Department of Clinical Pharmacology, First Floor, New MS Building,
Seth GS Medical College & KEM Hospital, Parel, Mumbai 400012.

Category: Study conduct

Title: Serious Adverse Event (SAE) Documentation.

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SOP team:

Author: Dr. Vinayak A.
DM Resident

Signature with date Vinayak A 23/Dec/2023

Reviewer: Dr. Mahesh Belhekar
Associate Professor

Signature with date 26/DEC/2023
Dr. Mahesh N. Belhekar
Associate Professor
Department of Clinical Pharmacology
New MS Building, First Floor,
Seth GS Medical College and KEM Hospital
Acyarya Donde Marg, Parel,
Mumbai- 400 012, India.

Approved by: Dr. Nithya Gogtay
Professor and Head

Signature with date 31-12-23
Dr. Nithya Gogtay
Professor & Head
Department of Clinical Pharmacology
1st Floor, MS Building,
Seth GS Medical College & KEM Hospital,
Parel, Mumbai - 400 012.

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1. Purpose

This standard operating procedure (SOP) describes the responsibilities of the study team for documenting a serious adverse event (SAE) from the time it is identified until all follow-up activities associated with its resolution have been completed.

2. Scope

This SOP applies to all clinical studies involving human participants.

3. Responsibilities

Principal investigator (PI), Co-Investigator (Co-I), Study Co-Ordinator, or any other appropriately qualified staff in the team, as delegated by the Principal Investigator, will be responsible for documenting serious adverse events.

4. Applicable rules, regulations, and guidelines

- New Drugs and Clinical Trials Rules 2019
  https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/NewDrugs_CTRules_2019.pdf

- National Ethical Guidelines for Biomedical and Health Research involving Human Participants ICMR, 2017
  https://www.indiascienceandtechnology.gov.in/sites/default/files/file-uploads/guidelineregulations/1527507675_ICMR_Ethical_Guidelines_2017.pdf

- ICH-GCP E6 (R3) Draft Guidelines dated 19th May 2023
  https://database.ich.org/sites/default/files/ICH_E6%28R3%29_DraftGuideline_2023_0519.pdf

5. Reference to other applicable SOPs

- SOP No D 03/06: Responsibilities of the Study Team

- SOP No D 14/06: Adverse event monitoring, recording, and reporting.
- SOP No D 21/06: Contact and communication with sponsor
- Addendum to SOP for SAE Reporting

6. Detailed Instructions:

6.1 Identify SAE

A Serious Adverse Event (SAE) is defined as-

Any untoward medical occurrence that at any dose:

- Results in death,
- Is life-threatening,
- Requires in-patient hospitalization or prolongation of existing hospitalization,
- Results in persistent or significant disability/incapacity, or
- Is a congenital anomaly/birth defect.
- Is a significant medical event.

6.2 Medical management of an SAE

6.2.1. Appropriate medical management of the SAE by referring to the appropriate collaborating (or any other as applicable) department in the institute. Supportive measures should be immediately used as appropriate and are directed towards participant safety and well-being.

6.2.2. Participant will be followed up till complete resolution.

6.3 Documentation of an SAE

6.3.1. Document the nature of the SAE, which includes onset, duration, progress, management, and outcome in the participant's source document/s.

6.3.2. Relatedness of the SAE to the clinical trial must be assessed by the PI and reported in the SAE form (Appendix 1 and 2)

6.3.3. The SAE reporting form of the Department (See Appendix 1) and the SAE assessment form along checklist of the IEC (see Appendix 2) should be used for documentation in case of academic studies.

6.3.4. The SAE assessment form and checklist of the IEC (see Appendix 2) and SAE form provided by sponsors (if any) have to be filled in case of pharma sponsored studies.

6.3.5. In case the sponsor does not have a form then the SAE reporting form of the department (Appendix 1) should be used for documentation.

6.3.6. Complete documentation should be done in the source documents and case record forms (CRFs).

6.4 Reporting of an SAE

6.4.1. Inform the Sponsor, Licensing Authority and Chairperson of Ethics Committee within 24 hours using the SAE reporting form (Appendix 1).

6.4.2. For an SAE (causing Death/ other than death): PI have to send a detailed report (after due analysis) within 14 days of the occurrence of the SAE (death) to the IEC, Head of the Institution and Licensing Authority (Appendix 3).

6.4.3. SAE Reporting is to be done online on the SUGAM portal as per the CDSCO order dated March 2021. Refer to Addendum SOP for SAE Reporting for details.

6.5 Compensation- medical management and if related further compensation

6.5.1. Reimburse the participant for all expenses toward the medical management of the SAE in case of academic studies.

6.5.2. In the case of sponsored studies, compensation to the participant will be provided by the sponsor as recommended by the Licensing authority.

6.5.3. If there is a clinical trial related death, the nominee will be contacted by the PI/ designated study team member for compensation as per regulatory rules.

6.6 Further steps

6.6.1. Various steps may be taken with respect to further use of the investigational product, comparator, or placebo (in the interest of participant safety). This decision may only be made by the PI and will be as prescribed in the protocol, for example,

- Discontinue the investigational product, comparator, or placebo (Dechallenge)
- Reduce the dose.
- If necessary, for the immediate medical care of the participant, break the drug blind after consultation with the sponsor.

7. <u>Appendices:</u>

Appendix 1: Table V for SAE Reporting

1.	Country (name of the country should be specified)	
2.	SAE report of death or other than death	
3.	Patient details	
	Initials and other relevant identifier [hospital or outpatient department (OPD) record number etc]	
	Gender	
	Age or date of birth	
	Weight	
	Height	
4	Suspected Drug (s)	
	Generic name of the drug	
	Indication(s) for which suspect drug was prescribed or tested	
	Dosage form and strength	
	Daily dose and regimen (specific units- e.g., mg, ml, mg/kg)	
	Route of administration	
	Starting date and time of day	
	Stopping date and time, or duration of treatment	
5	Other treatment (s)	
	Provide the same information for concomitant drugs (including non-prescription or over the counter OTC drugs) and non-drug therapies, as for the suspected drug(s)	
6	Details of serious adverse events	
	Full description of the event including body site and severity as well as the criterion (or criteria) for considering the report as serious. In addition to a description of the reported sign and symptoms, whenever possible describe a specific	

	diagnosis for the event	
	Start date (and time) of the onset of event	
	Stop date (and time) or duration of event	
	Dechallenge and rechallenge information	
	Setting (e.g. hospital, outpatient clinic, home, nursing home)	
7	Outcome:	
	Information on recovery and any sequelae; results of specific tests or treatment that may have been conducted	
	For a fatal outcome cause of death and a comment on its possible relationship to the suspected event. Any post-mortem findings	
	Other information: anything relevant to facilitate assessment of the case, such as medical history including allergy drug or alcohol abuse, family history, findings from special investigations etc.	
8	Details about the investigator*	
	Name and address	
	Telephone number	
	Profession (Specialty)	
	Date of reporting the event to Central Licensing Authority	
	Date of reporting the event to ethics committee overseeing the site:	
	Signature of the investigator or Sponsor	
	Note: Information marked * must be provided	

Appendix 2: IEC Checklist and Serious Adverse Event Report Assessment Form

SOP 11-B/V6.1 available at https://www.kem.edu/sae-annexures

Appendix 3: Timelines for reporting SAE

PI shall report all serious and unexpected adverse events to the Licensing Authority, the Sponsor or his representative and the Ethics Committee within **24 hours** of their occurrence.
PI shall be forwarded the report of the SAE, after due analysis, to the Licensing Authority, the Chairman of the Ethics Committee, and the Head of the institution within **14 days** of the occurrence.
The Sponsor or his representative shall submit details of compensation provided or paid for clinical trial related injury or death, to the Licensing Authority within **30 days** of the receipt of the order of the Licensing Authority

8. Abbreviations:

i.	CDSCO	: Central Drugs Standard Control Organization
ii.	Co-I	: Co-Investigator
iii.	CRF	: Case Record Form
iv.	GCP	: Good Clinical Practice
v.	ICH	: International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use
vi.	ICMR	: Indian Council of Medical Research
vii.	IEC	: Institutional Ethics Committee
viii.	OPD	: Out Patient Department
ix.	OTC	: Over The Counter
x.	PI	: Principal investigator
xi.	SAE	: Serious Adverse Event
xii.	SOP	: Standard Operating Procedure

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