



CASE STUDY



Advancing Small Cell Lung Cancer Research Through Strategic Clinical Trial Management

A collaborative approach to managing a complex oncology study while supporting quality, efficiency, and continued study momentum

SITUATION

Emerald Clinical supported the delivery of a China based, Phase III, multi-center recurrent small cell lung cancer clinical trial, helping coordinate this study activities across multiple stakeholders and operational functions. The study scope was more than 80 sites and over 400 patients. The study required focused project management, effective communication, and close oversight to support execution in a complex oncology environment.

CHALLENGES

Conducting a clinical trial in the complex small cell lung cancer landscape required careful coordination and strong operational oversight. Emerald Clinical worked across sponsors, sites, investigators, vendors, and other stakeholders to maintain alignment throughout study execution. Competing priorities, evolving study needs, and time-sensitive decisions made it essential to identify potential issues early, support prompt resolution, and sustain momentum through key milestones—without compromising quality, compliance, or patient-centered delivery.

SOLUTIONS

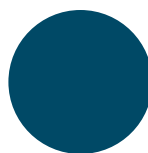
To address recruitment pressures, we prioritized site selection strategies that minimized reliance on oversubscribed sites and investigators involved in highly competitive studies. We also broadened recruitment beyond traditional channels by engaging internal departments and external sites, while leveraging the expertise of investigators, clinical research

coordinators, research nurses, and dedicated recruitment personnel.

Clear enrollment targets were established at the site level and supported by a unified incentive plan. To ensure that every potential participant was appropriately followed up, we implemented a close-tracking process designed to minimize missed opportunities and prevent the loss of viable leads.

Because recruitment challenges varied across locations, we developed customized, locally adapted strategies to address the competitive trial environment at each site and support enrollment. We also analyzed the underlying causes of elevated screen-failure rates and worked closely with the sponsor and principal investigators to evaluate potential amendments to the inclusion and exclusion criteria.

In parallel, we provided timely support to investigators in managing adverse events and introduced reimbursement for prophylactic medications where appropriate. Together, these measures strengthened site engagement, improved recruitment efficiency, and supported continued enrollment across the study.





RESULTS

Despite launching six months after competing studies, the Phase III small-cell lung cancer trial achieved a successful latecomer catch-up through differentiated recruitment strategies, expanded recruitment channels, site-tailored management, and closed-loop follow-up of potential participants.

These efforts doubled the monthly enrollment rate per site from the planned participants. The study completed enrollment six months ahead of the contractual schedule, surpassing competing trials, and successfully completed interim data cleaning.

By maintaining rigorous SDV standards, the team identified no critical findings. Interim results met prespecified expectations and were presented at the 2026 World Conference on Lung Cancer, generating significant interest in China and internationally.

The accelerated enrollment and strong execution enabled CDE acceptance of the sponsor's NDA on the same timeline as competing products, despite the study's later start. This provided the sponsor with a valuable competitive advantage for subsequent product development and earned strong client recognition.

