

ABACTERIAL PROSTATITIS

Creative recruiting strategies result in over-enrollment in a limited population for a phase II study.

ResearchPoint SERVICES:

- ▶ Project Management
- ▶ Site Selection
- ▶ Clinical Monitoring

This phase II urology study evaluated a new treatment for moderate to severe abacterial prostatitis involving 33 sites, enrolling 153 subjects within the Sponsor's timeline.

CHALLENGES: Abacterial prostatitis is an atypical condition with only 5% – 16% of males suffering from prostatitis. Additionally, the Sponsor's protocol specified that patients taking alpha blockers (a drug class typically prescribed for men with prostate problems) could not enroll in the study, further limiting the patient population considerably. Consequently, enrolling qualified subjects presented significant challenges for this study.

ACTIONS: ResearchPoint addressed the study design with the Sponsor and developed a comprehensive enrollment strategy. We conducted thorough site level outreach efforts and implemented a more efficient approach to site selection that included a feasibility survey to target patients. We recommended adding 10 sites (almost a 50% increase) to the Sponsor's original plan.

We also managed all patient recruitment efforts and developed a series of recruitment strategies. These strategies served as a proactive means of directing potential subjects

to the sites to boost enrollment. Examples included providing financial incentives to study coordinators; conducting a re-launch of the protocol via on-line meetings; using a "Best Recruitment Idea" and other drawings to promote review of the newsletter and increase site awareness of the study; creating an incentive program for site coordinators to enroll the study.

Additionally, we ensured team continuity throughout the study by involving four clinical monitors who each developed an in-depth understanding of the study's protocol and its unique challenges. These monitors built camaraderie with the sites and maintained excellent relationships with them to address and mitigate any site specific challenges.

RESULTS: ResearchPoint exceeded enrollment goals by recruiting more subjects than the original targeted amount. The Sponsor was impressed with our ability to approach a difficult enrollment situation with proactive and strategic solutions, which resulted in an immediate surge in enrollment with an increase of 30%. We further solidified relationships with investigative sites with which we will collaborate on future studies. We are also pleased to report that the drug has been approved for other indications.

"Your regulatory experience and guidance was invaluable. I would love to add these individuals to my own team."

—Sponsor's Associate Director, Clinical Research