

Case study: Tumor measurement creep

## START saves study costs using Median's image analysis and tracking software

### Background

START, the world's largest Phase I clinical trial organization, was working with a large pharmaceutical Sponsor on a Phase 1 cancer study of a novel therapeutic agent. To calculate and interpret the measurements of tumors from the study, START utilized Median's software. During its review of several patient images, START's physicians discovered a challenge with the study that could have cost the Sponsor additional time and expense.

#### 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.

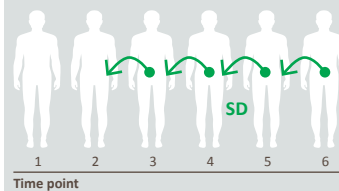
#### The Challenge

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.

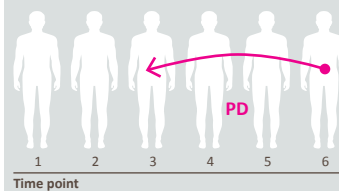
#### The Solution

When START examined the tumor measurements using Median's legacy LMS\* software, they identified progression where the Sponsor reader designated stable disease. Because Median's software records and allows for easy viewing and comparison of the measurements across all time points of a trial, a more accurate analysis of progression versus stable disease can be made. When START compared the most recent scan to the nadir tumor (initial 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.

#### Showing stable disease (SD) when compared to prior time point



#### Showing progressive disease (PD) when compared to earlier time point



#### Comparison of measurements across all time points

"Median's software 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."

#### The 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 legacy LMS software, START was able to save its Phase I study Sponsor time and cost, as well as to put the patient in a more appropriate care cycle. This led to several favorable outcomes for the Sponsor:

1. The patient was able to avoid continuing on a study with no benefit and move to care of a progressing disease.
2. If the decision to continue to treat the patient was based on the radiology report, which indicated stable disease, the Sponsor would have incurred extra cost by paying for additional treatment cycles.

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