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per the 2019 ctrules the g icmr and ind 31 the dcgi and a dcgi registered ethics committee ec must approve a clinical trial application prior to the sponsor applicant initiating the trial except

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this guideline describes requirements for approval of clinical trials and new drugs and the procedure for review of technical dossiers of such applications by cdsco under rule 122 a 122b 122da

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dec 1 2025 india s biotechnology and life sciences industry has rapidly evolved into one of the most dynamic sectors globally with its vast and diverse patient pool cost effective research capabilities

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