

3rd International Conference and Exhibition on Pharmacovigilance & Clinical Trials

October 27-29, 2014 Hyderabad International Convention Centre, India

Review of the softwares used in pharmacovigilance and clinical trials

Apoorva B M, Kiran L J and Chethan Kumar S
S. S Institute of Medical Science and Research Centre. India

Starting from study start up to study close out, software plays a crucial role in clinical research. Softwares helps in reducing the administrative burdens and workloads by consolidating information in a single location, supports the trial by facilitating the collaboration between all the research personnel. Integration of these softwares greatly enhances the speed and efficiency in maintaining, managing, planning, performing and reporting of the study data. For clinical trial management certain software like OpenClinica, RealTime-CTMS were used for patient management and recruitment, investigator management, regulatory compliance at the study site and CRO (Contract Research Organization) site. ClinTrial, Macro, eClinical Suite were used in the Clinical Data Management for CRF(Case Report Form) designing, CRF annotation, database designing, data-entry, data validation, discrepancy management and data extraction at the sponsor or CRO site, where as Pharmacovigilance software like Argus, ArisGlobal, PvNETwere the drug safety databases used during the study and VigiFlow, VigiBase were used in post marketing surveillance at the sponsor site, CRO site, hospitals, AMC's(Adverse Drug Reaction Monitoring Centres) to store the safety profile and adverse event reports of the drug. Thus these softwares are the great tools in clinical research domain to collect trial specific data to track study performance, schedule, monitor, and more.

Biography

Apoorva B M has completed her undergraduate is S. S Institute of Medical Science and Research Centre, Davangere under Rajiv Gandhi University of Health Sciences. Currently she is pursuing her postgraduate degree in MD Pharmacology in S. S Institute of Medical Science and Research Centre. She is working on the research project entitling "To evaluate and compare the efficacy of prednisolone, dexamethasone and difluprednate eye drops on intraocular pressure in post cataract surgery patients".

bmapoorva1@gmail.com