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## Participant Flow Data Preparation Checklist

**Overview:** The Participant Flow module is a tabular summary of participants' progress through each stage of a study by assignment group. Use this checklist with the Participant Flow Template and Results Data Element Definitions to complete this module of the results section.

| Select | Information to have available for Participant Flow | Data Element |
|---|---|---|
| ☐ | • Conceptual overview of the study design, including the type (e.g., single group, cross-over, parallel) and any distinct stages (e.g., double-blind then open-label)<br>◦ Tip: Have a CONSORT flow diagram available. | |
| ☐ | • Description of any significant study events that occurred after participants were enrolled, but before they were assigned to a study group (e.g., run-in phase or washout) | [*]Pre-assignment Details |
| ☐ | • Number of groups that accurately describes the study design from participant assignment to completion<br>◦ Tip: The number of groups is typically equal to the number of unique paths (participant experiences) in a CONSORT flow diagram, from beginning to end. Each group will be reported as a table column. | *Arm/Group Information |
| ☐ | • For each group:<br>◦ Title—Descriptive label for the group<br>▪ Tip: Use informative labels (e.g., "Placebo"), not generic labels (e.g., "Group 1"). The label will become the header for that table column.<br>◦ Description—Detailed explanation of the interventions administered or the groups observed during each stage of the study<br>▪ Tip: Include details about the intervention (e.g., dosage, dosage form, frequency and duration of administration) or observation. | *Arm/Group Title<br><br>*§Arm/Group Description |
| ☐ | • Number of discrete stages or intervals of activity in the study | *Period(s) |
| ☐ | • Descriptive title for each period (the default for one Period is "Overall Study")<br>◦ Tip: A Period Title should describe what happened during that period of the study. For example, "Double-blind (0 to 24 weeks)" and "Open-label (24 to 48 weeks)" are more descriptive than "Period 1" and "Period 2." | *Period Title |
| ☐ | • Number of participants that Started and Completed each period:<br>◦ Started—Participants initiating each period (e.g., the number of participants assigned or randomized to each group for that period)<br>▪ Tip: If the number of participants starting the first period is different from the total enrolled in the study, explain why in Pre-assignment Details.<br>◦ Completed—Participants still in the study at the end of the period<br>◦ Tip: If the unit of assignment is a unit other than participants, specify the name of the unit (e.g., eyes, lesions, implants) and provide the number of units.<br>◦ Tip: Each unit of assignment (participants or units other than participants) should only be represented in one group. 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.<br>◦ Tip: Use the Additional Milestone field to record any specific events or time points in the study between the Started and Completed milestones. | *Started<br><br>*Completed<br><br>[*]Type of Units Assigned<br><br>Additional Milestone |

**Required*

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

*[*] Conditionally required*

| Select | Information to have available for Participant Flow | Data Element |
|---|---|---|
| ☐ | • Number of participants for each period and group that did not complete and the reasons they did not complete | Not Completed<br><br>Reason Not Completed |

*Required

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

[*] Conditionally required

# *Participant Flow Template* — *ClinicalTrials.gov*

| | |
|---|---|
| Recruitment Details | |
| [*] Pre-assignment Details | |

## *Period* ①

| * Period Title | Overall Study ① | | |
|---|---|---|---|
| * Arm/Group Title | | | |
| *§ Arm/Group Description ② | | | |
| | Number of Participants ④ | Number of Participants ④ | Number of Participants ④ |
| * Started | | | |
| [*] Milestone Title ③ | | | |
| [*] Milestone Title ③ | | | |
| [*] Milestone Title ③ | | | |
| * Completed | | | |
| Not Completed | *(automatically calculated)* | | |
| **Reason Not Completed Type ③** | | | |
| [*] Adverse Event | | | |
| [*] Death | | | |
| [*] Lack of Efficacy | | | |
| [*] Lost to Follow-up | | | |
| [*] Physician Decision | | | |
| [*] Pregnancy | | | |
| [*] Protocol Violation | | | |
| [*] Withdrawal by Subject | | | |
| [*] Other Reason | | | |
| [*] Other Reason | | | |
| [*] Other Reason | | | |

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

① Complete a Period table for each stage of the study. If only one Period, the Title is "Overall Study". For multiple Periods, include descriptive Titles for each Period.
② Arm/Group Description describes details about the intervention strategy (e.g., dose, dosage form, frequency, duration) or groups evaluated.
③ [Optional] Add as many Milestone Title or Other Reason Not Completed rows as needed. A descriptive title for each row is required.
④ Number and Type of Units Assigned may also be specified.

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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)<br>◦ 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<br>◦ 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:<br>◦ Title—Descriptive label for the group<br>▪ Tip: Use informative labels (e.g., "Placebo"), not generic labels (e.g., "Group 1"). The label will become the header for that table column.<br>◦ 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)<br>▪ Tip: This may include a description of how groups of participants were recombined for analysis purposes. | *Arm/Group Title<br><br>*§Arm/Group Description |
| ☐ | • Number of participants in each group and in the entire study population (total) from which data were collected and summarized<br>◦ 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.<br>◦ 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<br><br>[*]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*

| 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<br>• 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<br>◦ Tip: Write the description for a public audience (i.e., not specialists in your field, but general readers of the medical literature).<br>◦ 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<br><br>Baseline Measure Description |
| ☐ | • Method used to summarize baseline data, using one of the following:<br>◦ Measure of central tendency used to aggregate continuous data (e.g., mean, median)<br>◦ Count of Participants or Count of Units<br>▪ Tip: A percentage of participants or units may also be reported if a "count" is used.<br>◦ Number<br>▪ 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)<br>◦ 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

# Baseline Characteristics Template — Age* (use at least one) — ClinicalTrials.gov

| | | | | | |
|---|---|---|---|---|---|
| * Arm/Group Title | | | | | Total |
| *§ Arm/Group Description ① | | | | | |
| * Overall Number of Baseline Participants ② | | | | | ③ |
| [*] Baseline Analysis Population Description | | | | | |
| **Age, Categorical** | | | | | |
| <=18 years | | | | | ③ |
| Between 18 and 65 years | | | | | ③ |
| >=65 years | | | | | ③ |
| * Unit of Measure | Participants | | | | |
| **Age, Continuous** | | | | | |
| * Measure Type | * Measure of Dispersion | | | | |
| (Select One)<br>Mean<br>Median<br>Least Squares Mean (LSM)<br>Geometric Mean<br>Geometric LSM | (Select One)<br>Standard Deviation<br>Inter-quartile Range<br>Full Range | | | | |
| * Unit of Measure | | | | | |
| **Age, Customized** | | | | | |
| * Measure Type | * Measure of Dispersion | | | | |
| (Select One)<br>Count of Participants ④<br>Mean<br>Median<br>Least Squares Mean (LSM)<br>Geometric Mean<br>Geometric LSM<br>Number<br>Count of Units ④ | (Select One)<br>Not Applicable ⑤<br>Standard Deviation<br>Inter-Quartile Range<br>Full Range | | | | |
| [*] Row/Category Title ⑥ | | ④ ⑤ | ④ ⑤ | ④ ⑤ | ③ ④ ⑤ |
| [*] Row/Category Title ⑥ | | ④ ⑤ | ④ ⑤ | ④ ⑤ | ③ ④ ⑤ |
| * Unit of Measure | | | | | |

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

① Arm/Group Description describes details about the intervention strategy (e.g., dose, dosage form, frequency, duration) or groups evaluated.

② Overall Number of Units Analyzed and Type of Units Analyzed may also be specified.

③ Total values are automatically calculated for Overall Number of Baseline Participants and for data reported with a Measure Type of Number, Count of Participants, or Count of Units.

④ If Measure Type is a "count," percentage of participants/units is automatically calculated from Overall Number of Baseline Participants/Units Analyzed. The percentage can be hidden (display is optional).

⑤ Not Applicable should be used only if Measure Type is Number, Count of Participants, or Count of Units. No dispersion value is needed if Measure of Dispersion is Not Applicable.

⑥ [Optional] Add as many Rows/Categories as needed. If more than one is entered, a Row/Category Title and Baseline Measure Data are required for each row.

# Baseline Characteristics Template — Sex/Gender* (use at least one) — ClinicalTrials.gov

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| * Arm/Group Title | | | | | | | | Total | |
| *§ Arm/Group Description ① | | | | | | | | | |
| * Overall Number of Baseline Participants ② | | | | | | | | ③ | |
| [*] Baseline Analysis Population Description | | | | | | | | | |
| **Sex: Female, Male** | | | | | | | | | |
| Female | | | | | | | | ③ | |
| Male | | | | | | | | ③ | |
| * Unit of Measure | Participants | | | | | | | | |
| **Sex/Gender, Customized** | | | | | | | | | |
| * Measure Type | * Measure of Dispersion | | | | | | | | |
| (Select One)<br>Count of Participants ④<br>Mean<br>Median<br>Least Squares Mean (LSM)<br>Geometric Mean<br>Geometric LSM<br>Number<br>Count of Units ④ | (Select One)<br>Not Applicable ⑤<br>Standard Deviation<br>Inter-Quartile Range<br>Full Range | | | | | | | | |
| [*] Row/Category Title ⑥ | | | ④ ⑤ | | ④ ⑤ | | ④ ⑤ | ③ | ④ ⑤ |
| [*] Row/Category Title ⑥ | | | ④ ⑤ | | ④ ⑤ | | ④ ⑤ | ③ | ④ ⑤ |
| [*] Row/Category Title ⑥ | | | ④ ⑤ | | ④ ⑤ | | ④ ⑤ | ③ | ④ ⑤ |
| * Unit of Measure | | | | | | | | | |

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

① Arm/Group Description describes details about the intervention strategy (e.g., dose, dosage form, frequency, duration) or groups evaluated.
② Overall Number of Units Analyzed and Type of Units Analyzed may also be specified.
③ Total values are automatically calculated for Overall Number of Baseline Participants and for data reported with a Measure Type of Number, Count of Participants, or Count of Units.
④ If Measure Type is a "count," percentage of participants/units is automatically calculated from Overall Number of Baseline Participants/Units Analyzed. The percentage can be hidden (display is optional).
⑤ Not Applicable should be used only if Measure Type is Number, Count of Participants, or Count of Units. No dispersion value is needed if Measure of Dispersion is Not Applicable.
⑥ [Optional] Add as many Rows/Categories as needed. If more than one is entered, a Row/Category Title and Baseline Measure Data are required for each row.

# Baseline Characteristics Template — Race*§, Ethnicity*§, and Region — ClinicalTrials.gov

| | | | | |
|---|---|---|---|---|
| * Arm/Group Title | | | | Total |
| *§ Arm/Group Description ① | | | | |
| * Overall Number of Baseline Participants ② | | | | ③ |
| [*] Baseline Analysis Population Description | | | | |
| **Race (NIH/OMB) ④** | | | | |
| American Indian or Alaska Native | | | | ③ |
| Asian | | | | ③ |
| Native Hawaiian or Pacific Islander | | | | ③ |
| Black or African American | | | | ③ |
| White | | | | ③ |
| More than one race | | | | ③ |
| Unknown or Not Reported | | | | ③ |
| * Unit of Measure: Participants | | | | |
| **Ethnicity (NIH/OMB) ④** | | | | |
| Hispanic or Latino | | | | ③ |
| Not Hispanic or Latino | | | | ③ |
| Unknown or Not Reported | | | | ③ |
| * Unit of Measure: Participants | | | | |
| **Region of Enrollment** | | | | |
| United States | | | | ③ |
| Region/Country Name ⑤ | | | | ③ |
| Region/Country Name ⑤ | | | | ③ |
| Region/Country Name ⑤ | | | | ③ |
| * Unit of Measure: Participants | | | | |

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

① Arm/Group Description describes details about the intervention strategy (e.g., dose, dosage form, frequency, duration) or groups evaluated.
② Overall Number of Units Analyzed and Type of Units Analyzed may also be specified.
③ Total values are automatically calculated for Overall Number of Baseline Participants and for each Baseline Measure.
④ If not using NIH/OMB categories, use Race/Ethnicity, Customized (not shown); if not collected, use Race and Ethnicity Not Collected (not shown).
⑤ [Optional] Region of Enrollment Baseline Measure is optional, but at least one Region/Country is required if reporting Region of Enrollment. Add as many Regions/Countries as needed.

# Baseline Characteristics Template — Study-Specific Measure*§ — ClinicalTrials.gov

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| * Arm/Group Title | | | | | | | | Total | |
| *§ Arm/Group Description ① | | | | | | | | | |
| * Overall Number of Baseline Participants ② | | | | | | | | ③ | |
| [*] Baseline Analysis Population Description | | | | | | | | | |
| [*] Study-Specific Baseline Measure Title | | | | | | | | | |
| Baseline Measure Description | | | | | | | | | |
| * Measure Type | * Measure of Dispersion | | | | | | | | |
| (Select One)<br>Count of Participants ④<br>Mean<br>Median<br>Least Squares Mean (LSM)<br>Geometric Mean<br>Geometric LSM<br>Number<br>Count of Units ④ | (Select One)<br>Not Applicable ⑤<br>Standard Deviation<br>Inter-Quartile Range<br>Full Range | | | | | | | | |
| [*] Row/Category Title ⑥ | | | ④ ⑤ | | ④ ⑤ | | ④ ⑤ | ③ | ④ ⑤ |
| [*] Row/Category Title ⑥ | | | ④ ⑤ | | ④ ⑤ | | ④ ⑤ | ③ | ④ ⑤ |
| * Unit of Measure | | | | | | | | | |

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

① Arm/Group Description describes details about the intervention strategy (e.g., dose, dosage form, frequency, duration) or groups evaluated.
② Overall Number of Units Analyzed and Type of Units Analyzed may also be specified.
③ Total values are automatically calculated for Overall Number of Baseline Participants and for data reported with a Measure Type of Number, Count of Participants, or Count of Units.
④ If Measure Type is a "count," percentage of participants/units is automatically calculated from Overall Number of Baseline Participants/Units Analyzed. The percentage can be hidden (display is optional).
⑤ Not Applicable should be used only if Measure Type is Number, Count of Participants, or Count of Units. No dispersion value is needed if Measure of Dispersion is Not Applicable.
⑥ [Optional] Add as many Rows/Categories as needed. If more than one is entered, a Row/Category Title and Baseline Measure Data are required for each row. Row/Category Titles are only required if more than one row.

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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<br>◦ All pre-specified primary and secondary outcome measures (required)<br>◦ 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<br>◦ 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."<br>• 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<br>◦ Tip: Write the description for a public audience (i.e., not specialists in your field, but general readers of the medical literature).<br>◦ 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<br><br>[*]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.<br>◦ 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).<br>◦ 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<br>◦ 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:<br>◦ Title—Descriptive label for the group<br>▪ Tip: Use informative labels (e.g., "Placebo"), not generic labels (e.g., "Group 1"). The label will become the header for that table column.<br>◦ 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)<br>▪ Tip: This may include a description of how groups of participants were recombined for analysis purposes. | *Arm/Group Title<br><br>*§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<br>◦ 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<br><br>[*]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<br>◦ 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:<br>◦ Measure of central tendency used to aggregate continuous data (e.g., mean, median)<br>◦ Count of Participants or Count of Units<br>▪ Tip: A percentage of participants or units may also be reported if a "count" is used.<br>◦ Number<br>▪ 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)<br>◦ 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:<br>◦ Primary and Secondary Outcome Measures (required)<br>◦ Other Pre-Specified and Post Hoc Outcome Measures (optional)<br>• 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<br>◦ Tip: Include any of the following in the comments, if applicable:<br>▪ Null hypothesis for the comparison<br>▪ Power calculation | *Comparison Group Selection<br>Comparison Comments |
| ☐ | • Type of analysis: Superiority, Non-inferiority, Equivalence, or Other (e.g., for single group or other descriptive analysis)<br>◦ 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<br>[*]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)<br>◦ Tip: Explain any of the following in the comments, if relevant:<br>▪ Adjustments for multiple comparisons or covariates<br>▪ *A priori* threshold for statistical significance (e.g., < 0.05)<br>▪ Degrees of freedom | Statistical Test of Hypothesis<br>[*]P-Value and Method<br>P-Value Comments<br>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:<br>◦ Confidence Interval<br>◦ Standard Deviation or Standard Error of the Mean<br>◦ Additional explanatory comments to interpret the value, if needed<br>▪ 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<br>[*]Estimation Parameter and Estimated Value<br>Confidence Interval<br>Parameter Dispersion Type and Dispersion Value<br>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<br>◦ 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

# *Outcome Measure Template* *ClinicalTrials.gov*

| | |
|---|---|
| * Outcome Measure Type | (Select One) Primary Secondary Other Pre-specified Post-Hoc |
| * Outcome Measure Title | |
| [*] Outcome Measure Description | |
| * Outcome Measure Time Frame | |

| | | | | |
|---|---|---|---|---|
| * Arm/Group Title | | | | |
| *§ Arm/Group Description ① | | | | |
| * Overall Number of Participants Analyzed ② | | | | |
| [*] Analysis Population Description | | | | |
| * Measure Type | * Measure of Dispersion/Precision | | | |
| (Select One)<br>Count of Participants ③<br>Mean<br>Median<br>Least Squares Mean (LSM)<br>Geometric Mean<br>Geometric LSM<br>Number<br>Count of Units ③ | (Select One)<br>Not Applicable ④<br>Standard Deviation<br>Standard Error<br>Inter-Quartile Range<br>Full Range<br>_____ % Confidence Interval<br>Geometric Coefficient of Variation | | | |
| [*] Row/Category Title ⑤ | | ③ ④ | ③ ④ | ③ ④ |
| [*] Row/Category Title ⑤ | | ③ ④ | ③ ④ | ③ ④ |
| * Unit of Measure | | | | |

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

① Arm/Group Description describes details about the intervention strategy (e.g., dose, dosage form, frequency, duration) or groups evaluated.
② Overall Number of Units Analyzed and Type of Units Analyzed may also be specified.
③ If Measure Type is a "count," percentage of participants/units is automatically calculated from Overall Number of Participants/Units Analyzed. The percentage can be hidden (display is optional).
④ Not Applicable should be used only if Measure Type is Number, Count of Participants, or Count of Units. No dispersion/precision value is needed if Measure of Dispersion is Not Applicable.
⑤ [Optional] Add as many Rows/Categories as needed. If more than one is entered, a Row/Category Title and Outcome Measure Data are required for each row. Row/Category Titles are only required if more than one row.

# *Statistical Analysis Template* — *ClinicalTrials.gov*

| | | |
|---|---|---|
| **Statistical Analysis Overview** | * Comparison Group Selection ① | ☐ Arm/Group 1 ☐ Arm/Group 2 ☐ Arm/Group 3 |
| | Comments ② | |
| | * Type of Statistical Test | **(Select One)** Superiority; Equivalence; Non-inferiority; Other (for example, single group or other descriptive analysis) |
| | **[*]** Comments ③ | |
| **Statistical Test of Hypothesis** | **[*]** P-Value (if applicable) | _____ *(calculated value, not the a priori threshold for statistical significance)* |
| | Comments ② | |
| | **[*]** Method (required if p-value entered) | **(Select One)** ANCOVA; ANOVA; Chi-Squared; Chi-Squared, Corrected; Cochran-Mantel-Haenszel; Fisher Exact; Kruskal-Wallis; Log Rank; Mantel Haenszel; McNemar; Mixed Models Analysis; Regression, Cox; Regression, Linear; Regression, Logistic; Sign Test; t-Test, 1-Sided; t-Test, 2-Sided; Wilcoxon (Mann-Whitney); Other (_____) |
| | Comments ② | |
| **Method of Estimation** | **[*]** Estimation Parameter (if applicable) | **(Select One)** Cox Proportional Hazard; Hazard Ratio (HR); Hazard Ratio, Log; Mean Difference (Final Values); Mean Difference (Net); Median Difference (Final Values); Median Difference (Net); Odds Ratio (OR); Odds Ratio, Log; Risk Difference (RD); Risk Ratio (RR); Risk Ratio, Log; Slope; Other (_____) |
| | Estimated Value | _____ *(calculated value)* |
| | Confidence Interval (if applicable) | **Level:** _____ % Confidence Interval<br>**Number of Sides: (Select One)** 2-sided 1-sided<br>**Lower Limit:** _____<br>**Upper Limit:** _____ |
| | Parameter Dispersion | **Type: (Select One)** Standard Deviation; Standard Error of the Mean<br>**Value:** _____ |
| | Estimation Comments ② | |
| **Other Statistical Analysis ④** | | |

*** Required** **[*] Conditionally required**

**① Use the checkboxes to select the Arms/Groups (pre-populated from the Outcome Measure) involved in the statistical analysis.**

**② (Optional) Include any relevant information about the row above (e.g., the null hypothesis, details of the power calculation, adjustment for multiple comparisons, the *a priori* threshold for statistical significance, the direction of the comparison). Do not include written results or conclusions.**

**③ If a non-inferiority or equivalence analysis, information on the definition of the non-inferiority or equivalence margin is required.**

**④ If the statistical analysis cannot be submitted using the Statistical Test of Hypothesis or Method of Estimation options, provide a description and the results of the scientifically appropriate test of statistical significance.**

# *All-Cause Mortality and Serious Adverse Events Template* ClinicalTrials.gov

| | |
|---|---|
| *§ Time Frame | |
| [*] Adverse Event Reporting Description | |
| Source Vocabulary Name for Table Default ① | |
| *§ Collection Approach for Table Default ① | **(Select One)** Systematic Non-Systematic |

| | | | |
|---|---|---|---|
| * Arm/Group Title | | | |
| *§ Arm/Group Description ② | | | |

***§ All-Cause Mortality**

| | *§ Number Participants Affected | *§ Number Participants at Risk | *§ Number Participants Affected | *§ Number Participants at Risk | *§ Number Participants Affected | *§ Number Participants at Risk |
|---|---|---|---|---|---|---|
| *§ Total | | | | | | |

*** Serious Adverse Events**

| | | * Number Participants Affected | * Number Participants at Risk | Number Events | * Number Participants Affected | * Number Participants at Risk | Number Events | * Number Participants Affected | * Number Participants at Risk | Number Events |
|---|---|---|---|---|---|---|---|---|---|---|
| * Total | | | | | | | | | | |
| * Adverse Event Term | * Organ System | | | | | | | | | |
| | ③ | | ④[*] | | | ④[*] | | | ④[*] | |
| | ③ | | ④[*] | | | ④[*] | | | ④[*] | |
| | ③ | | ④[*] | | | ④[*] | | | ④[*] | |
| | ③ | | ④[*] | | | ④[*] | | | ④[*] | |
| | ③ | | ④[*] | | | ④[*] | | | ④[*] | |
| | ③ | | ④[*] | | | ④[*] | | | ④[*] | |

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

① If entered, the table default values apply to all Adverse Event Terms. The values may be changed for any single Adverse Event, if different from the table default.
② Arm/Group Description describes details about the intervention strategy (e.g., dose, dosage form, frequency, duration) or groups evaluated.
③ Organ System must be selected from a pick-list of high-level categories. See the Results Data Element Definitions for details.
④ Number of Participants at Risk for an Adverse Event Term is only required when the value differs from the Total Number of Participants at Risk.

# *Other (Not Including Serious) Adverse Events Template* — *ClinicalTrials.gov*

| | |
|---|---|
| *§ Time Frame | |
| [*] Adverse Event Reporting Description | |
| Source Vocabulary Name for Table Default ① | |
| *§ Collection Approach for Table Default ① | **(Select One)** Systematic Non-Systematic |

| | | | |
|---|---|---|---|
| * Arm/Group Title | | | |
| *§ Arm/Group Description ② | | | |

*** Other (Not Including Serious) Adverse Events**

| * Frequency Threshold for Reporting Other Adverse Events (0–5%) _____% | * Number Participants Affected | * Number Participants at Risk | Number Events | * Number Participants Affected | * Number Participants at Risk | Number Events | * Number Participants Affected | * Number Participants at Risk | Number Events |
|---|---|---|---|---|---|---|---|---|---|
| * Total | | | | | | | | | |

| * Adverse Event Term | * Organ System | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | ③ | | ④[*] | | | ④[*] | | | ④[*] | |
| | ③ | | ④[*] | | | ④[*] | | | ④[*] | |
| | ③ | | ④[*] | | | ④[*] | | | ④[*] | |
| | ③ | | ④[*] | | | ④[*] | | | ④[*] | |
| | ③ | | ④[*] | | | ④[*] | | | ④[*] | |
| | ③ | | ④[*] | | | ④[*] | | | ④[*] | |
| | ③ | | ④[*] | | | ④[*] | | | ④[*] | |
| | ③ | | ④[*] | | | ④[*] | | | ④[*] | |

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

① If entered, the table default values apply to all Adverse Event Terms. The values may be changed for any single Adverse Event, if different from the table default.
② Arm/Group Description describes details about the intervention strategy (e.g., dose, dosage form, frequency, duration) or groups evaluated.
③ Organ System must be selected from a pick-list of high-level categories. See the Results Data Element Definitions for details.
④ Number of Participants at Risk for an Adverse Event Term is only required when the value differs from the Total Number of Participants at Risk.