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Challenges and regulatory implications of CRO industry to meet global quality standards

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Abstract

Changes are bound to continue during the clinical research process across the pharma industry. Selection and enrollment of subjects in a trial needs to be emphasized for cross participation. The ethical committee continuous efforts to review and inspection to ensure that the subject's rights and safety are protected and data generated meet GCP standards. The quality of global trials and academic clinical research are not at par. During the bioanalytical methods used to support the drug development process. The Incurred Sample Reanalysis (ISR) program has been implemented as an additional measure to evaluate the reliability of the data and assay performance. A failed ISR requires an investigation to determine why the assay is not performing at the same level during sample analysis as compared to the initial method validation runs. It is important that the approach to handling outliers is also considered at the outset of any work where this may become an issue. A clear communication strategy should be developed for every output, which will include an assessment of what, if any, outlier handling is required. The approach to outlier handling should remain proportionate and it is expected that most outputs will continue to be non-controversial and that outlier handling will be the exception rather than the rule. The decision on the level of effort to devote to outlier handling should be informed by an assessment of the likely sensitivity of the outputs. Hence, there is a need of global uniform quality standards for pharmaceutical industry and CROs while conducting Bioavailability/Bioequivalence studies without affecting cost and time.

Biography

Ravi Kanneti has completed his Ph.D in pharmacy (pharmacology) from Gujarat University, India and he was awarded his masters in Clinical Pharmacy. He is having more than a decade of experience in Pharmaceutical, Clinical, Bioanalytical, Pharmacokinetics and Quality Assurance. In his current role, he is responsible for selection/qualification of CRO's national/international as per GCP, GLP and applicable regulatory requirements for conducting clinical studies. He had several publications in peer reviewed journals and serving as reviewer for research publications. He also guided several students for their dissertation preparation in the field of Clinical pharmacy, bioanalytical and pharmacokinetics.