BioSpect
the business of Bi
24 years of leveraging the business of Bio
www.biospectrumindia.co

ISCR welcomes CDSCO restrictions on investigators, sites

08 August 2016 | News | By BioSpectrum Bureau

ISCR welcomes CDSCO restrictions on investigators, sites



Welcoming the recent announcements by the DCGI with regard to the cap on the number of trials per investigator and number of beds per site, the Indian Society for Clinical Research (ISCR) has said that it is a welcome move that will enhance the overall quality of clinical research being done in India.

ISCR also acknowledged the collaborative approach by the regulators in making the changes in response to stakeholder feedback.

On August 2, 2016, CDSCO released two circulars by the DCGI regarding the conduct of clinical trials in India.

As per the revised rules, the cap on the number of trials an investigator can undertake at any point in time has been removed and the Ethics Committees have ben empowered to decide on how many trials an investigator can undertake after examining the risk and complexity involved in the trials being conducted.

The cap on a minimum number of 50 beds for a clinical trial site has also been revised with the Ethics Committees now being vested with the responsibility of examining and deciding whether a clinical trial site is suitable for a trial or not, irrespective of the number of beds.

Â

"The earlier restrictions impacted a sponsor's ability to choose the best qualified investigators and sites for a study. Every investigator and site is unique in terms of their capacity, capability and infrastructure and, therefore, their ability to do quality clinical research. The new announcements vest this decision with the Ethics Committees who are best positioned to deliberate on this and take a well calculated decision. This is something we at ISCR have been making submissions on behalf of all the clinical research stakeholders we represent and we are pleased that the regulators have responded positively to stakeholder feedback," said Ms Suneela Thatte, President, ISCR. "Ultimately what this translates into is qualitatively better clinical trials as decisions will be guided by which investigator or site is best suited for a particular trial and not by any arbitrary limits."

ISCR also acknowledged the efforts and contribution of late Prof Ranjit Roy Chaudhury, who headed the Expert Committee constituted by the Ministry of Health & Family Welfare in February 2013 to formulate policy and guidelines for approval of new drugs, clinical trials and banning of drugs.

One of the recommendations in a report by the Executive Committee submitted to the government was that any clinical trial of a new or existing drug or medical device should be carried out at a centre where facilities for carrying out such trials exist, and

the investigators carrying out the trial are competent and have experience in the successful conduct of such trials.

The Committee also recommended that the decision regarding the number of clinical trials a Principal Investigators can undertake should be taken by the Principal Investigators and the Institute Ethics Committee.

Acknowledging the contribution of late Prof Chaudhury, Suneela Thatte said, "Late Prof Chaudhury's recommendations paved the way for many of the regulatory reforms we have seen in India and we would like to place on record once again his immense contribution to the development of clinical research in India."

Â