CATALYST
CLINICAL RESEARCH

Case Study

ONCOLOGY CRO OVERSIGHT FSP

SITUATION

To ensure compliance with the updated ICH E6 (R2) guidelines and to address internal capacity issues, a midsized biopharmaceutical Sponsor required qualified support to help ensure appropriate oversight of several large, global CRO providers. The Sponsor's internal systems for oversight were adequate, but internal capacity proved insufficient, thereby choosing Catalyst as their 3rd party oversight partner.

SOLUTION

Catalyst custom built a global, functional team of 11 experienced, oncology clinical operations professionals (CRAs and CTAs) in the US and the UK dedicated to providing review and oversight of clinical operations services performed by their CROs including review of monitoring reports, the eTMF, and other clinical activities across 31 oncology studies. A seasoned Catalyst Team Leader serves as both liaison with the Sponsor's division directors and Catalyst staff, ensuring resources are allocated where and when needed to meet the current and projected work load. Working with the Sponsor's legacy systems and SOPs, an integrated approach supporting our customer's clinical teams was critical to the initiative's success.

OUTCOME

The oversight team is fully embedded within the Sponsor's team, using their systems and SOPs to alleviate a backlog of activities, while providing effective CRO oversight. According to our customer, the initiative has been highly successful evidenced by two annual contract extensions.

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