CASE STUDY

EMERALD CLINICAL TRIALS

Emerald Clinical Conducts First Oncology Immunonutrition Trial in China

Regulatory knowledge, strong communication skills and flexibility to adapt helped move this novel trial forward.

SITUATION

Emerald Clinical was contracted by a globally recognized leader in the field of nutritional science to conduct a prospective, multi-center, randomized, open-label clinical trial to compare the effects of immunonutrition in patients undergoing surgery for gastrointestinal cancer with two parallel groups in China. The Investigational Product (IP) is categorized as a Food for Special Medical Purpose (FSMP)—a formula food specially processed and prepared to meet special needs for nutrient or diet of those suffering from food intake restriction, disorder of digestive absorption, disorder of the metabolic system or certain diseases. These foods are used under the guidance of a doctor or clinical nutritionist. FSMPs help improve the nutritional status of patients, increase recovery rate and reduce complications caused by malnutrition and the number of hospitalization periods.

This was the first oncology FSMP clinical trial performed in China, and Emerald Clinical was the first CRO involved in a Chinese oncology FSMP trial. One of two FSMPs were given to gastrointestinal cancer surgical patients for five days before and seven days after surgery during the trial.

As China is currently in the process of upgrading regulations and guidelines for FSMPs, and specifically for their use with cancer patients, it was essential to provide continuous regulatory surveillance and collaborate smoothly and effectively with Chinese clinical and regulatory professionals.

Emerald Clinical was a good fit for this novel trial as China is our largest hub outside the head office of Sydney, offering full CRO services and a site network that spans the country. We have been conducting clinical 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 are experienced in navigating the nuances of the changing Chinese regulatory landscape and ensuring that the quality of data from China will support a sponsor's global program and meet key endpoints.

This groundbreaking clinical trial in China required full knowledge and continuous surveillance of the regulatory process, as China is currently upgrading regulations and guidelines for immunonutrition products, and specifically for their use with cancer patients. Emerald Clinical's clinical trial experience in China since 2007 ensured regulatory diligence and that the quality of data from China will support the sponsor's global program and meet key endpoints.

CHALLENGES

As this was the first oncology FSMP trial in China, there were many challenges during the process of the full-service trial scope provided by Emerald Clinical, beginning with protocol development which took time to develop and was amended several times. This trial involved an FSMP rather than a traditional pharmaceutical, so it was necessary to establish cooperation between the Surgery/Oncology and Nutrition departments who needed to work together to conduct the trial.

Regulatory issues were complex and included submissions to the Ethics Committee (EC), the Human Genetic Resources Administration of China (HGRAC), Clinical Trial Application negotiation and FSMP filing— all complicating site start-up and requiring knowledge of navigating the system.

Logistics also came into play with unusual challenges due to storage requirements for 30-60 bottles of IP (500ml) per patient that needed a temperature-controlled environment.

Recruitment, compliance and follow-through were challenged by the fact that some patients' perioperative emergency was much greater than anticipated, that study treatment days were longer than normal hospitalization days, and the fact that there were limited beds at the sites due to high bed turnover rate requirement. Furthermore, patient compliance required some education about the IP due to various factors.

Consequently, withdrawal and dropout rate were affected by many variables including adverse events, cancellation of surgery, revocation of informed consent, treatment prohibited, need for second surgery and reluctance to comply.

RESULTS

Emerald Clinical enrolled more than 300 subjects in two years during impact of COVID-19, and the milestone of database lock and CSR finalization were achieved on time.

The experience and attention to detail of the Emerald Clinical investigation team helped assure the successful initiation of this atypical and complex trial in a location where regulatory regulations are sometimes difficult to navigate and often in flux.

Our teams operational practice of true partnership with both our sponsors and our investigational sites/teams on the ground meant that challenges were handled pro-actively when possible. Clear communication channels helped balance the needs of sponsors, investigators and patients, anticipate potential issues and keep teams motivated.

Flexibility, while particularly applicable in a novel trial such as this, is how Emerald Clinical approaches all trials. Our ability to adapt to new and/or changing situations as a part of our normal operational methods resulted in successfully completing a novel trial with new challenges and parameters. The lessons learned during this FSMP trial will be carried forward to other trials in the future that may offer patients a better chance for recovery and a shorter hospital stay.

Emerald Clinical provided a full-service scope including:

- Protocol Development
- Feasibility/Site Identification
- FSMP Qualification Registration
- Site EC Submission, HGRA Submission, Site Contract Negotiation
- Trial Master File, Critical Document Collection and Maintenance
- Project Management
- Site Management (SIV, MV, COV, Audit/Co-Monitoring, Recruitment Support, Site Budget/Payment Data Management and Statistics)
- Safety Reporting
- Medical Writing and Medical Monitoring
- Vendor Management (SMO, Central Lab, IP Purchase and Management, Equipment Management)

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