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| PRE-DEFINED SUSPECTED GRADE 3 or 4 DRUG TOXICITY |

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| *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*](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.*  |

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| 1. **STUDY MEDICATION DETAILS**
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| * 1. **Which study drugs is the child receiving?**
1. **Pancreatic Enzymes/Placebo**
	1. Date and time of start
	2. How many doses have been given?
 | 🞏 **Pancreatic Enzymes/Placebo** \_\_ \_\_ / \_\_ \_\_ / \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ : \_\_ \_\_ *24h Clock* ***D D / M M / Y Y Y Y***  *h h m m*\_\_\_ \_\_\_ doses |
| 1. **Bile Acids/Placebo**
	1. Date and time of start
	2. How many doses have been given?
 | 🞏 **Bile Acids/Placebo** \_\_ \_\_ / \_\_ \_\_ / \_\_ \_\_ \_\_ \_\_ \_\_ \_\_ : \_\_ \_\_ *24h Clock* ***D D / M M / Y Y Y Y***  *h h m m*\_\_\_ \_\_\_ doses |

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| *tick all that apply* | 1. SUSPECTED GRADE 3 or 4 TOXICITY Definition
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| * 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 |
| * 1. Diarrhoea
 | **🞏 Not applicable**🞏 Increase of ≥ 7 stools per 24-hour period 🞏 IV fluid replacement indicated 🞏 Life-threatening consequences (e.g., hypotensive shock) |
| * 1. Hepatic
 | **🞏 Not applicable**🞏 Abnormal liver function ALT 5.0 to < 10.0 x ULN 🞏 Abnormal liver function Total bilirubin 2.6 to <5.0 x ULN🞏 Abnormal liver function ALT > 10.0 x ULN 🞏 Abnormal liver function 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***

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| * 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***

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| * 1. **Description** *including concurrent medication, management undertaken and outcome*
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| 1. **Toxicity CRF completed by***initials*
 | \_\_ \_\_ \_\_ | Date \_\_ \_\_ / \_\_ \_\_ / \_\_ \_\_ \_\_ \_\_ ***D D / M M / Y Y Y Y***  | Time\_\_\_ \_\_\_: \_\_\_ \_\_\_ |
| 1. **Toxicity CRF Reviewed by***initials*
 | \_\_ \_\_ \_\_ | Date \_\_ \_\_ / \_\_ \_\_ / \_\_ \_\_ \_\_ \_\_ ***D D / M M / Y Y Y Y***  | Time\_\_\_ \_\_\_: \_\_\_ \_\_\_ |