

Case Study



PHASE III RARE DISEASE RESCUE

SITUATION

A small biotech with limited internal capacity outsourced a phase III clinical program in patients with Necrotizing Soft Tissue Infections, a rare, life threatening infection for which no therapy currently exists, to a CRO. The study was to be conducted with 60 US sites with the objective of enrolling 290 patients.

After nearly 16 months, patient enrollment was still a major challenge and the CRO was not proactive in addressing the issues and providing solutions. Adding to the difficulties, the study was over budget and CRO staff turnover on the project was extremely high. The CRO-Sponsor relationship had deteriorated significantly. The Sponsor wanted control back.

The Sponsor's executive management made the decision to bring the study inhouse, hiring targeted operations professionals to accommodate the new workload. Despite the hiring they still had infrastructure and resourcing gaps including no access to clinical SOPs or a blinded and unblinded field monitoring team, before they could begin to transition the study from the existing CRO.



SOLUTION

The Sponsor engaged Catalyst to provide a blinded and unblinded monitoring team that reported into the Sponsor's CTM using Catalyst's SOPs. The team consisted of veteran CRAs with extensive critical care, hospital-based study experience. They were hand-selected by Catalyst and Sponsor to ensure geographic, therapeutic, and cultural alignment.

OUTCOME

The monitoring team became an extension of the Sponsor's team, serving as ambassadors to their assigned study centers.

The Sponsor is thrilled with the model of internal management and study oversight and utilizing Catalyst for their blinded and unblinded monitoring support, allowing them to retain control of their program. Although patient enrollment continued to be a study challenge, significant headway was made over the 18 months in which the study was rescued due to the ability to apply resources where needed, including site support and enrollment strategies. In addition, the Sponsor acknowledged that Catalyst pricing saved them ~\$1M in study execution as compared with their previous CRO projections, yet they realized high quality service delivery. Since, Catalyst has been awarded a second study providing unblinded and blinded monitoring for a phase II study in Acute Kidney Injury in the US and Europe.