Case study: In-progress trial

Median's flexibility provides successful outcomes for an in-progress clinical trial

Background

A Pharma Sponsor had begun a large Phase I multi-arm, multiple indication clinical study. The complex study involved 644 patients with one of the following: ovarian, urothelial, gastric and head and neck squamous cell carcinomas.

The Situation:

Expanded in-progress trial

After the start of the study, the Sponsor recognized the need for a central review of the data and reached out to Median to help. Median coordinated their central review process, utilizing RECIST 1.1 criteria for data analysis. This consisted of a read by a radiologist in an Independent Central Review and then a second read by two oncologists in an Independent Endpoint Review Committee.

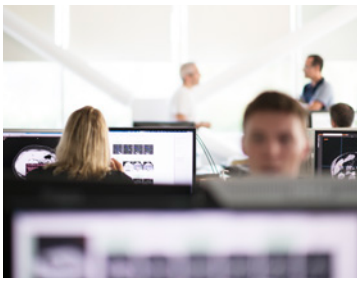
The Sponsor also needed to expand the study with the addition of 100 patients to the original urothelial cohort, AND the addition of a new urothelial cohort with 44 patients and 240 time points, all to be collected over a 2 month timeframe.

Challenge

The Sponsor needed a fast and reliable imaging partner to help them stay on track for their Phase I study and deliver an exceptional number of additional patients with an additional cohort in a very tight window – AND deliver them right.

Solution

Median provided the speed and flexibility to quickly and accurately process the additional samples, both the addition of samples to one cohort and the addition of a new cohort. Additionally, Median provided the expert project management support to coordinate a smooth transition for this clinical trial already underway to include central review. Median trained and qualified 150 sites according to image acquisition and transfer guidelines. Overall, Median obtained data from approximately 600 patients in 4 cohorts.



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Results

Median and the Sponsor successfully completed this large clinical trial with 4 cohorts in less than 1 year. Within this period, Median completed 5 interim analyses, which involved acquiring data, QC of data and review by an Independent Endpoint Review Committee. Median successfully delivered more than 1400 independent radiologist reviews on 592 patients with 1800 images/exams received by investigational sites and 5 IERC meetings – a significant achievement within a one year period! The sponsor was very satisfied with the results and the efficiency with which Median worked with them to complete the clinical trial on time and within scope.

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