### SAE Initial Details

| **DATE of onset** | ___ / ___ / ___ ___ ___ ___ |
| **DATE seen by research team** | ___ / ___ / ___ ___ ___ ___ |

#### Classification at presentation

*When the study team first became aware of the SAE. Tick the highest one applicable*

- [ ] Death
- [ ] Readmission to study hospital
- [ ] Readmission to non-study hospital
- [ ] Readmission is indicated but parent/carer declines admission
- [ ] Life-threatening event
- [ ] Persistent or significant disability/incapacity
- [ ] Event that prolongs hospitalisation whilst already in hospital
- [ ] Other serious medical event where medical intervention was required to prevent any of the above e.g. TB, sickle cell disease

#### Reported by

*(Tick one)*

- [ ] Parent/caregiver
- [ ] Health Professional
- [ ] From medical records or discharge letter

#### On study drugs at onset?

*(tick all that apply)*

- [ ] No
- [ ] Penicillin
- [ ] Gentamicin
- [ ] Ceftriaxone
- [ ] Metronidazole/Placebo

#### Any other medication in the last 7 days?

*(tick all that apply)*

- [ ] No medication
- [ ] Antibiotic
- [ ] Antimalarial
- [ ] IV fluids
- [ ] Blood Transfusion
- [ ] Anticonvulsants
- [ ] Anti-TB
- [ ] ARVs/ARTs
- [ ] Traditional or Herbal
- [ ] Co-trimoxazole Prophylaxis
- [ ] Yes, but unknown
- [ ] Other ______________________

#### Currently in a nutrition program?

*tick one*

- [ ] No
- [ ] Supplementary Outpatient (corn soy blend, RUSF)
- [ ] Therapeutic Outpatient (RUTF, Plumpy-nut)
- [ ] Therapeutic in hospital

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**SUMMARY:** What was the event, when did it occur, where did it occur, was there any relation to study drug administration or other study procedure

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**Relevant clinical findings**

**Relevant laboratory findings**

**Action taken**
**SAE Conclusion**

<table>
<thead>
<tr>
<th>End date (dd/mm/yyyy)</th>
<th>__ __ / __ __ / __ __ __ __ or if no end date, ☐ On-going &amp; receiving care ☐ Unknown</th>
</tr>
</thead>
</table>

**Final Classification**

1. ☐ Death
2. ☐ Readmission to study hospital
3. ☐ Readmission to non-study hospital
4. ☐ Readmission is indicated but parent/carer declines admission
5. ☐ Life-threatening event
6. ☐ Persistent or significant disability/incapacity
7. ☐ Event that prolongs hospitalisation whilst already in hospital
8. ☐ Other serious medical event where medical intervention was required to prevent any of the above e.g. TB, sickle cell disease

**Was this event a suspected unexpected serious adverse reaction (SUSAR)?** ☐ Y ☐ N

**Relationship of the event to study drugs**

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
2. 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
3. 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
4. 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
5. Reasonable temporal relationship to drug; and event not readily produced by clinical state, environment, or other interventions; and known pattern of response seen with other drugs ☐ Definite
## Diagnosis of the causes of the SAE

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

<table>
<thead>
<tr>
<th>Respiratory</th>
<th>Infection</th>
<th>CNS</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ LRTI/pneumonia</td>
<td>☐ Gastroenteritis</td>
<td>☐ Febrile convulsions</td>
</tr>
<tr>
<td>☐ Bronchiolitis</td>
<td>☐ Sepsis</td>
<td>☐ Epilepsy</td>
</tr>
<tr>
<td>☐ URTI</td>
<td>☐ Confirmed Malaria</td>
<td>☐ LP confirmed meningitis</td>
</tr>
<tr>
<td>☐ Pulmonary TB</td>
<td>☐ Extra pulmonary TB</td>
<td>☐ Clinically suspected meningitis</td>
</tr>
<tr>
<td>☐ Otitis media</td>
<td>☐ Soft tissue infection</td>
<td>☐ Other encephalopathy</td>
</tr>
<tr>
<td>☐ Asthma</td>
<td>☐ UTI</td>
<td>☐ Hydrocephalus</td>
</tr>
<tr>
<td>☐ Aspiration e.g. of feed</td>
<td>☐ HIV related illness</td>
<td>☐ Developmental delay unspecified</td>
</tr>
<tr>
<td></td>
<td>☐ Measles</td>
<td>☐ Cerebral palsy</td>
</tr>
<tr>
<td></td>
<td>☐ Varicella</td>
<td>☐ Congenital syndrome</td>
</tr>
<tr>
<td></td>
<td>☐ Osteomyelitis</td>
<td></td>
</tr>
<tr>
<td></td>
<td>☐ Confirmed enteric fever</td>
<td></td>
</tr>
<tr>
<td></td>
<td>☐ Febrile illness unspecified</td>
<td></td>
</tr>
<tr>
<td></td>
<td>□ Bacterial pathogen(s)isolated (complete microbiology CRF)</td>
<td></td>
</tr>
<tr>
<td>General</td>
<td></td>
<td></td>
</tr>
<tr>
<td>☐ Anaemia</td>
<td></td>
<td></td>
</tr>
<tr>
<td>☐ Sickle Cell Disease</td>
<td></td>
<td></td>
</tr>
<tr>
<td>☐ Renal impairment</td>
<td></td>
<td></td>
</tr>
<tr>
<td>☐ Nephrotic syndrome</td>
<td></td>
<td></td>
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<tr>
<td>☐ Nephritis</td>
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<td></td>
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<tr>
<td>☐ Liver dysfunction</td>
<td></td>
<td></td>
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<tr>
<td>☐ Ileus</td>
<td></td>
<td></td>
</tr>
<tr>
<td>☐ Cardiac disease</td>
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<td></td>
</tr>
</tbody>
</table>

**Other diagnosis:**

- ☐ Failed appetite test only/Malnutrition only.
- ☐ Suspected drug toxicity *(if due to study drug, complete toxicity CRF)*
- ☐ Other known diagnosis

☐ Unknown diagnosis

**SAE CRF completed by**

*initials* __ __ __

**Date** __ __ / __ __ / __ __ __ __

**Time** ___ ___ :___ __

24 h clock

END of SAE CRF
Additional notes (Not for entry into database) all entries should be initialled and dated