

Standard Level of Adverse Event Reporting

Serious Adverse Events (According to ICH guidelines) **	Adverse Event	Relationship to Study Product	AE Log CRF (DataFax to SCHARP)	EAE Form to DAIDS RCC
	Results in Death	Regardless of relationship	YES	YES
	Congenital anomalies, birth defects or fetal loss*	Regardless of relationship	YES	YES
	Results in persistent or significant disability or incapacity	Regardless of relationship	YES	YES
	Requires or prolongs existing hospitalization	All relationships except for "Not Related"	YES	YES
	Requires intervention to prevent significant/permanent disability or death	All relationships except for "Not Related"	YES	YES
	Is life-threatening (including all Grade 4 adverse events)	All relationships except for "Not Related"	YES	YES
	All other SAEs	Not related to study product	YES	NO

Non-serious Adverse Events	All other non-serious AEs	Regardless of relationship	YES	NO
-----------------------------------	---------------------------	----------------------------	-----	----

* Fetal Loss (e.g. spontaneous abortion) may or may not meet criteria to be an SAE according to ICH guidelines. Please refer to Section 2.1 "Seriousness" in the *Manual for Expedited Reporting of Adverse Events to DAIDS* (dated May 6, 2004) for additional details.

** Please refer to Section 2.1 "Seriousness" in the *Manual for Expedited Reporting of Adverse Events to DAIDS* (dated May 6, 2004) for additional details.

Please refer to your protocol for any additional protocol-required expedited reporting requirements as well as the required expedited adverse event reporting period. Also, please see Section 3.2 - 3.4 in the *Manual for Expedited Reporting of Adverse Events to DAIDS* (dated May 6, 2004) for additional details.