Title: Adverse Events (AE) Reports: Review and Management

SOP Code: SOP12/v3

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Prepared by:

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1. **Purpose:** The purpose of this Standard Operating Procedure (SOP) is to describe the procedures to be followed for the review and assessment of initial and follow-up reports of on-site and off-site adverse events (AE) and adverse drug reports (ADR) including serious adverse events (SAE) reported to the YEC-1 for any study approved by the Yenepoya Ethics Committee (YEC-1). The purpose of this SOP is also to describe the functioning of the SAE subcommittee.
2. **Scope:** This SOP applies to all the YEC-1 activities related to the review of AE/ADR reports related to AE/ADR including reports of on-site AEs/off-site AEs/on-site SAEs/off-site SAEs submitted to the YEC-1 and to the functioning of SAE subcommittee.
3. **Definitions:**
   - 3.1. **Adverse Event:** "An AE is any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and that does not necessarily have a causal relationship with this treatment. An AE can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal (investigational) product, whether or not related to the medicinal (investigational) product."[1]
   - 3.2. **Adverse Drug Report:** "In the pre-approval clinical experience with a new medicinal product or its new usages, particularly as the therapeutic dose(s) may not be established: all noxious and unintended responses to a medicinal product related to any dose should be considered adverse drug reactions. The phrase responses to a medicinal product means that a causal relationship between a medicinal product and an adverse event is at least a reasonable possibility, i.e., the relationship cannot be ruled out.
     Regarding marketed medicinal products: a response to a drug which is noxious and unintended and which occurs at doses normally used in man for prophylaxis, diagnosis, or therapy of diseases or for modification of

[1] ICH GCP-Guideline https://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R2__Step_4_2016_1109.pdf accessed on 24 September 2019 at 1045

physiological function."[2]

3.3. **Serious Adverse Event or Serious Adverse Drug Reaction:** "An AE or ADR that is associated with death, inpatient hospitalization (in case the study was being conducted on out-patients), prolongation of hospitalization (in case the study was being conducted on in-patients), persistent or significant disability or incapacity, a congenital anomaly or birth defect, or is otherwise life threatening."[3]

"An adverse event is serious when the research outcome for the participant is death, life-threatening injury requiring hospitalization, prolongation of hospitalization, significant disability/incapacity, congenital anomaly, or requirement of intervention to prevent permanent impairment or damage."[4]

4. Responsibilities:

4.1. YEC-1 Chairperson will:

4.1.1. Nominate members for the SAE subcommittee

4.1.2. Oversee the functioning of the SAE subcommittee

4.2. YEC-1 Member-Secretary will:

4.2.1. Communicate the nomination of the SAE subcommittee members to the Registrar, Yenepoya deemed to be University

4.2.2. Communicate the notification of the SAE subcommittee to the Chairperson and the concerned members

4.2.3. Be an ex-officio member of the SAE subcommittee and provide logistic support to the SAE subcommittee to facilitate its smooth functioning

4.2.4. Table the minutes and reports of the SAE subcommittee in the YEC-1 meetings

4.2.5. Prepare the communication letters related to the adverse event reports.

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[2] ICH GCP-Guideline https://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6/E6_R2__Step_4_2016_1109.pdf accessed on 24 September 2019 at 1055

[3] https://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E2A/Step4/E2A_Guideline.pdf accessed on 24 Septembre 2019 at 1625

[4] ICMR's National Ethical Guidelines for Biomedical Research involving Human Subjects. 2017

4.2.6. Communicate with the YEC-1 members, regulatory authorities and investigators in a timely manner.

4.2.7. Provide necessary administrative support for SAE subcommittee related activities.

4.3. **Registrar, Yenepoya deemed to be University will:**

4.3.1. Notify the constitution of the SAE subcommittee

4.4. **YEC-1 SAE subcommittee Chairperson will:**

4.4.1. Ensure that all AEs/ADRs/SAEs are reviewed and necessary action taken in a timely manner.

4.4.2. Ensure that the quorum for the meeting is met.

4.4.3. The Chairperson of the SAE subcommittee will be responsible for conducting SAE subcommittee meetings, and will lead all discussions and deliberations pertinent to the review of adverse event reports including:

4.4.3.1. Determining the relatedness of SAE to the research

4.4.3.2. Determining quantum and type of assistance/compensation required for research participants as per the licencing authorities

4.4.3.3. Reviewing measures taken for SAEs

4.4.4. Ensure that the SAE subcommittee minutes and any SAEs reported are deliberated upon by the YEC-1 members

4.4.5. Nominate another SAE subcommittee member as acting Chairperson, if he/she anticipates being absent on the day of the meeting. The acting Chairperson will have all the powers of the Chairperson of SAE subcommittee for that meeting.

4.4.6. Approve the minutes of the SAE subcommittee meeting

4.5. **YEC-1 SAE subcommittee Executive Secretary will:**

4.5.1. Assign subcommittee members for review of AE/SAE reports, if required.

4.5.2. Prepare and circulate the agenda for the SAE subcommittee meeting

4.5.3. Schedule, organize and conduct the SAE subcommittee meetings.

4.5.4. Prepare and circulate the minutes of the SAE subcommittee meetings after due approval from the Chairperson

4.5.5. Communicate the decisions of the SAE subcommittee to the YEC-1 members in the YEC-1 meeting.

4.5.6. Ensure adherence of the SAE subcommittee functioning to the SOPs.

4.6. **YEC-1 SAE subcommittee member(s) will:**

4.6.1. Attend the meetings regularly and inform absence in writing

4.6.2. Review and assess the AEs/SAEs assigned to him/her, wherever applicable

4.7. **YEC-1 layperson will**

4.7.1. In addition to what is described in 4.6, monitor the compensation provided to the participants in case of SAEs

4.8. **YEC-1 Secretariat will:**

4.8.1. Receive communications from the PI regarding AEs/SAEs/Dear Investigator Letter (DIL) and inform the SAE subcommittee Chairperson/Executive Secretary

4.8.2. Provide support to the Chairperson/Executive Secretary of the SAE subcommittee in the conduct of its meetings, preparation of agenda and minutes

4.8.3. Maintain the files of the SAE subcommittee.

5. Detailed instructions:

5.1. **Formation of SAE subcommittee:**

5.1.1. The members of the SAE subcommittee will be suggested by the YEC-1 members and approved by the Chairperson of YEC-1

5.1.2. The Registrar of the Yenepoya deemed to be University will notify the subcommittee.

5.2. **Composition of SAE subcommittee**:

5.2.1. The SAE subcommittee will be composed of at least 4 and a maximum of 10 members from within the YEC-1.

5.2.2. The SAE subcommittee will be multidisciplinary and multi-sectoral in composition.

5.2.3. The committee will consist of members who collectively have the qualifications and experience to review and evaluate the scientific, medical and ethical aspects of adverse event reports involving human participants.

5.3. **Members of the SAE subcommittee:** the SAE subcommittee will consist of

5.3.1. Chairperson

5.3.2. Executive Secretary

5.3.3. At least one member with postgraduate qualification in the discipline of Medicine or Pharmacology or any other relevant clinical specialty

5.3.4. The YEC-1 Member-Secretary shall be an ex-officio member of the SAE subcommittee.

5.3.5. The SAE subcommittee may invite the legal expert of YEC-1 to provide opinion on the legal implication of adverse event.

5.4. **Quorum for the SAE subcommittee meetings:** A quorum will consist of at least 3 members as follows:

5.4.1. Chairperson/Acting Chairperson of the SAE subcommittee

5.4.2. Executive Secretary and

5.4.3. One member (preferably pharmacologist)

5.5. **Tenure and terms of reference of the SAE subcommittee members:**

5.5.1. The tenure of SAE subcommittee will be for a continuous period from the date of appointment until the end of the tenure of the existing YEC-1 committee/SAE subcommittee members.

5.5.2. The SAE subcommittee may be reconstituted each time the YEC-1 is reconstituted, or if the existing subcommittee members have changed.

5.5.3. A YEC-1 member will be eligible to be appointed for the new tenure of the SAE subcommittee consecutively for three terms.

5.5.4. An SAE subcommittee member is expected to attend the regular and extraordinary meetings and contribute responsibly to the review and

decision making on SAE related reports.

5.5.5. When an SAE subcommittee member is unable to attend the meeting, he/she will inform the Executive Secretary in writing or by email.

5.5.6. An SAE subcommittee member may resign from membership by submitting a letter of resignation to the Executive Secretary of the SAE subcommittee. The member may or may not assign reasons for resignation.

5.5.7. A member may be liable to be disqualified from the SAE subcommittee if the member fails to attend more than 3 consecutive SAE meetings without prior intimation in writing.

5.5.8. The Chairperson of the SAE subcommittee will inform the Chairperson YEC-1, in writing, if a member has not attended 3 consecutive meetings of the SAE subcommittee.

5.5.9. The Chairperson, YEC-1 will take up the issue of disqualification for discussion at the YEC-1 meeting and allow the concerned SAE subcommittee member to state his reasons for unauthorized absence.

5.6. **Schedule of the SAE subcommittee meetings**

5.6.1. The ordinary meetings of the SAE subcommittee will be conducted at least once a month.

5.6.2. In the event of a report of SAE, the subcommittee will convene an extraordinary meeting within two calendar days of receiving the SAE report at the YEC-1 office and may conduct such meetings as many times as necessary depending on the developments.

5.7. **Timelines for the PI/Sponsor/YEC-1 to submit SAE reports:**

5.7.1. Initial SAE report will be submitted by the Principal Investigator (PI) within 24 hours of occurrence as per the format specified in Ann01/SOP12/v3.

5.7.2. Due analysis will be submitted by the PI/sponsor within 14 calendar days in the format specified in Ann02/SOP12/v3.

5.7.3. The opinion of YEC-1 with regard to causality and compensation will

be communicated to the Drugs Controller General of India, Central Drugs Standard Control Organization, Ministry of Health and Family Welfare, Government of India within 30 calendar days of receiving the SAE report.

5.7.4. The follow up reports of all on-site SAEs till the events are resolved will be submitted by the PI as and when required.

5.8. **On-site SAE reporting:**

5.8.1. **Receipt of on-site SAE related reports by the YEC-1:**

5.8.1.1. The YEC-1 Secretariat will receive, sign and date the report

5.8.1.2. The Secretariat will inform the reports to the YEC-1 SAE subcommittee Executive Secretary on the same day of receiving the report

5.8.1.3. The YEC-1 SAE subcommittee Executive Secretary will verify the completeness of the report and adherence to timelines

5.8.1.4. If the report has been received beyond the specified time, it will be considered as a protocol violation and action will be taken as described in SOP11/v3.

5.8.2. **Review of on-site SAE Reports:**

5.8.2.1. The YEC-1 SAE subcommittee Executive Secretary will review the reports of the SAE-related reports. Alternatively, the Executive Secretary will assign reviewer from within the SAE subcommittee to review the report and present in the meeting.

5.8.2.2. The YEC-1 SAE subcommittee Executive Secretary, in collaboration with the Member-Secretary, YEC-1, will review the seriousness and urgency of the SAE and decide to call an extraordinary meeting of the SAE subcommittee within 2 calendar days or consider the matter for the subsequent SAE subcommittee meeting as per the schedule.

5.8.2.3. The reviewers will take into consideration the possibility of research-related causality, the quantum of harm caused, the

quantum of compensation, the immediate and ancillary care provided to the participant, and the need for change in protocol/informed consent documents to safeguard the participants in view of the SAEs.

5.8.2.4. Even before the SAE subcommittee meets to discuss and deliberate on the SAE report, the Executive Secretary can write to the PI seeking further clarification. The report and the clarification(s) can be tabled together for discussion in the SAE subcommittee meeting.

5.8.3. **SAE subcommittee meeting (for on-site SAE reporting):**

5.8.3.1. The Executive Secretary/reviewing member will present the findings to the SAE subcommittee in the meeting

5.8.3.2. The members will discuss the findings of the SAE reports and clarifications (if any), with a special focus on relatedness to the clinical trial, medical management and financial compensation to be given to the research participants.

5.8.3.3. The SAE subcommittee will discuss the compensation issues based on the current applicable formulae and guidelines from the regulatory authority[5], including formula for calculating the amount of compensation in case of study-related death[6,7] and study-related injury other than death[8].

5.8.3.4. The SAE subcommittee may refer the SAE report to the YEC-1 for review if deemed necessary.

5.8.3.5. The SAE subcommittee may even decide to call an emergency YEC-1 meeting to decide on the financial compensation issues, if deemed necessary within 2 calendar days of the decision.

5.8.3.6. If deemed necessary, the SAE subcommittee may seek the

[5] http://cdsco.nic.in/writereaddata/GSR%2053(E)%20dated%2030.01.2013.pdf
[6] http://www.iscr.org/pdf/Gazaate_notification.PDF dated 12th December 2014,
[7] http://www.cdsco.nic.in/writereaddata/formula2013SAE.pdf
[8] http://www.cdsco.nic.in/writereaddata/uploaded_for_website.htm

opinion of an Independent expert to establish relatedness and medical management as per SOP04/v3.

5.8.3.7. The Executive Secretary will prepare the minutes within 2 calendar days of the meeting.

5.8.4. **YEC-1 emergency meeting (for on-site SAE reporting:**

5.8.4.1. If the Executive Secretary perceives the need, an emergency YEC-1 meeting may be scheduled within 2 calendar days from the SAE subcommittee meeting

5.8.4.2. The Executive Secretary will present the findings in the SAE subcommittee meeting to decide on the relatedness, medical management and financial compensation

5.8.5. **YEC-1 Scheduled Meeting (for on-site SAE reporting):**

5.8.5.1. The Executive Secretary will present the findings in the YEC-1 meeting to inform the members on the relatedness, medical management and financial compensation

5.8.5.2. Minutes of the SAE subcommittee/emergency YEC-1 meeting will be read, discussed and approved in the YEC-1 meeting.

5.8.5.3. The minutes will be circulated to the YEC-1 members via email and approval/objection will be sought from the members in a period of 5 calendar days.

5.8.6. **Decision making (for on-site SAE reporting):**

5.8.6.1. The following should be considered during the decision making

5.8.6.1.1. The outcome of the SAE

5.8.6.1.2. The possible relatedness to the intervention

5.8.6.1.3. The number of participants and bystanders affected

5.8.6.1.4. The immediate and ancillary medical care provided

5.8.6.1.5. Compensation

5.8.6.1.6. Need for change in the protocol/informed consent process/participant information sheet

5.8.6.1.7. Need for change in the research team/training

5.8.6.1.8. Need for withholding the investigational drug

5.8.6.1.9. Need for suspending/terminating the study

5.8.6.1.10. Need for site monitoring

5.8.6.1.11. Adherence to timelines of SAE reporting and protocol deviations/violations, if any

5.8.6.1.12. Need for more clarification

5.8.7. **Type of Actions Taken by SAE subcommittee on Review of SAE Report:** Following detailed review of the SAE reports and related documents, the SAE subcommittee can suggest one of the following actions:

5.8.7.1. Note the information about the SAE in records for future reference

5.8.7.2. Request further follow-up information and/or additional details

5.8.7.3. Ask for periodic follow-up of the research participant till SAE is resolved

5.8.7.4. Depending on the complexities of the issue, YEC-1/ SAE subcommittee may decide to seek the opinion of outside expert consultant who will be requested to respond within 14 calendar days.

5.8.7.5. Provide recommendations regarding/raise queries related to compensation for study related injury and death.

5.8.8. **Type of possible actions taken by YEC-1 following full review:**

5.8.8.1. The YEC-1 may take one or more of the following decisions on review of the on-site SAE report:

5.8.8.1.1. Suggest changes amendments in protocol, participant information sheet/informed consent document/ investigator brochure/any other study-related documents.

5.8.8.1.2. Suspend the study until additional information is

available.

5.8.8.1.3. Suspend the study till review is completed (safety monitoring of ongoing patients to be continued).

5.8.8.1.4. Suspend the study until the amendments requested by YEC-1 are carried out.

5.8.8.1.5. Suspend enrollment of new participants.

5.8.8.1.6. Suspend certain activities under the protocol.

5.8.8.1.7. Direct the PI to inform participants already enrolled in the study about the AEs and if required obtain their consent again (re-consent) regarding continuation in the research trial.

5.8.8.1.8. Direct the PI to inform participants already enrolled in the study about the AE and request them to undertake additional visits, additional procedures, additional investigations, etc as prescribed in the amendment.

5.8.8.1.9. Inform the Yenepoya deemed to be University authorities if the PI is not cooperating with YEC-1.

5.8.8.1.10. Any other appropriate action

5.8.8.2. Decision shall be recorded in the minutes of YEC-1 meeting.

5.8.8.3. The decision of the YEC-1 requiring immediate action, from the PI, will be conveyed to the PI through email within 24 hours. Such a communication will be documented by the YEC-1 Member-Secretary in the study file.

5.8.8.4. A formal letter to the PI informing about the YEC-1 recommendations in such situations will be sent within 5 calendar days of the YEC-1 meeting having taken place.

5.8.9. **YEC-1 communications and archiving (for on-site SAE reporting):**

5.8.9.1. The YEC-1 Member-Secretary will draft a letter to the concerned PI and inform him/ her about the YEC-1 decision. This letter will be signed and dated by the Member-

Secretary/Chairperson and sent to the PI within 7 calendar days from the date of SAE subcommittee meeting.

5.8.9.2. If there is a need for more clarification, the YEC-1 Member-Secretary will request the PI to reply to the query letter on the SAE report within 7 calendar days.

5.8.9.3. The opinion regarding relatedness, medical management and compensation for research-related injury will be communicated to the central licensing authority (DCGI) within 30 calendar days of the occurrence of the SAE in case of regulatory clinical trials.

5.8.9.4. The YEC-1 will confirm the nature of action taken by the PI/Sponsor regarding the management of the AEs as per the existing guidelines, including ancillary care, emergency care and compensation paid.

5.8.9.5. YEC-1 Secretariat will file a copy of the letters in the study file

5.9. **Reporting of the off-site AE/ADR/SAE (DIL):**

5.9.1. **Receipt of off-site AE/ADR/SAE (DIL) and related reports by the YEC-1:**

The investigator will submit the off-site AE/ADR/SAE reports (also known as Dear Investigator Letter - DIL) occurring at other sites in the form of soft /hard copies along with a covering letter mentioning the total number of reports and its details as per the format: (Ann2B/SOP12/v3) with details of each SAE separately and its relatedness to the investigational product.

5.9.2. **Review of the off-site AE/ADR/SAE (DIL):**

5.9.2.1. The off-site AE/ADR/SAE (DIL) will be reviewed by the YEC-1 SAE subcommittee Executive Secretary/Member and tabled for the subsequent SAE subcommittee meeting.

5.9.2.2. The subcommittee will take into consideration the need for change in protocol/informed consent documents to safeguard

the participants in view of the AE/ADR/SAE.

5.9.3. **SAE subcommittee meeting (for off-site AE/ADR/SAE):**

5.9.3.1. The off-site AE/ADR/SAE (DIL) will be discussed with regard to the outcome and relatedness to the investigational product and the possible impact on the participants

5.9.3.2. The minutes of the SAE meeting will be tabled for discussion in the subsequent YEC-1 meeting.

5.9.3.3. **YEC-1 Meeting (for off-site AE/ADR/SAE - DIL):** The minutes of the SAE subcommittee will be read out and discussed with the YEC-1 members.

5.9.3.4. **Decision making (for off-site AE/ADR/SAE - DIL):** The agenda and minutes of the meeting will include decision based on the information on SAEs at other sites.

5.9.3.5. **Communication and Filing (for off-site AE/ADR/SAE):**

5.9.3.5.1. The Secretariat YEC-1 will sign one copy of the covering letter that is submitted by the PI to acknowledge the receipt of the DIL report.

5.9.3.5.2. After the discussion and deliberations in the YEC-1 meeting, the Secretariat will file a copy of these reports and communications in the study file.

6. References to other applicable SOPs

6.1. **SOP 7A/v3** - Initial Full Review of Research Study Protocols

6.2. **SOP 08/v3** - Agenda Preparation, Meeting Procedures and Recording of Minutes

6.3. **SOP 10/v3** - Continuing Review of Study Protocols

7. Annexures

7.1. Ann01/SOP12/v3: Checklist for Adverse Events/Serious Adverse Event (SAE) submission (For Onsite SAE)

7.2. Ann02/SOP12/v3: Checklist for Adverse Event/Adverse Drug Reaction/ Serious Adverse Event (SAE) submission (For Offsite SAE)

Annexure 1: Ann01/SOP12/v3

Checklist for Adverse Events/Serious Adverse Event (SAE) submission

(For Onsite SAE)

Sl No.	**Details**		
1.	**Country** (Name of the country should be specified)		
2.	**SAE report of death or other than death** **Please tick (✓)**	**Death** **Yes/No**	**Other than death** **Yes/No**
3.	**In case of Serious Adverse Event(SAE), please specify if there is any injury to the participant** (Please specify Yes/No) in the box	**Yes/No**	
4.	Protocol Title		
5.	Protocol Study No./ ID /Code		
6.	Copy of Clinical Trial permission obtained from CDSCO		
7.	CTRI Registration No.		
8.	Sponsor (Address with contact no and Email)		
9.	CRO (Address with contact no and Email)		
10.	Initial/Follow-up (FU)		
11.	In case of follow-up: Date & Diary no of initial or recently submitted report information		
12.	**Participant Details:** Initials & other relevant identifier (hospital/OPD record number etc.) Gender Age and/or date of birth Weight Height		

13	**Nature of the intervention:** a. Suspected Drug(s) i. Generic name of the drug ii. Indication(s) for which suspect drug was prescribed or tested iii. Dosage form and strength iv. Daily dose and regimen (specify units - e.g., mg, ml, mg/kg) v. Route of administration vi. Starting date and time of day vii. Stopping date and time, or duration of treatment b. Any other intervention (specify) *Provide the same information for concomitant drugs (including non prescription/ OTC drugs) and non-drug therapies, as for the suspected drug(s).*	
14	**Details of clinical findings:** a. Full description of reaction(s) including body site and severity, as well as the criterion (or criteria) for regarding the report as serious. b. In addition to a description of the reported signs and symptoms, whenever possible, assign a specific diagnosis for the reaction. c. Start date (and time) of onset of reaction. d. Stop date (and time) or duration of reaction. e. Dechallenge and rechallenge information (if any) f. Setting (e.g. hospital, out-patient clinic, home, nursing home).	

15	**Outcome:** a. Required hospitalization: Yes/No b. Number of admission days: c. Please provide results of specific tests and other laboratory reports (if any) that were carried out in relation to the adverse event: d. Details of the treatment provided (including any procedures or surgeries or any other interventions done in relation to the adverse event): e. Details on the recovery or other sequelae: f. If discharge summary is available please provide a copy: g. Is there a permanent disability or functional loss? h. Is the adverse event associated with a congenital anomaly? i. For a fatal outcome, cause of death and a comment on its possible relationship to the suspected reaction (include post mortem findings - if any):	
16.	**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*	

17.	**Details about the Investigator** CT Site number, if any Name Address Telephone/Mobile Number & Email Profession (speciality) Date of reporting the event to Licensing Authority Date of reporting the event to Yenepoya Ethics Committee - 1	
18	**Details about Yenepoya Ethics Committee - 1** Name and address Name of Chairman & Address Telephone/Mobile Number Email Whether EC is recognized by DCGI	Yes/No
20	**Causality assessment** by investigator.	Related/Unrelated
21	**Causality Assessment** by sponsor/CRO	Related/Unrelated
22	**Details of compensation provided for injury or death.** *In case no compensation has been paid, reason for the same*	
23	**Other related documents:** a. Duly filled SAE Form as per current regulations b. Post-mortem report (if applicable) c. Any additional documents	

24	**Details of payment for medical management of SAE?** (please give information who paid, how much was paid, to whom and evidence of the same.	
25	**What is the investigator's assessment for the amount of compensation to be paid?**	
26	**What is the sponsor's assessment for the amount of compensation to be paid?**	
27	**Has the participant made a claim?**	Yes/No Comment
28	**If yes for 27, then, for how much amount?**	
29	**If no, please ensure that the participant/nominee have been made aware of his/her rights regarding compensation.** *Please submit documentation regarding the same*.	
30	**Signature of the Principal Investigator with date**	

Note: Information not relevant to a particular SAE should be marked with NA

Ann02/SOP12/v3: Checklist for Adverse Event/Adverse Drug Reaction/ Serious Adverse Event (SAE) submission (For Offsite SAE)

Sr. No.	Details		
1.	**Country** (Name of the country should be specified)		
2.	**SAE report of death or other than death** Please tick (✓)	**Death** Yes/No	**Other than death** Yes/No
3.	**In case of Serious Adverse Event (SAE), please specify if there is any injury to the participant** (Please specify Yes/No) in the box	Yes/No	

4.	If not SAE, then reporting as AE/ADR?	Yes/No
5.	Protocol Title	
6.	Protocol Study No./ ID /Code	
7.	Copy of Clinical Trial permission obtained from CDSCO for the centre overseen by YEC-1	
8.	CTRI Registration No.	
9.	Sponsor(Address with contact no and Email)	
10.	CRO (Address with contact no and Email)	
11.	Initial assessment of participant/ Follow-up (FU)	
12.	In case of follow-up: Date & Diary no of initial or recently submitted report information	
13.	**Participant Details:** Initials & other relevant identifier (hospital/OPD record number etc.)\ Gender Age and/ or date of birth Weight Height	

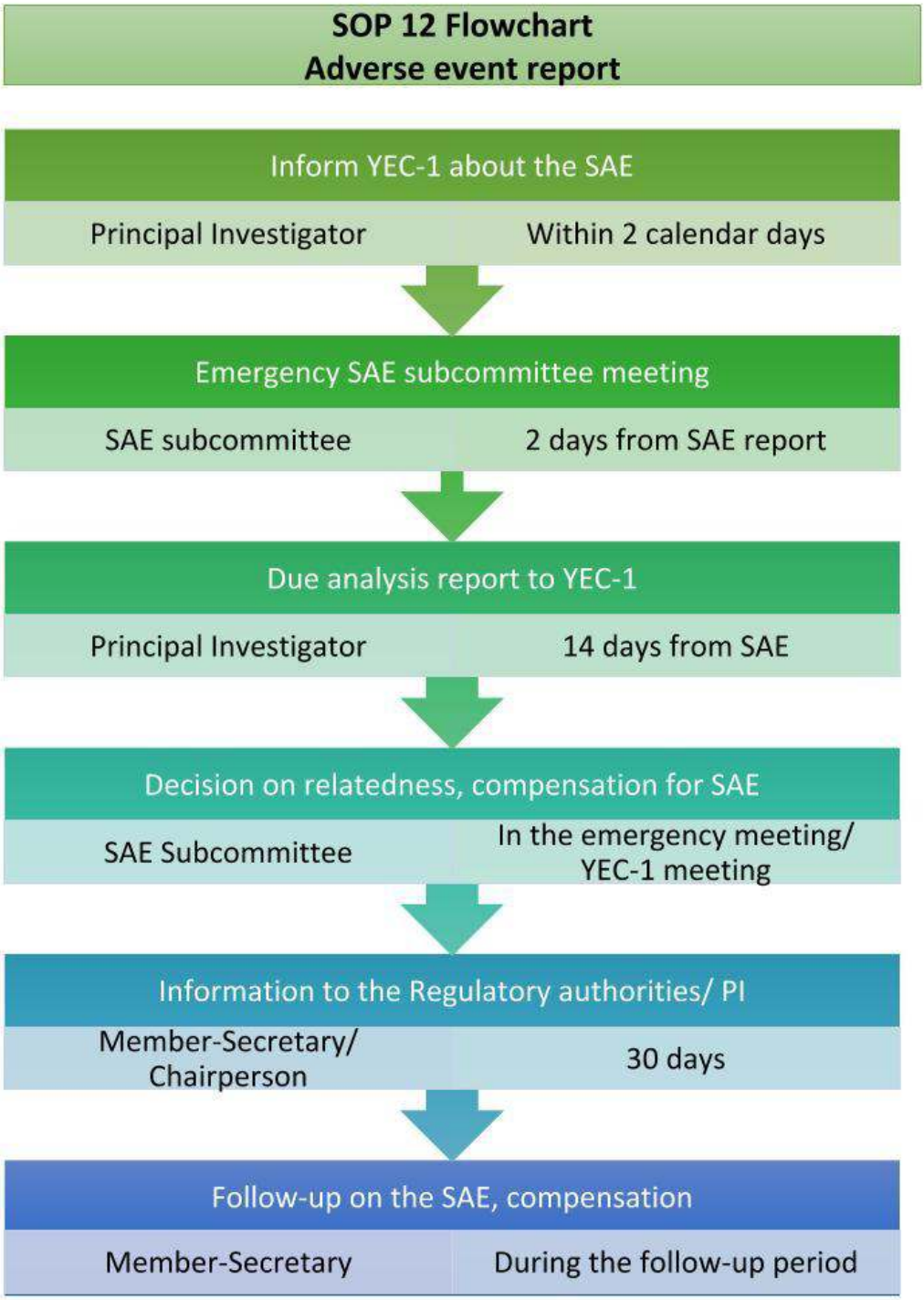
14.	**Nature of the intervention:** Suspected Drug(s) i. Generic name of the drug ii. Indication(s) for which suspect drug was prescribed or tested iii. Dosage form and strength iv. Daily dose and regimen (specify units - e.g., mg, ml, mg/kg) v. Route of administration vi. Starting date and time of day vii. Stopping date and time, or duration of treatment b. Any other intervention (specify) *Provide the same information for concomitant drugs (including non prescription/ OTC drugs) and non-drug therapies, as for the suspected drug(s).*	
15.	**Details of clinical findings:** a. Full description of reaction(s) including body site and severity, as well as the criterion (or criteria) for regarding the report as serious. b. In addition to a description of the reported signs and symptoms, whenever possible, assign a specific diagnosis for the reaction. c. Start date (and time) of onset of reaction. d. Stop date (and time) or duration of reaction. e. Dechallenge and rechallenge information (if any) f. Setting (e.g. hospital, out-patient clinic, home, nursing home).	

16.	**Outcome:** a. Required hospitalization: Yes/No b. Number of admission days: c. Please provide results of specific tests and other laboratory reports (if any) that were carried out in relation to the adverse event: d. Details of the treatment provided (including any procedures or surgeries or any other interventions done in relation to the adverse event): e. Details on the recovery or other sequelae: f. If discharge summary is available please provide a copy: g. Is there a permanent disability or functional loss? h. Is the adverse event associated with a congenital anomaly? i. For a fatal outcome, cause of death and a comment on its possible relationship to the suspected reaction (include post mortem findings - if any):	
17.	**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*	

18.	**Details about the Investigator** CT Site number, if any Name Address Telephone/Mobile Number & Email Profession (speciality) Date of reporting the event to Licensing Authority Date of reporting the event to Ethics Committee overseeing the site Signature of the Investigator	
19.	**Details about the Ethics Committee** Name and address Name of Chairman & Address Telephone/Mobile Number Email Whether EC is recognized by DCGI	Yes/No
20.	Causality assessment by investigator	Related / Unrelated
21.	Causality Assessment by sponsor/CRO	Related / Unrelated
22.	Details of compensation provided for in case of injury or death. *In case no compensation has been paid, reason for the same*	
23.	**Other related documents:** a. Duly filled SAE Form as per current regulations b. Post-mortem report (if applicable) c. Any additional documents	

Note: Information not relevant to a particular SAE should be marked with NA

7. Flowchart:


SOP 12 Flowchart
Adverse event report
Inform YEC-1 about the SAE
Principal Investigator
Within 2 calendar days
Emergency SAE subcommittee meeting
SAE subcommittee
2 days from SAE report
Due analysis report to YEC-1
Principal Investigator
14 days from SAE
Decision on relatedness, compensation for SAE
SAE Subcommittee
In the emergency meeting/ YEC-1 meeting
Information to the Regulatory authorities/ PI
Member-Secretary/ Chairperson
30 days
Follow-up on the SAE, compensation
Member-Secretary
During the follow-up period