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Bracing up to the needs of clinical trials in developing countries

Nusrat Shafiq and Malhotra S
Postgraduate Institute of Medical Education and Research, India

Conducting clinical trials in developing countries is associated with several challenges which are not limited to constraints of resources. The process of informed consent, reporting of adverse events and quality of data generated are often circumspect. Though several clinical trials sponsored by multinational pharmaceutical companies are being undertaken in these countries, the procedures followed with regards to above mentioned aspects of clinical research are found lagging in several instances. It is a common belief that a relatively uneducated population particularly those in lower income groups, the informed consent process was not adequately administered. We developed informed consent comprehension forms and evaluated the comprehension of participants in an exploratory first in human study and a confirmatory phase-3 study. We identified the informed consent comprehension tool very useful in addressing specific doubts of potential participants. Further, we identified factors which were associated with a low comprehension score. Reporting of adverse events, serious adverse events have been subject to a lot of debate. Regulations regarding reporting of serious events and compensation were laid down. In order to meet these requirements mechanisms were set up by sites for meeting the needs of timely reporting. The current presentation would like to share the lessons learnt and way forward. Trials sponsored by pharmaceutical companies are often monitored by a monitor appointed by the sponsor or the contract research organization. It is now required of ethics committees in India to undertake onsite monitoring of clinical trials. The mechanism initiated to meet this regulatory requirement has proven to be very useful. It was interestingly noted that the focus of regulator's monitors on documentation to meet the requirements of GCP, took the attention away from clinical and ethical aspects with regards to patient's well-being. An additional monitoring mechanism could be helpful in working towards ensuring participant's well-being and his/her rights. In conclusion, with the new awakening with regards to ethics of clinical trials, sites in developing country would need to initiate endeavors such as above to reinstill the confidence in clinical trials conducted there.

Biography

Nusrat Shafiq is currently working as an Additional Professor at Department of Pharmacology, Postgraduate Institute of Medical Education and Research, India.

nusha.pgi2302@yahoo.com

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