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Interactive meet on New Drugs and Clinical Trials Rules 2019 by CDSA, THSTI and CDSCO

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The New Drugs and Clinical Trials Rules 2019 was released on March 19, 2019 by CDSCO, Ministry of Health & Family Welfare, Government of India. This regulation is a turning point for drug innovation and promoting ethical clinical research in India. It is of utmost importance that all stakeholders (pharmaceutical industry, national scientific laboratories, contract research organisations, scientists and academicians, innovators and start-ups) including international partners are fully aware of the transformed regulatory landscape in India.

There has a been demand from all over the country seeking clarifications on various issues. Realising this, Clinical Development Services Agency (CDSA), Translational Health Science & Technology Institute (THSTI), Department of Biotechnology, Government of India organised a half day 'Interactive meet on New Drugs and Clinical Trials Rules 2019: Its understanding and impact' at THSTI, NCR Biotech Science Cluster in collaboration with Central Drugs Standard Control Organization (CDSCO), Ministry of Health and Family Welfare.

Over 535 participants from more than 180 institutions participated in this interactive meet. The interactive session was live streamed and was viewed by institutions in India and abroad.

The Keynote Address was delivered by Dr. S. Eswara Reddy [DCG(I), CDSCO] and Prof. Y. K. Gupta [Principal Adviser (Projects), THSTI, DBT] delivered the talk highlighting the changes and rationale behind.

The panel discussion was addressed by Prof. Gagandeep Kang [Executive Director, THSTI], Prof. Shinjini Bhatnagar [Dean, Clinical Research, THSTI], Prof. Usha Menon [Strategy Lead, CDSA, THSTI], Prof. Y. K. Gupta and A. K. Pradhan [DDC(I), CDSCO].

Following regulatory changes were highlighted:

- For the first time, orphan drug has been defined as a drug intended to treat a condition which affects less than five lakh persons in India. Clinical trial fee for such drugs have been waived off with a provision of fast track approval.
- To promote drug development and research in India, the timelines of approval process has been defined as 30 days. If no objection/query is raised by the CDSCO (regulators), then the application will be deemed as 'approved'.

- Provision of post trial access was made for patients for whom, the new drug has been found to be effective and there is no alternative. This will be provided free of cost by the sponsor.
- It is now clarified that any type of study involving human which is not a drug trial under regulation will be governed by the National ethical guidelines for biomedical and health research involving human participants by ICMR. Compensation of any study related serious adverse events will be decided by the Ethics Committee.
- It is now mandatory that all Ethics Committees must be registered with CDSCO before they can approve any regulatory clinical trial. However, accreditation by NABH, QCI is not mandatory although recommended. For granting approval of non-regulatory trials, there should be Ethics Committee which need to be registered with DHR, Ministry of Health. This will be effective September, 2019.

Several queries by the attendees were responded succinctly by the regulator and panelists. CDSA, THSTI announced starting of an interactive discussion forum on clinical research related issues in national interest.