



## PHARMACEUTICALS EXPORT PROMOTION COUNCIL

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### **Health ministry to upgrade Clinical Trial Registry to cope with momentum in registration**

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<http://www.pharmabiz.com/article/detnews.asp?articleid=57225&sectionid=>

Even as the momentum in registration of clinical trials in the country is picking up fast ever since the DCGI made it mandatory from June 15, 2009 with total registration crossing 1300 mark, the Union Health Ministry will soon upgrade the Clinical Trial Registry of India (CTRI) which was introduced by the government in July 2007 as part of its exercise to regulate the by far unregulated clinical trial industry in the country.

Though the ministry had initiated the process last year, it has been going on at a snail's pace, due to the indifferent attitude of senior officials in the ministry. Now that the National Institute of Medical Statistics (NIMS), an arm of the ministry mandated with the responsibility of setting up and maintaining the Registry, is finding it difficult to cope with the rush in registration with its existing technology, there is an urgency to upgrade the system, sources said.

Sources said that a lot of new features have to be incorporated in the existing Registry which the NIMS has been running as a pilot project for about three years. Since the Indian Registry is getting applications from all over the world, it has to be on line with the international standards. In the present Registry, a lot of requirements of the WHO are missing. For example, there is no clause for audit of trial without which the authorities will not be able to track the changes constantly in the data of the trial. As the companies very often make changes in the data, it is very necessary to include such a clause in the Registry.

Based on the experience in the pilot project, it was decided to implement a fresh well designed Web Hosted Clinical Trial Registry to meet the expectations of the various stakeholders including the pharmaceutical industry, researchers, publications, administrators and the public at large. Being a front runner, among the first ten across the world, in the implementation of the mandate of registration of clinical trials, the Clinical Trial Registry of India will be keenly monitored across the world, sources 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. Now, the total number stands at 1300.