

GENERAL SURGERY

Contingency planning and strong site relationships allow study to meet original timelines, in spite of mid-stream client changes for a phase IV study.

ResearchPoint SERVICES:

- ▶ Project Management
- ▶ Clinical Monitoring
- ▶ Data Management
- ▶ Medical Monitoring
- ▶ Quality Assurance
- ▶ Statistics

This phase IV, open-label, clinical study involved approximately 50 sites and approximately 550 subjects. The study assessed the effect of the drug on perioperative outcomes using multiple laboratory assessments post surgery.

CHALLENGES: The Sponsor initially elected to conduct this Phase IV study like a Phase III study to include traditional monitoring with CRAs visiting the selected sites at regular intervals. But, midway through the study, the Sponsor changed the scope, reducing the need for on-site monitoring, in favor of remote monitoring.

ACTIONS: ResearchPoint revised our site management strategy to ensure the project met the targeted enrollment timeline. From the study's onset, our CRAs had built strong, working relationships with the sites, which allowed us to effectively manage the sites remotely. We maintained regular contact and received weekly updates related to screening, enrollment, CRF and query completion, SAE occurrences, and IRB follow-up.

ResearchPoint conducted an interim analysis, which required the submission of approximately 3,500 CRF pages and the resolution of 150 queries. With our set of best practices for receiving unmonitored data submitted directly from the 50 sites, ResearchPoint coordinated with multiple local labs, along with the central lab and a specialty lab to ensure the collection, analysis, and storage of all laboratory samples. We tracked and managed more than 4,400 specialty lab samples. By accessing the on-line inventory reports generated by the central lab, our CRAs regularly reviewed the data and communicated with the sites if there were any missing samples or issues with the samples that were received. The ResearchPoint CRAs then confirmed the accurate documentation of the issue with the sample in the CRF. After enrollment was complete, samples were identified to be shipped from the central lab to the specialty lab.

RESULTS: ResearchPoint's contingency planning and ability to quickly implement new processes in response to mid-stream client changes, allowed us to meet enrollment, complete the interim analysis, and ensure the laboratory samples were collected and analyzed within the original timeline. The team's ability to form strong partnerships at the site level facilitated a revised schedule that required remote site management, rather than on-site monitoring; thus meeting the Sponsor's expectations for comprehensive, quality data while reducing the number of traditional on-site monitoring visits.