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CTRI records over 1000 clinical trials after registering made mandatory in June, 2009

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Ramesh Shankar, Mumbai

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<http://www.pharmabiz.com/article/detnews.asp?articleid=55947§ionid=>

More than 1000 clinical trials were registered with the Clinical Trial Registry of India (CTRI) during the last one year since the registration of clinical trials was made mandatory for getting approval for the clinical trials in the country. This is against the 298 clinical trials registered during the last two years before the registration was made mandatory.

Dr Abha Agarwal, co-ordinator of the Registry, said that there has been a marked increase in the number of registration of clinical trials ever since the registration was made mandatory by DCGI Dr Surinder Singh from June 15, 2009. 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. After registration was made mandatory, around 1050 trials were registered with the CTRI, Dr Abha said.

Clinical trial industry was by and large an unregulated sector in India till early 2009 and the registration was only voluntary. That the clinical trial organisations were not much interested in registration of trials for obvious reasons was clear from the fact that the total number of trials registered from July 2007, when the Registry was launched in the country, to December 2007 was just 11. In the year 2008, the number of registration went up to 137, still far from the desired level, given the size of the clinical trials going on in the country. From January 1 to June 15, 2009, the total number of trials registered was just around 150.

The CTRI was set up by the National Institute of Medical Statistics (NIMS) which is an arm of Indian Council of Medical Research (ICMR) and is funded by the Department of Science and Technology (DST) through ICMR. It also receives financial and technical support through the WHO, WHO-SEARO, and the WHO India Country office.

The main objective of the CTRI is to ensure that every clinical trial conducted in the region is prospectively registered with full disclosure of the 20-item WHO ICTRP dataset, as well all items of the CTRI dataset, in order to improve transparency and accountability; improve the internal validity (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) of trials right from the design, through conduct and reporting; conform to accepted ethical standards; and lead to reporting of all relevant results of all clinical trials in India and the region.