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Clinical trial numbers in India drop drastically

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According to figures released by Clinical Trial Registry of India (CTRI), the number of approved trials registered in 2012 were only 262, close to half of the figure of 500 in 2010, a period which marked the rise of a number of CROs in India. The number of trials have been on a downward spiral since then with only 321 trials being registered in 2011 as well.

Contrary to popular public perception , very few clinical trials are conducted in India, as compared to other countries. As per the Clinical Trial Registry maintained by the National Institute of Health, USA, as against 1,30,302 clinical trials reported from various parts of the world as on 3.8.2012, only 2010 clinical trials were conducted in India as compared to 63,036 in USA, 34,616 in Europe, 3,091 in China and 3,551 in South Korea.

Recently the Ministry of Health and Family Welfare has come up with various directives for compensation to be provided for deaths caused due to clinical trials. Last month the Supreme Court of India held up the health ministry and CDSCO, the nation's main regulatory body for pharmaceuticals and medical devices, for not providing data on clinical trials as per its earlier order, in an ongoing case about illegal trials.

The Ministry also states that the Drugs and Cosmetics Rules, 1945 have been amended by the notifications G.S.R. 53(E) dated 30.1.2013, G.S.R. 63(E) dated 1.2.2013 and G.S.R No. 72(E) dated 8.2.2013 for strengthening of regulatory mechanism for the conduct of clinical trials, which inter alia include a provision for compensation in case of injury or death due to clinical trials and free medical management as long as required. This also includes expansion of responsibilities of sponsor, investigator and ethics committees to ensure that the reports of serious adverse events (SAEs) including deaths are reported, analyzed as per the prescribed timelines and in case of clinical trial related injury or death, compensation is paid as per the prescribed procedures. Also informed consent documents have been revised and are more elaborate.

The revised provisions also provide a provision for suspension or cancellation or debarment from conduct of clinical trials in case of non-compliance to the provisions and provide authorization to CDSCO to inspect, search and seize any records, documents, drugs.