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Indian clinical trials- The unaddressed challenges of regulatory amendment

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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 be worth around USD 500 million, which projects that it will grow to USD 1 billion by 2016. This avoidable situation is the result of stringent regulatory amendments and the business projections of clinical trial sector are far reaching as it is experiencing huge losses in revenues.

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.

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HPLC fingerprinting for quality control of herbal drugs

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According to World Health Organization's (WHO's) survey there is increasing demand of traditional medicines all over the world. Such increase in the popularity of herbal products is also associated with the problems of adulteration, safety and efficacy issues. Review of literature of over last decade reveals that HPLC and hyphenated techniques are the most widely used techniques for the quality control of medicinal plants. Different HPLC methods have been developed for quality control evaluation process of herbal medicines. The level of methods varies from simple qualitative comparison of HPLC chromatograms with the available standards of marker compounds to the complex quantitative generation and interpretation of data obtained by advanced hyphenated HPLC methods. Combining a chromatographic separation system with a spectroscopic system on-line or with a spectroscopic detector in order to obtain structural information on the analytes present in a sample has become the most important approach for the identification and/or confirmation of the identity of target and unknown chemical compounds. These techniques not only gives a better fingerprint picture but smartly spells out each and every components in either the raw materials or in the most complex formulations of medicinal plants. Chromatogram and spectrum generated by these methods could provide efficient separation of metabolites and valuable structure information .Various hyphenated procedures have been reported, such as HPLC-MS, HPLC-DAD-MS and HPLC-NMR. In this paper advancements in the field of HPLC fingerprinting technique in last decade will be presented.

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