CASE STUDY

EMERALD CLINICAL TRIALS
A Global CRO

Emerald Clinical Team Guides Unique Multiple Sclerosis Trial Through Difficult Circumstances

Challenges included specialized equipment, interaction with multiple departments and stringent COVID restrictions.

SITUATION

Emerald Clinical was chosen by a biopharmaceutical company focused on neurodegenerative disease to conduct a Phase II, randomized, double-blind, parallel group, placebo controlled clinical trial for the treatment of visual pathway deficits in chronic optic neuropathy. The study assessed the efficacy, safety, tolerability and pharmacokinetics of a bioenergetic nanocatalyst as a remyelinating and neuro-reparative treatment in stable relapsing multiple sclerosis (MS) patients with chronic visual impairment. Remyelination therapy is not a cure, but can bring hope and maybe even a reversal of symptoms for many who are severely affected by MS.

Today, all available MS medications are for slowing progression or relieving symptoms. There is no cure, and no current treatment promotes repair of the long-term neuronal damage. Remyelination is a new and exciting treatment approach that can actually restore neuronal function, prevent further damage and potentially reverse the expected outcome of disability for MS patients. The nanocatalyst in this study has been shown to have the potential to drive meaningful neurological improvements, giving MS patients hope for a treatment that actually improves their condition.

This study sought to improve vision for MS patients and was unique in involving both ophthalmic and neurologic experts, very specific equipment and long assessments for patients. It required special training, persistence, compassionate understanding of patients and a long-term commitment by all stakeholders to move this study forward and pursue this potential life-changing treatment. It was conducted in both Australia and North America.

Emerald Clinical was a good fit for this study due to the flexibility and dedication of our people and our deep experience in Australia. Team members were motivated by the possibility of a treatment that could ultimately provide such rich benefits. For this study, Emerald Clinical provided investigator payments, medical monitoring, project management, quality management, regulatory services, safety management and site management.

CHALLENGES

Initial startup was delayed with necessary protocol amendments prior to ethics approval. Some systems and processes required extra efforts and a high level of communication and trust among stakeholders to accomplish. The complex technical equipment provided by the sponsor necessitated extensive training and a time-consuming certification process.

Screening was slow and difficult, partially due to site activation occurring in December and over the holiday period, with heat sensitivity causing temporary worsening of MS signs and symptoms for many patients. Inclusion requirements were very specific, and multiple assessments

with long onsite visits put additional pressure on site staff and patients. Participation is both physically difficult for MS patients and may also force them to reveal their condition to family members or co-workers who are not currently aware that they have MS.

COVID-19 also presented considerable challenges with multiple lockdowns occurring, strict travel restrictions and reduction of non-essential hospital visits, as well as the extra stress of the situation placed on staff and particularly on the patients who wished to continue in the study but were kept at their homes.

SOLUTIONS

Emerald Clinical has been conducting clinical trials in the region for more than 20 years and has longstanding relationships with multiple sites in Australia that we have developed over many years.

The complex nature of the study required quick team building between Emerald Clinical, the sponsor and the sites. Communication was constant and consistent, with all stakeholders involved in addressing issues related to the complicated protocol and the specialized equipment.

Through good communications, we were able to help solve early issues, and our systems and processes—including templates, guidance documents and comprehensive SOP—were quickly approved of and adopted by the sponsor. Weekly phone calls ensured sponsor inclusion and satisfaction. As protocol amendments were made, Emerald Clinical kept HREC and RGO submissions on track and adapted to the amendments rapidly.

Extensive equipment training was provided to all members of the CRA team with remote refresher calls between sites and equipment vendors. Emerald Clinical also facilitated interaction between neurology and ophthalmology departments since both were integral to this unique study. This reflected the unified team approach of this study where a mutual understanding between site staff, Emerald Clinical and the sponsor ensured success.

Keeping the study active during multiple lockdown periods required flexibility and extended hours as well as a keen understanding of the added burden for the patients to remain in compliance. Patients are always at the forefront in our studies, and both Emerald Clinical's people and site investigators displayed great perseverance and compassion while working to ensure best options for all enrolled patients. The study team helped to set up Telehealth visits for patients and have their IP delivered directly to their home so they could remain enrolled and have access to study care.

Emeral Clinical Team Goes Above and Beyond

When Emerald Clinical lead CRA and Clinical Trial Manager Manuela Glinski-Smith learned that one study participant leaving on a five-leg European holiday had not been able to obtain customs information from one of the airlines booked, she sprang into action to ensure that the patient's investigational drug would be allowed in the country. Where the travel agent hadn't been able to get a response, the CRA contacted Dublin airport security at 2 a.m. to discuss the matter and confirm what documentation was needed for the drug to be allowed into the country. All was resolved, and the patient was able to travel with the assurance they would have their medication with them on the entire journey. We are extremely proud of the dedication and personal commitment of all of Emerald Clinical's extraordinary people working across the globe, and this is just one small example of how they always go above and beyond to serve our clients and patients.

Emerald Clinical's "can do" attitude is driven by the exciting possibility for MS patients to actually see improvement in their condition. We are proud to play a part in these important advancements for a patient population that is so deserving of added hope for a higher quality of life.

RESULTS

Screening and recruitment activities are ongoing. All sites and the Emerald Clinical team remain enthusiastic about the study and the product. The sponsor has a very collaborative approach to problem solving and all stakeholders are working as a team. At all times communication is fluid and positive. Study enhancements are underway to move this product one step closer to success, and the sponsor, Emerald Clinical and the sites are all prepared to maintain the current teams in place as these enhancements come on line. There are also sites being considered in the USA, and the sponsor has indicated that Emerald Clinical will be responsible for management there.

Initial top-line results have been released and are favorable towards the extension of the current study. The sponsor is considering running a larger trial with the involvement of Emerald Clinical in all relevant planning and management activities.