AUTOIMMUNE DISORDER

Creative strategies and collaborative partnerships result in accelerating the original timeline by 10% and beating enrollment goals for a potential cost savings of $7.5 million.[1]

ResearchPoint SERVICES:

- Clinical Monitoring
- Project Management
- Data Management

CHALLENGES: ResearchPoint identified several challenges expected to impact the results of the study. The indication was a prevalent, but underdiagnosed autoimmune disorder; individuals with this condition may only have positive blood work 65% of the time. Once subjects were identified, they were asked to adhere to a very rigorous visit and procedure schedule. The study required 216 procedures over four visits, each of which lasted two consecutive days and nights. Given the number and intensity of procedures, the Sponsor was expecting a 25% attrition rate for this phase II autoimmune disorder study.

ACTION: Expert planning and proactively addressing study needs drove the team toward success. ResearchPoint's engagement began with an intensive feasibility analysis, which revealed that it would be necessary to select more sites than the Sponsor had initially projected. In an effort to ensure that all study challenges would be addressed by the study team, ResearchPoint decided that a five-day kick-off meeting would be necessary. The face-to-face meeting included all stakeholders from the Sponsor company, EDC provider, Biostatistics group, and ResearchPoint.

The Sponsor and ResearchPoint decided to forego a traditional Investigator Meeting in exchange for two-day, all-hands-on-deck training and initiation visits. Key stakeholders from the Sponsor company and ResearchPoint, including senior leaders, were in attendance for each visit. Participation by senior leadership reiterated the importance of the study and commitment to the research sites. After enrollment began, the collaboration continued in the background. The teams met regularly to conduct blinded listings review meetings.

RESULT: As a result of the kick-off meeting, all study forms were developed prior to enrollment, contingency plans were identified, and all stakeholders were unified in their vision of what it would take to move the study forward successfully. One of the outcomes of this meeting was a Site Visit Procedure Tool that was pre-populated with all of the procedures and associated time-points. This simple tool helped sites to more effectively plan visits and manage the schedule of events.

Taking the time to review the data on a regular basis and sharing the findings with sites allowed study personnel to recognize and rectify data capture errors and inconsistencies, and ultimately resulted in cleaner data at the end of the study and the ability to lock the database ahead of schedule.

Despite the projected 25% drop-out rate, enrollment goals were exceeded by 9%, all randomized patients completed the study, and the enrollment timeline was decreased by 10%.

The combination of unparalleled high-touch initiatives and buy-in from all members of the study team was critical in exceeding the enrollment goal. While five-day kick-off meetings and two-day site initiation visits may seem extravagant in this industry, they provided the foundation for a very successful study and may save the Sponsor millions of dollars.

"The primary takeaway from this week, is that with ResearchPoint, I am with a company of problem solvers. This fact, in and of itself, could be a differentiator."

–Sponsor's Chief Medical Officer

1 Tufts Center for the Study of Drug Development. Impact Report. Post-Approval R&D Raises Drug Development Costs to $897 million. May/Jun 2003; 5(3):1-4.

