

Case Study 2 – Confirmation of fraud at a center where patient diaries were ultimately found to have been completed by site staff

The subject of this case study is a phase III trial in vascular disease. Over 4,500 patients were randomized across 160 sites. The CRF included 480 variables for 32 domains. The CluePoints solution was deployed after the last patient last visit. The sponsor had a specific concern regarding a center suspected to have falsified patient questionnaires.

More than 45,000 p-values (a single p-value being the probability of an observed result arising by chance) were generated by the SMARTTM engine as part of the analysis. The scoring algorithm summarized the information from the tests into a summary indicator or “score” that pinpoints atypical centers and data subsets. In this analysis, center R38 was among the centers with the highest scores. Individual tests revealed that most of the signals were focused on patient diary data. The patients’ answers in these diaries were showing distribution of values that were completely different compared to the same data from other centers. The scores are given in Table 1 for the 5 top sites of interest (i.e. sites with the lowest score). It is interesting to note that in addition to site R38 which was known to have potential issues, other centers were also exhibited atypical patterns. In an ongoing trial, it would have been beneficial to trigger on-site monitoring visits in all sites identified as outliers in the CluePoints analysis.

TABLE 1 – Site scoring

Center	Rank	Score
R56	1	0.000001
R38	2	0.000035
R129	3	0.000550
R131	4	0.000745
R61	5	0.001460