ADVERSE EVENT CRF RECORD ONLY GRADE 3 AND GRADE 4 ADVERSE EVENTS AND SAES IF PARTICIPANT HAS RECEIVED STUDY DRUGS

To be completed by study physician on date event recorded										*To be completed by study coordinator*					*Data entry*	
Parameter	**AE Code**	**Date of event onset**	**Date of first awareness**	**Max Severity***	**Relationship§**	**Hospitalized** ***(Y/N)***	**SAE** ***(Y/N)***	**Un-expected** ***(Y/N)***	**Init**	**Event reported: Y/N**		**Outcome#**	**Date final outcome assigned**	**Init**	**Enter Init**	**Verify Init**
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Severity** *(may be updated):** Rank on scale of 1-5: 1 = *mild;* 2 = *moderate;* 3 = *severe;* 4 = *life-threatening*; 5 = *death*

§Relationship to SP or DP *(may be updated)***: I**ndicate either: 1 = *definitely related*; 2 = *probably related*; 3 = *possibly related*; 4 = *unlikely related*; 5 = *not related*; 6 = *pending*

 # Outcome *(may be updated)***:** 1 = *recovered/resolved without sequelae*; 2 = *recovering/resolving*; 3 = *not recovered/not resolved*; 4 = *recovered/resolved with sequelae*; 5 = *death;* 6 = *unknown*