

NIH gets candid on Indian clinical trial cancellations

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Singapore: Days after cancelling around 40 ongoing clinical trials in India, the National Institutes of Health (NIH) has finally spoken about the problems the global drug industry is facing in the subcontinent

A spokesperson of the National Institutes of Health (NIH), which is part of the US department of health and human services, said that the recent changes in the country's clinical trials regulatory atmosphere have hindered progress.

"The recent clinical trial regulations in India have affected some NIH studies. Some trials have stopped enrollment and some others have been postponed," the spokesperson was quoted in a statement.

Further, the government body has expressed concerns claiming that the regulatory environment is unstable. "NIH has expressed its concerns about the new regulations, and looks forward to hearing clarifications from the Indian government on this important issue. The NIH hopes that future changes will enable studies to resume, and that we will be able to continue collaborations with colleagues in India for the mutual benefit of our citizens," the spokesperson said.

Further explaining that many of the new processes had practices that would require that anyone injured in a clinical trial would have to be given free medical management as long as required. In addition, all the clinical trial sponsors will be liable for damages for injury or death. And the liability extends to anyone who dies or is injured due to the 'failure of investigational product to provide intended therapeutic effect' or the use of a placebo.