

Adverse Event (data domain: AE)	
Adverse Event Name	AETERM
Relationship to Study Drug <ul style="list-style-type: none"> <li><input type="radio"/> Related</li> <li><input type="radio"/> Not Related</li> </ul>	AEREL
Outcome <ul style="list-style-type: none"> <li><input type="radio"/> Recovered</li> <li><input type="radio"/> Recovering</li> <li><input type="radio"/> Not Recovered</li> <li><input type="radio"/> Fatal</li> </ul>	AEOUT
Start Date (DD-MMM-YYYY)	AESTDT
Ongoing? <ul style="list-style-type: none"> <li><input type="radio"/> Yes (Y)</li> <li><input type="radio"/> No (N)</li> </ul>	AEONGO
End Date (DD-MMM-YYYY)	AEENDT
CTCAE Grade <ul style="list-style-type: none"> <li><input type="radio"/> Grade 1</li> <li><input type="radio"/> Grade 2</li> <li><input type="radio"/> Grade 3</li> <li><input type="radio"/> Grade 4</li> <li><input type="radio"/> Grade 5</li> </ul>	AETOXGR
Serious Adverse Event (SAE)? <ul style="list-style-type: none"> <li><input type="radio"/> Yes (Y)</li> <li><input type="radio"/> No (N)</li> </ul>	AESER
Action Taken with Study Drug <ul style="list-style-type: none"> <li><input type="radio"/> Dose Not Changed</li> <li><input type="radio"/> Dose Interrupted</li> <li><input type="radio"/> Dose Reduced</li> <li><input type="radio"/> Drug Withdrawn</li> </ul>	AEACN