

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”](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	<ul style="list-style-type: none"> ➤ Sponsor ➤ CMC Ethics committee ➤ DCGI 	<ul style="list-style-type: none"> ➤ 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	<ul style="list-style-type: none"> ➤ CMC Ethics Committee ➤ Principal of CMC ➤ DCGI 	<ul style="list-style-type: none"> ➤ This is an analysed report of the SAE
30 Days of receipt of SAE report	CMC Ethics Committee	<ul style="list-style-type: none"> ➤ DCGI 	<ul style="list-style-type: none"> ➤ Recommendation of SAE analysis and compensation (if needed)
60 Days of receipt of SAE report	Expert committee of DCGI	<ul style="list-style-type: none"> ➤ DCGI 	<ul style="list-style-type: none"> ➤ 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	<ul style="list-style-type: none"> ➤ Sponsor 	<ul style="list-style-type: none"> ➤ DCGI's order
30 Days of receipt of order from DCGI	Sponsor	<ul style="list-style-type: none"> ➤ Through PI 	<ul style="list-style-type: none"> ➤ 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?

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