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Adverse Event Data Preparation Checklist

Overview: The Adverse Events module includes a summary of anticipated and unanticipated events that were collected during the study. This information is submitted as three tables: (1) All-Cause Mortality*§, (2) Serious Adverse Events*, and (3) Other Adverse Events*. Use this checklist with the All-Cause Mortality and Serious Adverse Events Template, Other (Not Including Serious) Adverse Event Template, and Results Data Element Definitions to complete this module of the results section.

Select	Information to have available for General Adverse Event (AE) table	Data Element
☐	• Information to complete three tables summarizing anticipated and unanticipated adverse events temporally associated with the research, whether or not considered related to the participant's participation in the research: ◦ All-Cause Mortality (all deaths)*§ ◦ All Serious Adverse Events* ◦ Other (Not Including Serious) Adverse Events* that exceed a frequency of 5 percent within any arm of the study	
☐	• Specific period of time over which AEs were assessed/collected ◦ Tip: Express the Time Frame from the participants' perspective (e.g., "8 weeks after participant received first dose" and not "end of study").	*§Time Frame
☐	• Explanation of methods used for adverse event data collection or reporting, including any definition of adverse events that is different from the Results Data Element Definitions for Adverse Events • Information about how the number of participants assessed (at risk population) was determined	[*]Adverse Event Reporting Description
☐	• The name and version of any standard dictionary or structured vocabulary (e.g., MedDRA 10.0) used to describe AEs	Source Vocabulary Name for Table Default
☐	• Method for AE assessment—Systematic Assessment (e.g., solicited by a questionnaire) or Non-Systematic Assessment (e.g., unsolicited)	*§Collection Approach for Table Default
☐	• Number of analysis groups for which summary AE data will be provided ◦ Tip: Generally, the number of analysis groups will be equal to the number of intervention strategies evaluated.	*Arm/Group Information
☐	• For each group: ◦ Title—Descriptive label for the group ▪ Tip: Use informative labels (e.g., "Placebo"), not generic labels (e.g., "Group 1"). The label will become the header for that table column. ◦ Description—Detailed explanation of the participants included in the group and the interventions they received (e.g., dosage, dosage form, frequency and duration of administration) ▪ Tip: This may include a description of how groups of participants were recombined for analysis purposes.	*Arm/Group Title *§Arm/Group Description

**Required*

**§ Required if Primary Completion Date is on or after January 18, 2017*

[*] Conditionally required

Select	Information to have available for All-Cause Mortality Table	Data Element
☐	• For each group, the total number of participants that: ◦ Died due to any cause ◦ Were assessed for death (typically the same as the number assigned to each arm at the start of the study)	*§**Total** Number Affected by All-Cause Mortality *§**Total** Number at Risk for All-Cause Mortality
Select	**Information to have available for Serious Adverse Event (SAE) Table**	**Data Element**
☐	• For each group, the total number of participants that: ◦ Had at least one SAE ◦ Were assessed for SAEs (i.e., could have had an SAE)	***Total** Number Affected by Any Serious Adverse Event ***Total** Number at Risk for Serious Adverse Events
☐	• Name of each SAE and its Organ System (see categories in the Results Data Element Definitions)	*Adverse Event Term *Organ System
☐	• Number of participants with the SAE in each group • Number of occurrences of each event (optional)	*Number of Participants Affected Number of Events
Select	**Information to have available for Other (Not Including Serious) Adverse Event (OAE) Table**	**Data Element**
☐	• Frequency above which OAEs will be reported (0–5%) ◦ For example, if "5," report each OAE occurring in more than 5% of participants in any group.	*Frequency Threshold for Reporting Other (Not Including Serious) Adverse Events
☐	• For each group, the total number of participants that: ◦ Had any OAEs above frequency threshold ◦ Were assessed for OAEs (i.e., could have had an OAE)	***Total** Number Affected by Any Other (Not Including Serious) Adverse Event Above the Frequency Threshold ***Total** Number at Risk for Other (Not Including Serious) Adverse Events
☐	• Name of each OAE and its Organ System (see categories in the Results Data Element Definitions)	*Adverse Event Term *Organ System
☐	• Number of participants with the OAE in each group • Number of occurrences of each event (optional)	*Number of Participants Affected Number of Events

**Required*

**§ Required if Primary Completion Date is on or after January 18, 2017*

[*] Conditionally required