Case study: Analysis protocol improvement

Adapting a Sponsor's analysis protocol for improved accuracy and cost savings

Background

Median Technologies is working with a large pharmaceutical organization as the Imaging CRO for a Phase III clinical trial involving a new investigational drug for the treatment of glioblastoma. For the analysis, the immunotherapy response assessment for neuro-oncology (iRANO) criteria were used. Median was contracted to assess the eligibility of subjects by measuring the lesion volume (lesions had to be less than 1 cubic centimeter). Median also confirmed that the subjects had no progression according to RANO after standard chemoradiation treatment, and therefore, were still eligible for inclusion in the trial. Additionally, Median performed a central progressive disease assessment determined in the protocol as 2 successive assessments of progressive disease in a central read.

The Situation:

Adapting the Analysis Protocol

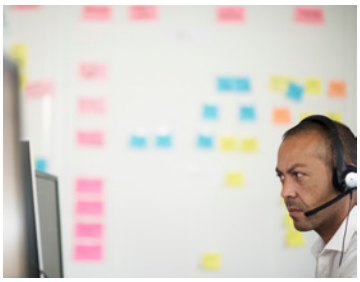
The Sponsor was using a protocol for analysis that was a mix of parameters utilizing volumetric assessment and RANO assessment, and as a result, the assessment needed a more accurate definition.

Challenge

The sponsor needed a better analysis protocol to objectively and accurately assess eligibility for the clinical trial.

Solution

Median utilized their extensive expertise and experience to solve the challenge. After a 5 hour consultation between Median and the sponsor, the protocol was modified to be accurate and to fit with criteria. The Sponsor agreed that the eligibility criteria they were using was inaccurate. There were 880 lesions assessed, with 470 patients' enrolled over 3650 time points.



"Median utilized their extensive expertise and experience to solve the challenge"

Results

By strictly adhering to inclusion criteria, the central read coordinated by Median made the clinical trial much stronger. In this study, almost 50% of the subjects (11 of 19) submitted for central eligibility were deemed ineligible to be recruited for the trial. There were 880 lesions assessed, with 470 patient assessments over 3650 time points, which were ultimately included in the study. Median's expertise prevented the use of inconsistent criteria, ultimately saving the sponsor time and money.

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