## **Adverse Events**

What is the adverse event	
term? IT.AETERM	AETERM
Start Date (MM/DD/YYYY)	AFOTRIO
IT.AESTDAT	AESTDTC
End Date (MM/DD/YYYY)	
IT.AEENDAT	AEENDTC
Severity	Mild Adverse Event
IT.AESEV	<ul> <li>Moderate Adverse Event</li> </ul> AESEV
	Severe Adverse Event
Was the adverse event serious?	o No AESER
IT.AESER	o Yes AESEK
Did the adverse event result in	○ No AESDTH
death? IT.AESDTH	o Yes
Was the event life threatening?	o No
IT.AESLIFE	o Yes AESLIFE
Does the event involve cancer?	o No
AESCAN	o Yes
Was the adverse event AESCN	VO
associated with a congenital	o Yes AESCONG
anomaly or birth defect?	
Did the adverse event result in	o No
disability or permanent	o Yes AEDISAB
damage? AEDIS	

Did the adverse event result in	o No
initial or prolonged IT.AESHO	SP o Yes AESHOSP
hospitalization for the subject?	
Did the adverse event occur	o No AESOD
with overdose? AESOD	o Yes AESOD
Is the adverse event related to	o Probably Related
study treatment?	o Possibly Related AEREL
IT.AEREL	O Remotery Related
	Not Related
Action taken with study	<ul> <li>Dose increased</li> </ul>
treatment	Dose not changed
IT.AEACN	<ul> <li>Dose rate reduced</li> </ul> AEACN
	o Dose reduced
	<ul> <li>Drug interrupted</li> </ul>
	<ul> <li>Not applicable</li> </ul>
	o Unknown
Outcome of the adverse event	o Fatal
AEOUTCOME	<ul> <li>Not recovered or not resolved</li> </ul>
	Recovered or resolved     AEOUT
	Recovering or resolving
	o Unknown
Collection date (MM/DD/YYYY)	
AEDTCOL	