CASE STUDY

EMERALD CLINICAL TRIALS

Emerald Clinical Successfully Delivers Complex Phase I Oncology Trial Within Agreed Timeline Despite Competitive Recruitment Landscape

Early phase oncology expertise and established local relationships make Emerald Clinical the CRO of choice for Chinese biotech.

SITUATION

Australia remains the location of choice for the conduct of early phase oncology clinical trials presenting a highly competitive landscape for the identification and enrollment of participants to a particular trial when they meet the eligibility criteria of multiple trials. The oncology landscape continues to rapidly evolve with many therapeutic agents progressing through identification, pre-clinical evaluation and into clinical trials presenting a plethora of choice for participants needing alternate treatment options where standard of care options are no longer able to be utilized.

Through our nimble, flexible approach to the undertaking of early phase oncology trials, Emerald Clinical was seen by an innovative, global, Chinese biotech as the best fit for a Phase I, multicenter, open-label, dose-escalation, oncology clinical trial. With a need to start, conduct and complete the trial in the shortest possible timeline, and in the absence of a US required IND, the company elected to conduct the trial in Australia due to its streamlined Clinical Trial Notification (CTN) system, the capabilities of Australian sites in undertaking early phase oncology trials and the country's R&D Tax Incentive.

Emerald Clinical's extensive Asia-Pacific experience, strong Australian presence, proven track record of conducting early phase studies, utilization of exceptional recruitment strategies and our end-to-end service ideally positioned us to undertake the trial and to meet the sponsor's specifications. These key Emerald Clinical offerings were further enhanced by our partnerships with world-class oncology Scientific Leaders and deep and current knowledge of the oncology landscape in Australia and New Zealand.

Our full-service offerings for this study included input into the study design and protocol development, project management, medical oversight from practicing clinicians, feasibility, pharmacovigilance, site management and monitoring, regulatory affairs, statistics and data management.

Highlights At A Glance

- Australia chosen as trial location due to its competitive landscape & incentives
- Emerald Clinical chosen for its early phase oncology experience and deep knowledge of AU/NZ oncology landscape
- Shortest possible timeline met by exceptional recruitment strategies and full service, adaptable solutions
- Patient safety and care prioritized in study design and protocol development

CHALLENGES

Despite a large number of ongoing competing early phase oncology trials in Australia involving diverse therapeutic agents, timeliness of trial conduct was critical to the sponsor's development plans. The ensuring of quality data and participant safety were of primary importance, as was the selection of the right sites to ensure their early phase capabilities and potential for rapid and efficient recruitment. Solid relationships with practicing oncologists were necessary to support site selection and recruitment goals, thereby enabling the identification of optimum patients for maximum retention to trial completion.

Patient safety and consideration is critical in all trials, but no more so than in early phase oncology trials, where patients are in an advanced state of cancer. This must be supported by a study design that reduces the patient burden, enabling their maximum comfort and protecting their safety throughout their trial participation.

SOLUTIONS

Our nimble and highly responsive team includes therapeutic-specific Scientific Leaders who have strong relationships with local oncologists, enabling the quick identification and selection of qualified and motivated sites.

Emerald Clinical excels in the early phase trial landscape through our ability to provide expertise in support of study design and protocol development. The use of an adaptable study design enabled the flexibility to accommodate the potential for cohort expansion and alterations in dosing schedule without prolonged delays in the study timeline. The details of the drug under study and the study plan were shared with study sites enabling investigators to make informed decisions throughout the study and to support successful study completion.

Recruitment was completed ahead of enrollment timelines observed in similar trials, despite the highly competitive landscape. Established relationships with early phase study capable local vendors, a specialized early phase operational team and the implementation of a strong communication framework enabled successful trial completion despite several landscape obstacles.

Led by an experienced early phase project manager based in Australia, our team worked tirelessly to meet every challenge and was motivated and empowered to achieve the goals for the sponsor. Positive teamwork and efficient work plans kept the study on track and running smoothly.

RESULTS

Emerald Clinical provided this study with the expertise required 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, it is hoped, will help provide better cancer treatments for all in the future.