Dear Investigators,

1. As per CDSCO NOTICE dated 25-02-2021, 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)on 14.11.2015

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 and which will be effective from 14th March 2021 and from this date physical and 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 and is attached for reference

2. The sites conducting regulatory clinical trials, maintain Departmental SOPs in your Department master file and also submit Departmental SOPs to IEC -I for records within 15 days of notice.

Regards,

Dr. Yashashri Shetty
Member Secretary
IEC-I