CASE STUDY

EMERALD CLINICAL TRIALS

Established Relationships Allow Emerald Clinical to Meet Tight Timelines and Recruitment Challenges in Critical Early Phase Oncology Study

Local knowledge combined with Australia's favorable conditions keep trial on track and on time.

Early phase clinical trials are the first-line research studies in drug development and assess therapies for safety, dosage levels and side effects. These studies form the basis for all further research on a therapy, so they must be conducted to very high standards whether the trial involves healthy volunteers or patients with a specific disease such as cancer. Fully-equipped early phase specialty research centers conduct these studies in strict accordance with the protocol and provide very close monitoring of the trial participants.

Emerald Clinical offers a full range of services for Phase I-II clinical trials including study design, protocol development, medical oversight from practicing clinicians, site monitoring, regulatory affairs, database development, and statistics and data management. Our home base of Australia is well-equipped for early phase trials with a network of around 200 beds ready for Phase I-II trials in dedicated units across the country. These centers can conduct trials from small first-in-human (FIH) to complex multi-center Phase I, II patient trials. Emerald Clinical has strong relationships with these sites throughout Australia and New Zealand.

In conjunction with a Chinese biotech company, Emerald Clinical recently initiated an early phase oncology study being conducted in patients with advanced cancers that have not responded to commercially available treatments and who have no other current treatment options. This study addresses the critical need to get a new drug to market that may provide these patients with a treatment option—and hope. With a very short timeline for completion of this early phase trial, the sponsor elected to conduct this trial in Australia. Benefits of this strategy include Australia's streamlined Clinical Trial Notification (CTN) system, the comparatively lesser impact of the COVID-19 pandemic and the country's R&D Tax Incentive.

Emerald Clinical's goal going forward is to continue to provide this study with the support it needs to be successfully completed within the sponsor's timeline and to ensure the safety and attention to all participating patients whose important contribution to this study will help provide better cancer treatments for all in the future.

Emerald Clinical was selected by the sponsor as the best fit for this trial with our offering of end-to-end CRO services, our partnerships with key oncology Scientific Leaders, and our deep and current knowledge of the oncology landscape in Australia and New Zealand.

CHALLENGES

Despite a large number of ongoing competing trials in Australia, timeliness of trial conduct was critical to the sponsor's development plans. They needed assurance that the trial design would meet requirements without sacrificing quality or safety. Site selection was important with respect to both the early phase ability of the site and the best opportunity for rapid and efficient recruitment. In addition, it was necessary for local physicians to have buy-in on the study for recruiting optimum patients most likely to complete the study and preserve retention in the trial.

Patient safety and consideration is important in all trials, but in this case, where patients are in an advanced state of cancer, study design must also strive to reduce the burden on participants and ensure their maximum comfort and safety throughout all aspects of the study. At Emerald Clinical, we work to ensure that all team members keep patient compassion at the forefront of all operations.

SOLUTIONS

Through a detailed review of the protocol and planned study design, Emerald Clinical was able to provide the client with a sound framework to ensure the study achieves its primary objectives within timelines whilst maintaining robust quality and ensuring patient safety.

Strong relationships between our Scientific Leaders and local oncologists enabled the **accelerated identification and selection of four sites** interested in and able to conduct the trial. We implemented a competitive recruitment environment resulting in the enrollment of the first cohort very quickly after the required approvals were received and **ahead of enrollment timelines** as are being observed in similar trials currently.

Established relationships with early phase study capable local vendors, a **specialized early phase operational team** and the implementation of a strong communication framework has enabled trial activities to progress rapidly despite several landscape obstacles, with the **trial well on track to complete within planned timelines.**

Emerald Clinical's scientific leadership model has proven to be a significant advantage for this trial. The **level of trust created with this peer-to-peer communication** model has multiple benefits for sponsors, research teams, participating physicians and patients. The scientific integrity of studies is protected, physicians are more willing to recommend studies when a fellow clinician is on the team, and there is a greater likelihood of recruiting optimum patients for the study who will be most likely to stay engaged to conclusion. In addition, **patient needs and concerns are understood and addressed** more adequately by those who are personally involved in the day-to-day care of the patients and are considerate of their conditions and thoughtful to their needs.

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