



Patient Initials [][][][][]

PB-SAM Number [2][0][][][][]

Serious Adverse Event - A

| 1. SAE INITIAL DETAILS | | |
|------------------------|--|--|
| 1.1. | DATE of SAE onset | ____/____/_____ D D/M M/ Y Y Y Y |
| 1.2. | DATE child seen or information received by research team | ____/____/_____ D D/M M/ Y Y Y Y |
| 1.3. | Classification at presentation <i>When the study team first became aware of the SAE. Tick the highest <u>one</u> applicable</i> | <input type="checkbox"/> Death <input type="checkbox"/> Readmission to study hospital <input type="checkbox"/> Readmission to non-study hospital <input type="checkbox"/> Readmission is indicated but parent/carer declines admission <input type="checkbox"/> Life-threatening event <input type="checkbox"/> Persistent or significant disability/incapacity <input type="checkbox"/> Event that prolongs hospitalisation whilst already in hospital (deterioration) <input type="checkbox"/> Other serious medical event where medical intervention was required e.g. new diagnosis of TB, sickle cell disease |
| 1.4. | Reported by <i>(Tick one)</i> | <input type="checkbox"/> Parent/caregiver <input type="checkbox"/> Health Professional <input type="checkbox"/> From medical records or discharge letter |
| 1.5. | On study drugs at the onset of the SAE? <i>(tick all that apply)</i> | <input type="checkbox"/> None <input type="checkbox"/> Pancreatic enzymes/Placebo <input type="checkbox"/> Urso/Placebo |
| 1.6. | Any other medication in the last 7 days prior to onset of SAE? <i>(tick all that apply)</i> <i>Give details with specific medications used in the text box below (section 1.07)</i> | <input type="checkbox"/> No medication <input type="checkbox"/> Antibiotics <input type="checkbox"/> Antimalarial <input type="checkbox"/> IV fluids <input type="checkbox"/> Blood Transfusion <input type="checkbox"/> Anticonvulsants <input type="checkbox"/> Anti-TB <input type="checkbox"/> ART <input type="checkbox"/> Traditional or Herbal <input type="checkbox"/> Co-trimoxazole <input type="checkbox"/> Yes, but unknown <input type="checkbox"/> Other _____ |
| 1.7. | Circumstances: What was the SAE, where and when did it occur, was there any relation to timing of study drug administration or other procedure, or relation to any other medication, who was involved? Describe any background factors or co-morbidities that may have contributed to the SAE event | |



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| | |
|-------|---|
| 1.8. | <p>Describe the <u>new</u> clinical features of this SAE event (<i>describe clinical findings from examination, medical records, or from caregiver</i>)</p> |
| 1.9. | <p>Describe any investigations or changes to lab results <u>RELEVANT</u> to this SAE event for its diagnosis or management* (<i>i.e. Were there investigations done to investigate this SAE? The text needs to be sufficient to enable an independent reviewer to assess severity, type of illness and whether there is relationship to study drugs/medications</i>)</p> |
| 1.10. | <p>Describe the initial treatment given or other actions taken for this SAE*</p> |
| 1.11. | <p>Describe the response to initial treatment *</p> |
| 1.12. | <p>Describe any further clinical investigations and clinical progress*</p> <p><i>* write N/A if not applicable (e.g. death in the community)</i></p> |
| 1.13. | <p>Suspected initial diagnosis for the cause of the SAE (e.g. pneumonia, sepsis etc)</p> <hr/> <hr/> |



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2.0 Additional Documentation

| | | |
|-----|---|---|
| 2.1 | Is there any additional documentation for this SAE | <input type="checkbox"/> YES <input type="checkbox"/> NO |
| 2.2 | <p>If Yes, select all that apply</p> <p><i>(Make copies of selected documents, certify and attach to the SAE CRF)</i></p> | <input type="checkbox"/> Clinical notes <input type="checkbox"/> Lab results <input type="checkbox"/> X ray <input type="checkbox"/> Death certificate <input type="checkbox"/> Discharge summary <input type="checkbox"/> Other, Specify <hr/> |

3.0 PART A CRF COMPLETION

| | | |
|-----|---|---|
| 3.1 | a) CRF Completed by (Initials) – to be signed when complete. <i>Do not sign if any fields are empty</i> | _____ |
| | b) Date | ____/____/_____ <i>D D / M M / Y Y Y Y</i> |
| | c) Time | ____:____ <i>24 h clock</i> |

| | | |
|------|--------------------------------------|---|
| 3.2. | a) CRF Reviewed by (Initials) | _____ |
| | b) Date | ____/____/_____ <i>D D / M M / Y Y Y Y</i> |
| | c) Time | ____:____ <i>24 h clock</i> |



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Serious Adverse Event - B

4.0 SAE FINAL DETAILS

| | |
|-----|--|
| 4.1 | <p>Circumstances: What was the SAE, where and when did it occur, was there any relation to timing of study drug administration or other procedure, or relation to any other medication, who was involved? Describe any background factors or co-morbidities that may have contributed to the SAE event</p> |
| 4.2 | <p>Describe the additional clinical features of this SAE event (describe clinical findings from examination, medical records, or from caregiver)</p> |
| 4.3 | <p>Describe any investigations or changes to results <u>RELEVANT</u> to this SAE event for its diagnosis or management* (i.e. Were there investigations done to investigate this SAE? The text needs to be sufficient to enable an independent reviewer to assess severity, type of illness and whether there is relationship to study drugs/medications)</p> |
| 4.4 | <p>Describe the treatment given or other actions taken for this SAE*</p> |
| 4.5 | <p>Describe the response to treatment, any further clinical investigations and clinical progress* * write N/A if not applicable (e.g. death in the community)</p> |



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5.0 SAE CLASSIFICATION

| | | |
|--|--|--|
| 5.1 | End date <i>(dd/mm/yyyy)</i> | ___/___/___ or if no end date (<i>died, or recovered</i>) <i>D D / M M / Y Y Y Y</i> <input type="checkbox"/> On-going & receiving care <input type="checkbox"/> Unknown |
| 5.2 | Final Classification <i>Tick the highest <u>one</u> applicable</i> | <input type="checkbox"/> Death <input type="checkbox"/> Readmission to study hospital <input type="checkbox"/> Readmission to non-study hospital <input type="checkbox"/> Readmission is indicated but parent/carer declines admission <input type="checkbox"/> Life-threatening event <input type="checkbox"/> Persistent or significant disability/incapacity <input type="checkbox"/> Event that prolongs hospitalisation whilst already in hospital <input type="checkbox"/> Other serious medical event where medical intervention was required e.g. new diagnosis of TB, sickle cell disease |
| Was this event a suspected unexpected serious adverse reaction (SUSAR)? | | <input type="checkbox"/> Y <input type="checkbox"/> N |

6.0 RELATIONSHIP OF EVENT TO STUDY DRUGS

| | | |
|-----|--|--|
| 6.1 | No temporal relationship to drug; and alternate aetiology (clinical state, environmental or other interventions); and does not follow known pattern of response to study product | <input type="checkbox"/> No Relationship |
| | Unlikely temporal relationship to drug; and alternate aetiology likely (clinical state, environmental or other interventions); and does not follow known typical or plausible pattern of response to drug. | <input type="checkbox"/> Unlikely |
| | Reasonable temporal relationship to drug; or event not readily produced by clinical state, environmental or other interventions; or similar pattern of response to that seen with other drugs | <input type="checkbox"/> Possible |
| | Reasonable temporal relationship to drug; and event not readily produced by clinical state, environment, or other interventions or known pattern of response seen with other drugs | <input type="checkbox"/> Probable |
| | Reasonable temporal relationship to drug; and event not readily produced by clinical state, environment, or other interventions; and known pattern of response seen with study drugs | <input type="checkbox"/> Definite |



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7.0 DIAGNOSES OF THE CAUSES OF SAE

Do not include unchanged conditions that existed prior to the SAE. Tick up to THREE diagnoses.

Clinical diagnosis should be based on examination and investigation findings. Tick up to **three** most likely diagnoses.

| | | | | |
|-----|---------------------------|---|--|--|
| 7.1 | General | <input type="checkbox"/> Anaemia <input type="checkbox"/> Renal impairment <input type="checkbox"/> Liver dysfunction <input type="checkbox"/> Congenital cardiac disease confirmed by echo | <input type="checkbox"/> Sickle Cell Disease <input type="checkbox"/> Ileus <input type="checkbox"/> Nephrotic syndrome | <input type="checkbox"/> Thalassemia <input type="checkbox"/> Nephritis |
| 7.2 | Respiratory | <input type="checkbox"/> LRTI/pneumonia <input type="checkbox"/> Pulmonary TB <input type="checkbox"/> Otitis media | <input type="checkbox"/> Bronchiolitis <input type="checkbox"/> Asthma | <input type="checkbox"/> URTI <input type="checkbox"/> Aspiration e.g. of feed |
| 7.3 | Infection | <input type="checkbox"/> Gastroenteritis <input type="checkbox"/> Malaria <input type="checkbox"/> Extra pulmonary TB <input type="checkbox"/> HIV related illness <input type="checkbox"/> Osteomyelitis <input type="checkbox"/> Confirmed enteric fever | <input type="checkbox"/> Sepsis <input type="checkbox"/> Soft tissue infection <input type="checkbox"/> Measles <input type="checkbox"/> Febrile illness unspecified <input type="checkbox"/> Typhoid/paratyphoid with perforation | <input type="checkbox"/> Confirmed <input type="checkbox"/> UTI <input type="checkbox"/> Varicella |
| 7.4 | CNS | <input type="checkbox"/> Febrile convulsions <input type="checkbox"/> Other encephalopathy <input type="checkbox"/> Probable meningitis <input type="checkbox"/> LP confirmed meningitis <input type="checkbox"/> Confirmed diagnosis congenital syndrome | <input type="checkbox"/> Epilepsy <input type="checkbox"/> Hydrocephalus <input type="checkbox"/> Clinically suspected meningitis | <input type="checkbox"/> Cerebral palsy |
| 7.5 | Other confirmed diagnosis | <input type="checkbox"/> Failed appetite test only/severe malnutrition only (readmission). <input type="checkbox"/> Suspected drug toxicity (if due to study drug, complete toxicity CRF) <input type="checkbox"/> Other known diagnosis: _____ | | |

8.0 Additional Documentation

| | | |
|-----|--|---|
| 8.1 | Is there any additional documentation for this SAE | <input type="checkbox"/> YES <input type="checkbox"/> NO |
| 8.2 | If Yes, select all that apply <i>(Make copies of selected documents, certify and attach to the SAE CRF)</i> | <input type="checkbox"/> Clinical notes <input type="checkbox"/> Lab results <input type="checkbox"/> X ray <input type="checkbox"/> Death certificate <input type="checkbox"/> Discharge summary <input type="checkbox"/> Other, Specify _____ |
| | | |



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9.0 Part B CRF Completion

| | | |
|-----|---|---------------------------------------|
| 9.1 | a) CRF Completed by (Initials) – to be signed when complete. <i>Do not sign if any fields are empty</i> | _____ |
| | b) Date | ____/____/____ D D / M M / Y Y Y Y |
| | c) Time | ____:____ 24 h clock |

| | | |
|-----|--------------------------------------|---------------------------------------|
| 9.2 | a) CRF Reviewed by (Initials) | _____ |
| | b) Date | ____/____/____ D D / M M / Y Y Y Y |
| | c) Time | ____:____ 24 h clock |

Additional notes (*Not for entry into database*) **all entries should be initialed and dated**



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END of SAE CRF