

**Other (Not Including Serious) Adverse Events Template**

<b>*§ Time Frame</b>	
<b>[*] Adverse Event Reporting Description</b>	
<b>Source Vocabulary Name for Table Default ①</b>	
<b>*§ Collection Approach for Table Default ①</b>	<b>(Select One)</b> Systematic      Non-Systematic

<b>* Arm/Group Title</b>			
<b>*§ Arm/Group Description ②</b>			

**\* Other (Not Including Serious) Adverse Events**

<b>* Frequency Threshold for Reporting Other Adverse Events (0–5%)</b>	<b>_____%</b>	<b>* Number Participants Affected</b>	<b>* Number Participants at Risk</b>	<b>Number Events</b>	<b>* Number Participants Affected</b>	<b>* Number Participants at Risk</b>	<b>Number Events</b>	<b>* Number Participants Affected</b>	<b>* Number Participants at Risk</b>	<b>Number Events</b>
<b>* Total</b>										

<b>* Adverse Event Term</b>	<b>* Organ System</b>									
	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**      **\*§ Required if Primary Completion Date is on or after January 18, 2017**      **[\*] Conditionally required**

① If entered, the table default values apply to all Adverse Event Terms. The values may be changed for any single Adverse Event, if different from the table default.

② Arm/Group Description describes details about the intervention strategy (e.g., dose, dosage form, frequency, duration) or groups evaluated.

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

④ Number of Participants at Risk for an Adverse Event Term is only required when the value differs from the Total Number of Participants at Risk.