Comp. No.: 23948
File No.: CELL-14011(11)/24/2025-eoffice
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(Cell and Gene Therapeutic Products Division)

FDA Bhawan, Kotla Road,
New Delhi-110002.

09 JUL 2025

NOTICE

Subject: Clinical Trial Applications (Phase I, II and III) for Cell and Gene Therapeutics Products through SUGAM Online portal system- regarding.

In order to streamline the regulatory submission and procedure, CDSCO has made provision for filling of Clinical Trial Applications (Phase I, II and III) for Cell and Gene Therapeutics Products (CGTP) through SUGAM Online portal system(www.cdscoonline.gov.in).

This provision is now made functional and the applicants seeking for such permission may now submit the clinical trial applications (Phase I, II and III) through SUGAM Online portal system as per the checklist in the developed modules. The user manual and video tutorial for filling of Clinical Trial Applications on SUGAM portal is also available on CDSCO website i.e. https://cdscoonline.gov.in/CDSCO/Industry.

It is hereby informed that the offline submission of clinical trial applications of CGTP will not be accepted by CDSCO for processing after 10th July, 2025.

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

To

1. All the stakeholders involved in Clinical Trials.
2. CRU Division, CDSCO-HQ, New Delhi
3. CDAC Team

Copy to: CDSCO IT cell for uploading in CDSCO website.

Copy for information to: PS to JS (Drugs Regulation), Ministry of Health and Family Welfare, Nirman Bhavan, New Delhi.