Serious Adverse Events Template

ClinicalTrials.gov

Time Frame for Adverse Event Reporting			
Adverse Event Reporting Additional Description			
Source Vocabulary Name for Table Default ①			
Assessment Type for Table Default ①	(Circle One) Systematic Non-Systematic		
Arm/Group Title *	*	*	*
Arm/Group Description ②			

Serious Adverse Events *

		Number Participants Affected *	Number Participants at Risk *	Number Events	Number Participants Affected *	Number Participants at Risk *	Number Events	Number Participants Affected *	Number Participants at Risk *	Number Events
Total Number for Serious Adverse Events *		*	*		*	*		*	*	
Adverse Event Term *	Organ System *									
*	③ *	*	④[*]		*	④[*]		*	④[*]	
*	③ *	*	④[*]		*	④[*]		*	④[*]	
*	③ *	*	④[*]		*	④[*]		*	④[*]	
*	③ *	*	④[*]		*	④[*]		*	④[*]	
*	③ *	*	④[*]		*	④[*]		*	④[*]	
*	③ *	*	④[*]		*	④[*]		*	④[*]	
*	③ *	*	④[*]		*	④[*]		*	④[*]	
*	③ *	*	④[*]		*	④[*]		*	④[*]	

* Required by ClinicalTrials.gov

[*] Conditionally required by ClinicalTrials.gov

① The table defaults provide a short-cut for entering the Source Vocabulary Name or Assessment Type for all Adverse Events in a study. If entered, the table default values respectively apply to any Adverse Event with a blank Source Vocabulary Name or Assessment Type. The table default values may be changed for any single Adverse Event , if necessary.

② Arm/Group Description describes details about the interventions administered (e.g., dosage, dosage form, frequency of administration) or groups evaluated.

③ Organ System must be selected from a pick-list of high-level categories. See the "Basic Results" Data Element Definitions for details.

④ Number of Participants at Risk for a single Adverse Event in an Arm/Group is only required when the value differs from the Total Number of Participants at Risk for Serious Adverse Event in the Arm/Group.