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Outcome Measure Data Preparation Checklist

Overview: The Outcome Measures module is a tabular summary of data for each primary and secondary outcome measure by arm or comparison group. You may also report other pre-specified and post hoc outcome measures in this section. Outcomes pre-specified in the Protocol Section of the record will be available to use and edit during results data entry. Use this checklist with the Outcome Measure Simple Results Template and Results Data Element Definitions to complete this module of the results section.

Select	Information to have available for each Outcome Measure	Data Element
☐	• A list of all outcome measures assessed in the study ◦ All pre-specified primary and secondary outcome measures (required) ◦ Any additional outcome measures of interest to report in the record, e.g., other pre-specified or exploratory, and post-hoc (optional)	
☐	• Label for each outcome measure (Primary, Secondary, Other Pre-specified, or Post hoc)	*Outcome Measure Type
☐	• Title— Descriptive name for each measure that specifically indicates what was measured and will be reported as data ◦ Tip: Ensure the title is as precise and clear as possible. For example, "Change from Baseline in Systolic Blood Pressure at 6 Months" rather than "Principal Vital Signs." • Description—Additional information needed to understand the measure and the reported data, including how the measure was taken, relevant definitions (e.g., define "response"), criteria, any methods of assessment, and/or details about calculations that were performed to summarize the data ◦ 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.	*Outcome Measure Title [*]Outcome Measure Description
☐	• Time point(s) or specific duration over which a participant was assessed for the measure, and for which data are being reported. ◦ Tip: For a time-to-event measure, include a definition of the stopping rule and the longest duration over which a participant was observed (e.g., from randomization until death, up to 3 years). ◦ Tip: Express the time frame from the participants' perspective (e.g., "8 weeks after participant receives first dose" and not "end of study")	*Outcome Measure Time Frame
☐	• 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 intervention strategies or groups compared.	*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 each Outcome Measure	Data Element
☐	• Number of participants in each group 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.	*Overall Number of Participants Analyzed [*]Overall Number of Units Analyzed and Type of Units Analyzed
☐	• Detailed explanation of the criteria used to determine which participants were included in the analysis ◦ Tip: Acronyms (e.g., ITT, LOCF) should be expanded and explained.	[*]Analysis Population Description
☐	• Method used to summarize outcome 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" or an estimate of the precision of the data (e.g., Standard Deviation, Inter-Quartile Range, Confidence Interval) ◦ Tip: A Measure of Dispersion/Precision must be specified for continuous data. Select "Not Applicable" for Count of Participants, Count of Units, and Number.	*Measure of Dispersion/Precision
☐	• Numerical values for the summary-level data in each group	*Outcome 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

Outcome Measure: Statistical Analyses Data Preparation Checklist

Overview: The statistical analysis section is a tabular summary of statistical tests of significance or other parameters estimated from the Outcome Measure data. If a statistical analysis is provided, you must include either a P-Value, Estimation Parameter, or Other Statistical Analysis. You may include as many statistical analyses as is necessary to accommodate all data calculations. Use this checklist with the Results Data Element Definitions to complete this part of the results section.

Select	Information to have available for each Statistical Analysis	Data Element
☐	• Computed results for all scientifically appropriate tests of statistical significance (e.g., p-value or estimation parameter) for the following: ◦ Primary and Secondary Outcome Measures (required) ◦ Other Pre-Specified and Post Hoc Outcome Measures (optional) • Tip: Examples of tests may include those that were pre-specified in the protocol and/or statistical analysis plan, made public by the sponsor or responsible party, or conducted on a primary outcome measure in response to a request made by FDA.	
☐	• Outcome Measure arm(s) or group(s) used in the analysis ◦ Tip: Include any of the following in the comments, if applicable: ▪ Null hypothesis for the comparison ▪ Power calculation	*Comparison Group Selection Comparison Comments
☐	• Type of analysis: Superiority, Non-inferiority, Equivalence, or Other (e.g., for single group or other descriptive analysis) ◦ Tip: If the analysis was a test of Non-inferiority or Equivalence, you must include the non-inferiority or equivalence margin in the comments.	*Type of Statistical Test [*]Non-inferiority/ Equivalence Comments
Select	**And have one or more of the following:**	**Data Element**
☐	• Calculated p-value and the statistical method used (e.g., ANOVA, t-Test) ◦ Tip: Explain any of the following in the comments, if relevant: ▪ Adjustments for multiple comparisons or covariates ▪ *A priori* threshold for statistical significance (e.g., < 0.05) ▪ Degrees of freedom	Statistical Test of Hypothesis [*]P-Value and Method P-Value Comments Method Comments
☐	• Description of any parameter derived from the outcome measure data (e.g., Hazard Ratio, Mean Difference, Odds Ratio) and the associated value for the parameter, including any of the following, if applicable: ◦ Confidence Interval ◦ Standard Deviation or Standard Error of the Mean ◦ Additional explanatory comments to interpret the value, if needed ▪ For example, the directionality of the comparison (i.e., A – B or B – A for subtraction or A/B or B/A for a ratio)	Method of Estimation [*]Estimation Parameter and Estimated Value Confidence Interval Parameter Dispersion Type and Dispersion Value Estimation Comments

*Required

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

[*] Conditionally required

Select	And have one or more of the following (continued):	Data Element
☐	• Description and results of any other scientifically appropriate tests of statistical significance ◦ Tip: Use this option if the statistical analysis cannot be submitted using the Statistical Test of Hypothesis or Method of Estimation options.	Other Statistical Analysis

*Required

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

[*] Conditionally required