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Challenges in ethical conduct of clinical trials in India – root cause for non-compliance

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Statement of Research: With raising concerns in the changing environment of clinical research in India, both from the regulators and general population point of view there is a need to determine the root cause of non-compliance. The research would thus focus on identifying the loopholes in ethical conduct of clinical research in India. The project would help researchers in understanding the major challenges while conducting a clinical trial and equip them with fundamentals that need to be considered while conducting the study.

Methodology: Data from 121 clinical research professionals were collected electronically through a web survey based application and responses were recorded in the form of tabulated spreadsheet using Microsoft Office Excel. Data collected were statistically analyzed using SPSS software.

Result: Of the different data sets that were assessed statistically to determine the reasons for non-compliance; the results generated from the research have clearly indicated fraud, bias and misconduct are the primary reasons for non-compliance followed by deviations and violations to protocol, procedures or applicable guidelines. The research has indicated that the investigators conduct and expertise could be the root cause for non-compliance as these hints towards investigator responsibilities.

Conclusion: From the study it is evident that it should be the responsibility of all the stake holders to ensure that precautionary measures in the form of audits, inspection, monitoring, etc. are taken to ensure quality and ethical standards are met when governing a clinical study. Vigilance and sense of responsibility of each of the stake holders is crucial for the ethical conduct of clinical trial. Having identified the root cause for non-compliance through this study it can be concluded although clinical research professionals are aware of the norms and standard put forth in the ICH-GCP and other applicable regulatory guidelines; more efforts needs to be taken by the stake holders to improvise the processes that are currently being followed.

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