All-Cause Mortality and Serious Adverse Events Template

ClinicalTrials.gov

*§ Time Frame										
[*] Adverse Event Reporting Description										
Source Vocabulary Name for Table Default ①										
*§ Collection Approach for Table Default ①	(Select One) Systei	matic	Non-Systemat	tic					
* Arm/Group Title										
*§ Arm/Group Description ②										
*§ All-Cause Mortality										
	*§ Numb Participar Affected	nts Pa	Number rticipants at Risk	*§ Numb Participar Affected	nts Par	Number ticipants t Risk	*§ Numb Participar Affected	nts Par	*§ Number Participants at Risk	
*§ Total										
* 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										
* Adverse Event Term * Organ System										
3		4 [*	1		4 [*]			4 [*]		
3		4 [*	1		4 [*]			4 [*]		
3		4]	1		4 [*]			4 [*]		
3		4]			4 [*]			4 [*]		
3		4]	+		4 [*]			4 [*]		
3		4][*] v 18 2017		(4)[*]			4 [*]		

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.

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

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

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.