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Indian clinical trial regulations to get tougher

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India's clinical trials system has been under intense scrutiny after the scandals involving alleged malpractice and patient deaths. During a recent discussion in the Rajya Sabha, the minister for health and family welfare, Mr Ghulam Nabi Azad spoke about the efforts planned to strengthen the regulations surrounding clinical trials in India. Recently, measures such as making notifications for registration of CROs mandatory, to help curb the rampant rise in unauthorized organizations have been introduced to substantiate clinical trial regulations in India.

A number of draft rules have been proposed with regards to compensation in case of clinical trial related injury or death, which includes the incorporation of a new appendix in Schedule-Y. The draft specifies that the compensation will be borne by the sponsor or representative, who should prove before the ethics committee that the injury or death is not due to clinical trial within 30 days; failing which they shall be liable to provide the compensation within 60 days as decided by the ethics committee. The quantity of compensation in case of trial related injury or death is to be decided by the committee as per prescribed guidelines. Another important development has been the provision for claims made by the subject to be settled within a period of 90 days and the sponsor will also have to submit the details of compensation provided to the Drug Controller General of India within 90 days.

Mr Azad also said that several proposals including ones such as allowing clinical trial inspections by CDSCO, assisted by concerned state authority and the power to take administrative actions like suspension or cancellation of clinical trial permission, restriction of investigator, sponsor or CRO to conduct future clinical trial, in case of non-compliance, have been approved.

Informed consent has been a contentious issue, with various methods such as video recording of the entire process being floated around, to avoid future claims of consent being taken in an improper way. Mr Azad informed that the consent format will now be amended to capture the details of address, qualification and occupation, and annual income of the subject. The patient information sheet will also be changed to mention that the applicant will provide compensation in case of trial related injury or death.

The responsibilities of the investigators will be expanded to ensure the trial subject being informed about his/her rights to claim compensation in case of trial related injuries or death. Also the contact details of representatives of sponsors or CRO and ethics committee will be provided.
Although, ethics committees will be mandatory at clinical trial sites, bioavailability (BA) and bioequivalence (BE) studies could be conducted with an approval obtained from independent ethics committee of same areas where the site is located.