World Academy of Science, Engineering and Technology
International Journal of Biomedical and Biological Engineering
Vol:18, No:02, 2024

Examining Statistical Monitoring Approach against Traditional Monitoring Techniques in Detecting Data Anomalies during Conduct of Clinical Trials

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Abstract : Introduction: Monitoring is an important means of ensuring the smooth implementation and quality of clinical trials. For many years, traditional site monitoring approaches have been critical in detecting data errors but not optimal in identifying fabricated and implanted data as well as non-random data distributions that may significantly invalidate study results. The objective of this paper was to provide recommendations based on best statistical monitoring practices for detecting data-integrity issues suggestive of fabrication and implantation early in the study conduct to allow implementation of meaningful corrective and preventive actions. Methodology: Electronic bibliographic databases (Medline, Embase, PubMed, Scopus, and Web of Science) were used for the literature search, and both qualitative and quantitative studies were sought. Search results were uploaded into Eppi-Reviewer Software, and only publications written in the English language from 2012 were included in the review. Gray literature not considered to present reproducible methods was excluded. Results: A total of 18 peer-reviewed publications were included in the review. The publications demonstrated that traditional site monitoring techniques are not efficient in detecting data anomalies. By specifying project-specific parameters such as laboratory reference range values, visit schedules, etc., with appropriate interactive data monitoring, statistical monitoring can offer early signals of data anomalies to study teams. The review further revealed that statistical monitoring is useful to identify unusual data patterns that might be revealing issues that could impact data integrity or may potentially impact study participants' safety. However, subjective measures may not be good candidates for statistical monitoring. Conclusion: The statistical monitoring approach requires a combination of education, training, and experience sufficient to implement its principles in detecting data anomalies for the statistical aspects of a clinical trial.

Keywords : statistical monitoring, data anomalies, clinical trials, traditional monitoring
Conference Title : ICPCT 2024 : International Conference on Pharmacovigilance and Clinical Trials
Conference Location : Barcelona, Spain
Conference Dates : February 05-06, 2024