KEMRI | Wellcome Trust
Clinical Trials

# Study Specific Procedure	**SOP No:** 012 **Version No:** 2.0 **Supersedes:** 1.0 **Effective Date:**

Title: ADVERSE EVENT REPORTING

	NAME	**SIGNATURE**	**DATE**
PREPARER	Shalton Mwaringa		
REVIEWING AUTHORITY	Laura Mwalekwa		
QUALITY ASSURANCE AUTHORITY	Aisha Bwika		
APPROVING AUTHORITY	Caroline Ogwang		

1.0 PURPOSE:

The purpose of this SSP is to guide reporting of serious adverse events (SAEs) and grade 4 toxicity events in the study. These will not be reported for FC non-SAM participants.

2.0 SCOPE / RESPONSIBILITY:

2.1 This SSP applies to all clinicians and nursing staff, involved in the clinical management of study participants.

2.2 SAE and toxicity forms will be completed by clinicians at site as close to the occurrence as possible.

2.3 A summary report of all SAEs and suspected toxicity events will be reported every 3 months to the LSM, the national ethics and regulatory committees and sponsor.

2.4 The Principal Investigator through the lead clinician retains the overall responsibility on implementation of this SSP.

3.0 DEFINITIONS:

3.1 **AE's** Adverse Events

3.2 **LSM** Local Safety Monitor

3.3 **DSMC** Data & Safety Monitoring Committee

3.4 **PI** Principle Investigator

3.5 **SAEs** Serious Adverse Events

3.6 **SSP** Study Specific Procedure

3.7 **SUSAR** Suspected and Unexpected Serious Adverse Reaction

3.8 **Serious Adverse Event (SAE)**: Any untoward medical occurrence or effect that is:

i. Death (from any cause at any time)

ii. Life-threatening event (i.e., the subject was, in the view of the investigator, at immediate risk of death from the event that occurred).

iii. Persistent or significant disability or incapacity (i.e., substantial disruption of ability to carry out normal life functions).

iv. Hospitalisation or an important medical event requiring medical or surgical intervention to prevent one of the outcomes listed above. Examples include severe

adverse drug reactions such as severe allergic reaction or blood dyscrasias requiring intensive treatment.

4.0 EQUIPMENT / MATERIALS:

4.1 Serious Adverse Events Form

4.2 Toxicity form

4.3 Pens

5.0 METHODOLOGY:

5.1 Introduction and general consideration

1. Children admitted to hospital with complicated SAM are highly likely to experience many clinical events and deteriorations including mortality, often related to their background clinical condition. The FLACSAM study will use marketed routinely used drugs whose safety profile is well established and documented. However, there are rare reported toxic events that could result from the trial drugs.
2. Serious Adverse Events and grade 4 toxic events will be documented.

5.2 SAE/Toxicity/SUSAR reporting

1. If an adverse event occurs in a participant and meets the criteria for SAE (see definition above) or grade 4 toxic event (see appendix 1 below) the clinician should consider this as an SAE/toxic event requiring reporting. NB: Some toxic events may require reporting in addition as an SAE where they meet the criteria for an SAE.
2. Should there be an emergency or serious safety concern the clinical lead/ chief investigator /LSM should be informed immediately when the event is identified.
3. The site clinician will document the event in the patient's ward file / clinical notes, the investigations done and the management of the SAE. This should continue throughout the progress of the event until an outcome is arrived at. Recording will also begin the SAE CRF/toxicity form CRF whichever applicable.
4. At resolution of the event, the clinician will summarize the entire SAE/grade 4 toxic event in the SAE form/toxicity form of the CRF or both where applicable.
5. Data entry will be done in the eCRF/ database once entry in SAE/toxicity form has been completed. The P.I or designee will compile a summary of all SAEs and suspected grade 4 toxic events which will be reported every 3 months. The report will

include the site; study number; date of event; subject details (initials, sex and age); nature of event; relevant history; outcome and a judgement of causality. This report will be sent to the LSM, DSMC, the ethical research committees and regulatory committees. If the PI/designee requires further details, clinical notes or their scan shall be provided to contribute to report writing.

6. SAEs that are deemed causally related to the study drug and SUSARs will be initially reported to the sponsor, DSMC and regulatory bodies within 7 days of the investigators becoming aware of the event with a follow up report being provided within a further 8 calendar days.

6.0 APPENDICES

Appendix 1: Pre-defined Grade 4 suspected toxicity events

New episodes of:

Allergic and Cutaneous reactions one or more of:	• Anaphylaxis • Bronchospasm requiring treatment • Exfoliative dermatitis		
Severe anaemia **Neutropenia** **Thrombocytopenia**	• Severe anaemia • Neutrophil count • Platelets	Hb	<4g/dl <0.4 x 10^9 /L <25 x 10^9 /L
Encephalopathy & Neurological one or more of:	• Impaired consciousness: • Convulsions • New focal neurological signs	AVPU	P or U
	• >3.5 x upper limit of normal:	Creatinine	>138 µmol/L
Abnormal liver function one or more of:	• >10 x upper limit of normal:	ALT AST ALP	>450 IU/L >620 IU/L >4,060 IU/L
	• >5 x upper limit of normal:	Bilirubin	>63 µmol/L

7.0 REFERENCES:

7.1 Study protocol.

7.2 Pre-defined Grade 4 suspected toxicity events

7.3 SAE form

7.4 Toxicity form

8.0 DOCUMENT CHANGE HISTORY

Version Table:

Version 1: Title: **Adverse Event Reporting SOP**	Dated: **13/07/2017**	SOP No.:**012**	No. Pages: **5**
Version 2: Title: **Adverse Event Reporting SSP**	Dated: **26/11/2019**	SOP No.:**012**	No. Pages: **6**
Version 3: Title:	Dated:	SOP No.:	No. Pages:

SOP Review and Updating Logs

DATE	NAME OF REVIEWER	SIGNATURE	REASON FOR REVIEW
26/11/2019	Laura Mwalekwa		• Periodic SOP review • Adopted the SSP template.

SSP AWARENESS LOG

I, the undersigned below, hereby confirm that I am aware that the accompanying SSP is in existence from the date stated herein and that I shall keep abreast with the current and subsequent SSP versions in fulfilment of Good Clinical Practice (GCP).

Number	Name	Signature	Date (dd/mmm/yyyy)
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