CASE STUDY

George Clinical
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George Clinical Exceeds Recruitment and Retention Goals in Important Global IgA Nephropathy Study

At the peak of the COVID pandemic, recruitment was met, and patient visits continued safely.

SITUATION

IgA Nephropathy (IgAN) is a disease with a relative lack of progress in innovation and a population largely absent from research data until recently. It's a disease that behaves differently in different populations. For example, in people of East and Southeast Asian origin, IgAN is more common and more likely to lead to dialysis. This highlights the need for globally diverse and inclusive clinical research across all populations to gain an understanding of how drugs work in people with different genetic backgrounds from different parts of the world.

George Clinical was called upon to handle the Asia-Pacific operations of a global Phase II double-blind randomized trial for a treatment to decrease proteinuria in IgAN patients. Working alongside a global CRO, George Clinical was responsible for Project Management, site management/monitoring, regulatory services, safety reporting and add-on Scientific Leadership.

With a reputation as the leading kidney and metabolic CRO and a broad resume of landmark studies, George Clinical was an excellent collaborator to help ensure the success of this milestone trial.

A strength of this trial was the racial and demographic composition, which was consistent with the known distribution of IgAN and supported the generalizability of the results—reflecting the higher prevalence and more rapid progression of IgAN in Asian populations.

CHALLENGES

George Clinical realized early on that this study would greatly benefit from our Scientific Leadership services, which were not originally contracted. Due to the rare nature of the disease and the difficulty in recruiting patients for trials, we recommended our Scientific Leadership expertise be part of the study.

Phase II IgAN Study Succeeds at Height of Pandemic

	Scientific Leadership model proved invaluable for recruitment and study cohesion
	Safety was enhanced with PPE and safe travel arrangements for patients and staff
	Recruitment in Asia-Pacific region exceeded expectations and met timelines
	Asia-Pacific retention rates were highest in study with no loss to follow up

Recruitment was also challenged as it began at the height of the pandemic when everything was suddenly shut down and travel became difficult for patients and staff alike. Safety of all operational teams and patients became a primary concern for keeping the study on track.

SOLUTIONS

George Clinical's Scientific Leadership services were added to the study, and once in place, were vigorously supported by the sponsor. Our renal key opinion leaders' personal relationships and influence were impactful in communicating scientific goals to investigators and lending cohesion across all sites. And having our National Leaders on the ground with previous knowledge of sites and investigators was pivotal for motivation, optimum recruitment and communicating critical information throughout the study while facing the added pressures of the growing COVID pandemic.

To ensure safety protocols were met, our teams provided all sites and patients with PPE and made safe transportation arrangements for patient visits. Despite the many disruptions, we continued to recruit and maintain patient visits.

Our Scientific Leadership team also enhanced patient retention when, after interim analysis showed positive safety data and clear benefits, they recommended that all study participants have the opportunity to go into the sponsor's upcoming open-label trial. This promise gave patients greater motivation to remain in the study.

RESULTS

With a majority of the patients recruited from the Asia-Pacific region, this study represented a relevantly diverse population, and the Asia-Pacific recruitment rates were higher than the rest of the world (RoW). The Asia-Pacific retention rate was double RoW with no loss to follow up despite the challenges created by the pandemic.

In patients with IgAN, 12 months of treatment with the study drug resulted in a significantly greater decrease in proteinuria than placebo. This is a positive conclusion for IgAN patients, most of whom are at risk of kidney failure in their expected lifetime without lowering eGFR rate. A Phase III follow-up study is in progress with George Clinical as the global Scientific Lead and in charge of all APAC operations.