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Case study: Tumor measurement creep

START saves study costs using Median's Lesion Management Solutions (LMS) software

Background

START, the world's largest Phase I clinical trial organization, was working with a large pharmaceutical sponsor on a Phase 1 study of a novel therapeutic agent. To calculate and interpret the measurements of tumors from the study, START uses Median's LMS technology. During their review of several patient images, START's physicians discovered a challenge that could have cost the study additional time and expense without benefit to the patient.

The Situation:

Tumor measurement creep

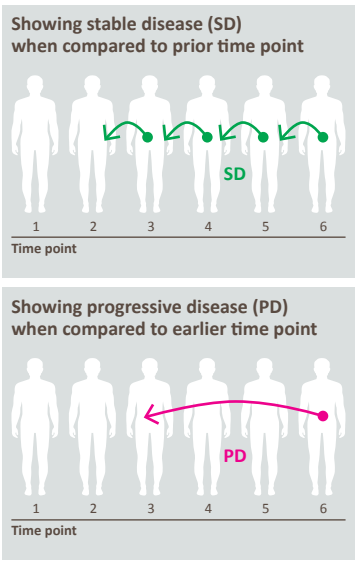
In keeping with standard clinical practice, the sponsor radiologist had compared the most recent image to that of the immediate prior time point only. This had been done over several time points. Each time, the tumor measurements were recorded as within the range of stable disease (SD), so the treatment was noted as having clinical benefit.

Challenge

The issue with comparing tumor measurements against the prior time point only, is that true progression of the tumor may be missed due to tumor measurement creep.

Solution

When START examined the tumor measurements using Median's LMS technology, they identified progression where the sponsor reader designated stable disease. Median's LMS records and allows for easy viewing and comparison of the measurements across all time points of a trial, so a more accurate analysis of progression versus stable disease can be made. When START compared the most recent scan to the nadir tumor measurement scans from three scans prior, the software revealed that the patient actually had progressive disease (PD) compared to the nadir, despite having had a documented excellent response throughout the trial. It was important that the tumor was compared BOTH ways: to most recent consecutive time point AND nadir or earlier time points to avoid issues with tumor measurement creep.



Comparison of measurements across all time points
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Results

Inaccuracy in tumor measurements in clinical trials often leads to additional treatment cycles being administered. By easily comparing scans from earlier time points using Median's LMS software, START was able to save their Phase I study sponsor time and cost, as well as putting the patient in a more appropriate care cycle.

1. The patient was able to avoid continuing on a study with no benefit and move to care of a progressing disease.
2. The Sponsor was no longer paying for continued treatment cycles of the patient for this study, ultimately reducing the cost of this trial for them. If the decision to treat was based on the radiology report as stable, they would have incurred this extra cost.

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