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Site Number

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Subject Number

Form AE - Adverse Events**1 AE - Adverse Events**

1.1	Were any adverse events experienced?	<input type="radio"/> [N] No <input type="radio"/> [Y] Yes	AEYN										
1.2	What is the adverse event term?		AETERM										
1.3	Start Date (DD-MMM-YYYY)	<table border="1"><tr><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr></table>											AESTDAT
1.4	Ongoing	<input type="radio"/> [N] No <input type="radio"/> [Y] Yes	AEONGO										
1.5	End Date (DD-MMM-YYYY)	<table border="1"><tr><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr></table>											AEENDAT
1.6	Severity	<input type="radio"/> [MILD] Mild <input type="radio"/> [MODERATE] Moderate <input type="radio"/> [SEVERE] Severe	AESEV										



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1.7	Was the adverse event serious?	<p><input type="radio"/> [N] No AESER</p> <p><input type="radio"/> [Y] Yes</p> <p>Did the adverse event result in death? <input type="radio"/> [N] No AESDTH <input type="radio"/> [Y] Yes</p> <p>Was the adverse event life threatening? <input type="radio"/> [N] No AESLIFE <input type="radio"/> [Y] Yes</p> <p>Did the adverse event result in initial or prolonged hospitalization for the subject?</p> <p><input type="radio"/> [N] No AESHOSP</p> <p><input type="radio"/> [Y] Yes</p> <p>Did the adverse event result in disability or permanent damage?</p> <p><input type="radio"/> [N] No AESDISAB</p> <p><input type="radio"/> [Y] Yes</p> <p>Was the adverse event associated with a congenital anomaly or birth defect?</p> <p><input type="radio"/> [N] No AESCONG</p> <p><input type="radio"/> [Y] Yes</p> <p>Was the adverse event a medically important event not covered by other serious criteria?</p> <p><input type="radio"/> [N] No AESMIE</p> <p><input type="radio"/> [Y] Yes</p>
1.8	Relationship to Study Treatment	<p><input type="radio"/> [N] No AEREL</p> <p><input type="radio"/> [Y] Yes</p>



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1.9	Action Taken with Study Treatment	<input type="radio"/> [DOSE INCREASED] Dose Increased <input type="radio"/> [DOSE NOT CHANGED] Dose Not Changed <input type="radio"/> [DOSE RATE REDUCED] Dose Rate Reduced <input type="radio"/> [DOSE REDUCED] Dose Reduced <input type="radio"/> [DRUG INTERRUPTED] Drug Interrupted <input type="radio"/> [DRUG WITHDRAWN] Drug Withdrawn <input type="radio"/> [NOT APPLICABLE] Not Applicable <input type="radio"/> [UNKNOWN] Unknown	AEACN
1.10	Other Action Taken	AEACNOTH	
1.11	Outcome	<input type="radio"/> [FATAL] Fatal <input type="radio"/> [NOT RECOVERED/NOT RESOLVED] Not Recovered or Not Resolved <input type="radio"/> [RECOVERED/RESOLVED] Recovered or Resolved <input type="radio"/> [RECOVERED/RESOLVED WITH SEQUELAE] Recovered or Resolved with Sequelae <input type="radio"/> [RECOVERING/RESOLVING] Recovering or Resolving <input type="radio"/> [UNKNOWN] Unknown	AEOUT