

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○ Drug Withdrawn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