CASE STUDY

EMERALD CLINICAL TRIALS
A Global CRO

Emerald Clinical's Audit Readiness Provides Successful Inspection of Long-Finished Phase III Trial for Chinese Regulatory Agency

With tight turnaround and five years after study completion, Emerald Clinical brings new staff up to inspection standards and trial passes inspection with no significant findings.

SITUATION

Emerald Clinical completed a Phase III, randomized, double-blind, double-dummy, parallel group, local registration trial on cancer pain in 2013 and 2014. The trial covered 28 sites and 230 patients. In 2019, the national drug administration of China (NMPA) scheduled a regulatory authority inspection of clinical sites as part of a new drug application process implemented in 2015 when Chinese regulators began to mandate several processes such as self-assessment and on-site inspection to be required for NDA approval. This was done to improve the quality of data generated in clinical trials, and there are penalties in place for non-compliance with the mandate. The long delay in inspection resulted from the need to finish any other clinical trials within the same program and submit a complete dossier to the NMPA followed by the actual evaluation process, which can take a significant amount of time.

CHALLENGES

Clearly, the length of time from study completion to the inspection created many challenges including the fact that some of the site monitors from the original trial were no longer with Emerald Clinical. Guidelines and regulations had also changed in this time, and both Principal Investigators from the trial had retired from the sites.

We were also given the extremely short notice of only one week prior to inspection for preparations including supply procurement and getting a new Emerald Clinical team familiar with the study materials. This was also an insufficient time period in which to perform 100% source data review and verification.

SOLUTIONS

China is Emerald Clinical's largest hub outside the head office of Sydney, Australia where we offer full CRO services and a site network that spans the country. We have been conducting trials in China since 2007 with an extensive network of over 260 trial centers in 60 cities for Phase II-IV trials, and a wider network that includes community health centers in semi-urban and rural areas for Phase IV trials. We have experienced staff in place who are familiar with the regulatory system and are able to enlist the assistance of those who are rich in inspection experience.

With a network already in place, Emerald Clinical's heads of various functional areas came together rapidly (within a matter of days) and decided on a plan of action. This included setting up two teams of staff, each headed by a Project Manager and supported by the Quality Manager in China. Communication channels were established

between teams in different cities, and administrative and financial exceptions were requested to support the inspection. Team members were allocated specific areas of focus, such as review of the safety reporting from the site, review of the informed consent documentation, regulatory/IRB documents, monitoring reports, etc. This allowed detailed and targeted review to be performed in a very short space of time.

With more than a decade of experience in China and a flexible, adaptable and proactive staff, Emerald Clinical was able to prepare a five-year old study for regulatory inspection within one week of notice and successfully pass the inspection to the full satisfaction of both the sponsor and the regulatory institution.

The Project Manager who managed the Phase III trial then trained additional Emerald Clinical staff on:

- Project-specific protocol, Investigator's Brochure (IB), Clinical Study Report (CSR), etc.
- History of the study
- Any areas or issues that needed clarification
- Tips and requirements from Chinese regulators to support the inspection from sponsor, quality and experienced teams
- Target site-specific requirements for the inspection
- Necessary documentation to prepare to provide for inspectors

Throughout the process, Emerald Clinical staff remained enthusiastic and volunteered their time working around the clock to prepare for the inspection. In order to ensure success, Emerald Clinical staff kept training and communicating with investigators when performing monitoring activities, which served as an effective method to keep the team confident and on track with duties and timelines.

OUTCOME

As a result of the flexibility and adaptability of the Emerald Clinical team to pick up an old study, rapidly familiarize themselves with the necessary information and then apply their audit readiness training and experience to support an investigational site from prep to wrap-up, the inspection was successful.

Our site staff were able to answer all inspectors' questions, and there were no significant findings in this inspection. The trial was passed from onsite inspection. Both the sponsor and the institution were pleased with the performance of the Emerald Clinical team.