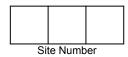


Form AE - Adverse Events					
1 AE	1 AE - Adverse Events				
1.1	Were any adverse events experienced?	○ M No ○ M Yes	AEYN		
1.2	What is the adverse event term?		AETERM		
1.3	Start Date (DD-MMM-YYYY)		AESTDAT		
1.4	Ongoing	○ N No ○ M Yes	AEONGO		
1.5	End Date (DD-MMM-YYYY)		AEENDAT		
1.6	Severity	[MILD] Mild [MODERATE] Moderate [SEVERE] Severe	AESEV		





Sub	iect Nun	nher	

Form AE - Adverse Events				
1 AE	- Adverse Events			
1 AE 1.7	Was the adverse event serious?	No AESDTH Was the adverse event result in death? No AESDTH Was the adverse event life threatening? No AESLIFE Did the adverse event result in initial or prolonged hospitalization for the subject? No AESHOSP No AESHOSP Did the adverse event result in disability or permanent damage? No AESDISAB Was the adverse event associated with a congenital anomaly or birth defect? No AESCONG		
		Was the adverse event a medically important event not covered by other serious criteria? ○ NO AESMIE ○ Yes		
1.8	Relationship to Study Treatment	○ No AEREL No Yes		



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Site Number			Subject Number					

Form AE - Adverse Events						
1 AE	1 AE - Adverse Events					
1.9	Action Taken with Study Treatment	[DOSE INCREASED] Dose Increased [DOSE NOT CHANGED] Dose Not Changed [DOSE RATE REDUCED] Dose Rate Reduced [DOSE REDUCED] Dose Reduced [DRUG INTERRUPTED] Drug Interrupted [DRUG WITHDRAWN] Drug Withdrawn [NOT APPLICABLE] Not Applicable [UNKNOWN] Unknown				
1.10	Other Action Taken	AEACNOTH				
1.11	Outcome	[RECOVERED/RESOLVED] Not Recovered or Not Resolved [RECOVERED/RESOLVED] Recovered or Resolved [RECOVERED/RESOLVED WITH SEQUELAE] Recovered or Resolved with Sequelae [RECOVERING/RESOLVING] Recovering or Resolving [UNKNOWN] Unknown				