11th December, 2012

ADVISORY - NOTICE

Professor Ranjit Roy Chaudhury, an eminent Scientist of this country has advocated for proper system and procedures to be put in place while conducting clinical trials in India. His comments and suggestions are of great help in building confidence among various stakeholders to safeguard the rights, safety and well being for the trial subjects.

An article which is published recently presenting overview of Prof. Chaudhury depicts about the quality of clinical research to be conducted in the country. It is put for sensitization of the stakeholders and wherever feasible for their compliance.

Drugs Controller General (India)

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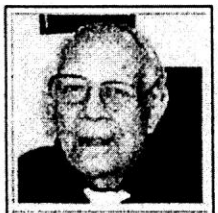
EXPRESS Pharma
FORTNIGHTLY INSIGHT FOR PHARMA PROFESSIONALS

Saturday, 20th October 2012

'Unless an ethics committee is accredited, it should not function'


Dr Ranjit Roy Chaudhury

Category: Management

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In a high level meeting held at the Apollo Group of Hospitals, Delhi, experts from various institutions, deliberated on the need for quality and ethical practices in clinical trials by ethics committees. ***Dr Ranjit Roy Chaudhury,*** *Chairman Task Force for Research, Apollo Hospitals Educational & Research Foundation (AHERF) who also chaired the various sessions, gives an overview of the key points in a chat with* ***Shalini Gupta***

Simple direct consent forms: Currently information to the people is very technical. The translation made in Hindi is so stylised that the patient cannot understand its implication. It was recommended that for the lay people of the ethics committees or the patient, a simpler, more accurate version of the information sheet should be provided, that he/ she can read in his/her mother tongue.

Consent of children and challenged patients: For children upto the age of 14 years, consent of a legal guardian is required; however, if the child understands the information in the form, he/she can also give assent. In case of mentally challenged, schizophrenic patients, consent of a guardian can be taken into account.

Compensation: There is a proposal to put the decision on the quantum of compensation to be paid in the ambit of ethics committees. The group, while discussing this, felt that most ethics committees did not have the expertise to make the calculation for payment to participants of clinical trials in cases of unfortunate outcome.

Should they look at how much pharma companies are paying per patient for trial? Should the institution conducting the trial be involved? How many clinical trials should one investigator handle at a time? The consensus was that there has to be a limit on the number of clinical trials one investigator is handling.

Biobanking and ethics: In some cases tissues of patients are taken as part of the trial and may be banked for further studies or research such as to study the efficacy of a drug. However, if this tissue need to be used for any purpose other than the original one an informed consent of the person from whom the tissue is being taken should be agreed upon.

Ethics of international collaborative research: With an increasing number of collaborations in research, it is imperative that there are certain safeguards for the same. For instance, if a clinical trial is carried out in India, the resultant drug should be released here and not in the US. Also, the number of patients in India on whom the study is conducted needs to be sufficient enough to give information as to how the drug functions in Indian patients. Conducting studies in 2-3 cases in India is fairly insignificant.

Choosing clinical sites: The centres where clinical trials are conducted should be chosen by the Drug Controller General (India) (DCGI) on a randomised basis and not by pharmaceutical companies. This will bring in greater transparency and help avoid any conflict of interest. This was decided in the light of the latest report by the Parliamentary Standing Committee that exposed the nexus between Pharma companies and those managing trial sites. An unbiased approach would only benefit everyone involved in the process.

http://www.expresspharmaonline.com/sections/management/1202-unless-an-ethics-committee-is-accredited-it-should-not-function

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Accreditation of ethics committee: The number of clinical trials is going down in India. While the country was a preferred destination for foreign MNC's, China is now fast taking over. The falling credibility of clinical trials in India has led to drug regulatory centres not accepting results from India. An assessment body for ethics committees that accredits them would help bring in more standardisation. Such a body is envisaged in and may function under proposed National Council for Human Resources of Health, which will have a council for accreditation. Apart from this, institutes and investigators should also be accredited, it was felt.

Clinical trials of medical devices: Medical devices regulation remains a grey area due to the lack of a specialised regulatory body for the same and hence it was strongly recommended that a medical devices agency be set up. As opposed to drugs, devices need to be tested for the material which might react with the body, dissolve in it and hence proper research and investigation needs to be undertaken while conducting clinical trials of devices.

Stem cell treatments and ethics: Both clinicians and patients are eager to use stem cells for treatments of various disorders. However, as per regulations, only the use of hematopoietic stem cells is allowed for certain well established haemotological indications. All other types of stem cells therapy can be done only in an investigative mode. We need to find out if there is a legal

way to give stem cell treatments to a patient with spinal cord injury. According to the Indian Council of Medical Research (ICMR), there is no proven evidence that stem cell treatment works. In the light of the above facts, it was recommended that a fund should be created that is run by government (ICMR) and anyone who wants to conduct a clinical trials for stem cell treatments should apply to it and if selected the study would be funded by government research agency. The Indian patient has a right to know that stem cell treatment works. At the same time, scientists have a duty to inform them on the same. Only when clinical trials are done using stem cells on patients, can we establish them as a suitable course of treatment.

Incentives for more involvement in clinical trials: Most of the members of ethics committees do not read the forms carefully. This includes lay members usually from civil society, academia, social work and the legal field. They need to be better informed about the ethical implications of trials (a part of ICMR guidelines) probably by giving them a background of the same. This would help protect the patient from any doctor conducted trials.

Stop mushrooming of independent ethics committees: Currently there are 100-120 ethics committees in India. However, institutes which do not have ethics committees get their trials approved by independent ethics committees. The registration and accreditation of ethics commitees will put a stop to this illegal practice. It should be made mandatory that unless an ethics committee is accredited, it cannot function.

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