F.No.CT/SAE-Misc-10/2020
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(Medicines Safety Monitoring Division)
FDA Bhawan, Kotla Road,New Delhi-110002.

NOTICE

As per "The New Drugs and Clinical Trials Rules, 2019", Investigator, Sponsor/CT-NOC Holder and Ethics Committee shall report all Serious Adverse Events (SAE's)to the Central Licensing Authority within a prescribed time bound manner as specified in Rule 42 of the said rules.

The CDSCO, in pursuance to implementation of the e-Governance has launched various online services through the portal "SUGAM" (www.cdscoonline.gov.in) on14.11.2015.

In the latest phase, the development of software for online submission of SAE reports has been completed and the stakeholders are requested to avail this facility which is intended to further reduce the time and transaction cost. Therefore, it is now decided that it will be effective from **14.03.2021**, and from this date physical/offline files of SAE reports may not be accepted for processing.

However, follow up reports of the already submitted SAE reports shall be continued to be submitted in offline mode.

User manual and video tutorial for SAE reporting on SUGAM portal is available on CDSCO website.

Signed by Dcgi Cdsco
Date: 25-02-2021 12:22:01
Reason: Approved

(Dr. V. G. Somani)
Drugs Controller General (India)

To,
All concerned stakeholders involved in Clinical Trials.

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