Implementing central statistical monitoring (CSM) in a risk-based monitoring model

CASE STUDY

Situation

Biopharmaceutical companies often rely on FSPs for flexible model options and the ability to access specialty skills and expertise. When identifying FSP staff, it's important to find the right match who can integrate into the organization's culture to work together and deliver as one, seamless team.

When one biopharmaceutical company transitioned its clinical study portfolio to a risk-based monitoring model, they sought expert guidance to implement central statistical monitoring (CSM) in support of this new approach. Identifying biostatistics resources in the clinical research industry is relatively easy, but it was imperative for this company to find the right expert to create complex statistical algorithms that would detect data outliers and anomalies across multi-site clinical trial conduct and many different sources of patient data.

Parexel's Approach

Parexel FSP's operational head recommended a specialized team in Taipei, Taiwan who offered deep experience in both clinical research and statistical theory. After a trial period of creating statistical algorithms and method tests on various data sets, the client accepted Parexel's approach. The Parexel team began performing statistical reviews on the reports generated by the CSM algorithms, which helped build their understanding of each mechanism/algorithm behind the different statistical tests and how they affected the report. Additional components included:

- Continuous monitoring of data generated by the CSM algorithms allows for continual refinements to issue identification and predictive compliance risk scenarios
- Quality control support of analysis tools
- Applications were expanded to include detection of erroneous lab data values

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Results

Following implementation across hundreds of studies within the client's development portfolio, this CSM tool, incorporating Parexel's new algorithms, has generated scores of benefits, with an 85% positive rate from signals detected to date. Additional benefits included:

- Not only improved clinical trial data integrity through granular sensitivity analysis, but also significant labor-saving efficiencies through the reduction of on-site visits.
- Clinical study teams can now focus their efforts on select problematic sites for greater impact.
- Issues uncovered through continuous data monitoring also provide new insights into protocol design optimization.
- Early identification allowing for intervention and corrective actions, to prevent problematic trends from escalating into larger challenges.

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