CATALYST
CLINICAL RESEARCH

Case Study

SCALING A SOLID TUMOR STUDY

SITUATION

A mid-sized multinational biopharmaceutical company opted to internalize the study management and execution of their Phase Ib/II multicenter oncology program. The original objective was to enroll 120 subjects among 18 sites, across 6 cancer types. The Sponsor chose Catalyst as their clinical monitoring partner to augment their internal team.

As a result of positive treatment outcomes, patients continued in the trial for significantly longer than originally projected, creating a large data backlog that required source document verification. A study that was initially forecasted to complete within 16 months, created both opportunities and challenges for the Sponsor including multiple protocol amendments, expansion of study centers into Europe, and expanding patient enrollment three-fold in specific tumor types. The initial CRA monitoring team needed to scale to meet the realities of this high priority program.

> *"I think Catalyst has done a good job accommodating our needs and has been flexible with shifting demands"*
>
> *– Oncology CRO oversight customer*

SOLUTION

Catalyst and the Sponsor analyzed the monitoring needs of each of the study centers and deployed both short and long term resourcing strategies, including a SWAT approach, to obtain data currency at the high enrolling sites while expanding the study with new sites and patients in two of the tumor types showing promise. Utilizing Catalyst's deep network of highly experienced, oncology CRAs, we scaled from 5 to 20 CRAs, adding a Clinical Trial Manager for management oversight, to meet the program's expansion. Realizing that the asset was providing particular benefit in select tumor types, the Sponsor and Catalyst were able to increase cohort size and focus resources toward those target areas. To ensure success, the solution required a highly integrated team approach with Catalyst serving as an extension of the Sponsor's study team.

OUTCOME

Working hand-in-hand with our customer to meet the shifting study demands, Catalyst quickly scaled and deployed senior oncology CRA resources based on need. Because data currency was a high priority, our team tackled the data backlog at the high enrolling sites, meeting numerous interim data cuts required to support FDA interactions, publications and industry conference presentations.

Due to the program's overwhelmingly success and its high-profile status within the organization, the Sponsor's leadership continued to expand the program both in the US and Europe, and with limited internal resources, opted to outsource the program to a large, multinational CRO. Catalyst US CRAs continue to maintain involvement in the program providing a great degree of stability and continuity during this transition and beyond.

Our customer has been extremely pleased with Catalyst's flexibility and the ability to quickly adapt to meet the evolving scope of the program, and since has awarded Catalyst additional opportunities within and outside the oncology business unit.