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Health Ministry begins process for upgradation of Clinical Trial Registry of India

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Aiming to incorporate several new features as per the requirements of the World Health Organisation (WHO), 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.

According to senior ICMR officials, the National Institute of Medical Statistics (NIMS), an arm of ICMR mandated with the responsibility of setting up and maintaining the CTRI, has already started the process of upgradation of the Registry. The NIMS, mandated to provide latest methodologies in the field of biostatistics for project planning with a component of research and to conduct need based training programmes in medical statistics, has invited expression of interest to develop the website for this purpose.

Senior officials 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 two and a half 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, officials said.

Besides, ever since the registration of clinical trial was made mandatory by the DCGI Dr Surinder Singh from June 15, 2009, there has been an added momentum in the number of registration of clinical trials in the country. Under this background, the NIMS 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, an official said.