Child Initials | | | |

FLACSAM
First Line Antimicrobials in Children with Complicated Severe Acute Malnutrition

F				

PRE-DEFINED SUSPECTED GRADE 4 DRUG TOXICITY

The medicines being used in FLACSAM are licensed drugs with a known profile of adverse reactions. Assessment of safety will therefore focus on severe and causally related events. Clinical or laboratory toxicity will be reported if Grade 4 according to the Division of AIDS table for grading severity of adverse events:
http://rsc.techres.com/Document/safetyandpharmacovigilance/DAIDS_AE_Grading_Table_v2_NOV2014.pdf

If abnormalities are known to be already present at enrolment, or are due to other identifiable factors, this need not be reported as a causally-related toxicity. Only record new events whilst the child is receiving study drugs.

Always act in the best interests of the child. When possible, discuss any decisions regarding stopping study drugs because of suspected toxicity with the FLACSAM PI, clinical lead, designee or local safety monitor. They can also prove information on other aspect of management of adverse reactions.

A toxicity event may also meet the criteria for an SAE, and should also be reported on an SAE CRF.

DATE of onset	__ __ / __ __ / __ __ __ __ *D D/M M / Y Y Y Y*			
TIME of onset	__ __: __ __ *24h Clock* ☐ Unknown			
Which study drugs is the child receiving? **How many doses have been given?**	☐ Penicillin ___ ___ doses	☐ Gentamicin ___ ___ doses	☐ Ceftriaxone ___ ___ doses	☐ Metronidazole/Placebo __ ___ doses

tick all that apply	**Suspected Pre-Defined Grade 4 Toxicity**	**Definition**
Allergic & Cutaneous	☐ Anaphylaxis	Clinical diagnosis
	☐ Bronchospasm requiring treatment	Clinical diagnosis
	☐ Exfoliative dermatitis/Stevens-Johnson Syndrome	Clinical diagnosis
Haematological	☐ Severe anaemia	Hb<4g/dl
	☐ Neutropenia	<0.4 x 10^9/L
	☐ Thrombocytopenia	<25 x 10^9/L
Neurological	☐ Impaired consciousness	AVPU = P or U
	☐ Convulsions	Report or clinical diagnosis
	☐ New focal neurological signs	Clinical diagnosis
Renal	☐ Abnormal renal function	Creatinine >138 µmol/L
Hepatic	☐ Abnormal liver function	ALT >450 IU/L
	☐ Abnormal liver function	AST >620 IU/L
	☐ Abnormal liver function	ALP >4,060 IU/L
	☐ Abnormal liver function	Bilirubin>63 µmol/L

Write details in the description box on the next page

Was the study drug stopped?	☐ Y* ☐ N	If Y, Date: __ __ / __ __ / __ __ __ __ *D D / M M / Y Y Y Y*	Time: __ __:__ __

** if Y, also complete the drug discontinuation section in the Study Conclusion CRF*

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Circumstances of the event, including in relation to study drug administration or other study procedures
Relevant clinical findings
Relevant laboratory findings
Action taken
Progress & outcome

Toxicity CRF completed by		Date	Time
initials	__ __ __	__ __/ __ __/ __ __ __ __ *D D/ M M/ Y Y Y Y*	__ __:__ __ *24 h clock*

END

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