CASE STUDY

EMERALD CLINICAL TRIALS

Emerald Clinical Brings Robust Retention Strategy and Tactics to Global Rare Renal Disease Studies

We work to keep every patient engaged to the end, from risk retention matrix and personal contact with CRAs, to patient-facing animation in 20 languages.

SITUATION

Clinical trials for rare diseases pose specific challenges due to their elusive nature and low patient populations. Research is critical for these often serious and even life-threatening diseases that also affect pediatric patients and generally have no known cures. When studies are done, retention of patients in these relatively small trials is of utmost importance and must include strong patient knowledge and communication.

Emerald Clinical is working on two interventional kidney clinical trials now in progress: one that seeks to help patients with focal segmental glomerulosclerosis (FSGS) and another that is one of the largest studies to date in IgA nephropathy (IgAN). Both are Phase III global studies that span several years and several hundred patients each.

FSGS can have many different causes. It is a leading cause of end-stage renal disease (ESRD) in children, although it occurs more frequently in adults. Trials are critical as there is currently no FDA-approved treatment.

IgAN is an autoimmune disease that results in the development of ESRD in 10%–20% of patients occurring most frequently in Caucasian and Asian populations and almost twice as common in males. Typically, it affects young and middle-aged adults.

There is no cure and no way to determine what course it will take in any given individual. Therapies are currently targeted at slowing its progress, but some treatments, such as high-dosage corticosteroid therapy, pose a risk of toxicity, and KDIGO guidelines suggest that this should "...be given with extreme caution or avoided entirely in certain situations."(KDIGO 2021 Clinical Practice Guideline For the Management of Glomerular Diseases. Kidney Int Suppl 2021).

Emerald Clinical has been involved in the IgAN trial from the beginning, with full global Scientific Leadership and also operational responsibility in the Asia-Pacific region. In the FSGS trial, Emerald Clinical was invited to provide global Scientific Leadership services after the trial had commenced and the sponsor introduced a Retention program across both trials.

Emerald Clinical Scientific Leadership Teams

Our teams in APAC, Latin America, Europe and North America each consist of a Regional Scientific Lead, Manager and Associate, and National Leaders/Lead Investigators in 21 individual countries. They are:

- The driving force for retention
- Intimately involved in the studies
- Bringing retention experience from other studies in their locales
- Contributing cultural expertise and knowledge of local clinical practices, patient populations and specific sites

With our deep renal experience, global network of influential renal Scientific Leaders and excellent track record of high retention in past global trials, Emerald Clinical is a very good fit for these two trials.

CHALLENGES

The FSGS trial has completed enrollment with over 300 enrolled patients. Retention of these patients until the trial's end will be imperative to achieve desired results. The IgAN study is fully enrolled with approximately 400 patients and will assess the treatment effect on eGFR slope. With enrollment successfully completed, **Emerald Clinical's primary focus at this point is keeping every patient in the study until close of trial to avoid a negative impact on the final study results.**

SOLUTIONS

Emerald Clinical has drawn from previous successful retention strategies and tactics to formulate a retention program designed specifically for these two important studies, which includes: monitoring patient risk of discontinuation based on a risk assessment matrix; generating site and CRA training materials; generating patient facing materials; and generally streamlining communication between the sponsor, medical monitoring team and the participating CROs on all retention cases.

Our **retention monitoring** activities include weekly updates, reviews of each individual case, support to CRAs in individualized approaches and detailed tracking and running logs of all correspondence related to each case. A retention risk report, designed by our Scientific Leadership Team in coordination with the sponsor, is regularly performed, and patients are given a risk score which determines whether further investigation is warranted.

"Our retention team ensures that every patient is tracked and followed up, and that the Medical Monitor and CRAs are giving the study site the right support they need in order to achieve the best outcome with the patient. We are also constantly monitoring for potential risks that are not yet known to the study team. If we detect a potential red flag from our risk monitoring reports (based on significant disease specific elements as well as patient centered elements), Emerald Clinical contacts the CRA to have them check in with the site and determine the best course of intervention to retain that patient in the study." **Sarah Coggan, Global Scientific Manager, Emerald Clinical.**

CRA training has been extensive, and we have used several different methods to help emphasize the importance of retention and give CRAs the tools they need. We're also using new media approaches, with a site training animation designed specifically for these studies to better engage CRAs in the material. Completion of viewing is tracked as the video is viewed on the website. Positive feedback from the sponsor on this tactic led us to also create a patient-facing animation that will be translated into approximately 20 languages for all the global sites.

One unique aspect of the patient video is the participation of **The George Institute Kidney Patient Panel** in its design and messaging. This group, run by The George Institute in Sydney, Australia, reviewed our original ideas and made suggestions to make the animation more informative and applicable to the intended audience. This panel of kidney patients who have participated in clinical trials gave us invaluable input, and we will continue to seek their opinion on future patient communication strategies.

Our **Retention Team** meets weekly and holds monthly meetings with the sponsor—more often if issues arise. Our national leaders are fully engaged and will instantly step in to prevent cases from being discontinued from the studies. We have found that early intervention increases both staff and patient engagement.

Feedback from our sponsor has been very positive and we continue to work in close partnership with them to maintain the integrity of the studies with focus on patient retention. Recruitment is completed in both studies but retention will remain a key priority until follow up is completed and primary results of both studies are released at the end of 2023.

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