**Case study:** Eligibility inclusion

# Adapting analysis to expand eligibility inclusion

## Background

A Sponsor contracted with Median as their Imaging CRO for their Phase II clinical trial for treatment of East Asian Patients with Advanced ALK-Negative Non-Small Cell Lung Cancer. The study involved 127 patients with 600 images read and analyzed by RECIST 1.1. Median coordinated the independent review process, which involved first an evaluation by 2 radiologists independently assessing the tumors. Secondly, an adjudicator independently assessed each case to make the final decision. Successful completion of 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. Median found 5 patients with non-measurable disease (therefore non-target lesions) according to RECIST 1.1 criteria. Strict application of the Imaging Review Charter should have excluded these 5 patients from the study.

### Challenge

The Sponsor desired a methodology to incorporate these 5 subjects with non-measurable disease into the study so that they would not be excluded, if possible.

### Solution

After discussions with the Sponsor, Median addressed the issue of these 5 subjects with nonmeasurable disease by providing an option to modify the analysis. 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. All of this was addressed over an extremely short timeline: Only 10 days to implement the changes, review and make the final transfer of data.

*"By keeping these 5 patients in the study, the Sponsor was able to save costs of having to find new eligible patients. By enabling the technology changes so quickly, this challenge did not affect the overall time line of the trial"*

### Results

Using the new criteria, these 5 subjects were found to have not progressed but were stable, and so these samples could then be included in the study endpoints. Median, through their expertise and consultation, provided a flexible system to address the case of subjects with nonmeasurable disease according to RECIST 1.1 criteria, which allowed these samples to be included in the study endpoints instead of being ineligible. By keeping these 5 patients in the study, the Sponsor was able to save costs of having to find 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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