

ADVERSE EVENT (AE) REPORT FORM

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This form captures adverse events of a single participant throughout the study.

STUDY TITLE							
PROTOCOL NO.		PATIENT ID		DATE			
SITE					SITE NUMBER		

ADVERSE EVENT	START DATE dd-mm-yyyy	STOP DATE dd-mm-yyyy	SEVERITY	RELATIONSHIP	ACTION TAKEN	OUTCOME OF AE	EXPECTED (Y/N)	*SAE (Y/N)

Participant had no adverse events (to be completed at the end of study): NONE

*Fill out SAE form if Yes is answered.

<i>Print Name of Principal Investigator</i>	<i>Signature of Principal Investigator</i>	<i>Date</i>
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Adverse Event (AE) Report Form Key

CODE	SEVERITY	RELATIONSHIP	ACTION TAKEN	OUTCOME OF AE
00		Not related	None	
01	Mild	Unlikely related	Does modification	Resolved
02	Moderate	Possibly related	Medical intervention	Recovered with minor sequelae
03	Severe	Probably related	Hospitalization	Recovered with major sequelae
04	Life-threatening	Definitely related	Intervention discontinued	Ongoing treatment
05			Other, describe	Condition worsening
06				Death
07				Unknown

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