GUIDELINES FOR REPORTING SERIOUS ADVERSE EVENTS (SAE) IN PARTICIPANTS FROM CMC – FOR CLINICAL TRIALS

New drugs and Clinical Trials Rules 2019 (GSR 227E -19th March 2019)

Kindly visit this link "http://cmc-research.in/cmc_sae.zip"
to download the CMC SAE access database, for generating the SAE report .

For Industry - Sponsored Trials and Investigator initiated trial which are UNDER THE SUPERVISION OF DCGI

Serious Adverse Event Reports			
Time Periods	**Reported by**	**Reported to**	**ACTIONS & COMMENTS**
Within 24 Hours of SAE occurrence	PI	➢ Sponsor ➢ CMC Ethics committee ➢ DCGI	➢ This is an initial report ➢ If PI does not report within the time frame, a letter of explanation has to be sent to the CMC Ethics Committee.
Within 14 Days of knowledge of occurrence of SAE	PI and Sponsor	➢ CMC Ethics Committee ➢ Principal of CMC ➢ DCGI	➢ This is an analysed report of the SAE
30 Days of receipt of SAE report	CMC Ethics Committee	➢ DCGI	➢ Recommendation of SAE analysis and compensation (if needed)
60 Days of receipt of SAE report	Expert committee of DCGI	➢ DCGI	➢ Recommendations of SAE analysis and compensation (if needed) ➢ In non deaths, sometimes DCGI will directly recommend to the sponsor
90 Days of receipt of SAE report	DCGI	➢ Sponsor	➢ DCGI's order
30 Days of receipt of order from DCGI	Sponsor	➢ Through PI	➢ Sponsor to pay compensation to the patient

What do I submit to Ethics Committee and How?

1. Soft copies of generated pdf form of the CMC SAE report and the generated Access database(Zipped file) : Emailed to saeclinpharm@cmcvellore.ac.in

2. Hard copy of emailed pdf form of CMC SAE report with signature : to the Clinical Pharmacology Unit. (in person)

For queries , please contact: SAE co-ordinator, Clinical Pharmacology Unit (Room no. 809), 2nd Floor, above Accounts section, CMCH, Vellore. Phone: 0416-228-2721

For Investigator initiated (academic) trials, NOT under the supervision of DCGI

Serious Adverse Event Reports			
Time Periods	**Reported by**	**Reported to**	**ACTION & COMMENTS**
Within 24 Hours of SAE occurrence	PI	➢ Ethics Committee	➢ This is an initial report
Within 14 Days of knowledge of occurrence of SAE	PI	➢ Ethics Committee	➢ This is an analysed report
	Compensation committee	➢ Ethics committee	➢ Recommendation of SAE analysis and compensation (if needed)

What do I submit to Ethics Committee and How?

- Soft copies of generated pdf form of the CMC SAE report : Emailed to **saeclinpharm@cmcvellore.ac.in**

For queries , please contact: SAE co-ordinator, Clinical Pharmacology Unit (Room no. 809), 2nd Floor, above Accounts section, CMCH, Vellore. Phone: 0416-228-2721