PB-SAM Toxicity CRF v1
PB-SAM Number [1][0] [0][0][2] [ ][ ][ ]

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 severe and causally related events. 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**	☐ **Pancreatic Enzymes/Placebo**
i. Date and time of start	__ __ / __ __ / __ __ __ __ *D D / M M / Y Y Y Y* __ __ : __ __ *24h Clock* *h h m m*
ii. How many doses have been given?	___ ___ doses
b) **Bile Acids/Placebo**	☐ **Bile Acids/Placebo**
i. Date and time of start	__ __ / __ __ / __ __ __ __ *D D / M M / Y Y Y Y* __ __ : __ __ *24h Clock* *h h m m*
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
2.2. Diarrhoea	☐ Not applicable	
	☐ Increase of ≥ 7 stools per 24-hour period	

	☐ IV fluid replacement indicated ☐ Life-threatening consequences (e.g., hypotensive shock)	
2.3. Hepatic	☐ Not applicable ☐ Abnormal liver function ☐ Abnormal liver function ☐ Abnormal liver function ☐ Abnormal liver function	 ALT 5.0 to < 10.0 x ULN Total bilirubin 2.6 to <5.0 x ULN ALT > 10.0 x ULN Total bilirubin >5.0 x ULN

Write details in the description box on the next page; ULN, upper limit of normal based on local laboratory reference values

3.1. 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*

3.2. Description *including concurrent medication, management undertaken and outcome*

4. Toxicity CRF completed by *initials*	__ __ __	Date __ __ / __ __ / __ __ __ __ *D D / M M / Y Y Y Y*	Time __ __ : __ __