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International Clinical trials day Special: India to decide on its regulations

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Singapore: "The regulatory pathway is in place, a compensation system is in place, and with the call for 'Make in India', we should aspire to be a global clinical hub," said Mr GN Singh, drug controller general of India. He was speaking at a workshop on clinical trials and issues organised by Fortis Health Care and JK Risk Managers and Insurance Brokers, in April.

Mr AK Pradhan, deputy drug controller general, informed that the roadmap for conducting clinical trials was approved last month by the Technical Advisory Board and is now under the Health Ministry's consideration.

By mid-June, online processing and monitoring of applications for clinical trials will be operational, and the mandatory accreditation process is also due to start in July, as per the reports.

The draft guidelines put out by the DGCI in March this year make any violation punishable with debarment, putting investigators, ethics committee members and even hospitals on notice.