Monitoring purpose to conduct of the trial

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Monitoring purpose is to see the conduct of the trial is in compliance with the currently approved protocol/amendment(s), GCP and the applicable regulatory requirements. The reported trial data are accurate, complete and verifiable from source documents. The rights and well-being of the human subjects are protected. Monitoring is to guarantee data accuracy and to prevent or detect protocol violations such as enrollment of non-eligible patients or assignment of improper treatment. Monitor has to maintain a good communication with the director of each centre, clinicians, patients and laboratory examiners, to have information on every concrete flow of procedure and the progress; Summarizing the monitoring results and evaluate the integrity of data's from recruiting, enrolling, screening, randomized allocation, treating patients and follow-up and credibility of clinical data collections. Monitoring program includes number of monitors in each clinical center, according to the number of centers. And plan the supervision frequency between them in terms of pace of clinical trial progress and adjustment with other monitors. Monitoring is essential for data accuracy and proper evaluation of study objectives in clinical trials. A multicentre trial helps to collaborate among study coordinators and sponsors and propose and exchange the opinions, suggestion and solutions with other coordinators. It has high-quality requirements in inclusion criteria, the treating course and follow-up period and the clinicians have to pay much attention to complete the entire study. Monitoring is an important step to exchange the trial experience, it is scientifically stringent; it develops and promote to reach quality of international recognition.

Tamilselvi has graduated from University of Hyderabad and has done her post doc in the field of signal transduction in abroad later she has joined in Quest life sciences as a Head Quality and continued her career in different positions in the QLS. And she has participated in several workshops, conferences, and seminar related to the clinical trial and ethics. Presently she is handling regulatory affairs in the QLS.

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