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5 steps to strengthen approval procedures for clinical trials

07 March 2013 | News | By BioSpectrum Bureau

5 steps to strengthen approval procedures for conducting clinical trials

The government of India has taken five following steps to strengthen the approval procedures and monitoring mechanism for clinical trials of drugs in the country to ensure that safety, rights and well-being of clinical trial participants are protected:

1.12 New Drug Advisory Committees (NDAC) consisting of leading experts mostly from the Government medical colleges and institutes from all over the country have been constituted to advise the Central Drugs Standard Control Organization (CDSCO) in matters related to approval of clinical trials and new drugs.

2. Applications of Investigational New Drugs (IND) i.e, New Drug Substances which have never been used on human beings are evaluated by an IND Committee, chaired by the director general, Indian Council of Medical Research (ICMR).
3. Registration of clinical trial in ICMR's registry at www.ctri.in has been made mandatory.

4. Guidelines for conducting inspection of clinical trial sites and sponsor / Clinical Research Organizations (CROs) have been prepared.

5. To further strengthen the regulatory provisions and the monitoring mechanism of clinical trials in the country, the Drugs and Cosmetics Rules, 1945 have been amended as follows:
A. Amendment vide Gazette Notification G S R 53 (E) dated January 30, 2013 specifying procedures to analyze the reports of serious adverse events occurring during clinical trials and procedures for payment of compensation in case of trial related injury or death as per prescribed timelines.

B. Amendment vide Gazette Notification G S R 63 (E) dated February 01, 2013 specifying various conditions for conduct of clinical trials, authority for conducting clinical trial inspections and actions in case of non-compliance.

C. Amendment vide Gazette Notification G S R 72 (E) dated February 08, 2013 providing for the requirements and guidelines for registration of ethics committee.