

TRANSDERMAL IONTOPHORETIC DELIVERY SYSTEM

Superior team communication and a true collaborative partnership result in a 13% savings on labor and a query rate of only 4.5%.

ResearchPoint SERVICES:

- ▶ Project Management
- ▶ Clinical Monitoring
- ▶ Medical Monitoring
- ▶ Data Management
- ▶ Site Management
- ▶ Medical Writing

This phase II study investigated the tolerance and effectiveness of a transdermal iontophoretic delivery system to treat pain associated with lateral epicondylitis, involving 200 subjects at 10 sites throughout the U.S. The product provides local delivery of a corticosteroid drug through a patch placed on the skin, eliminating the need for a local injection.

CHALLENGES: The study protocol required a frequent visit schedule with patients receiving treatment every other day for a total of seven visits over a two-week period. These frequent visits required meticulous coordination and oversight to ensure subjects adhered to this heavy visit schedule.

Additionally, the study involved coordinating multiple vendors and several outside consultants, which had the potential to cause communication breakdowns and delays in decision making.

ACTIONS: ResearchPoint worked with the Sponsor to create a detailed "visit schematic" that coordinated and arranged study visits. We communicated with the study coordinator and principal investigator early in the study to ensure they thoroughly reviewed this visit schedule with the subjects so that the study progressed within timeline parameters.

ResearchPoint also collaborated with the Sponsor to establish the best approach to product adherence and study procedure training. As a result, we created diagrams and conducted breakout sessions at the Investigators' meeting to train sites on the proper application and removal of this transdermal patch as well as assessment review standardization.

ResearchPoint assigned a seasoned project manager with 17 years' industry experience to lead the study. Her expertise and strong clinical background allowed her to successfully evaluate study needs and proactively identify risks. She demonstrated an in-depth understanding of the study's scope to effectively manage resources, time, and money, accomplishing outlined goals while keeping the study on budget. The project manager also possessed the solid communication and collaboration skills to ensure all team members, including vendors and consultants, remained sufficiently informed and on the same page throughout the study.

RESULTS: ResearchPoint accommodated the heavy visit schedule, while maintaining site satisfaction, ensuring successful enrollment and retention of subjects throughout the study, resulting in a low drop rate. Our query rate was only 4.5%, far below the industry average, saving the Sponsor money and demonstrating superior team communication along with our ability to provide clean data from the study's onset. A user-friendly CRF design and first-rate training, combined with the strong relationships we built with the sites also contributed to this low query rate. We successfully cleaned and locked this study database within the Sponsor's timeline, while delivering the study 13% under budget on labor.

Above all, ResearchPoint served as a true partner to this Sponsor, acting as a dedicated extension of their project team and good steward of project funds. We provided proactive risk mitigation, addressed concerns realistically and delivered valid solutions to educate the sponsor with their decision making. Moreover, we managed downstream services to ensure resources were not used when not needed, further containing study costs.