



George Clinical Renal Scientific Leadership Team Keeps Recruitment on Target in Difficult CKD Study

Despite operational delays, COVID interruptions and Ukraine war outbreak, targets were met.

SITUATION

George Clinical was chosen by a large pharmaceutical company to provide scientific leadership services across all participating countries in an ongoing Phase IIb, randomized, double-blind, placebo-controlled, multicenter study to assess the reduction of albumin in the urine of participants with proteinuric CKD, as well as to determine optimum dosage of the study drug.

The study was conducted in over 100 sites across multiple countries in the Americas, Europe and Asia, and enrolled over 600 adults.

George Clinical's global kidney and metabolic scientific leadership team has a proven track record in important renal trials with a reputation for maintaining the scientific integrity of the trial, optimizing recruitment and retention, and ensuring cultural alignment.

CHALLENGES

Recruitment and retention of CKD patients is always challenging, as they are severely ill and either on dialysis or trying to avoid going on dialysis. This study required that patients be screened for certain inclusion criteria and, once enrolled, monitored for specific reactions—both of which required a level of precise investigator knowledge.

There were also logistical problems at the outset of the study that delayed screening, created communication issues and could have potentially caused sites to lose focus on the study while waiting for resolution. And once the study was in progress, the sponsor was concerned

over a lack of subjects enrolling in the sub study and the low usage of e-diaries, which were key to the success of the study.

Language barriers in global meetings conducted in English reduced site input and sharing of information that could improve operational success.

Outside circumstances also challenged this study. COVID outbreaks caused delays and made patients hesitant to participate. With some staff taking ill, resources were stretched, and those remaining had to take on extra duties to cover the shortages. COVID also meant that important early meetings to energize teams could not be held in person as usual, but instead had to be virtual. Furthermore, there were more than a dozen sites in Ukraine that were very successfully recruiting when the war broke out, where the safety of our colleagues and patients had to then become paramount.

SOLUTIONS

George Clinical's global scientific leadership team of respected and influential renal researchers and clinicians created an immediate and strong communication pipeline among all stakeholders—from the sponsor to the CRO and the individual sites, including PIs, staff and even local physicians and patients when necessary throughout the study.

Even though George Clinical was not in charge of operations, the high level of early communication and trust established meant they were able to quickly

alert the sponsor to the logistical issues, expediting resolution. They were also able to keep sites engaged, preventing loss of focus on the study during the delay.

Webinars conducted for education, training, updates and inspiration helped maintain the scientific integrity throughout all sites and continually motivated all stakeholders. Investigators were trained in the specific screening criteria and potential negative effects of the study drug to ensure optimum enrollment and patient safety. When more participants were needed for the sub study, and e-diary usage lagged, webinars proved successful in improving both situations.

To address potential language barriers when main agenda meetings were held in English, some national leaders held break-out sessions to give PIs and site staff the opportunity to ask questions, express concerns and share successful strategies for solving issues in their native language.



These extra steps do take more time and effort, but it's always worth it in the end," said Sergio Godoy, Regional Project Manager, the Americas. "Part of successful communications is having respect for and listening to every person. Every person is important"

During COVID interruptions, communication was key to keeping the morale of the study going during staff shortages and to maintaining a high level of interest in the study during delays. Special attention and compassion was needed to keep patients protected and feeling secure to continue in the study if possible.

"During COVID the most important thing was to keep in touch," said Barbara Williams, EMEA Regional Project Manager, UK. "It's how we kept up morale and maintained a level of interest in the study as activity slowed. And in the case of Ukraine, our ability to maintain contact with all sites helped assure

the safety of staff and patients alike. Really, communication is the key, and that is one of George Clinical's strong points in any study."

When the situation in Ukraine became untenable for continuation of the study, our team fortunately had a regional scientific leader who had a strong relationship with our Ukrainian national leader and could stay in close contact with all the sites during this delicate situation. Regrettably, screening was put on hold for all study sites in Ukraine. Nevertheless, our first concern was the safety of all involved as the crisis escalated.

RESULTS

The early establishment of a strong communication conduit established mutual trust and confidence among all stakeholders. This assured a shared vision of scientific goals that were well understood and respected, helped to resolve operational issues quickly, and expedited a difficult and very specific recruitment. Once patients were enrolled, the exponential value of sharing information across sites and countries enhanced success in a mutually beneficial manner. Recruitment and randomization were successful and timely across all sites.

The expertise of George Clinical to put renal scientific leaders and national leaders on the ground across the globe lent success not only to recruitment, but also to solving operational issues that could have hindered the study. Because our team is first and foremost focused long-term on the health and well-being of our patients, all actions taken in these studies are designed to help find new and better treatments for CKD patients around the world.



George Clinical

Science. Service. Solutions.

20+
years