Patient Initials [ ][ ][ ] PB-SAM Number [1][0] [ ][ ][ ]

# Serious Adverse Event - A

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

| | |
|---|---|
| **1.8.** | **Describe the <u>new</u> clinical features of this SAE event** *(describe clinical findings from examination, medical records, or from caregiver)* |
| **1.9.** | **Describe any investigations or changes to lab 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)* |
| **1.10.** | **Describe the initial treatment given or other actions taken for this SAE*** |
| **1.11.** | **Describe the response to initial treatment *** |
| **1.12.** | **Describe any further clinical investigations and clinical progress*** <br><br> ** write N/A if not applicable (e.g. death in the community)* |
| **1.13.** | **Suspected initial diagnosis for the cause of the SAE (***e.g. pneumonia, sepsis etc***)** <br><br> _____ <br><br> _____ |

| **2. PART A CRF COMPLETION** | | |
|---|---|---|
| **2.1.** | a) **CRF Completed by (Initials) – to be signed when complete.** *Do not sign if any fields are empty* | __ __ __ |

| | | |
|---|---|---|
| | b) **Date** | __ __ / __ __ / __ __ __ __<br>*D D / M M / Y Y Y Y* |
| | c) **Time** | __ __ : __ __<br>*24 h clock* |

# Serious Adverse Event - B

| 3. SAE FINAL DETAILS | |
|---|---|
| **3.1.** | **Circumstances**: What was the SAE, w*here 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* |
| **3.2.** | **Describe the additional clinical features of this SAE event** *(describe clinical findings from examination, medical records, or from caregiver)* |
| **3.3.** | **Describe any investigations or changes to results RELEVANT 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)*** |
| **3.4.** | **Describe the treatment given or other actions taken for this SAE*** |

| | |
|---|---|
| **3.5.** | **Describe the response to treatment, any further clinical investigations and clinical progress*** <br> ** write N/A if not applicable (e.g. death in the community)* |

| **4. SAE CLASSIFICATION** | | | |
|---|---|---|---|
| **4.1.** | **End date** <br> *(dd/mm/yyyy)* | __ __ / __ __ / __ __ __ __ or if no end date *(died, or recovered)* <br> *D D/M M/ Y Y Y Y* <br> ☐ On-going & receiving care ☐ Unknown | |
| **4.2.** | **Final Classification** <br> *Tick the highest <u>one</u> applicable* | ☐ Death <br> ☐ Readmission to study hospital ☐ Readmission to non-study hospital <br> ☐ Readmission is indicated but parent/carer declines admission <br> ☐ Life-threatening event <br> ☐ Persistent or significant disability/incapacity <br> ☐ Event that prolongs hospitalisation whilst already in hospital <br> ☐ 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)?** | | ☐ Y ☐ N |

| **5. RELATIONSHIP OF EVENT TO STUDY DRUGS** | | |
|---|---|---|
| **5.1.** | 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 | ☐ 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. | ☐ 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 | ☐ 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 | ☐ 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 | ☐ Definite |

## 6. 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.*

| | | |
|---|---|---|
| 6.1. | General | ☐ Anaemia ☐ Sickle Cell Disease ☐ Thalassaemia<br>☐ Renal impairment ☐ Ileus ☐ Nephritis<br>☐ Liver dysfunction ☐ Nephrotic syndrome<br>☐ Congenital cardiac disease confirmed by echo |
| 6.2. | Respiratory | ☐ LRTI/pneumonia ☐ Bronchiolitis ☐ URTI<br>☐ Pulmonary TB<br>☐ Otitis media ☐ Asthma ☐ Aspiration e.g. of feed |
| 6.3. | Infection | ☐ Gastroenteritis ☐ Sepsis ☐ Confirmed Malaria<br>☐ Extra pulmonary TB ☐ Soft tissue infection ☐ UTI<br>☐ HIV related illness ☐ Measles ☐ Varicella<br>☐ Osteomyelitis ☐ Febrile illness unspecified<br>☐ Confirmed enteric fever ☐ Typhoid/paratyphoid with perforation |
| 6.4. | CNS | ☐ Febrile convulsions ☐ Epilepsy<br>☐ Other encephalopathy ☐ Hydrocephalus ☐ Cerebral palsy<br>☐ Probable meningitis ☐ Clinically suspected meningitis<br>☐ LP confirmed meningitis<br>☐ Confirmed diagnosis congenital syndrome |
| 6.5. | Other confirmed diagnosis | ☐ Failed appetite test only/severe malnutrition only (readmission).<br>☐ Suspected drug toxicity *(if due to study drug, complete toxicity CRF)*<br>☐ Other known diagnosis: _____ |

## 7. Part B CRF Completion

| | | |
|---|---|---|
| **7.1.** | a) **CRF Completed by (Initials) – to be signed when complete.**<br>*Do not sign if any fields are empty* | __ __ __ |
| | b) **Date** | __ __ / __ __ / __ __ __ __<br>*D D / M M / Y Y Y Y* |
| | c) **Time** | __ __:__ __<br>*24 h clock* |

**END of SAE CRF**

| | | |
|---|---|---|
| **7.2.** | d) **CRF Reviewed by (Initials)** | __ __ __ |
| | e) **Date** | __ __ / __ __ / __ __ __ __<br>*D D / M M / Y Y Y Y* |
| | f) **Time** | ___ ___:___ ____<br>*24 h clock* |

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

Patient Initials [ ][ ][ ] PB-SAM Number [1][0] [ ][ ][ ]