



## CASE STUDY



**EMERALD**  
CLINICAL TRIALS

# Emerald Clinical Proves to be Trusted Partner in Large Breast Cancer Trial

Ability to work across cultural, language and timeline barriers sets benchmark and achieves record patient recruitment in China despite pandemic.

## SITUATION

A Canadian CRO conducting a large and important Phase III early breast cancer trial for a major pharmaceutical company engaged Emerald Clinical as its partner for the Chinese portion of the trial. Globally, the study covered more than 400 sites in 20 countries and has currently enrolled more than 5,000 patients.

For the 15 sites in China, Emerald Clinical was selected due to our extensive experience as the leading Asia-Pacific CRO. China is one of Emerald Clinical's largest hubs, outside the head office of Sydney, offering end-to-end CRO services and a site network that spans the country. We have been conducting clinical trials in China since 2007 with a network of over 300 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.

## CHALLENGES

This study required a rapid startup while partnering with a Canadian company that was not familiar with Chinese regulations, requirements, practices and culture. The Emerald Clinical team needed to help manage expectations and create a level of comfort during the initial stages of knowledge transfer based on our China experience.

Because rapid startup was required, insufficient time for training was allotted for teams to adapt to the Chinese clinical trial environment. Both the timeline and the differences in trial practices put a great deal of responsibility on the operational team to manage all aspects of initiating recruitment while also training team members and creating strong communication and trust to build solid and engaged teams.



"We've seen outstanding recruitment these few weeks over a very challenging startup period to achieve a rate that's now considered a record by the sponsor in China. Despite the very rapid ramp up, our team still maintained high quality in recruitment resulting in a significantly lower screen failure rate in China compared to sites in the rest of the world. It's very satisfying to see all the hard work and perseverance pay off. The Emerald Clinical team must be commended for a job very well done." **James Cheong, CEO, Emerald Clinical.**

The pandemic added further challenges to the study startup, but our team was quick to rise to all challenges with agility and a can-do attitude to keep the study progressing smoothly during this unprecedented time. Delays due to the pandemic were overcome, and recruitment ramped up quickly.

## SOLUTIONS

The Emerald Clinical team worked under tremendous pressure to build and bond teams across time zones, language and cultural differences to meet the demands of this rapid startup. When extra hours were required to do proper training, our team dug in and worked hard with local scientific leaders to achieve the required level of efficiency.

We were proactive in addressing issues in all aspects including the timeline, the work process and the management of expectations from all stakeholders. The team persevered through the difficulties of a pandemic and was able to create the atmosphere and engagement necessary to reach a high quality of recruitment within the designated timeline.

## RESULTS

Emerald Clinical achieved a **record-breaking recruitment rate for China**. The high quality of the recruitment was reflected in the significantly lower screen fail rate in the China sites compared to the sites in the rest of the world. The hard work and diligence of the team resulted in 15 successful recruitment sites with 151 patients randomized—over and beyond the 120 patients targeted by the sponsor for China sites.

Emerald Clinical's performance did not go unnoticed by our sponsor in China who was highly complementary and reported that this trial was "a record" for China, and "Emerald Clinical set the benchmark for other trials to follow."



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