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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.

NOTICE

27 OCT 2025

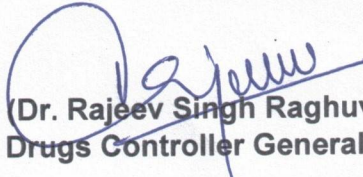
Subject: Post Approval Changes for Clinical Trials (Form CT-06) For Form CT-04 for Cell and Gene Therapeutics Products through SUGAM Online portal system- regarding.

In continuation to this office notice dated 09.07.2025 regarding Clinical Trial Applications (Phase I, II and III) for Cell and Gene Therapeutics Products through SUGAM Online portal system and to streamline the regulatory submission and procedure, CDSCO has made provision for filing of Post Approval Changes pertaining to Clinical Trials (Form CT-06) through SUGAM Online portal system(www.cdscoonline.gov.in).

This provision is now made functional and the applicants seeking permission, acknowledgement or for notification purpose may now submit their application through SUGAM Online portal system as per the checklist in the developed modules.

The user manual and video tutorial for filing of PAC to Clinical Trials (Form CT-06) 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 24th October, 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.