KEOSYS Medical Imaging

CASE STUDY

RESCUING A COMPLICATED TRIAL

Complex trials with multiple efficacy endpoints or multiple imaging modalities can lead to elaborate central read designs that create challenges for readers and slow study progress. The situation is worse when multiple vendors are involved. This was the case with a recent phase II, dose-confirmation study involving 24 patients and 6 sites in Europe and the U.S.

As the CRO was using multiple imaging vendors, there were multiple systems involved. The workflow was unmanageable and the readers were not able to carry out their assessments using the standard tools on the market. As a result, the study was falling behind the established timeline.

The Challenge:

The Keosys team needed to provide a customized, end-to-end solution as soon as possible to simplify the read process and get the study back on track.

The solution needed to fit the sponsor's requirements, but also be cost effective, sensible from the perspective of the central readers, and in line with FDA recommendations and expert guidelines.

The Solution:

Keosys worked with the sponsor and CRO to design and deliver, in record time, a single, customized imaging system capable of readily managing the study's complex read design. The solution included . . .

- 8 dedicated, customized reading workflows developed for 2+1 reads
- Automated blinded/randomized comparison displays
- Dedicated standard of truth lesion matching
- Standardized uptake values (SUV) quantification reading sessions
- 7 external central readers trained on quantitative and qualitative tumour assessment

The Results:

Within 3 months, the challenges of the read design had been met and the trial was back on track. The net result was 656 central reads performed with technical support of selected readers provided 24/7.

The Takeaway:

- To avoid unanticipated challenges and delays once a trial is underway, sponsors and CROs should engage in close collaboration with imaging experts on imaging specifications early on.
- Reader calibration meetings are a must for complex read designs.
- Keosys can provide all the support sponsors and CROs need to ensure that the imaging component of their trials is as efficient and effective as possible.