

# 3<sup>rd</sup> International Conference and Exhibition on Pharmacovigilance & Clinical Trials

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## Multi-center clinical trials and monitoring

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Today is the era of multi-center clinical trials. Multi-center clinical trials have its importance in the present medical research due to the emergence of different variants, resistant strains, and genetic mutations of common and uncommon diseases. These changes have left us to explore more into developing valuable molecules which can be translated into regular medical practices which are safe and effective for the wider and global patients. A single investigator is not capable of recruiting enough patients and the need for wider patient profiles gives great demand for multicenter trials. To have a multicenter trial run efficiently and to be monitored effectively we need certain factors to be looked into very vigilantly. We will have to understand in depth the sponsor responsibilities, investigator responsibilities and the monitoring group responsibilities. The important aspects to be looked into are a) Patient safety, b) Proper reporting of AEs on clinical trials to IRB/Sponsors/Regulatory authorities, c) Safety monitoring boards that monitor the trials scientifically and d) Quality-control procedures for assuring data accuracy and completeness. It's the new era of Centralized Risk-Based Monitoring and Safety Monitoring Processes for building efficient multicenter clinical trials. FDA has issued guidelines to the industry regarding this on Aug 2013 to facilitate Centralised Monitoring. We have to utilise e-CRFs and import the data into a central repository, along with the full complement of operational, quality and clinical safety data from all sites. The future of Multicenter Clinical Trial Monitoring in clinical research is by linking risk-based/Safety monitoring with quality management principles.

## Biography

Anju Gopan, MBBS, had her training in Clinical Oncology and Clinical Research at Regional Cancer Center Trivandrum, India. She also did training in Cancer epidemiology and Cancer registration from International agency for Research in Cancer (IARC)-WHO, Lyon, France. She has 12 years of experience before joining Oncology and clinical research in Gynecology, Pediatrics and General medicine. She has worked simultaneously at Regional cancer center, Trivandrum as Medical officer for two major screening projects of IARC/RCC (Oral Cancer and Breast Cancer), as Clinician at Head and Neck Specialty Oncology Clinic and as Sub-investigator for multiple international oncology clinical trials of RCC. She joined ICON Clinical research in 2012 as Clinical Research Physician. In that role she has worked as Medical Monitor associated with ICONs Oncology and Non -Oncology studies. She is associated with using ICONs centralized monitoring tool for safety monitoring and report preparations and medical review unit in India. She has co-authored articles in oncology in indexed journals. She had been awarded as the best coordinator for site management for RCC.

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