Case Study

Endpoint Protection Solution

Osteoarthritis (OA) of the Knee

Challenge

In a placebo-controlled clinical trial for the treatment of osteoarthritis (OA) of the knee, Sponsor X—a Top 20 Pharma Company—needed to verify that their primary endpoint was fully protected. Because the primary endpoint was subjective in nature, their concerns stemmed from issues of variability and measurement error that typically influences study conduct and the detection of true drug effect.

Highlights

Before the Timely, Targeted Intervention:

.28

The standardized effect size (SES) of the treatment at Site 103 was **0.28 (p=0.34).**

After the Timely, Targeted Intervention:

.67

The SES **more than doubled to 0.67 (p=0.13).**

The intervention caused conformance in the study conduct at all sites.

If the issue had remained undetected, Site 103 could have single-handedly led the study to failure.

Solution

Sponsor X implemented WCG's Endpoint Protection Solution to determine whether there were any fundamental issues that could impact their primary endpoint.

As the trial progressed, data aberrancies were detected at one of the five clinical trial sites. Specifically, Site 103 had much lower scores for the change in pain (related to their primary endpoint) than the other four sites.

In visiting the sites for the OA study, it was discovered that, although there were no deviations from the protocol, the principal investigator at Site 103 had been encouraging patients to get up and walk around to reduce their pain while waiting to be tested and that patients were active during the testing day.

This difference in study conduct between sites explained the reduced evoked-pain scores at Site 103 compared to the other sites that did not encourage walking.

Results

By implementing WCG's Endpoint Protection Solution, Sponsor X was able to:

1) Monitor the right variables,
2) Rectify the differences in study conduct,
3) Retrain to bring the outlier site into conformance with the other sites on this key endpoint, and
4) Have confidence in the standardization of their clinical trial.

The detection of data aberrancies, root-cause analysis, and implementation of retraining rectified the original issue of variability in study conduct, thus, increasing effect size and the difference between active and placebo treatments.

Standardized effect size (SES) at site 103 before and after retraining to correct variability in study conduct