

## Outcome Measure Data Preparation Checklist

**Overview:** A tabular summary of outcome measure results by comparison group. You must report tables for each pre-specified primary and secondary outcome and any appropriate statistical analyses. The outcomes that were pre-specified in the Protocol Section of the record will be available to use and edit during results data entry. You may also include other pre-specified and *post hoc* outcomes. Use this checklist with the [Outcome Measure Simple Results Template](#)<sup>Δ</sup> and [Results Data Element Definitions](#).

	Information to have available for each Outcome Measure	Term
<input type="checkbox"/>	<ul style="list-style-type: none"> <li>Label the measure as Primary, Secondary, Other Pre-specified, or Post hoc.</li> </ul>	* <sup>Δ</sup> Outcome Measure Type
<input type="checkbox"/>	<ul style="list-style-type: none"> <li>Title—Describe specifically what was measured and will be reported as data                             <ul style="list-style-type: none"> <li>For example, “Change from baseline in systolic blood pressure at 6 months” specifically describes what was measured and how the outcome data will be reported; “Principle Vital Signs” does not.</li> </ul> </li> <li>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).                             <ul style="list-style-type: none"> <li>For example, a description of how the measure was taken, relevant definitions (e.g., explain “response”), any methods of assessment, and/or calculations that were performed to summarize the data</li> <li>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.</li> </ul> </li> </ul>	* <sup>Δ</sup> Outcome Measure Title  <sup>Δ</sup> Outcome Measure Description
<input type="checkbox"/>	<ul style="list-style-type: none"> <li>The time point(s) or duration over which a participant was assessed for the measure, and for which data are being reported                             <ul style="list-style-type: none"> <li>For a time-to-event measure—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)</li> </ul> </li> </ul>	* <sup>Δ</sup> Outcome Measure Time Frame
<input type="checkbox"/>	<ul style="list-style-type: none"> <li>The number of separate groups for which summary data will be provided</li> <li><u>Tip:</u> Generally equal to the number of intervention strategies or groups compared</li> </ul>	Arm/Groups
<input type="checkbox"/>	<ul style="list-style-type: none"> <li>For each group:                             <ul style="list-style-type: none"> <li>Title—A descriptive label for the group (header for table column). Use informative labels (e.g., “Placebo”), not generic labels (e.g., “Group 1”).</li> <li>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.</li> </ul> </li> </ul>	* <sup>Δ</sup> Arm/Group Title  <sup>Δ</sup> Arm/Group Description
<input type="checkbox"/>	<ul style="list-style-type: none"> <li>Number of participants, in each group, from whom data were collected and summarized.                             <ul style="list-style-type: none"> <li>If the unit of analysis is not participants, also provide the name of the unit (e.g., eyes, lesions) and the number of units [Type/Number Units Analyzed].</li> </ul> </li> </ul>	* <sup>Δ</sup> Number of Participants Analyzed

Information to have available for each Outcome Measure	Term	
<input type="checkbox"/>	<ul style="list-style-type: none"> <li>• An explanation of the criteria used to determine which participants were included in the analysis.</li> </ul>	<sup>Δ</sup> Analysis Population Description
<input type="checkbox"/>	<ul style="list-style-type: none"> <li>• The method used to summarize outcome data:             <ul style="list-style-type: none"> <li>○ Central tendency—E.g., mean, median, geometric mean</li> <li>○ Number—E.g., count, percentage or proportion</li> </ul> </li> </ul>	<sup>*</sup> <sup>Δ</sup> Measure Type
<input type="checkbox"/>	<ul style="list-style-type: none"> <li>• For a measure of central tendency, specify a measure that represents “the spread” of the summary data (e.g., standard deviation) or an estimate of precision (e.g., confidence interval).             <ul style="list-style-type: none"> <li>○ <u>Tip</u>: Either Not applicable or Confidence interval may be appropriate for a Number (e.g., count or percentage of participants).</li> </ul> </li> </ul>	<sup>*</sup> <sup>Δ</sup> Measure of Dispersion/Precision
<input type="checkbox"/>	<ul style="list-style-type: none"> <li>• Numerical values for the summary-level data in each group</li> </ul>	<sup>*</sup> Outcome Data
<input type="checkbox"/>	<ul style="list-style-type: none"> <li>• The specific unit associated with the numerical data (e.g., mg/dL)             <ul style="list-style-type: none"> <li>○ If a proportion or percentage, indicate what it is “of” (e.g., “percentage of participants”)</li> </ul> </li> </ul>	<sup>*</sup> <sup>Δ</sup> Unit of Measure

<sup>\*</sup>Required  
<sup>Δ</sup>Template Field

## Outcome Measure - Statistical Analysis (optional)

**Overview:** The statistical analysis section is a table associated with an Outcome Measure. It summarizes the results of any scientifically appropriate tests of statistical significance or other parameters estimated from the Outcome Measure data. If a statistical analysis is provided, it must include either a P-Value<sup>[\*]</sup> or an Estimation Parameter<sup>[\*]</sup>. You may include as many statistical analyses as is necessary to accommodate all data calculations. Use this checklist with the [Results Data Element Definitions](#).

	Information to have available for each Statistical Analysis	Term
<input type="checkbox"/>	<ul style="list-style-type: none"> <li>• The Outcome Measure group(s) used in the analysis               <ul style="list-style-type: none"> <li>○ Explain any of the following, if applicable:                   <ul style="list-style-type: none"> <li>▪ Null hypothesis for the comparison</li> <li>▪ Power calculation</li> </ul> </li> </ul> </li> </ul>	*Comparison Group Selection  Comparison Comments
<input type="checkbox"/>	<ul style="list-style-type: none"> <li>• Was the analysis a test of non-inferiority or equivalence? [Yes or No]               <ul style="list-style-type: none"> <li>○ If Yes, provide the defined non-inferiority margin.</li> </ul> </li> </ul>	*Non-inferiority or Equivalence Analysis?  [*]Non-inferiority/Equivalence Comments
	<b>And have one or both of the following:</b>	
<input type="checkbox"/>	<ul style="list-style-type: none"> <li>• Computed p-value and the statistical method used (e.g., ANOVA, t-test)               <ul style="list-style-type: none"> <li>○ Additional explanatory comments to interpret the value, if needed:                   <ul style="list-style-type: none"> <li>▪ Adjustments for multiple comparisons or covariates</li> <li>▪ Degrees of freedom</li> <li>▪ <i>A priori</i> threshold for statistical significance (e.g., &lt; 0.05)</li> </ul> </li> </ul> </li> </ul>	[*]P-Value and Method  P-Value Comments
<input type="checkbox"/>	<ul style="list-style-type: none"> <li>• Value of any parameter derived from the outcome measure data (e.g., hazard ratio, mean difference, correlation coefficient)               <ul style="list-style-type: none"> <li>○ Any of the following, if available:                   <ul style="list-style-type: none"> <li>▪ Confidence Interval</li> <li>▪ Standard deviation or standard error</li> </ul> </li> <li>○ Additional explanatory comments to interpret the value, if needed:                   <ul style="list-style-type: none"> <li>▪ Directionality of comparison. For subtraction (i.e., A – B or B – A) or a ratio (i.e., A/B or B/A)</li> </ul> </li> </ul> </li> </ul>	[*]Estimation Parameter and Value  Confidence Interval  Parameter Dispersion  Estimation Comments

\*Required

[\*] Conditionally required