Looking Ahead to 2018:
Insights into Clinical Research Trends from Our Experts

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2017 was a fascinating year for those of us closely following the clinical research industry. And 2018 promises not to disappoint. Within the WIRB-Copernicus Group (WCG) family of companies, our subject matter experts are always watching regulatory, technology, and practice trends. Their observations, combined with a deep understanding of the science and practice of clinical research, provide the basis for our strategic planning. In this way, we support both our biopharma partners and our institutional partners to be prepared for not only what is currently happening in clinical research, but what is likely to happen in the future. In this paper, some of our thought-leaders provide their insights on what they are watching for and what they anticipate in 2018 in clinical trial technology, regulatory changes, and scientific developments.

Nicholas Slack, MBE, President, ePharmaSolutions and Chief Growth Officer, WIRB-Copernicus Group

The drug development industry is changing at an accelerating rate of speed, and we will continue to see these changes in 2018. We find ourselves in the midst of a massive shift in the clinical trials field, and many of us working in this field have not realized it yet. This shift is best defined by a movement away from massive scale studies, large labor forces, and generalist approaches in the conduct of clinical trials, to an emphasis on precision, a focus on knowledge and expertise, and the use of interconnected information sources and systems to simulate clinical trial outcomes. Simply put, we have left the era of general brute force methods of clinical research and have entered the era of specialization and predictability in clinical trial operations. This shift both creates and results in significant changes in the way that we plan, manage, and conduct clinical trials.

Stuart Horowitz, PhD, MBA, President of Institutions and Institutional Services, WIRB-Copernicus Group

The clinical trial landscape of 2018 will see more academic medical centers (AMCs) adopting solutions and partnerships that will enable them to compete for shrinking clinical research funding.

The greatest challenge for multicenter clinical trials is the timely recruitment of the required number of

participants who complete studies and contribute evaluable endpoint data. Many community-based investigators meet this challenge routinely. In contrast, investigators at hospitals and especially AMCs often do not. The problems include delays in Institutional Review Board (IRB) and other specialty committee review, contracting and budgeting. Consequently, institutional sites are still working toward study initiation while enrollment is underway elsewhere, resulting in reduced revenue for the site and fewer research opportunities for their patients. Recognizing this, NIH demands that many of the top AMCs—those that receive the Clinical and Translational Science Award—become more efficient at study startup and enrollment, and NIH expects to see measurable improvement. These efficiency challenges also apply to industry-sponsored clinical trials.

Industry already tracks these data, rewarding top-performing investigators with more studies. In 2018 we will begin to see AMCs rising to this challenge. It is imperative that institutions conducting clinical trials understand how their performance measures up to benchmarks among all sites, and how to adopt the most efficient solutions that already exist.

Emmanuel Olart, MS, Chief Technology Officer, WIRB-Copernicus Group

The biopharmaceutical industry experienced a shock in June 2017 when one of the world's leading pharma companies was hit by a ransomware attack that took most of their business down for days, with consequences reverberating throughout their operations long after the initial event. This came as a wake-up call and immediately brought information security back as a priority for corporate IT organizations. Cyber threats are evolving rapidly and are fast outpacing historical perimeter protections, requiring agile thinking and constant monitoring of the security landscape.

We can already see a heightened focus in the industry on ensuring that the risk of data breaches is mitigated and that appropriate steps are taken not only to detect threats, but also to educate employees on the large variety of clever ways attackers have to obtain sensitive information.

Mark Summers, Chief Executive Officer, ThreeWire

The evolution of pharmaceutical research away from blockbuster drug categories and toward more personalized therapies, at the forefront of which today are oncology and rare diseases, will accelerate and spread to other therapeutic areas. This trend will usher in fundamental changes in how potential clinical research participants are identified and interacted with by sponsors, as well as the basic clinical research site model.

The historical site model wherein participants are brought to the study site will increasingly give way to new models that entail bringing the study to the participants. Likewise, as participants have traditionally been expected to schedule their participation in research studies around site location, operating hours and availability, sites will have to move toward operational models wherein they will bring the study to the participant at times and places that are tailored to participant availability and convenience.

These changes will drive subsequent variations in the definition of what constitutes a research site along with traditional site operating models. Sites have historically been defined by their physician investigators and the clinical research experience, but sites will begin to be defined by their access to targeted study populations along with availability of physicians who can be trained and equipped to serve as investigators for a particular study.

Lindsay McNair, MD, MPH, MSB, Chief Medical Officer, WIRB-Copernicus Group

In no therapeutic area have we seen more significant and more rapid changes from the old paradigms of clinical trial design and conduct than we have in oncology, and we expect these changes to continue into 2018. Driven by new therapeutic mechanisms which no longer rely only on cytotoxicity and on regimens based on maximum tolerated dosing, we see that in early stage research, the "3 + 3" designs are giving way to pilot groups and expansion cohorts, allowing exploration of efficacy in Phase I. In later stage studies, we see "master protocols" including platform studies, basket protocols and umbrella designs, allowing much more rapid and flexible testing of drug combinations- often from multiple sponsors- as well as study populations that are based on tumor characteristics rather than disease location.

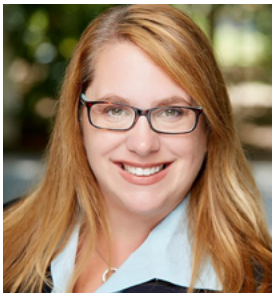
These new patterns of drug development require a research infrastructure and oversight system that is prepared for the new challenges they bring. Clinical research teams and the partners who work with them will need to be innovative and flexible in their selection of study sites, and to push beyond the "this is how we've always done it" mindset so that operational advances can move as quickly as scientific advances. IRBs and other oversight committees must be prepared to consider new situations, such as study populations who have not exhausted all other therapeutic options (as have often been the participants in oncology studies), but patients for whom there are promising investigative regimens but still approved therapies that have not been tried- how does this shift the relative risks and benefits of research participation, and how is appropriate informed consent ensured when there is so much excitement about new agents? These and other issues will continue to create important topics of discussion around these exciting medical advances.

Suzanne Caruso, Vice President of Clinical Solutions, WIRB-Copernicus Group

As we move into 2018, sponsors will face a dynamic and changing investigator landscape due to an increasing percentage of sites per study residing outside the United States and a shrinking overall investigator pool. In North America, the number of unique principal investigators (PIs) has decreased almost 10% from 2014 to 2015[1] and has decreased more than 10% from 2015 to 2016. The challenge posed by fewer investigators is compounded by the fact that the number of clinical research studies continues to be quite high as more and more pharmaceutical, biotech and technology companies begin running clinical research trials.

Unfortunately, the decreasing number of investigators available to support these studies will cause the industry to reach a tipping point: either study design must evolve to accommodate a smaller investigator pool or a higher percentage of studies will be terminated early due to lack of enrollment. This changing investigator landscape signals the need to develop stronger investigator relationships with those PIs who are starting out in clinical research. One novel trend we are starting to see at the end of 2017 is that sponsors are helping new investigators build the operational infrastructure they will need to support clinical research, instead of focusing only on the scientific rationale, inclusion/exclusion, and endpoints of the study. I believe sponsors who provide both scientific and operational support will develop strong relationships with their investigators resulting in more successful trials with optimized trial timelines.

[1] Kenneth Getz, MBA, Carrie Brown, MS, Stella Stergiopoulos, MS, MPH, CerdiBeltre, BA. Baseline Assessment of a Global Clinical Investigator Landscape Poised for Structural Change. *Therapeutic Innovation & Regulatory Science* Vol 51, Issue 5, pp. 575 - 581



Jill Johnston, President, WCG Clinical Services Organization at WIRB-Copernicus Group

In 2018 there are a number of trends that will continue to get traction.

Big Data and Informatics – organizations have been collecting a lot of operational data for many years, but due to limitations in technology, cost, and time, most of this information had been collected study-by-study and usually customized for each trial. Combining this data has been incredibly difficult. Normalizing, aggregating and accessing this data in such a way for experts to use it to inform study design, site identification, site selection and patient recruitment is one promising path for more streamlined, informed decision-making capabilities.

Automation, Transparency and Collaboration – many operational teams are trying to figure out ways to eliminate study trackers, weekly Excel status reports, and individual checklists to remind team members of what the next step in the process should be. Today, everyone expects real-time access to the data as the work is actually being completed. Clinical trial applications are now being developed incorporating workflow automation and helping to determine the optimal critical path of activities. Instead of manually entering data, the applications are automatically tracking the operational data as the individuals are doing their work. Employees can focus on doing their work, rather than on spending time tracking the status of the work they are doing.

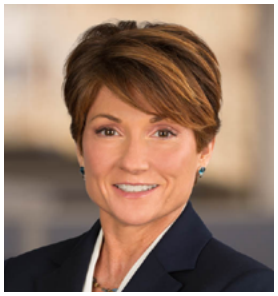
Relationships Matter – over the past year, I had the opportunity to speak to many individuals from investigational sites. Being a former CRA myself, I am simply shocked by how much the CRA role has changed during my time in the industry. Over the years, the site-facing roles have become very specialized where on-site activities have been narrowed down to only those with a specific deliverable, or concentrate on certain areas of interest—we are losing sight of the big picture. Relationships DO matter. My opinion is that we should get back to some of the basics, back to the foundation of developing deep relationships within the project team. I think we would find risk mitigation strategies right there in front of us, if we just broaden our views.

Jeff Litwin, MD, Chief Executive Officer, MedAvante-ProPhase

We can expect to see an increase in the number of anti-tau trials in neurodegenerative diseases, involving both Alzheimer's disease and other tauopathies. It is likely that anti-synuclein strategies will also influence the approach to neurodegenerative diseases. The advent of tau imaging is driving some of this, as well as the development of antibody treatment approaches for both of these proteinopathies. The expansion of Alzheimer's disease prevention trials can lead to novel approaches to subject recruitment with a heavier focus on social media and online prescreening.

In psychiatry, we will likely see more trials for rapid-acting antidepressants and anti-suicidality agents. We also expect to see continued interest in novel formulations of existing drugs for better pharmacokinetics and adherence (e.g. drug-device combinations, new long-acting formulations) and in sub-populations of existing diseases with high need untreated domains (e.g. negative symptoms in schizophrenia and anhedonia in depression).

Patient-centricity continues to be discussed and, although there has been progress in the area, there is much more to be done. The voice of the patient is growing louder and being heard more often. The adoption of eConsent is finally starting to grow, allowing patients to better understand the risks and benefits of clinical trials and more patients are receiving the results of the trials in which they have participated.



Amber Corbin, JD, President, Clintrax Global

Technology and medicine are becoming more intertwined, with the proliferation of CRISPR, CAR-T therapies, and individualized medicine. Protocols are also becoming more complex. Consequently, the demand for clinical research sites with the ability to execute these complex protocols and with access to patients who meet a specific profile is increasing. The increased demand for these highly qualified sites with specific patient populations tips the balance of power, garnering the sites greater negotiating power and the ability to command higher budgets. For these reasons, we may see the costs of clinical research increasing as the site budgets themselves increase. Identifying the present-tense increasing fair market value (FMV) of services in excess of the information provided by the

backward-looking, budget-aggregating tools will be a challenge requiring thoughtful scrutiny in this new environment.

As specialized sites require larger study budgets and the patient population targeted is more specific, ensuring that sites are initiated more quickly will become more important to maximize the patient enrollment period. In 2018, the focus will be on accelerating clinical trial start-up, making processes as efficient as possible, and ensuring that highly targeted populations can be reached effectively.

Lance Converse, Chief Innovation Officer, WIRB-Copernicus Group

As protocols continue to increase in complexity, finding patients for those trials becomes more difficult, which drives the pharmaceutical industry's adoption of more effective protocol design and patient recruitment solutions. Protocol inclusion/exclusion criteria will be checked against curated electronic health record (EHR) data sets to help ensure that an adequate pool of patients are available from which to recruit within a country or region, and then use that same data to recruit those patients using HIPAA-compliant methodologies. This will help to accelerate timelines and reduce the number of protocol amendments.

Pharma is taking back control of the critical process of recruiting and retaining participants into their trials. Enterprise participant recruitment platforms will allow study teams to quickly design, deploy, and track global participant recruitment programs in hours and, over time, leverage predictive analytics to determine which outreach tactics to use for each disease and geography. Using these new technologies, sponsors will have the ability to predict precisely how much they will need to spend to reach their enrollment targets. In the same way Expedia® disrupted the travel industry, these new data-driven recruitment platforms will disrupt the participant recruitment industry by empowering study teams to implement global recruitment programs in hours vs months.

David Forster, JD, MA, CIP, Chief Compliance Officer, WIRB-Copernicus Group

From my perspective the most fascinating development underway as we move into 2018 is FDA's stated interest in considering Real World Data (RWD) and associated Real World Evidence (RWE) in support

of regulatory decisions. The 21st Century Cures Act calls on FDA to consider the use of RWE to support approvals of new indications for approved drugs and to help satisfy post-approval requirements. In addition, the Center for Devices and Radiologic Health (CDRH) has released a guidance document[1] on the use of RWE to support regulatory decision-making for medical devices. In the past a significant impediment to the use of RWE for FDA decision-making was the requirement for informed consent for FDA-regulated clinical investigations except for emergency situations. However, this impediment was significantly reduced by the 21st Century Cures Act requirement that FDA allow waivers of consent for certain minimal risk clinical investigations including observational studies. FDA has implemented enforcement discretion to allow these waivers until such time as it issues a revision to the current formal regulations.[2]

While some critics have expressed concern that FDA's use of RWE will result in a lower standard for regulatory decisions to the detriment of the public health, the other side of the argument is that it provides a low-risk method to utilize previously unavailable information as an alternative to inherently riskier prospective clinical trials. Given the incredible growth of big data, this is an important addition to FDA's sources of information.

[1] Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices: Guidance for Industry and Food and Drug Administration Staff. Issued August 31, 2017

[2] IRB Waiver or Alteration of Informed Consent for Clinical Investigations Involving No More Than Minimal Risk to Human Subjects: Guidance for Sponsors, Investigators, and Institutional Review Boards. Issued July 2017

David Borasky, MPH, CIP is Vice President of Quality Management, WIRB-Copernicus Group

2018 will be a year of regulatory change that hasn't been experienced in over 20 years. 2017 was a year of preparation as researchers, sponsors, and IRBs braced themselves for implementation of the revised Common Rule[1], the NIH's policy mandating single IRB review of NIH-funded multisite research, and the requirements of the 21st Century Cures Act. However, we will enter 2018 with ongoing ambiguity.

The revised Common Rule is slated to go into effect on January 19th, 2018 and there are numerous substantive changes from the current rule. In October 2017 the Department of Health and Human Services submitted a proposal to suspend implementation of most of the rule for an additional year, and that proposal awaits action. A delay would provide the Office for Human Research Protections (OHRP) with time to develop formal guidance on the rule's implementation, and provide the FDA with time to prepare for their rule-making process that would allow for the regulatory harmonization that the FDA is committed to and that 21st Century Cures requires. In the interim, the FDA has taken action, such as exercising enforcement discretion

for waivers of informed consent, to bridge the gap until true regulatory harmonization is possible. Even with the interim adjustments by the FDA, IRBs will still be left with regulations that are even more discordant than the current state for an unpredictable period of time.

The National Institute of Health's single IRB policy is scheduled to go into effect on January 25, 2018 following two consecutive delays of the original effective date in 2017. Under this policy all multisite research studies must rely on a single IRB of record for all domestic sites. While independent IRBs are ready to support institutions with the implementation of this policy, few institutional IRBs appear to be prepared to serve as a central IRB for multi-site studies.

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

Jeffrey Cooper, MD, MMM, Vice President of Process and Strategic Improvement, WIRB-Copernicus Group

The revised Common Rule includes two new exemption categories intended to facilitate the creation of biobanks for future research. Many institutions will struggle with how to implement these exemption categories, and will likely give up or encounter difficulties with compliance. These new exemption categories allow an investigator to obtain an abbreviated "broad consent" as a convenient alternative to the full consent process. However, that convenience comes with a price. If an individual is asked to provide broad consent to participate in biobanking for future research and refuses, an IRB can never waive or alter consent for that individual to participate in another biobank for future research.

A feature of broad consent that is entirely unique is that compliance with the regulations for waiver of informed consent not only requires attention to the research protocol being reviewed, but also requires attention to all research that may have solicited broad consent, including research that may be unknown to the IRB.

Institutions that carefully study the new regulations will likely find alternatives. HIPAA-covered entities can use a new exemption category to conduct all research that would otherwise fall under the exemption categories requiring broad consent. Institutions may also use standard informed consent to create a biobank where the research use involves an honest broker process, which is allowable under both the current and revised Common Rule. Overall, institutions will either avoid broad consent or quickly realize the difficulties in implementation.

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

We will see an acceleration of top five trends in measurement of outcomes from 2017 into 2018. One, accommodation of patient perspectives in defining outcomes. Existing methodologies will be supplemented by patients individually defining symptom domains and tracking improvement in personalized increments. Two, increased use of technology to collect data and provide analytics. There will be more willingness to provide direct feedback to patients as primary data contributors. Three, patient participation in stewardship of their digital data, expanding the pool of patients to include healthy volunteers who are contributing data through a variety of commercial channels. Four, harnessing passively collected data to create actionable insights. Patients will be able to consent to the use of behavioral data from their smart phones, social networks, and online activity for research. Five, redefining treatment to include both the molecule and the data such as with the recent approval of the first digital pill coupled with an adherence tracking device. There are significant public health, privacy, and ethical considerations to such a pervasive expansion of data sources and uses, and it will be incumbent on the leaders in our field to begin the conversation about appropriate regulatory and reimbursement frameworks for this kind of innovation.

Daniel Kavanagh, PhD, Senior Director of Gene Therapy Research, WIRB-Copernicus Group

2018 promises to be an active and dynamic year for human gene transfer research, including in the areas of gene therapy, gene editing, and molecular vaccines.

Chimeric Antigen Receptor (CAR) T cell therapies and CRISPR-related technologies will continue to grab headlines. As clinicians run up against the limitations of CAR-T monotherapies, we will see a variety of combination therapy approaches, involving delivery of CARs directed against more than one antigenic target (e.g., CD19 and CD22), or in combination with checkpoint inhibitors and chemotherapies. New gene editing approaches—CRISPR-Cas9, Zinc Finger, and others will enter into Phase I clinical trials. Preclinical discoveries in gene editing will point the way to an ever-growing toolbox with many potential options for editing DNA and RNA in future clinical trials.

By early 2018 the FDA is expected to give marketing approval for the first time to a true gene replacement therapy for correction of an inherited genetic disorder—voretigene neparvovec (Luxturna®, Spark Therapeutics) for retinitis pigmentosa. 2018 is also likely to see new controversial developments as society struggles to come to terms with the potential for germline gene editing, "gene doping" in sports, and do-it-yourself gene transfer applications based on the availability of relatively affordable and accessible technology.

WCG Experts

David Borasky, MPH, CIP, Vice President of IRB Compliance, WIRB-Copernicus Group
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 sits on the Board of Public Responsibility in Medicine and Research (PRIM&R).

Suzanne Caruso, Vice President of Clinical Solutions, WIRB-Copernicus Group
Prior to joining WCG in 2015, Ms. Caruso worked at Novartis Oncology where she managed the study start-up process and the ongoing conduct of Phase II and III clinical research trials. Before Novartis, she was the Senior IRB Manager at Mount Sinai Hospital in New York City.

Lance Converse, Chief Innovation Officer, WIRB-Copernicus Group
Mr. Converse joined WCG as Chief Innovation Officer after the 2015 acquisition of ePharmaSolutions where he was founder and CEO. Prior to creating ePharmaSolutions, Mr. Converse founded Acurian and RPS (ReSearch Pharmaceutical Services). Mr. Converse started his career at the BOEING Company as a manufacturing engineer.

Jeffrey Cooper, MD, MMM, Vice President of Process and Strategic Improvement, WIRB-Copernicus Group
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.

Amber Corbin, JD, President, Clintrax Global
Prior to joining Clintrax, Ms. Corbin served as Global Head, Director of Regulatory, Contracts, and Investigator Budgets at Quintiles IMS in Durham, NC. She has extensive experience creating efficient processes for regulatory submissions, and overseeing the negotiation and execution of site contracts and investigator budgets in the European Union, Asia-Pacific, Middle East, and the Americas.

David Forster, JD, MA, CIP, Chief Compliance Officer, WIRB-Copernicus Group
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.

Stuart Horowitz, PhD, MBA, President of Institutions and Institutional Services, WIRB-Copernicus Group
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).

Jill Johnston, President, WCG Clinical Services Organization, WIRB-Copernicus Group
With more than 24 years of clinical research experience holding a variety of senior strategic and operational roles in clinical development, Ms. Johnston comes to WCG most recently from Veeva Systems and Covance.

Sofija Jovic, PhD, MBA, Business Transformation Advisor, 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.

Daniel Kavanagh, PhD, Senior Director of Gene Therapy Research, WIRB-Copernicus Group
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.

Jeffrey S. Litwin, MD, Chief Executive Officer, MedAvante-ProPhase
Dr. Litwin joined WCG as Chief Executive Officer of MedAvante-ProPhase after several years as the Co-founder of Patient Genesis, where he worked on the development of ConsentNow®, an innovative platform to provide clinicians, nurses and study coordinators with the tools to supply thorough, clear information to

those considering participation in clinical trials. Prior to joining Patient Genesis, Dr. Litwin was the CEO of ERT.

Lindsay McNair, MD, MPH, MSB, Chief Medical Officer, WIRB-Copernicus Group
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 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.

Emmanuel Olart, MS, Chief Technology Officer, WIRB-Copernicus Group
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.

Nicholas Slack, MBE, President, ePharmaSolutions and Chief Growth Officer, WIRB-Copernicus Group
After completing his Master's in Bioethics at the University of Pennsylvania, Mr. Slack was a Director of Accreditation for AAHRPP, overseeing the process through which IRBs and institutions become accredited. After working as a consultant to multiple institutional and biopharma clients to lead IRB and clinical research operations and accreditation projects, he joined WCG and is responsible for its strategy.

Mark Summers, Chief Executive Officer, ThreeWire
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.

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