CME Proceeding
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# CME ON CLINICAL RESEARCH

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Safety and efficacy are the two major concerns for any drug therapy. Globally clinical research plays an inevitable role in bringing a new molecule into the market after its synthesis by the pharmaceutical industries. Availability of large patient population, highly educated and skilled manpower, wide spectrum of diseases and favorable economic environment imply India's potential as a global hub for clinical research. Pharmaceutical companies and Clinical Research Organization (CRO)s will require many trained personnel to carry out the clinical research. Keeping in mind these facts a CME with the theme of "Clinical research" had been jointly organized by the Dept of pharmacology, K.L.E University's J.N.M.C, Belgaum and Indian Pharmacological Society (I.P.S), Belgaum branch on **20th February 2010**. In the first scientific session, Dr.P.A.Patil (JNMC) spoke on *"Preclinical studies"*. In vitro and in vivo experiments of various doses of 'study drug' can obtain preliminary efficacy, toxicity and pharmacokinetic information suggesting the scientific merit for further development as an investigational new drug (IND). Local or systemic toxicity studies can be conducted (ex: urine analysis, blood biochemical assay, gross and microscopic pathology etc). Dr. B.J. Mahendra Kumar (KLE University's College of pharmacy) talked on "*Role of Drug Controller General of India (DCGI) in Clinical Trials"*. He explained about Drug and cosmetic acts/rules, requirements/guidelines for permission to import and/or to manufacture new drugs or to undertake clinical trials i.e. Schedule Y and its appendices.

Dr.N.M.Patil (JNMC) elaborated about *"Ethical issues in clinical trials"*. Ethics is required to: avoid exploitation of the subjects (maintain safety and wellbeing), protect vulnerable groups, children, disabled, elderly etc. Independent Ethics Committees (IEC) and Institutional Review Boards (IRB) are concerned with medical ethics. IECs review, regulate, monitor and supervise the clinical trials or the research projects. Ethical decision is taken without coercion, influence, inducement and intimidation. Dr.S.S.Torgal (JNMC) spoke on *"Introduction to clinical trials"*. A systematic study of a new drug in human subjects to generate data for discovering and/or verifying the clinical, pharmacological (pharmacodynamic / pharmacokinetic) and/or adverse effects with the objective of determining safety and/or efficacy of the new drug is known as clinical trial (Phase I, II, III and IV). There are many types of trials viz., Prevention trials, Screening trials, Diagnostic trials, Treatment trials, Quality of life trials and Compassionate use trials. The Clinical Trials Registry-India (CTRI) is an online register of clinical trials being conducted in India.

In the second scientific session, Dr.A.Shrivastav (KLE Hospital) talked on *"Conducting clinical trials-Investigators perspective"*. He explained about good clinical practice, role of primary investigator, CROs, DCGI, site management office (SMO), regulatory requirements and data management. Essential trial documents include protocol, informed consent form, investigators brochure etc. Study team at site consists of investigator, co/sub-investigator, clinical research/study coordinator, research nurse, pharmacist, unblinded personnel etc. Dr.S.I.Majagi (JNMC) gave a lecture on "*Pharmacovigilance"* which is a science of activities relating to the detection, assessment, understanding and prevention of adverse drug reactions (ADR) or any other medicine related problem. He explained about history, need, objectives, applications, methods (spontaneous reports etc), organizations involved (WHO, National pharmacovigilance center etc) in pharmacovigilance, Risk assessment, Risk management (RM), goals of RM, Risk minimization action plan(Risk MAP), tools of RM process and *Signal*: detection, sources, data, data interpretation, selection or rejection, strengthening (by assessment criteria), reporting, monitoring, assessment and follow up. He enlightened on Good pharmacovigilance practice, PSUR (Periodic safety update report), case report, case series and pharmacovigilance plans. Dr.Tarun Wadhwa (JNMC) talked on *"ADR monitoring and reporting"*. He briefed about predisposing factors and classification of ADRs, adverse events, medication errors, preventable events, ADR reporting system, causality assessment criteria, severity assessment, WHO causality assessment scale and categories. More than 220 delegates from various medical colleges and other health institutions from Karnataka, Goa and Maharashtra participated in the C.M.E. In the valedictory function, Dr.S.I.Majagi, Organizing secretary of the C.M.E and Secretary, I.P.S, Belgaum branch proposed vote of thanks and the certificates were distributed to the delegates.