

## PULMONARY ARTERIAL HYPERTENSION rescue

*Utilizing creativity results in reduced enrollment timeline from previous large incumbent CRO by 15 months for a global phase III study.*

### ResearchPoint SERVICES:

- ▶ Project Management
  - Contract & Grant Negotiation
  - Vendor Management
- ▶ Clinical Monitoring
- ▶ Site Selection & Management

**CHALLENGE:** The rescue study was required to quickly enroll large number of patients for a global, multi-protocol program for an orphan-drug designated product, requiring use of institutions, hospitals and local IRBs. In addition, the lack of institutional resources to focus on the specific study and the typically longer approval processes with local IRBs would also prove to be a challenge.

**ACTION:** Our project team constructed a transition plan to build confidence between the Sponsor, the sites and ResearchPoint. With risks and challenges identified, ResearchPoint proposed solutions to minimize areas of concern, while working closely with existing investigators to better manage the start-up process.

To assist with the limited resources, the creation of tools to increase effectiveness and efficiency included a study coordinator network for use by sites to help differentiate the requirements for each protocol, in addition to providing source worksheets. We placed additional study coordinator help and in some instances, we identified additional internal resources to provide support.

Our team implemented creative solutions for patient recruitment in institution-based sites. Rather than follow a

traditional advertising approach, ResearchPoint developed a recruitment plan that targeted patient advocacy and support groups as a resource pipeline for potential patients.

**RESULT:** Enrolled 30% more patients than the Sponsor initially requested for a total of 677, while reducing enrollment timeline by 15 months.

Study Coordinators were able to focus on subject recruiting with the proper tools to more easily identify appropriate subjects.

Through these actions, we were able to increase accountability and communication between sites and ResearchPoint, earn their trust and revitalize the program.

ResearchPoint recruited 59% of the patients while the European CRO recruited 39% and the Latin America CRO recruited 5%.

ResearchPoint achieved these accomplishments with a team half the size of the original CRO with our creativity, communication and project management skills.

*“Nice save!... Makes you guys look great. With best regards and congratulations to your team.”*

*-Sponsor’s President and CEO*

*“...you achieved these accomplishment with the backdrop of a mid-stream transition- no small task.”*

*-Sponsor’s Project Manager*