R Manavalan, J Pharmacovigilance 2014, 2:5
http://dx.doi.org/10.4172/2329-6887.S1.012

OMICS Group Conferences
Accelerating Scientific Discovery

3rd International Conference and Exhibition on
Pharmacovigilance & Clinical Trials
October 27-29, 2014 Hyderabad International Convention Centre, India

Recent trends in clinical trial including pharmacogenomics approaches for drug development and rational therapy

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Over the last decade, there is an increasing focus on quality clinical trials to be carried out as per ICH guidelines so that the data will be accepted throughout the globe. Clinical pharmacologists, pharmacists trained in pharmacology are standing better chance along with doctors and pathologists to carry out clinical trials. Preformulation studies of the drugs are carried out to design a particular dosage form. These drugs are subject to preclinical studies in animal models to establish its pharmacological activity. With the Preformulation and animal study data, applications are made to regulatory authorities to get the drugs approved as "Investigational New Drugs" (IND). Subsequently clinical studies are carried out with the formulation in human beings at ascertain its safety and efficacy. Simultaneously large scale manufacturing of the formulation is developed with validation protocol.

In this topic the following items will be discussed as given in ICH guidelines:

i. Objective of clinical trials
ii. Test subjects and safe guards
iii. Principles of informed consent from human subject
iv. Process of New Drug Development and submission for NDA and ANDA for marketing approval
v. Clinical trial - Phase I, II and III
vi. Pharmacoepidemiology or Post marketing surveillance (Phase IV)
vii. Pharmacogenomics application in drug development and rational therapy

Using all the above data, submission are made to legal authorities about the formulation as a New Drug. It is called New Drug Application (NDA). The legal authorities after thorough review of the data conduct approval inspection of the manufacturing premises (Pre approval inspection). The whole process takes 10-12 years and costs about 80-100 corers of rupees. It follows post marketing surveillance study where safety and efficacy of the drug is established from the data generated after the use of the drug in the larger population (Pharmacoepidemiological study). Some drugs may fail during the study and may be withdrawn from the market. In the patent era as well as Globalization of trade, technological game already started to develop new formulations and market globally. In this context a common guideline is developed in "International Conference on Harmonization" to perform clinical trial of drugs which are acceptable to all the countries so that the drug can be marketed across the globe. India is becoming an important centre to carry out clinical trials in well established "Contractual Research Organisation" (CRO), which are approved and accredited by international bodies.

Biography

R Manavalan has completed his B.Pharm from Madurai Medical College, Madurai University with First Rank in University and G. P. Nairs Gold Medal. He has done his M.Pharm from Birla Institute of Tech & Science, Pilani. He achieved his PhD from Birla Institute of Tech & Science, Pilani in 1982. He has served as Lecturer and Reader in BITS, Pilani and Professor & Head in Annamalai University. Presently he is Professor & UGC-BSR Faculty and Research Director (PG and PhD). He has guided 08 PhD scholars and coordinated numerous M.Pharmacy Projects.

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