ABSTRACT

India is emerging as a global hub for vaccine development. Data quality and validated reproducible CDM (clinical data management) processes in conformance with regulatory requirements are of essence in accelerating drug development process. Quality data serves as a reliable evidence for drawing unbiased and meaningful analytic inferences from a clinical trial.

Indian regulatory framework for conduct of clinical trials does not provide detailed CDM procedural guidelines, common data standards, list of essential documents and methodology for evaluation of CDM process. To address this gap, CDM procedures were inferred in the context of Indian GCP and considering industry prevalent best practices. The procedures were implemented and QA (Quality Assurance Department) audited in Myfive™ vaccine trial, conducted by a leading Indian pharmaceutical company, Panacea Biotec Ltd., with an objective to develop common data processing standards for in-house vaccine trials. The evaluation criteria for QA audit were met with 1) no SOP (Standard Operating Procedures) deviations, 2) no ‘Critical/ Major’ findings, and 3) no need to unlock database. The QA validated CDM model developed in conformance with study protocol and Indian GCP was replicated in NUCOVAC® trial and the processes were re-audited to monitor procedural adherence to QA evaluation criteria to achieve CDM procedural standardization (harmonization). Effective documentation in MDMF (master data management file) was done to enhance the visibility of the quality assurance system. In a pilot study, it emerged that the common data processing standard developed may be used to generate performance metrics representing critical CDM procedural steps for effective CDM monitoring.