Child Initials | | | |

FLACSAM
First Line Antimicrobials in Children with Complicated Severe Acute Malnutrition

F | | | | | |

FLACSAM: Serious Adverse Event

SAE Initial Details	
DATE of onset	__ __ / __ __ / __ __ __ __ *D D/M M/ Y Y Y Y*
DATE seen by research team	__ __ / __ __ / __ __ __ __ *D D/M M/ Y Y Y Y*
Classification at presentation *When the study team first became aware of the SAE.* *Tick the highest <u>one</u> 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*

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*

Relevant clinical findings

***<u>Relevant</u>** laboratory findings*

Action taken

Child Initials | | | |

FLACSAM
First Line Antimicrobials in Children with Complicated Severe Acute Malnutrition

F				

SAE Conclusion	
End date *(dd/mm/yyyy)*	__ __ / __ __ / __ __ __ __ or if no end date, ☐ On-going & receiving care ☐ Unknown *D D/M M/ Y Y Y Y*
Final Classification *Tick the highest <u>one</u> 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
Was this event a suspected unexpected serious adverse reaction (SUSAR)?	☐ Y ☐ N

Relationship of the event to study drugs	
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*** *a*lternate aetiology likely (clinical state, environmental or other interventions) ***and*** *d*oes 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 s***imilar 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 other drugs	☐ Definite

Child Initials | | | | FLACSAM — First Line Antimicrobials in Children with Complicated Severe Acute Malnutrition | F | | | | |

Diagnosis of the causes of the SAE

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

Respiratory

- ☐ LRTI/pneumonia
- ☐ Bronchiolitis
- ☐ URTI
- ☐ Pulmonary TB
- ☐ Otitis media
- ☐ Asthma
- ☐ Aspiration *e.g. of feed*

General

- ☐ Anaemia
- ☐ Sickle Cell Disease
- ☐ Renal impairment
- ☐ Nephrotic syndrome
- ☐ Nephritis
- ☐ Liver dysfunction
- ☐ Ileus
- ☐ Cardiac disease

Infection

- ☐ Gastroenteritis
- ☐ Sepsis
- ☐ Confirmed Malaria
- ☐ Extra pulmonary TB
- ☐ Soft tissue infection
- ☐ UTI
- ☐ HIV related illness
- ☐ Measles
- ☐ Varicella
- ☐ Osteomyelitis
- ☐ Confirmed enteric fever
- ☐ Febrile illness unspecified
- ☐ Bacterial pathogen(s)isolated *(complete microbiology CRF)*

CNS

- ☐ Febrile convulsions
- ☐ Epilepsy
- ☐ LP confirmed meningitis
- ☐ Clinically suspected meningitis
- ☐ Other encephalopathy
- ☐ Hydrocephalus
- ☐ Developmental delay unspecified
- ☐ Cerebral palsy
- ☐ Congenital syndrome

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		Date	Time
initials	__ __ __	__ __ / __ __ / __ __ __ __ *D D / M M / Y Y Y Y*	__ __ : __ __ *24 h clock*

END of SAE CRF

Child Initials | | | |

FLACSAM
First Line Antimicrobials in Children with Complicated Severe Acute Malnutrition

F				

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