

Annexure 2
AX 03 / SOP 11-B/V6.1



(Annexure 6)

Serious Adverse Event Reporting Format (Biomedical Health Research)

INSTITUTIONAL ETHICS COMMITTEE (IEC)

Seth GS Medical College and KEM Hospital, Mumbai.

Project Registration No.

Title of study:

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Principal Investigator (Name, Designation and Affiliation):

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1. Participant details :

Initials and ID	Age at the time of event	Gender	Weight:.....(Kgs)
.....	Male <input type="checkbox"/> Female <input type="checkbox"/>	Height:.....(cms)
.....		

2. Suspected SAE diagnosis:.....

3. Date of onset of SAE:	<input type="text" value="dd"/> <input type="text" value="mm"/> <input type="text" value="yy"/>	Describe the event ¹⁹:
Date of reporting SAE:	<input type="text" value="dd"/> <input type="text" value="mm"/> <input type="text" value="yy"/>
	
	
	
	
	
	

4. Details of suspected intervention causing SAE ²⁰

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5. Report type: Initial Follow-up Final

If Follow-up report, state date of Initial report

6. Have any similar SAE occurred previously in this study? If yes, please provide details. Yes No

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¹⁹Duration, setting, site, signs, symptoms, severity, criteria for regarding the event serious

²⁰Refers to research intervention including basic, applied and operational research or clinical research, except for investigational new drugs. If it is an academic clinical trial, mention name, indications, dosage, form and strength of the drug(s)

Version 1.0

7. In case of a multi-centric study, have any of the other study sites reported similar SAEs ?

(Please list number of cases with details if available)

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8. Tick whichever is applicable for the SAE: (Kindly note that this refers to the Intervention being evaluated and NOT disease process)

A. Expected event Unexpected event

B.

Hospitalization Increased Hospital Stay Death Congenital anomaly/ birth defect

Persistent or significant disability/incapacity Event requiring intervention (surgical or medical) to prevent SAE Event which poses threat to life Others

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In case of death, state probable cause of death.....

C. No permanent/significant functional/cosmetic impairment
Permanent/significant functional/cosmetic impairment
Not Applicable

9. Describe the medical management provided for adverse reaction (if any) to the research participant. (Include information on who paid, how much was paid and to whom).

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10. Provide details of compensation provided / to be provided to participants (Include information on who pays, how much, and to whom).....

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11. Outcome of SAE

Resolved Ongoing Death Others (specify)

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12. Provide any other relevant information that can facilitate assessment of the case such as medical history

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13. Provide details about PI's final assessment of SAE relatedness to trial.

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Signature of PI: