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Edited: 19 August 2014

Adverse Event Data Preparation Checklist

Overview: Two tables reporting: (1) ALL anticipated and unanticipated **serious adverse events**; (2) anticipated and unanticipated **other adverse events.** Use this checklist with the Serious Adverse Event Template,[Δ] Other (Not Including Serious) Adverse Event Template,[Δ] and Results Data Element Definitions.

	General Adverse Event (AE) information to have available	Term
☐	• Time period over which AEs were assessed/collected ○ Be specific. Indicate the length of time each participant was followed. (e.g., "up to 2 years" is specific; "until end of study" is not)	[Δ]Time Frame for Adverse Event Reporting
☐	• If a standard dictionary or structured vocabulary was used to describe AEs, provide the name and version (e.g., MedDRA 10.0).	[Δ]Source Vocabulary Name for Table Default
☐	• Method for AE assessment: "Systematic" (e.g., solicited by a questionnaire) or "Non-systematic" (e.g., unsolicited)	[Δ]Assessment Type for Table Default
☐	• Explanation of methods used for adverse event data collection or reporting • Information about how you determined the number of participants assessed	[Δ]Adverse Event Reporting Additional Description
☐	• Number of separate groups for which summary AE data will be provided • Tip: Generally equal to the number of intervention strategies evaluated	Arms/Groups

☐	• For each group:
	  ○ Title—A descriptive label for the group (header for table column). Use informative labels (e.g., "Placebo"), not generic labels (e.g., "Group 1").
	  ○ Description—A detailed explanation of the participants included in the group and the interventions received. This may include a description of how groups of participants were recombined for analysis purposes.
		*[Δ]Arm/Group Title
		[Δ]Arm/Group Description

	Serious Adverse Event (SAE) information	**Term**
☐	• For each group, the total number of participants who: (1) reported at least one SAE; (2) were assessed for SAEs (i.e., could have reported an SAE)	**Total** for Serious AEs *[Δ]Participants Affected *[Δ]Participants at Risk
☐	• Name of each SAE and its Organ System (see categories in the Results Data Element Definitions)	*[Δ]Adverse Event Term *[Δ]Organ System
☐	• Number of participants with the SAE in each group ○ Optional—Number of occurrences of each event [Number of Events]	*[Δ]Number Participants Affected
	Other (Not Including Serious) Adverse Event (OAE) information	**Term**
☐	• 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.	*[Δ]Frequency Threshold
☐	• For each group, the total number of participants who: (1) reported any OAEs above frequency threshold; (2) were assessed for OAEs (i.e., could have reported an OAE)	**Total** for Other AEs *[Δ]Participants Affected *[Δ]Participants at Risk
☐	• Name of each OAE and its Organ System (see categories in the Results Data Element Definitions)	*[Δ]Adverse Event Term *[Δ]Organ System
☐	• Number of participants with the OAE in each group ○ Optional–Number of occurrences of each event [Number of Events]	*[Δ]Number Participants Affected

**Required*

[Δ]*Template Field*