median

Case study: Eligibility inclusion

Adapting analysis to expand eligibility inclusion

Background

A Sponsor contracted with Median Technologies as their Imaging CRO for its Phase II clinical trial for treatment of Advanced ALK-Negative Non-Small Cell Lung Cancer. The study involved 127 patients with 600 images read and analyzed using RECIST 1.1. Median coordinated the independent review process, which involved an evaluation by 2 radiologists independently assessing the tumors and an adjudicator independently assessing each case to make the final decision. This process continued until the interim analysis.

The Situation:

Expand Eligibility Inclusion

The Sponsor decided to extend the study with images for 2 additional time points. Using RECIST 1.1, Median found 5 patients with non-measurable disease (i.e., non-target lesions) who, according to strict application of the Imaging Review Charter, should have been excluded from the study.

The Challenge

The Sponsor required a methodology to incorporate these 5 subjects with non-measurable disease into the study, if possible.

The Solution

After discussions with the Sponsor, Median developed a plan to modify the analysis so it could incorporate these 5 excluded patients back into the study. The solution reached was to update Median's Lesion Management Solution (LMS) software to assess the lesions using RECIST 1.1 criteria for cases with non-measurable disease. This solution took only 10 days to implement the software changes, review the data and make the final transfer.

"By keeping the 5 patients in the study, the Sponsor saved time and the cost of finding new, eligible patients. By enabling the technology changes so quickly, this challenge did not affect the overall time line of the trial."

The Results

Using the newly updated criteria, these 5 subjects were not found to have progressive disease but were stable; so these outcomes could then be included in the study endpoints.

Median, through their expertise and consultation, provided a flexible software solution that was able to quickly address the case of subjects with non-measurable disease according to RECIST 1.1 criteria. This solution allowed these subjects to be included in the study endpoints instead of them being determined ineligible. By keeping the 5 patients in the study, the Sponsor saved time and the cost of finding new, eligible patients. By enabling the technology changes so quickly, this challenge did not affect the overall time line of the trial.

While the project was originally limited in scope, it expanded thanks to the trust established by Median's expert delivery of a flexible solution, rapid turn around and imaging expertise.

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