

ACUTE MACULAR DEGENERATION

Collaborative relationship and experienced leadership achieve targeted interim analysis date in an exceptionally short timeframe with Sponsor outsourcing additional data management activities during this phase III study.

ResearchPoint SERVICES:

- ▶ Data Management

CHALLENGE: The Sponsor had begun to conduct this large, global study in-house when they realized its size and scope exceeded their resources and capacity. With 200 sites and 2,600 subjects around the globe, receiving timely queries became an impediment to achieving targeted deadlines. Moreover, to meet additional needs on other projects, the Sponsor had to rearrange their team players twice during the study, making it more difficult to meet specific goals, as additional training was required for each new team.

ACTION: The Sponsor began by asking ResearchPoint to carry out a portion of their data management activities. Without delay, we held an extended kick-off meeting to ensure a seamless transition of responsibilities from Sponsor to ResearchPoint. We assigned a dedicated team to the study and made a resolute commitment to the Sponsor that the team would serve on the study for its 1.5 year-long duration. The ResearchPoint team quickly learned the Sponsor's study-specific processes, began using the Sponsor's proprietary database, and coordinated several teams and vendors worldwide. Our approach was to work as a hands-on team, working closely with the Sponsor to truly serve as an extension of their team. As a result, ResearchPoint exceeded the Sponsor's expectations with the Sponsor requesting we take over additional data management activities including query and listing management.

We held weekly meetings with the Sponsor and with the other vendors, capturing issues and resolving them in a timely manner. To maximize consistency across all sites, the ResearchPoint team created and maintained a global database of study issues for data cleaning conventions. Moreover, we proposed all sites fax their queries directly to ResearchPoint, instead of mailing them to promote efficiencies in data collection and data cleaning (to save time). ResearchPoint led the efforts to effectively launch this new process within each of the 200 sites, an initiative the Sponsor readily agreed was a more efficient data collection and data cleaning process.

RESULT: The Sponsor met their interim analysis deadline, a milestone that allowed them to strategically move ahead with study decisions. The collaborative working relationship between ResearchPoint and the Sponsor, along with creative strategies expedited data collection and brought cohesion and consistency to this worldwide study.

“Your strong relationship management skill to coordinate data collection among a variety of teams and hit our tight deadlines was key to our decision to outsource additional data management services to ResearchPoint. Keep up the great work!”

—Sponsor's Project Manager