Case study: Fast confirmation of PD

Accelerated turnaround time for confirmation of progressive disease (in-progress)

Background

Median Technologies is involved in a Phase II clinical trial focusing on solid tumors and cancer drug development. The Sponsor is testing a new approach to clinical trials by merging 3 studies into one. This approach will minimize the time needed to confirm the effectiveness of each patient's treatment. The study includes 250 sites, 11 cohorts and 600 patients with all types of cancer, but the primary indications are Non-Small Cell Lung Cancer and Colorectal Cancer. The Sponsor is using multiple criteria, which includes RECIST 1.1, RANO, and RANO BM, requiring the expertise of radiologists and neuro-radiologists.

The Situation:

Fast confirmation of PD

This highly complex trial requires a central read confirmation of progressive disease (PD) as detected by the site read. The principal investigator can then assess each patient using RECIST 1.1, RANO, and RANO BM. In cases where a patient's treatment is assessed as not effective, he/she is moved to a different treatment arm.

The Challenge

To ensure patient safety, the Sponsor requires a quick turnaround time of less than 48 hours for:

1. two blinded independent central reads with an adjudication using RANO BM criteria
2. two blinded independent central reads with an adjudication using RECIST 1.1
3. a blinded independent central read using RANO criteria

The fast turnaround time ensures confirmation of a patient's tumor progression so he/she can be removed and placed in an alternative treatment, if needed. The Sponsor also requires that the study readers receive no information about the Sponsor, drug, or patient to prevent any biases.

The Solution

Median customized its process and its legacy Lesion Management Solution (LMS)* software to fit the specific needs of this trial and Sponsor. The customization allows readers to streamline multiple criteria at the same time on a single platform, saving time while efficiently meeting the required 48-hour turnaround time. [See Chart] The customization of Median's legacy LMS software also removes all specific unwanted information about the Sponsor, drug and patient before it is sent to readers.

The Results

The Sponsor is very pleased with Median's turnaround time of under 48 hours with a 97% success rate. The results ensure patient safety and help maintain a strong relationship between the Sponsor, central readers and investigator sites. This clinical trial is still in progress with each party highly satisfied with the approach and the solution.

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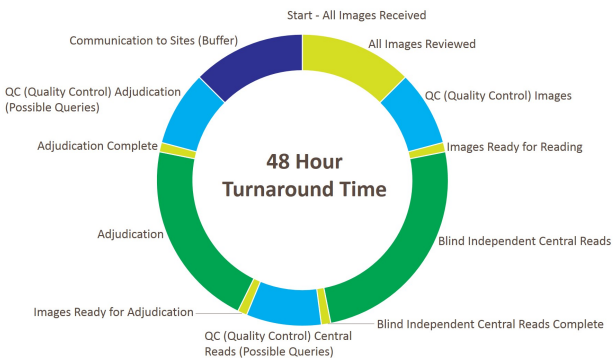

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www.mediantechnologies.com

Europe
Median Technologies SA
Les Deux Arcs B, 1800 route des Crêtes
06560 Valbonne, France

United States
Median Technologies Inc
300 TradeCenter, Suite 5610
Woburn, MA 01801, USA

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