Quality First:
Using Data to Inform Site Selection in CNS

An Interview with Christopher Randolph, PhD, ABPP-CN, WCG's Chief Scientific Officer and Suzanne Caruso, WCG's VP of Clinical Solutions

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Over 85% of new CNS drug trials fail to achieve the desired endpoints. Some fail because efficacy cannot be established. Others fail because of operational issues, including low enrollment and poor data management.

Incorporating leading scientific concepts at the start of the trial can create a cascade of benefits throughout. With proprietary technology, an unrivaled data base, and a cadre of the world's leading experts in the study of neuroscience and neurodegenerative disease, WCG MedAvante-ProPhase helps biopharma sponsors to mitigate the operational variability that interferes with good, clean science – a requisite to proper research.

"To maximize the quality of data — and therefore increase signal detection — we must minimize variability," said Christopher Randolph, PhD, ABPP-CN, WCG's Chief Scientific Officer. "One critical yet often overlooked source of variability is site selection. The data you collect is only as good as the investigators you choose. The scientific integrity and operational success of your trial is, essentially, in their hands."

WCG MedAvante-ProPhase espouses a rather simple philosophy: minimize variability, generate cleaner data. In the absence of objective data, reliable and consistent data is what CNS sponsors hope to attain.

As Randolph suggests, site selection is the most important decision a sponsor will make in a clinical trial. In CNS, the potential for variation — both within sites and across them — is enormous. WCG MedAvante-ProPhase helps sponsors to select high-performing investigators: ones with access to experienced, qualified raters, administrative support, and the right patient population. The selection of high-quality, "best-fit" sites is the most effective way to minimize variability and ensure high-quality data. Conversely, the selection of underperforming investigators can result in low enrollment, trial delays, poor quality data, and exposure to regulatory compliance risks, driving up costs and increasing the likelihood of failure.

"The site is where science and operations intersect," said Suzanne Caruso, WCG's VP of Clinical Solutions. "No matter how well your trial is planned or how sound your science, if you select sites that are incapable of proper and efficient execution, your trial will fail. When picking the right sites, sponsors and CROs should put quality first, ahead of randomization rates. You're looking for high enrollers that work with precision and accuracy: that's the recipe for success."

WCG MedAvante-ProPhase provides expert guidance to biopharma sponsors on protocol design, scale selection, and site selection. Once the trial is underway,

WCG MedAvante-ProPhase supports sponsors with solutions that include: electronic clinical outcomes assessment (eCOA) technology to assure the proper collection and management of data; industry-leading rater training to ensure consistency and accuracy across sites; and access to clinical experts evaluating data in real-time to adjust the course of the trial, if needed.

"We believe that a trial's operational success is determined it the planning stage," added Randolph. "Too often there's a huge chasm between science and operations. With decades of experience in the field, we help biopharma sponsors to bridge that gap with solutions that foster operational excellence and ensure scientific integrity."

Our understanding of the scientific causes of many CNS conditions is still in its earliest stage. However, our knowledge of the biological and chemical mechanisms involved in neurodegenerative and behavioral health disorders is advancing quite rapidly. As science evolves, so must trials.

"Data are transforming the way we think about research," concluded Caruso. "Today's CNS trials are incorporating more objective data than ever before, with biomarkers and genetic testing used as early indicators of trial success. In a similar way, investigator performance data can be used to greatly inform the site selection process with the identification of 'best-fit' sites, your trial's earliest signal of success."

About the Authors

Dr. Christopher Randolph is Chief Scientific Officer at WCG's MedAvante-ProPhase and Clinical Professor of Neurology at Loyola University Medical Center. Dr. Randolph has extensive experience in CNS clinical trials work as an investigator, consultant, and creator and supervisor of rater training programs for a large number of Phase II and Phase III multinational studies in Alzheimer's disease and other neurodegenerative conditions; schizophrenia; stroke; hepatic encephalopathy; and traumatic brain injury.

Suzanne Caruso serves as the Vice President of Clinical Solutions at WCG. 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.

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