CASE STUDY

# The Imaging Rescue Study: Vendor Transition and Performance Improvement in Clinical Trials

## THE SCENARIO

Our client, a global healthcare and technology company, needed an expert opinion on how the medical images in their pivotal oncology Phase 3 study was being managed by an imaging CRO. After an initial review, the Bracken team concluded there were major errors and omissions that required correction. Additionally, the adjudication rate was excessively high for the indication.

## THE CHALLENGE

During the review process, the client elected to switch imaging CROs to preserve the integrity of their study. The Bracken team was asked to step in, become embedded in the client's clinical team, and manage a new imaging CRO, requiring the transfer of thousands of images and processes from one vendor to the new vendor. Bracken's experts, now embedded within the client's imaging team, then had to undertake this time-sensitive switch to have the reads back up and running, all within a strict timeframe of 3 months for a study enrolling over 700 participants.

## THE STRATEGY

The Bracken team, now cross-functional with the client's operations and medical team, took over the vendor management. Bracken worked collaboratively with the new vendor to identify timelines and develop a new charter and read design to ensure complete alignment with the protocol and meet regulatory requirements. We then triaged the multifunctional process by breaking it down into distinct parallel workstreams to ensure the timelines could be met.

Bracken's experts selected new readers after a thorough review process. A 2-day in-person training program followed, ensuring the newly selected readers were aligned before embarking on their reading process.

## THE RESULTS

The adjudication rate was almost halved, and thorough inter- and intra- reader variability ensured the readers were monitored carefully and consistently throughout this process. From the initial kick-off, the new imaging CRO was fully up and running in 3 months and the imaging portion of the study was successfully rescued.

## CONCLUSION

Conducting a successful clinical trial with a primary end point with medical imaging is a multifaceted process, which requires a detailed, thorough, and robust management to ensure regulatory alignment. Furthermore, an "imaging rescue study" is a highly complex process conducted under compressed timelines.

After the initial work concluded, the Bracken team remained involved as vendor managers and informally in a "trouble shooter" capacity. The client also brought Bracken's experts in on future projects to evaluate and support other trials with imaging endpoints.

BRACKEN

TheBrackenGroup.com

215.648.1208

12 Penns Trail
Newtown, PA 18940