Clinical Trial Registry to be upgraded to make it at par with int'l standards

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After running the Clinical Trial Registry of India (CTRI) for over two years on a pilot basis in the country, the Indian Council of Medical Research (ICMR) has decided to upgrade the Registry to make it at par with international standards as per the norms set by the WHO.

Several new features as per the requirements of the WHO like audit trail (constant tracking of data) will be included in the new format. The software of the Registry will soon be upgraded to make it automatic, instead of manual checking of the quality parameters, said Dr Abha Agarwal, coordinator at the National Institute of Medical Statistics (NIMS), an arm of ICMR mandated with the responsibility of setting up and maintaining the National Clinical Trials Registry of India.

Dr Agarwal said that as the registration of a clinical trial in the country has been made mandatory by the DCGI, it has been 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.

She said that a lot of changes have to be made in the existing Registry as there are a lot of problems in it which was launched on July 20, 2007. 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 trail in the present Registry 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, Dr Agarwal said.

She said that since the DCGI has made it mandatory to get all new clinical trials registered with the CTRI as a pre-requisite for obtaining permission for clinical trials in the country, there has been a substantial increase in the number of applications. So, the entire system is being upgraded to make it automatic, instead of manual checking of the quality parameters and other criteria.

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