

8th Indo Global summit and Expo on **Vaccines, Therapeutics & Healthcare** November 02-04, 2015 HICC, Hyderabad, India

Indian clinical trials: The unaddressed challenges of regulatory amendments

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Today, the clinical trial industry in India is undergoing turmoil due to stringent regulatory scenario and is likely to face further decline because of delay/decreased clinical trial approvals. India was considered as one of the hubs for conducting major global trials and the business was projected to experience a boom across the country. According to the research firm Frost and Sullivan, the CTs business in India is estimated to grow to USD 1 billion by 2016 and these business projections of clinical trial sector are far reaching as it is experiencing huge losses in revenues. This avoidable situation is the result of stringent regulatory amendments and nonadherence to the timelines of regulatory approvals. The schedule Y amendments in past few years were long overdue, very much needed and is much welcomed after years of well-documented ethical lapses in good clinical practices of different kinds. The amendments have brought in several good changes such as requirement of EC/CRO registration, GCP Compliance and other related quality changes. Although the DCGI has brought stringent regulations creating a scenario similar or stricter than few regulated countries, there are still several lacunas which would have been avoided if done in consultation with the stakeholders such as sponsors, CROs, academia, ethics committees, regulators and public. There are several challenges that the sponsor companies are facing which are diverting them to conduct their trials in countries like China and Taiwan. These include issues of compensation for “any injury” during CTs due to failure of investigational product to provide the intended therapeutic effect and use of placebo in a placebo controlled trial. The contentious issues include medical coverage and compensation for any type of injury whether it is related or not and lack of clarity for how long and how much compensation need to be provided which will be decided by the regulatory authority and ECs on a case by case basis. The arbitrary time lines for reporting by investigators, sponsor, IEC which are much stricter than what is provided the international guidelines such as ICH-GCP. In fact, industry experts are of opinion that conducting trials in developed regions like US, European Union and Canada will be cheaper in the long run owing to the expertise and speedy clearances. There is an urgent requirement for readdressing some of the amendments to uphold scientific research and development that will be beneficial to society. This would help to bring back Indian clinical trial industry to the highest global ethical standards.

Biography

N Srinivas has completed his Masters in Pharmaceutics from Birla Institute of Technology, Ranchi and PhD from JNTUH. He is the Principal of Malla Reddy Institute of Pharmaceutical Sciences, Hyderabad, and possess a blend of industrial and teaching experience. He published more than 35 papers in international journals and has experience in training students in clinical research.

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