# CLINICAL TRIALS IN INDIA AND ITS REGISTRY



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**Clinical trials in India and its Registry**

From June 15, 2009, the Union health ministry made it mandatory to register all clinical trials conducted in India with the CTRI which was set up by the National Institute of Medical Statistics, a wing of the Indian Council of Medical Research as a registry of clinical trials approval. Since then more than 2000 clinical trials have been registered with them as against the 298 clinical trials registered during the two years before the registration was made mandatory. In order to improve transparency and accountability, registration is required with full disclosure of the 20-item WHO ICTRP dataset and the CTRI dataset. This also improves the internal validity of trials with details of the methods of the trial that produce reliable results, primarily the method of random sequence generation, concealment of allocation, blinding of participants and investigators, and inclusion of all participants results. This helps to accepted ethical standards and reporting of all relevant results of all clinical trials in India. Recently a team of pharmacologist in Andhra Pradesh conducted a study on the clinical trials on paediatric subjects and raised serious concerns regarding “selective reporting” to the CTRI. In selective reporting companies tend to report only the positive results while adverse results are often kept under cover.

**PSA view** – Registration of clinical trial was only voluntary till early 2009 in the country. The DCGI made registration of clinical trials mandatory as part of streamlining the clinical trials sector which remained largely unregulated in the country so far. The main objective of the CTRI is to ensure that every clinical trial conducted in the region is prospectively registered. There has been a marked increase in the number of registration of clinical trials in the country ever since the registration was made mandatory. Recently, the clinical trial industry is upset over the continued delay by DGCI in giving approvals for the clinical trials, including the bioavailability and bioequivalence (BA/BE) studies.

**New policy to force cut in imported drug prices**

With an aim to bring down the prices of drugs, the Draft National Pharmaceutical Pricing Policy (“**Draft Policy**”), released by the DoP, intends to put a ceiling on the price of the drugs. As per the Draft Policy the ceiling price of drugs under price control, both local and imported, will have to be the average price of the three top-selling brands in the segment at the time of policy implementation. At present, prices of imported brands are based on the landed cost declared by firms, which is difficult to verify.

If implemented, this move could drastically cut down prices of imported brands coming under the revised list of drugs under price control. For instance, if a foreign company is selling a monthly dose of its cancer medicine at a cost of INR 100,000, while the generic versions of a top three selling brand costs around INR 12,000 per month, the foreign company will be forced to cut down its price to meet the average price of the top three selling brands in its segment.

**PSA view** – The implementation of this policy shall slash down the prices of medicines which earlier, due to their exorbitant rates, could not be afforded by the common man. However, there could also be a negative impact. As it is not possible for companies to set up a manufacturing unit in each country where it does business, the cost of medicines include the cost of transportation for supplying these medicines and also the cost of production, which is higher in the western world. Though, this policy could force pharma companies to set up a manufacturing unit in India, it could also lead them to completely withdraw the drug from the Indian market. The government and the companies will have to sit and chalk out a common ground to ensure that the consumer does not suffer.

By:
Neeraj Dubey
Ashutosh Chandola
Divij Kumar