CT/SAE-Misc-02/2019
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(Medicines Safety Monitoring Division)

FDA Bhawan, Kotla Road,
New Delhi Dated the 09.01.2019

Circular

Ministry of Health and Family Welfare, Government of India had issued a notification GSR 53(E) dated 30.01.2013 for payment of compensation for clinical trial related injury/death. As per para (2) sub-para (2)(v) of Schedule Y to Drugs and Cosmetics Rules,1945, in case of injury or death occurring to the clinical trial subject, the Sponsor (whether a pharmaceutical company or an Institute) or his representative, whosoever had obtained permission from the Licensing Authority for conduct of the clinical trial, shall make payment for medical management of the subject and also provide financial compensation for the clinical trial related injury or death in the manner as prescribed in Appendix XII of Schedule Y to Drugs & Cosmetics Rules-1945. Serious Adverse Event's (injury/death) occurred during clinical trial are to be reported in prescribed manner and timelines under Drugs & Cosmetics Rules-1945 to the Licensing Authority.

During processing of these reports, it is observed that all the information as required under Drug and Cosmetic Rules within their timelines from all the concerned are not found provided, making examination of reports of SAE difficult to conclude.

Hence it is decided to convene a meeting with all the concerned stakeholders (Investigator, Sponsor and Ethics Committee) on 04.02.2019 at 2:30 pm at FDA Bhawan, New Delhi to discuss the various issues related to reporting of Serious Adverse Events. All the stakeholders/their representative looking after the reporting of SAE's are kindly requested to attend the meeting and also to acknowledge and confirm the participation by email to dci@nic.in and sae@cdsco.nic.in at the earliest.

(Dr. S. Eswara Reddy)
Drugs Controller General (India)

To,

All Stakeholders (Investigator, Sponsor and Ethics Committee)