Case study: In-progress trial

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

Background

A large 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:

Expanding a trial already underway

After the start of the study, the Sponsor recognized the need for a central review of the data and reached out to Median Technologies to help. Median coordinated the Sponsor's central review process, utilizing RECIST 1.1 for image analysis. The analysis 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 by 100 patients in the original urothelial carcinoma cohort, AND by adding a new urothelial carcinoma cohort consisting of 44 patients and 240 time points.

All data were to be collected over a very short 2 month time frame.

The Challenge

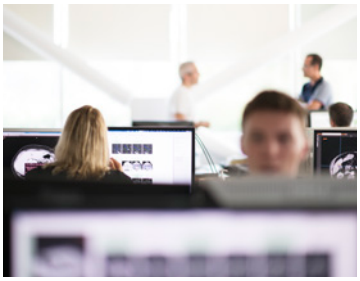
The Sponsor needed an efficient and reliable imaging partner to help it stay on track for its Phase I study. Median needed to deliver, in a very tight time frame, a large number of additional patients in an exiting cohort as well as add a new cohort of patients.

The Solution

Median provided the flexibility needed in a trial underway to quickly and accurately process the data from the additional patients in one existing cohort as well as the data from the new cohort.

Median also supplied expert project management support by implementing a smooth transition to a central review process as well as by qualifying and training 150 sites according to image acquisition and transfer guidelines.

Overall, Median obtained data from approximately 600 patients in 4 cohorts.



"Median supplied expert project management support by implementing a smooth transition to a central review process..."

The Results

Median and the Sponsor successfully completed this large clinical trial with 5 cohorts in less than 1 year. Within this period, Median completed 5 interim analyses, which involved acquiring data, quality checking the data and then having the data inspected by an Independent Endpoint Review Committee.

Median successfully delivered more than 1,400 independent radiologist reviews of 592 patients with 1,800 images/exams from 149 investigational sites - a significant achievement to complete within one year!

The Sponsor was very satisfied with Median's efficiency, flexibility and accuracy - all of which enabled them to complete the clinical trial on time and within budget.

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