workload management, and increased client satisfaction. This foundational operational work enables the efficient processing of millions of adverse events from diverse sources. This creates the quality data necessary to produce future artificially intelligent systems.

Exciting advances in hardware (GPUs, Cloud Computing) and machine learning (big data, attention-based neural networks, expert-defined Bayesian networks) will help us realize the FDA's vision of proactive pharmacovigilance. If operational improvements are made now to take advantage of future technological breakthroughs, then we can avert an iatrogenic crisis.

Research Institutions and Clinical Site Issues

Stuart Horowitz, PhD,
President, Institutions and Institutional Services, WCG

Effective management of clinical trials continues to be a challenge at many academic health centers and healthcare organizations engaged in clinical research. Despite an abundance of patients, most clinical trial enrollment occurs not at these institutions, but at community sites. To increase the benefits of clinical trial participation – both to patients and institutions – 2019 will bring renewed interest in partnerships and new management solutions.

To become more agile, institutions are collaborating, creating new research networks and consortia. Most are organized either with a focus on a broad therapeutic area (e.g. oncology), or a narrower therapeutic focus, (e.g. Alzheimer's disease). Some have a geographic focus. All hope to add efficiency by negotiating a single contract and budget with clinical trial sponsors, while offering multiple investigators and sites. The networks seek to adopt best business practices, often utilizing business partners to outsource contracting, budgeting, and central IRB review. These networks typically originate either at research foundations or within institutions, which themselves have utilized outsourcing partners to gain management efficiencies.

A key driver of these activities is data. As transparency increases, institutions have access to accurate, benchmarked data, clearly showing opportunities for improvement, and the need to adopt best practices.

Jonathan Zung, PhD,
President, WCG Clintrax, Advisor to WCG CEO

Making it easier for investigators and patients to participate in a clinical trial will continue to be an area of focus in 2019. The challenge however, continues to be the need to simplify and optimize the different steps in the clinical trial process so that trials are attractive to both the investigator and patient. Each step, whether it is site feasibility, site contracting, data collection, payments, etc. requires a different way of thinking, along with a set of tools and agile processes that can reduce trial burden and complexity, while introducing more consistency and simplicity. Niche clinical services providers deliver unique solutions that address specific

pain points, bringing simplicity and consistency to the processes they deliver.

In 2019, we will continue to see an increased use of niche providers by both sponsors and CROs. The focus will be on integrating the niche providers' offerings and processes with sponsors and CROs to reduce timelines, while bringing simplicity. This will allow sponsors to focus on what they excel at while leveraging their partners' expertise and technologies.

Underpinning the success of niche providers will be how they leverage artificial intelligence (AI) and machine learning (ML) in their work. AI and ML will continue to be disruptive and allow organizations to leverage their wealth of data (and data they have access to) in order to make more informed decisions in real time. These technologies will continue to re-shape how resources are used and work is performed.

Data and Technology

Emmanuel Olart,
Chief Technology Officer, WCG

The adoption of technology to streamline the conduct of clinical trials is still lagging despite the availability of proven solutions that can both accelerate and reduce the cost of each study.

One of the most interesting things is that while the benefits are generally well understood by all parties, the change required by the implementation of these systems is still perceived as a significant regulatory risk, and this perceived risk is often used as a reason to maintain the status quo and continue with inefficient manual processes or older systems despite overwhelming evidence of their inadequacy.

The FDA is aware of the problem and Scott Gottlieb recently delivered remarks[8] suggesting that they may take action in 2019 to accelerate the transition to digital solutions to enable clinical trials to support faster innovation.

It is fairly common for the larger players both on the sponsor and CRO sides to see the selection and implementation of enterprise systems supporting clinical trials to take years in an age where the evolution of technology solutions is measured in months.

From my perspective, reducing this cycle time and leveraging the benefits of modern tools to enable faster trials is critical, and having the support of the FDA is a key step in the right direction.

April Mulroney,
Senior Vice President, Chief Data Officer, WCG

The use of data to improve the return on investment (ROI) on creating innovative, lifesaving medicines in clinical trials is on the rise. Data should be used to lead decision making in areas such as efficiently finding patients, evaluating protocol design, and leveraging real-world evidence (RWE) in regulatory submissions to predict scientific outcomes, to name only a few. Everyone seems to have data, and lots of it. However, success in using data analytics will not only depend on the ability to mine useful insights out of these large data sets, but more importantly the ability to understand the data we are presented with. For example, can the insights predict a pathway to accelerated site activation? Is the data proving genetic correlations?

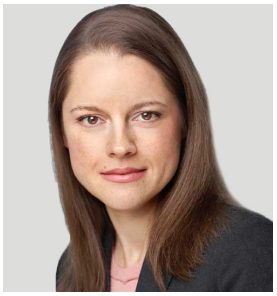
Data literacy has become as important a skill as reading and writing. We can easily be overwhelmed by the large volumes of data we handle in clinical trials, and so need to invest in the tools to interpret the data to make more informed and accurate decisions.

A study by Qlik showed that only 24% of business decision makers are fully confident in their ability to read, work with, analyze and argue with data[9]. In other words, three quarters of R&D pipeline decisions could be made by people who are data illiterate. Not everyone needs to be a data scientist or analyst, however all levels of stakeholders need to be comfortable when it comes to interacting with, utilizing, and questioning the data they handle. A true digital transformation in the way we leverage data to accelerate drug development, has data literacy in its DNA. This is imperative to get ready for the data-driven world of clinical trials, an industry that is in some ways catching up in the data analytics space.

Mark Summers,
President, Patient Engagement Division, WCG

Electronic informed consent is poised to make major inroads in adoption and use in 2019. Current informed consent processes and paper documents continue to represent a significant barrier to clinical trial enrollment, both for patients and investigative sites. Patients cannot comprehend much of the scientific and medical terminology and sites struggle with presenting the information to patients in ways in which they can verify and document patient comprehension. Wide variations in how paper informed consent is administered at sites and understood by patients negatively impact enrollment rates and result in inequitable patient experiences.

Electronic informed consent can address all of the above shortcomings by standardizing the presentation of informed consent for all patients while aiding in, and validating, their comprehension, all while reducing investigator and research coordinator workloads.



Sofija Jovic, PhD, MBA,
Business Transformation Advisor, WCG MedAvante-ProPhase

We are entering 2019 on the groundswell of technology adoption in clinical research that we have seen over the past two to three years. Use of technology to collect extensive data not just from patients and participants, but on a population level, has emerged from early adopters onto the main stage. Getting everyone more engaged with their health and raising their hand to participate in research is a trend that we will see continue.

With that trend will come a snowballing amount of data. In 2019, the question will shift from "what data can we collect and how?" to "what does it all mean?" This shift signals a return to basics of sound measurement science filtered through experienced clinical judgment. We will continue to be technology-enabled, but the true impact will be made by insights coming from deep clinical knowledge and scientific expertise to understand and interpret the data avalanche and arrive at treatment recommendations and breakthroughs that improve patient lives.

Market Intelligence and Insights

Linda B. Sullivan, MBA,
Executive Director, WCG Metrics Champion Consortium

In 2019, the industry will see continuing growth in the adoption of risk-based quality management and centralized monitoring approaches put forth in ICH-E6(R2) GCP addendum. Technology will play a major role in enabling the adoption as organizations improve access to information needed to assess risk and monitor study and site performance. Scalable, cloud-based data aggregation platforms and data analytic visualization programs will form the basis upon which organizations will analyze risk and monitor data that resides in disparate systems such as EDC, CTMS, IXRS, eCOA, issue management, and safety systems.

During the transition from traditional to risk-based, data-driven program management, organizations will face several key challenges: data stewardship and availability of staff able to interpret and act on the data. These challenges can be mitigated in several ways. The adoption of industry-based performance and quality data and metric standards can improve the consistency of the data utilized in data analytic programs. Additionally, new risk management and root cause analysis training programs—developed specifically for clinical research staff—are available to meet the unique training needs of study and site management teams. I believe that 2019 will be the year that the industry begins to realize the benefits of risk-based quality management and centralized monitoring—namely, using data to identify when human intervention is required to investigate whether patient safety and/or data integrity issues are occurring and take action before they impact the integrity of the research.

Linda Martin,
President, WCG KMR Group

For decades, data and benchmarks have been essential for effective R&D and clinical trial management. Over the last few years there has been a surge to integrate data to improve decision making and advance strategic objectives. This focus has come not only from the largest and more established players, but there has been real interest from smaller biotech companies, CROs, and even clinical sites.

Classically, companies have been focused on benchmarks relating to cycle times, costs, and productivity to evaluate and assess their performance. Now companies are using advanced analytics to ground their decisions and evaluate tradeoffs using a data driven approach. I believe that we will see more of this trend in 2019.

With the embrace of advanced analytics, companies are using data in their day-to-day operations to streamline planning and enhance execution. We have seen tremendous success in companies using our data and expertise to optimize the country and site selection process. Using a rich, comprehensive, and reliable dataset, we have been able to partner with companies to recommend and unearth a number of optimizations to reduce clinical trial costs and timelines and improve overall performance.

References

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2 Federal Policy for the Protection of Human Subjects Rules and Regulations; Final Rule Federal Register, Vol. 82, No. 12, Thursday, January 19, 2017, Rules and Regulations.

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4 (21st Century Cures Act, 2016; Section 3023)

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7 Lindsay Ellis, Rice U. Will Investigate Professor Who Says He Worked on First Genetically Altered Babies, Chronicles of Higher Education, November 26, 2018

8 Sue Sutter, Gottlieb Takes Aim At CROs' 'Outdated Processes' In Push For Clinical Trial Digitization. The Pink Sheet, November 26, 2018

9 Qlik, How to Drive Data Literacy With the Enterprise. 2018

WCG Experts

David Forster, JD, MA, CIP,
Chief Compliance Officer, WCG

Mr. Forster has a J.D. and a Masters in Medical Ethics from the University of Washington. He joined Western IRB (WIRB) in 1996 and is currently the Chief Compliance Officer for the WIRB-Copernicus Group (WCG).

Mr. Forster co-chairs the Secretary's Advisory Committee on Human Research Protections (SACHRP) Sub-Committee on Harmonization (SOH). He previously served a four-year term as a member of SACHRP, and was a member of the SACHRP Sub-Committee on Inclusion of Individuals with Impaired Decision-Making in Research (SIIIDR). Mr. Forster also serves on the Certified IRB Professional (CIP) Council.

Jeffrey A. Cooper, MD, MMM,
Vice President, Process and Strategic Improvement, WCG

Dr. Cooper has more than thirty years of experience applying DHHS and FDA regulations with regard to operational efficiency, use of information technology, standards-based evaluation, and quality improvement in human subject research. He was one of the co-founders of the Association for the Accreditation of Human Research Protection Programs (AAHRPP), and is a recipient of the PRIM&R Legacy Award for his work in protecting human research participants.

David Borasky, MPH, CIP,
Vice President, IRB Compliance, WCG

Mr. Borasky is responsible for leading the quality and compliance activities for all of the WCG institutional review boards (IRBs). He has 20 years of experience in managing IRBs in settings that include global public health organizations, large academic medical centers, and independent IRBs. In addition to his compliance oversight responsibilities at WCG, Mr. Borasky also serves as Co-Chair of the Subpart A Subcommittee of the Secretary's Advisory Committee on Human Research Protections (SACHRP) and previously sat on the Board of Public Responsibility in Medicine and Research (PRIM&R).

Jonathan Seltzer, MD, MBA, MA,
President, WCG ACI Clinical

Dr. Seltzer is a recognized leader in the area of cardiac safety, Endpoint Adjudication Committees and Data and Safety Monitoring Committees. He has chaired and served as a committee member for scores of protocols, and has functioned as an advisor for dozens more. He is actively publishing in these areas and participating in thought leadership efforts focused on defining best practices. Currently, Dr. Seltzer is on the scientific programs committee for the Cardiac Safety Research Consortium (CSRC) and the steering committee for the Clinical Trials Transformation Initiative (CTTI). Previously, he served as the president and chair of Trustees for the Academy of Physicians in Clinical Research.

Lindsay McNair, MD, MPH, MSB,
Chief Medical Officer, WCG

Dr. McNair has extensive experience in the pharmaceutical industry. Prior to joining WCG, she was a consultant to pharmaceutical and biotechnology companies, providing medical guidance on clinical development strategies and study designs for new drug studies, and medical oversight of all phases of clinical trials. Dr. McNair is also a member of the Human Subject Research Board at the Environmental Protection Agency, and teaches graduate-level courses on the scientific design of clinical research studies. She has been actively involved in IRB work for 18 years, and has a Master's of Science in Bioethics with a concentration in research ethics.

Mark G. A. Opler, PhD, MPH,
Chief Research Officer, WCG MedAvante-ProPhase

Dr. Mark Opler serves as Chief Research Officer, directing scientific research and development at MedAvante-ProPhase. Dr. Opler was the founder of ProPhase and served as its CEO and Chief Scientific Officer among other positions. He holds the titles of Adjunct Assistant Professor of Psychiatry at New York University and Assistant Professor of Clinical Neuroscience at Columbia University's College of Physicians and Surgeons. His academic research focuses on the etiology, phenomenology, and treatment of serious and persistent mental disorders. He is also leading the development of the new upcoming edition of the PANSS Manual©.

Daniel Kavanagh, PhD,
Senior Scientific Advisor, Gene Therapy, WCG

Prior to joining WCG, Dr. Kavanagh was a principal investigator and Assistant Professor at the Ragon Institute of Massachusetts General Hospital, MIT, and Harvard, Vice-Chair of the Partners Institutional Biosafety Committee, and a member of the Executive Committee of the Harvard Center for AIDS Research. He has chaired clinical trials of an investigational human gene transfer vaccine in HIV-infected subjects, and is the author of more than 35 peer-reviewed publications in microbiology and immunology.

James A Bannon,
President, Scientific and Regulatory Review, WCG

Dr. Bannon joined WCG in 2017 with the acquisition of Vigilare International, a leading provider of drug safety and pharmacovigilance solutions. Dr Bannon was the founder and CEO of Vigilare International.

As president, scientific review division for WCG, Dr. Bannon is responsible for the full range of global drug safety and pharmacovigilance services, including individual case safety reports (ICSR), aggregate safety reporting, data safety committees, safety report

distribution, risk management, signal detection, and regulatory safety reporting.

With more than 25 years' clinical research experience, Dr. Bannon has held positions of increasing responsibility in operations and executive management. Prior to Vigilare International, Dr. Bannon was executive chairman of IndiPharm, Inc., a global regional clinical research and training organization, for six years. IndiPharm provided high quality research services for western biopharmaceutical companies conducting clinical studies in India and the ASEAN nations.

Steven Beales,
Senior Vice President, Safety Solutions, Scientific and Regulatory Review, WCG

An expert in the field of safety reporting technology, Mr. Beales has 25 years of experience in IT, and has spent over 16 years in the pharmaceutical industry. He joined ePharmaSolutions (ePS) in 2009 and led implementation of the company's Clinical Trial Portal at Genentech across 100+ countries. In 2015, he led implementation of the Clinical Trial Safety Portal at a top 5 pharma organization, which included a data-driven rules engine configured with safety regulations from those countries, which saved this organization hundreds of millions of dollars. Over 50 million safety alerts have been distributed by these two portals via the cloud.

Prior to joining ePS, Mr. Beales was the Chief Software Architect at mdlogix, where he led the implementation of the CTMS systems for Johns Hopkins University, Washington University at St. Louis, the University of Pittsburgh, and the Interactive Autism Network for Autism Speaks.

Stuart Horowitz, PhD,
President, Institutions and Institutional Services, WCG

Stuart Horowitz has over 30 years of experience as a research professional. He began his career as a laboratory research investigator and advanced to leadership positions in both translational and clinical research in academic health centers. He has been instrumental in building and improving research programs at medical schools and hospitals throughout the US and the Middle East, as a consultant and Managing Director at Huron Consulting Group. He is currently on the editorial and advisory boards of Clinical Researcher and Therapeutic Innovation and Research Science (TIRS).

Jonathan Zung, PhD,
President, WCG Clintrax, Advisor to WCG CEO

Dr. Zung is an experienced industry executive with more than 25 years of pharmaceutical development experience in oncology, immunology, cardiovascular disease and other major therapeutic areas. He has held

executive leadership positions in the pharmaceutical and pharmaceutical services industries.

Most recently, Dr. Zung was group president, Clinical Development & Commercialization Services for Covance Drug Development where he led a global organization of over 8,000 employees in 60 countries spanning all phases of development (Phase I- IV), along with global market access services.

Prior to Covance Dr. Zung was vice president and head of Global Clinical Sciences and Operations at UCB, with responsibility for clinical operations, data management, statistical sciences, contracting, medical writing and operational excellence across the United States, Europe and Asia. Before joining UCB, he was vice president and head of Global Development Operations at Bristol-Myers Squibb, where he led a 1,400-person organization that managed clinical trials from Phase II through registration. He also held several positions of increasing responsibility at Pfizer Global Research and Development.

Emmanuel Olart,
Chief Technology Officer, WCG

Mr. Olart has 18+ years of experience in the clinical research and technology space leading global software engineering and IT teams and architecting solutions serving the pharmaceutical industry.

Prior to joining WCG, Mr. Olart worked for BioClinica in a series of increasingly senior positions leading to vice president, systems architecture.

April Mulroney,
Senior Vice President, Chief Data Officer, WCG

As Chief Data Officer, Ms Mulroney is responsible for the vision and direction of WCG's data and knowledge strategy. She brings a unique blend of general management, finance, strategic innovation and product development experience in Life Sciences to her role. A recipient of both the 2016 HBA Woman of the Year, and 2016 PharmaVoice Top 100 awards, Ms. Mulroney holds a CPA certification and BComm from University of Toronto.

Prior to joining WCG, Ms. Mulroney was with Medidata Solutions as general manager of Site Payments and FMV benchmarking. During her tenure, she incubated and launched the financial products component of Medidata's industry leading Clinical Trial Technology Platform. Ms. Mulroney led the Payments EDC to Cash launch in 2016, resulting in the SCRIP Award for Best Technology of the year.

Mark Summers,
President, Patient Engagement Division, WCG

As President of the Patient Engagement Division at WCG and with over thirty years of experience in pharmaceutical and medical device clinical research, Mark is widely recognized as a veteran entrepreneur and thought leader in the area of accelerating clinical trial patient enrollment. He is the founder and CEO of ThreeWire, Inc., and has led the company through the development and patenting of its proprietary model for maximizing clinical trial patient enrollment.

Prior to founding ThreeWire, Mr. Summers held executive positions at two early stage medical device firms where he drove more than $100 million in global growth following completion of extensive clinical trials. He is a graduate of the University of Michigan and is also a United States Navy veteran where he spent seven years flying F-14s from various aircraft carriers and at Topgun.

Sofija Jovic, PhD, MBA,
Business Transformation Advisor, WCG MedAvante-ProPhase

Dr. Sofija Jovic is focused on applying research and digital health innovation to transform the life science and healthcare industries. As an entrepreneur and business executive, Dr. Jovic has developed a reputation for commercializing innovation and creating new market opportunities. In her role as the CEO of ProPhase, Dr. Jovic drove business success by harnessing the power of data to revolutionize how we conduct research, deliver treatments, and understand and evaluate their outcomes. She is passionate about helping healthcare and biopharma businesses understand the transformative potential of data to help them grow and succeed. Dr. Jovic serves as an Advisor at MedAvante-ProPhase and holds current Board appointments at Inflexxion, CRA Assessments, and Gilda's Club of New York City.

Linda B. Sullivan, MBA,
Executive Director, WCG Metrics Champion Consortium

Ms. Sullivan has more than 30 years of experience working in the healthcare and clinical research industries helping organizations improve processes to improve financial and quality outcomes. She was a founder of Metrics Champion Consortium, an industry association dedicated to leading the drug-development enterprise in the adoption and utilization of standardized metrics and benchmarks to drive performance improvement.

Ms. Sullivan has been a featured speaker at Performance Metrics, Risk-Based Monitoring, Quality Management & Clinical Trial Oversight industry meetings, published articles in leading journals and served on industry advisory boards such as the NIH-NCATS Methods and Process Domain Task Force and the ACRP CRA Competency Steering Committee.

Linda Martin,
President, WCG KMR Group

Linda Martin was founder and President of KMR Group, a firm specializing in biopharmaceutical R&D performance, data and analytics. Her areas of expertise include the measurement and evaluation of R&D productivity and clinical development, including subspecialties of enrollment and site performance. Ms. Martin has a Master of Management degree from Northwestern University's Kellogg Graduate School of Management and an undergraduate degree from the Illinois Institute of Technology.

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