CASE STUDY

Caidya Rescues Four Global Rare Disease Studies for Biotech Company

Situation

A biotechnology company approached Caidya to rescue four global Phase II rare disease clinical trials that were in danger of missing significant study and enrollment milestones. Caidya provided project management, clinical monitoring, and medical management across the European Union and Asia-Pacific.

Challenges

To get the programs on track, Caidya's team needed to conduct a feasibility assessment and identify, recruit, and activate new global sites quickly.

Because there were two incumbent CROs involved, we were required to work with their electronic trial master file and clinical trial management system. The model proposed by the sponsor involved defining roles, leading multiple stakeholders, adapting to different processes, and coordinating everything to hit precise timelines.

Need to Revive a Study Behind in Enrollment?

Caidya Can Help

- Core teams quickly mobilize to carve out new strategies
- Site specific analysis and action plans are customized to initiate new sites
- Prepare multiple stakeholders through a series of tactical and strategic meetings and training sessions
- Rapidly plan and execute feasibility

Solution

The Caidya team identified core team members and clinical research associates (CRAs) to ensure consistency across the studies. We created a comprehensive transition plan comprised of timelines, role definitions, and transition checklists at the project and site level, and conducted in-person training on multiple systems. The thorough attention to detail we put into the planning and training set the stage for exemplary results. Specifically, we ensured a:

- **Seamless transition**
  Our project manager (PM), clinical trial manager (CTM), and regulatory lead prepared detailed study plans and checklists — a solid team model that facilitated seamless cooperation and consistent processes across the programs.
- **Meticulous, global execution**
  Our team organized kickoff meetings to train all personnel in roles, responsibilities, procedures, and systems management. To further ensure stellar execution, we conducted face-to-face training for two days on the eTMF, CTMS, and eCRF systems.
- **Smooth integration of existing sites**
  The Caidya CTM and PM supervised incumbent CRA visits at existing sites while Caidya CRAs completed detailed checklists and reports on site visits.
- **Personalized, optimized site selection**
  Leveraging data-driven evaluation tools, Caidya's in-country teams called key opinion leaders and investigators to discuss the protocol and find additional patients, improving investigator engagement. Sites with no eligible patients were eliminated.

Outcome

Caidya successfully transitioned all four studies from the incumbent CRO within three months. We completed site feasibility activities in two months' time in parallel and on schedule with the transition timeline. Furthermore, the country manager calls ensured sites and investigators remained engaged throughout.

Additionally, we provided a successful six-month interim data analysis. Because the biotech company was so pleased with the transition and our team's performance in the conduct of the four studies, it also awarded the follow-up Phase III study to Caidya.

Focus on Delivery Excellence

- **4 global studies transitioned**
- **Personalized execution**
- **Flexible, adaptable approach**