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Letter to the Editor

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Clinical Research and its Condition in India

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Abstract

This article depicts the deteriorating condition of clinical trial in India and its effect on people. In spite of having tight regulations, guidelines and various regulatory bodies to protect the volunteers and inspect the loopholes of clinical trials, the number of deaths is increasing due to SAEs.

Keywords: Central drug standard control organisation (CDSCO); Serious adverse event (SAE); International conference on harmonisation (ICH); Good clinical practices (GCP); Food and drug administration (FDA)

India has become a global hub for outsourcing clinical trials for many Pharma giants situated in developed countries. e reason for this is quite understandable. We are a country with a large pool of heterogeneous; Patheistsedadgenurannaer 2011 Bredical expertise with January 22, 2013

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every approval/permission for conducting clinical trials now includesconducted in 178 countries, less than 2,000 (2%) are being done in a condition that in case of study related injury or death; applicant wilndia compared to over 9,000 (9%) in China.

provide complete medical care as well as compensation for the injury Blame it on lack of credible regulation. e fact is that our current or death which has been incorporated in the informed consent formlegal framework is strong enough to ensure transparency and ethical Now, registration of clinical trials in the Clinical Trail Registry of the practices during the conduct of clinical trials. Instead of dismissing Indian Council of Medical Research is mandatory. India has set up we drug advisory committees to advice on matters to review clinical trials.

India is seen to be an attractive hub for drug innovation based on sian countries, as they are doing, we would end up losing our clients our cost and skills. However, out of over 1,00,000 human trials beinghich would be a huge loss to our country.