F.No.10171/DCGI/10/2024-eoffice
Government of India
Directorate General of Health Service
Central Drugs Standard Control Organization
FDA Bhawan, Kotla Road,
New Delhi-110002

26 DEC 2024

NOTICE

Sub: Submission of Clinical Trial Site Addition and change of Principal Investigator applications through SUGAM Portal-Reg.

In order to streamline the regulatory submission procedure, the submission of applications for addition of Clinical Trial Site and change of Principal Investigator are functional on online system of SUGAM Portal (www.cdscoonline.gov.in) for Global Clinical Trials, Clinical trials of New Drugs, Subsequent New Drugs, Investigational New Drugs, Fixed Dose Combinations and Bioavailability & Bioequivalence studies. Applicants seeking for approval of Clinical Trial Site Addition and change of Principal Investigator applications may apply through the online portal.

The applicant should submit application through SUGAM along with the checklist of documents along with the approval of the ethics committee. The proposed addition of the clinical trial sites is deemed to be approved if no objection is received from the CDSCO within 30days of the receipt of the application and the proposed change of Principal Investigator is deemed to be approved by the CDSCO from the date of receipt of application subject to the condition that application is complete as per the checklist.

Rajeev

(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General(India)

To,

1. All stakeholders through CDSCO website
2. CDAC Team