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Baseline Characteristics Data Preparation Checklist

Overview: The Baseline Characteristics module is a tabular summary of data for each demographic and baseline measure by arm or comparison group and for the entire population of participants in the clinical study. Use this checklist with the Results Data Element Definitions and the Simple Results Templates for Age, Sex/Gender, Race, Ethnicity, and Region, and Study-Specific Measures to complete this module of the results section.

Select	Information to have available for Baseline Characteristics	Data Element
	• A list of all baseline characteristics and the corresponding summary-level data (similar to Table 1 in a journal article) ◦ Tip: Each baseline or demographic characteristic measured in the clinical study should be reported, including Age*, Sex/Gender*, Race and Ethnicity (if collected)*§, and any baseline assessment(s) used in the analysis of the Primary Outcome Measure(s)*§.	
	• Number of analysis groups for which summary data will be provided ◦ Tip: Generally, the number of analysis groups will be equal to the number of groups/intervention strategies to which participants were assigned (randomized) at the beginning of the study.	*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

	• Number of participants in each group and in the entire study population (total) from which data were collected and summarized
	  ◦ Tip: If the unit of analysis is a unit other than participants, specify the name of the unit (e.g., eyes, lesions, implants) and provide the number of units.
	  ◦ Tip: The unit of analysis (participants or units other than participants) should only be represented in one group and once in the total. For example, if the unit of assignment is participants, do not count a participant more than once by including them in more than one group (other than total).
		*Overall Number Baseline Participants
		
		[*]Overall Number of Units Analyzed and Type of Units Analyzed

	• Explanation of the criteria used to determine which participants were included in the analysis	[*]Baseline Analysis Population Description

*Required
*§ Required if Primary Completion Date is on or after January 18, 2017
[*] Conditionally required

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Select	Information to have available for each Baseline Measure	Data Element

	• Title—Descriptive name for each measure that specifically indicates what was measured and will be reported as data
	• Description— Additional information needed to understand the measure and the reported data, including how the measure was taken, relevant definitions, criteria, and/or any methods of assessment
	  ◦ Tip: Write the description for a public audience (i.e., not specialists in your field, but general readers of the medical literature).
	  ◦ Tip: If the measure uses a scale, grading, or staging approach, then provide criteria for any categories or provide the range and direction of possible scores (e.g., 0=no pain; 10=worst possible pain) needed to interpret reported values.
		*Baseline Measure Title
		
		Baseline Measure Description

	• Method used to summarize baseline data, using one of the following:
	  ◦ Measure of central tendency used to aggregate continuous data (e.g., mean, median)
	  ◦ Count of Participants or Count of Units
	    ▪ Tip: A percentage of participants or units may also be reported if a "count" is used.
	  ◦ Number
	    ▪ Tip: A measure type of Number should be used when no other measure type applies (e.g., to report a proportion of participants).
		*Measure Type

	• Measure for "the spread" of the data (e.g., Standard Deviation, Inter-Quartile Range) ◦ Tip: A Measure of Dispersion must be specified for continuous data. Select "Not Applicable" for Count of Participants, Count of Units, and Number.	*Measure of Dispersion
	• Numerical values for the summary-level data in each group and overall (total)	*Baseline Measure Data
	• Specific unit associated with the numerical data (e.g., mg/dL, participants)	*Unit of Measure

*Required
*§ Required if Primary Completion Date is on or after January 18, 2017
[*] Conditionally required