Baseline Characteristics Data Preparation Checklist

Overview: A tabular summary of all characteristics measured at baseline for each group and overall. The table is similar to "Table 1" in a journal article. Use this checklist with the Results Data Element Definitions and the Simple Results Templates$^{\Delta}$ for Age; Gender; Race, Ethnicity, Region; and Study Specific Measures.

Information to have available for Baseline Characteristics	Term
☐ • Have a list of all baseline characteristics and the corresponding summary-level data (similar to Table 1 in a journal article). Age and Gender must be provided.	Background
☐ • The number of separate groups for which summary data will be provided. • Tip: Generally equal to the number of groups/intervention strategies to which participants were assigned (randomized) at the beginning of the study	Arm/Groups

☐ • For each group:
  o Title—A descriptive label for the group (header for table column). Use informative labels (e.g., "Placebo"), not generic labels (e.g., "Group 1").
  o 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.
	*$^{\Delta}$Arm/Group Title
	
	$^{\Delta}$Arm/Group Description

☐ • Number of participants, in each group and in the entire study population (total), from whom data were collected and summarized. Participants should only be represented in one group and in the total (i.e., do not double-count).	*$^{\Delta}$Overall Number Baseline Participants
☐ • An explanation of the criteria used to determine which participants were included in the analysis	$^{\Delta}$Baseline Analysis Population Description
Information to have available for each Baseline Measure	**Term**
☐ • Title—Describe specifically what was measured and will be reported as data • Description—Any elaboration needed to understand the measure and the reported data. Information should be written for a public audience (i.e., not specialists in your field, but general readers of the medical literature). o If the measure was based on a scale, explain any numerical categories or provide the range and direction of possible scores (0=no pain; 10=worst possible pain) to allow a reader to properly interpret any reported values.	*$^{\Delta}$Baseline Measure Title $^{\Delta}$Baseline Measure Description

☐ • The method used to summarize baseline data:
  o Central tendency—E.g., mean, median, geometric mean
  o Number—E.g., count (of participants)
	*$^{\Delta}$Measure Type

☐ • For a measure of central tendency, specify a measure that represents "the spread" of the summary data (e.g., standard deviation). o Tip: This is not applicable for a Number (e.g., count of participants)	*$^{\Delta}$Measure of Dispersion
☐ • Numerical values for the summary-level data in each group and overall (total)	*Baseline Data
☐ • The specific unit associated with the numerical data (e.g., mg/dL, participants)	*$^{\Delta}$Unit of Measure

*Required
$^{\Delta}$Template Field