

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 <u>severe and causally related events</u>. Clinical or laboratory toxicity will be reported if Grade 4 according to the Division of AIDS table for grading severity of adverse events: <u>http://rsc.techres.com/Document/safetyandpharmacovigilance/DAIDS AE Grading Table v2 NOV2014.pdf</u>

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	// /////////	<u></u> <u></u>		
TIME of onset	: 24h	<i>Clock</i> 🗖 Unkno	wn	
Which study drugs is the child receiving? How many doses have been given?	Penicillin doses	Gentamicin doses	Ceftriaxone	Metronidazole/Placebo doses

Suspected Pre-Defined Grade 4 Toxicity	Definition	
🗖 Anaphylaxis	Clinical diagnosis	
Bronchospasm requiring treatment	Clinical diagnosis	
Exfoliative dermatitis/Stevens-Johnson Synd	rome Clinical diagnosis	
Severe anaemia	Hb<4g/dl	
🗖 Neutropenia	<0.4 x 10 ⁹ /L	
Thrombocytopenia	<25 x 10 ⁹ /L	
Impaired consciousness	AVPU = P or U	
Convulsions	Report or clinical diagnosis	
New focal neurological signs	Clinical diagnosis	
Abnormal renal function	Creatinine >138 µmol/L	
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	
	 Anaphylaxis Bronchospasm requiring treatment Exfoliative dermatitis/Stevens-Johnson Synd Severe anaemia Neutropenia Thrombocytopenia Impaired consciousness Convulsions New focal neurological signs Abnormal renal function Abnormal liver function Abnormal liver function Abnormal liver function 	

Write details in the description box on the next page

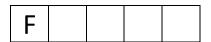
Was the study drug stopped?	te: Time:	
	$\frac{1}{MM/YYYY}$	

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

FLACSAM Suspected Toxicity v1.0 27/07/2017

Child Initials			
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Circumstances of the event, including in relation to study dru	g administration or other study procedu	res
Relevant clinical findings		
Nelevant chinear jinanigs		
Relevant laboratory findings		
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Action taken		
Progress & outcome		
Toxicity CRF completed by	Date	Time
initials	//	:
	D D/MM/YYYY	24 h clock

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