CASE STUDY

EMERALD CLINICAL TRIALS

Emerald Clinical Assists Small Biopharmaceutical Company in Important USA Osteosarcoma Study

Collaborative teamwork results in success for this study involving rare indication in a pediatric/young adult population.

SITUATION

A small biopharmaceutical company engaged Emerald Clinical's services for a Phase II open-label study of maintenance therapy after resection of recurrent osteosarcoma conducted in the USA. A solid tumor of the bone, osteosarcoma mostly affects adolescents, as well as young adults. Surgical procedures and chemotherapy are currently the standard therapies. Although osteosarcoma is the most common malignant bone tumor, it is rare, with an estimated 800 to 900 cases diagnosed annually in the USA.

According to research, emerging biopharma companies (EBPs) are responsible for two-thirds of all molecules in the R&D pipeline, and many of the drugs in development are promising candidates for rare diseases. However, only a small percentage of these are resulting in regulatory approval. This is due, in part, to the limited resources, infrastructure and experience of many of these companies in the intricate phases of conducting clinical trials.

This becomes even more challenging in the case of rare diseases such as osteosarcoma where the extremely small patient pool makes it imperative to maximize recruitment of the most likely patients to respond to the drug being tested and to complete the trial to its end.

A knowledgeable and well-connected CRO can be the difference for these companies in conducting a study that can successfully run the gauntlet of regulatory, operational and scientific obstacles that today's clinical trials often face. Emerald Clinical has developed a reputation for the ability to lead a study from protocol design to closeout in an efficient and effective manner for results that maximize the potential opportunities for the success of new therapies.

Emerald Clinical was a good fit for this study due to our extensive experience and comprehensive full-service offerings, which for this study included essential document collection, site management, project management, data management, biostatistics, safety/pharmacovigilance, medical monitoring, DSMC management, clinical supplies management, medical writing, vendor management and clinicaltrials.gov study page set up and maintenance.

Highlights At A Glance

- Emerald Clinical customized trial solutions for small biopharm from startup to end of study
- Rare indication in a pediatric/young adult population required expertise in recruitment and retention
- Proactive solutions ensured proper handling of temperature-sensitive investigational product
- Comprehensive monitoring of patient safety occurred in real time

CHALLENGES

The sponsor required assistance with organizational issues in order to get the study off to a smooth start. With multiple stakeholders and networks involved, communications issues arose that resulted in delays in site initiations and interrupted workflows.

A temperature-sensitive investigational product (IP) required close control of transport and storage conditions, as temperature excursions were noted during transport. It was also necessary to regulate shipments in order for patients not to experience interruptions in their treatments.

Recruitment was difficult and slow due to the rare indication in a pediatric/young adult population. Sites required education efforts and close monitoring of best practices to ensure patient safety.

SOLUTIONS

The collaborative teamwork of Emerald Clinical guided the sponsor through the protocol phase and organizational issues during the early phases of the study. By creating clear communications channels with all stakeholders, we were able to set up systems and guidelines to create greater efficiencies for all operations. Our close collaboration with our sponsor and participating sites resulted in strong partnerships with all stakeholders, reducing delays.

Safety issues and approvals were proactively addressed by Emerald Clinical resulting in faster site initiation visits (SIVs) and comprehensive monitoring of patient safety in real time.

As the IP required close attention due to strict temperature controls, Emerald Clinical recommended and assumed responsibility for clinical supplies management for the study—from vendor to couriers and ensuring proper storage equipment at individual sites. With process evaluation and improvements, temperature excursions decreased and there were no interruptions to patient treatment.

Emerald Clinical shared our best practices on patient recruitment from high enrolling sites. With a quarterly newsletter for sites with Principal Investigator input and focus on individual sites, motivation was maintained and a friendly atmosphere of competition was established that enhanced recruitment. Study updates were provided during site network meetings twice a year.

RESULTS

Emerald Clinical was able to assist this small biopharmaceutical company in running an efficient and effective study for this study involving a rare disease and a small, pediatric patient population. Our deep and comprehensive operational experience, flexibility and ability to customize solutions ensured that all regulatory and safety issues were addressed, and that comprehensive monitoring of patient safety occurred in real time. Our strong partnership with the client assured rapid attention to all pertinent aspects and proactive attention to potential issues. We are proud of our contributions in assisting small biopharmas seeking advancement of therapies for rare diseases such as osteosarcoma.

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