ResearchPoint®
Expect the destination. Enjoy the journey.

ONCOLOGY rescue

Communication, training, and team continuity bring two lagging Phase III oncology pain studies back on track to meet their NDA filing deadline with additional services being outsourced from the Sponsor.

ResearchPoint SERVICES:

- Project Management
- Clinical Monitoring
- Site Management

CHALLENGE: As the study was already behind schedule, sites became increasingly frustrated with inconsistent and/or incorrect communication and were not comfortable with the lack of continuity in assigned CRAs of the incumbent CRO. The Sponsor expressed concerns regarding site management, quality of data verification, speed of data verification and retrieval, as well as overall responsiveness and risk mitigation by the incumbent CRO. In addition, the coordination of work between multiple study vendors, including EDC, e-Diary, and Pharmacovigilance posed additional challenges.

ACTION: To overcome the lack of responsiveness from the previous CRO, our team proved to the Sponsor that we would do whatever it took to successfully complete the study, simply by acting on what the client requested and thinking outside of the box to re-vest the sites in the operation of the clinical trial.

ResearchPoint re-trained the clinical sites on data capture, completing outstanding queries, scheduling and treating on-going study subjects, and reconciliation of supplies and drug.

With hands-on senior management and a project team that the Sponsor was familiar with, ResearchPoint built trust among the different CROs and provided creative solutions for ongoing study issues. As our team showed its ability to collaborate with other CROs and deliver results, the Sponsor met with the ResearchPoint project management team to provide a landscape of the entire project, allowing our team to become increasingly involved.

RESULT: ResearchPoint was able to show increased efficiency over the other CRO, due to our site management strategy focused on developing and maintaining strong relationships. Based on the feedback provided by the selected sites regarding the more efficient data verification and retrieval process, ResearchPoint was asked to assume responsibility for 11 additional sites on the open label study.

With greater trust in ResearchPoint, the Sponsor added monitoring activities (those specific to the highest enrolling sites) for two eCRF Phase III oncology pain management studies, a double-blind and an open-label study that had been outsourced to one of the larger CROs. Monitoring activities for the double-blind study were isolated to closure of clinical sites and Schedule II drug accountability.

By the end of the study, ResearchPoint was responsible for all top enrollers and assisted the Sponsor with closing out all sites and locking the database. With ResearchPoint's assistance, the Sponsor was able to file their NDA within an acceptable timeframe.

"As always…you're on it! I will share with you that we are very pleased that our sites are truly happy with your team. The comments come from different directions. Keep up the great work!"

–Sponsor's Director of Clinical Operations

