Other (Not Including 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			

Other (Not Including 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 Other (Not Including 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 Other (Not Including Serious) Adverse Event in the Arm/Group.**