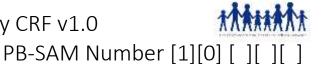
Patient Initials [][][]

PB-SAM Toxicity CRF v1.0



PRE-DEFINED SUSPECTED GRADE 3 or 4 DRUG TOXICITY

The medicines being used in PB-SAM 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 3 or 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 PB-SAM PI, clinical lead, designee or local safety monitor. They can also prove information on other aspect of management of adverse reactions.

A grade 3 or 4 toxicity event may also constitute an SAE, and should also be reported on an SAE CRF.

1. STUDY MEDICATION DETAILS						
1.1. Which study drugs is the child receiving? a) Pancreatic Enzymes/Placebo i. Date and time of start ii. How many doses have been given?	☐ Pancreatic Enzymes/Placebo //					
b) Bile Acids/Placebo	☐ Bile Acids/Placebo					
i. Date and time of start	/					
ii. How many doses have been given?	doses					
tick all that apply	2. SUSPECTED GRADE 3 or 4 TOXICITY Definition					
2.1. Allergic & Cutaneous	□ Not applicable □ Generalized urticaria Clinical diagnosis □ Angioedema with intervention indicated Clinical diagnosis □ Symptoms of mild bronchospasm Clinical diagnosis □ Acute anaphylaxis Clinical diagnosis □ Life-threatening bronchospasm Clinical diagnosis □ Laryngeal oedema Clinical diagnosis					

■ Not applicable

2.2. Diarrhoea

PB-SAM Toxicity CRF v1.0



Patient Initials [][][]

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

			☐ Increase of ≥ 7 stools per 24-hour period					
			□ IV fluid replacement indicated					
			· ·					
			Life-threatening consequences (e.g., hypotensive shock)					
			□ Not applicable					
ĺ								
	22 Ц	epatic	□ Abnormal li	ver function	ALT 5.0 to < 10.0 x ULN			
	2.3. п	epatic	□ Abnormal li	ver function	Total bilirubin 2.6 to <5.0 x ULN			
			☐ Abnormal li	ver function	ALT > 10.0 x ULN			
			☐ Abnormal li		Total bilirubin >5.0 x ULN			
M/rite	Write details in the description box on the next page; ULN, upper limit of normal based on local laboratory reference values							
vertic actains in the acsorption box on the fiext page, our, apper limit of normal based on local laboratory reference values								
				If V. Data	Time:			
				If Y, Date:	Time.			
3.	1. Was the study drug stopped	?	□ Y* □ N					
	ar a	•	_ ·	//	_ .			
				DD/MM/YYY	γ ——:——			
* if Y,	also complete the drug discontinuatio	n section	in the Study Cond	clusion CRF				
3.2. Description including concurrent medication, management undertaken and outcome								
4.	Toxicity CRF completed by			Date	Time			
	,							
	initials			/ /				
	initials		_	///	:			
					T'm-			
5.	Toxicity CRF Reviewed by			Date	Time			
	initials		_	//				
				/ /	··			