

Adverse Events

What is the adverse event term? IT.AETERM	<input type="text"/> AETERM
Start Date (MM/DD/YYYY) IT.AESTDAT	<input type="text"/> / <input type="text"/> / <input type="text"/> AESTDTC
End Date (MM/DD/YYYY) IT.AEENDAT	<input type="text"/> / <input type="text"/> / <input type="text"/> AEENDTC
Severity IT.AESEV	<input type="radio"/> Mild Adverse Event <input type="radio"/> Moderate Adverse Event <input type="radio"/> Severe Adverse Event AESEV
Was the adverse event serious? IT.AESER	<input type="radio"/> No <input type="radio"/> Yes AESER
Did the adverse event result in death? IT.AESDTH	<input type="radio"/> No <input type="radio"/> Yes If Yes then AESDTH = "Y" else "Not submitted"
Was the event life threatening? IT.AESLIFE	<input type="radio"/> No <input type="radio"/> Yes AESLIFE
Does the event involve cancer? AESCAN	<input type="radio"/> No <input type="radio"/> Yes
Was the adverse event associated with a congenital anomaly or birth defect? AESCNO	<input type="radio"/> No <input type="radio"/> Yes AESCONG
Did the adverse event result in disability or permanent damage? AEDIS	<input type="radio"/> No <input type="radio"/> Yes AEDISAB

Did the adverse event result in initial or prolonged hospitalization for the subject? <i>IT.AESHOSP</i>	<input type="radio"/> No <input type="radio"/> Yes AESHOSP
Did the adverse event occur with overdose? <i>AESOD</i>	<input type="radio"/> No <input type="radio"/> Yes AESOD
Is the adverse event related to study treatment? <i>IT.AEREL</i>	<input type="radio"/> Probably Related <input type="radio"/> Possibly Related AEREL <input type="radio"/> Remotely Related <input type="radio"/> Not Related
Action taken with study treatment <i>IT.AEACN</i>	<input type="radio"/> Dose increased <input type="radio"/> Dose not changed <input type="radio"/> Dose rate reduced AEACN <input type="radio"/> Dose reduced <input type="radio"/> Drug interrupted <input type="radio"/> Not applicable <input type="radio"/> Unknown
Outcome of the adverse event <i>AEOUTCOME</i>	<input type="radio"/> Fatal <input type="radio"/> Not recovered or not resolved <input type="radio"/> Recovered or resolved AEOUT <input type="radio"/> Recovering or resolving <input type="radio"/> Unknown
Collection date (MM/DD/YYYY) <i>AEDTCOL</i>	<div> <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> </div> AEDTC