CASE STUDY

EMERALD CLINICAL TRIALS

Emerald Clinical Rescues Phase III Oncology Study From Trial Closure and Initiates Global Expansion

First patient screening in seven months avoided lapse in Chinese regulatory approval.

SITUATION

A pharmaceutical sponsor with a US Phase III metastatic pancreatic cancer study had previously applied for Chinese regulatory approval (NMPA). However, due to the impact of COVID-19 and other administrative reasons, no site identification or site activation work had been undertaken by the sponsor or their partners for more than two years. A deadline is set by NMPA that in order for the approval to remain, the first patient must be screened within three years of the issuance of the approval.

As the deadline approached for the approval to lapse, Emerald Clinical was engaged to keep the trial application open by ensuring that the first patient within China would be screened within seven months.

The loss of trial application would have cost the sponsor financially and would have deprived the more than 200 Chinese patients (more than 400 globally) the opportunity to participate in this important study. Pancreatic cancer is a devastating prognosis with the lowest survival rate of any group of cancers and has limited treatment options. Clinical research in this area is imperative, and The Pancreatic Cancer Action Network strongly recommends clinical trials are considered at diagnosis and during every treatment decision for these underserved patients.

CHALLENGES

Emerald Clinical had less than seven months to get the first patient screened to avoid trial approval lapse in China, and the sponsor had no experience working in China. We were also contracted to open 60–70 sites in China.

In order to choose sites most likely to meet this incredible timeline, a small cohort of fast acting sites had to be identified and activated. In addition, because there had been no work done for such a long period of time, there were massive amounts of complex documentation and authorizations to manage, relating to both regulatory and the study— many needing significant translation.

Transfer of information from the previous CRO proceeded much slower than anticipated, and other unavoidable and unexpected delays continued to impact the study. Logistically, the truncated timeline also presented challenges. Sites in China mandated that the

Highlights At A Glance

- Given just 7 months to rescue study before trial NMPA lapsed in China
- First site initiated and first patient screened in < 1 week after full regulatory approval
- Network of key opinion leaders (KOLs) and investigators expedited documentation
- Relationship with Chinese pancreatic cancer KOL ensured enrollment success

investigational medical product (IMP) must be on site before patients can be screened, and drug importation into China is a lengthy process. Lab partners and lab depots needed to be identified, and lab kits, IMP and ancillary supplies sent to sites. Furthermore, each lab and drug depot had to submit significant amounts of business and contractual documentation in addition to their "standard" study documents.

Timelines were continually shifting due to various delays, and nearly every cushion that was built into the timeline disappeared. **Ultimately, Emerald Clinical had less than one week after receiving full regulatory approval to do a site initiation with 30 people and literally screen the first patient.**

SOLUTIONS

Emerald Clinical is no stranger to tight timelines and crucial deliverables where collaborative teamwork, dedication and flexibility are needed to succeed. These are hallmark traits of our people around the world, and our team in China worked tirelessly to meet every challenge—solve every problem. Under the leadership of Global Project Management in the UK and Regional Chinese Operations Management, the study team was motivated and empowered to achieve the goals for the sponsor and the potential patients.

In conjunction with the sponsor, Emerald Clinical mapped out clear timelines, roles and responsibilities as well as potential hurdles to manage expectations and prepare all team members for a race to the finish. Our network of key opinion leaders (KOLs) and willing investigators efficiently expedited the ethics, contracting and documentation processes. We proactively developed and created any study required templates and documentation, including and not limited to the creation of all required translated materials.

Collaborating closely with the sponsor, drug imports and vendor contracting was addressed with our extensive knowledge of the Chinese supply chain. We identified qualified lab partners, personally contacted import export officials and depots, and helped to push their timelines forward to ensure all expectations were met and that sites would be study-ready in a timely manner.

We identified the sites that could activate quickly, and using Emerald Clinical's existing relationships and efficiencies prioritized this group of sites to target the first patient to be screened prior to the regulatory deadline, keeping in mind the rarity of the patient pool and challenging inclusion/exclusion criteria. Through our long-established relationships, we were able to identify a very motivated Chinese KOL on pancreatic cancer who understood the value of the study and was excited and honored to "push the needle" from his end and ensure enrollment success.

Shout Out to Our China Team and Allen Wang, Senior Project Manager!

"With any multi-regional complex global study, close collaborative teamwork in many functional areas is crucial in meeting key deliverables and deadlines. I feel blessed to have worked with such a great team—our China team worked effortlessly to motivate and empower the entire study team to pursue clever out-of-the-box solutions to what sometimes seemed insurmountable obstacles. A special shout out goes to Allen Wang, Senior Project Manager at that time, whose efforts in leading our China team enabled them to excel in achieving two key milestones—1st SIV and FPI in the same day—and only one day after Chinese HGRAC approval was received." **– Mariny Kapsali, Director Project Operations, UK**

Although "choke points" had been identified early and built into the timeline, delays and obstacles meant our cushions kept disappearing. At each timeline crunch, team members would collaborate to break down the task-to-timeline ratio in depth and creatively work around every challenge that was causing delays. This meant working in conjunction

simultaneously with the sponsor, the sites, physicians, investigators, labs, vendors and regulatory agents—maintaining excellent and urgent communication channels open at all times, often outside of normal business hours.

RESULTS

Emerald Clinical's longstanding relationships in China, deep experience in regulatory procedures and knowledge and respect for local culture and practices enabled us to achieve what initially seemed nearly impossible and to hit all necessary timelines—with only three days to spare. By developing clear communications and a shared understanding of their goals, we formed a harmonious and collaborative relationship with the sponsor. We built strong relationships with over 60 high quality investigative sites in China for the future of the study and remain dedicated to keeping sites engaged and enthusiastic for the course of the study.

Most importantly, Emerald Clinical led the sponsor through a maze of difficulties and tackled an endless barrage of issues to meet all of their timelines. The first patient was screened within the given seven months, and this important trial was saved and can now move forward for the benefit of pancreatic patients everywhere.