Case study: Clinical trial rescue

A study in need of rescue (in-progress)

Background

A Phase II, renal cell carcinoma clinical trial with 20 US sites and 12 EU sites, 2 cohorts and a total of 150 patients, had been underway for 8 months when the Sponsor decided to change its incumbent imaging contract research organization (ICRO) due to doubts of data validity and concerns over quality. This change, which would improve the overall trial outcomes with the help of a new medical imaging company, would also drastically affect the 32 sites involved and potentially add a significant delay to the trial, if not implemented rapidly and seamlessly.

The Situation:

Clinical trial rescue

The outcome of any clinical trial is dependent on the quality of the data and metrics delivered. Unfortunately, this Sponsor began to doubt the validity of the imaging data it was receiving from the incumbent provider. These concerns put the trial in jeopardy, possibly requiring the study to be started over, resulting in a significant loss of time and money.

"The solution was implemented quickly and cleanly to maximize desired results and minimize risk."

The Challenge

This clinical trial was using a double read with adjudication paradigm utilizing RECIST 1.1 and Choi criteria to determine drug effectiveness. The interim analysis depended on two key outcomes that made the trial complex:

1) the number of events defined as radiologic progression per central read, and

2) patient death

There were about 250 time points that the new imaging provider needed to completely re-read within a very short time period in order to meet the trials expected end date.

The Solution

As the imaging CRO replacement, Median Technologies needed to start from the beginning, following a strict and accelerated timeline to meet specified dates. The Median team set up the study in under one month with new readers and brought the clinical trial back to its original timeline.

Through the setup process, Median created a database for information storage, customized the tools for the specific needs of the trial, implemented a rigorous quality check process and brought in imaging expertise to completely redesign the imaging charter in a way that best fit the trial.

The solution was implemented quickly and cleanly to maximize desired results and minimize risk.

The Results

Through a dedicated and flexible team, Median met the Sponsor's needs by initiating sites, collecting images, and completing the re-reads in under one month. This Phase II clinical trial, although still ongoing, now has the Sponsor's full confidence in the quality of the data and believes there is a high likelihood of passing to Phase III.

Median provided the Sponsor with in-depth reporting of every unit of service provided, including easy access to all images and data involved in the study. Also, the charter is now compliant with PhRMA.

Overall, the results allowed the Sponsor to meet its original timeline while eliminating the need to restart the study from the beginning, saving the Sponsor nearly $4 million USD.

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