

<http://health.economictimes.indiatimes.com/news/industry/number-of-clinical-trials-in-india-may-surge-by-2018-19-dr-chirag-trivedi/59571004>

Number of clinical trials in India may surge by 2018-19: Dr Chirag Trivedi

Recent regulatory reforms by CDSCO such as online submission of clinical trials, reduced timeline for the approval of clinical trials, clinical trials' result to be updated in online registry, and online availability of minutes of subject expert committee meetings have led to transparency in the system.

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By Priyanka V Gupta

New Delhi: As per reports of clinicaltrials.gov, 1.4% of global [clinical trials](#) are done in India, while the country has 16% of the world's population and carries 20% disease burden in the world. However, the number of clinical trials in India is expected to grow by 2018-19 as a result of regulations for clinical trials in India becoming more stable and predictable, according to [Dr Chirag Trivedi](#),

President, Indian Society for Clinical [Research \(ISCR\)](#).

“In 2010, more than 500 clinical trials were done in India, and later the number dropped to less than 200 per year because there were said to be many uncertainties and ambiguities and regulations were not conducive to conduct clinical researches, with which the companies did not want to deal. In 2013, new regulations were introduced due to which major changes took place and clinical trials nosedived. Over the years, many efforts were made into making the regulations more rationale and balanced by the government. We are now slowly observing the upsurge in numbers,” Dr Trivedi told ETHealthworld.

The timeline for the approval of clinical trials research has been reduced to six months by the Central [Drugs](#) Standard Control Organization (CDSCO). Initially, it used to take 12 months for any proposed clinical trials research to get approved. “So, by the time the trials body used to get the approval to conduct clinical research in India, globally similar trials had already been conducted in that time period resulting in India losing out its competitive edge. Since the timelines are defined now, this will help in introducing new trials and if they become successful, those molecules then subsequently can be introduced for our patients in India,” said Dr Trivedi.

According to Dr Trivedi, India, being the second most populated nations in the world, has 1/5th of the global disease burden and has large unmet medical needs for its patients. “We need new drugs to be developed. Clinical research is the only way to introduce safe and efficacious molecules in the market. Every drug that is being consumed today has passed through rigorous control of clinical trials. India has a high burden of infectious diseases and at the same time, lifestyle diseases and non-communicable diseases are on the rise. Hence, clinical research is an essential part of drug development, which takes around 10-12 years to develop a new drug,” he explained.

“Another development that happened is the scaling down of three levels of approval to only one, as now the approval process is done by a Subject Expert Committee. Only when there is a disagreement to the committee’s decision, the application is presented to a technical committee and the apex committee. Yet, there is a challenge in terms of standardization of the terms basis which the clinical trials applications are reviewed. Lots of work have been done in the last one to two years to set the expectations right. We have released a handbook, which serves as a guide for the subject expert committee on how to review the applications in a standardized way. We have also recently given our comments on the basic rules which govern the clinical trials approval. We hope the comments provided by ISCR are taken into consideration by the government,” concluded Dr Trivedi, denying more details on the provided comments.