

## ClinicalTrials.gov - Quality Assurance/Quality Control Review Detailed Review of Results Submission

### Background

Basic results information must be clear and informative. The Quality Assurance/Quality Control (QA/QC) staff at ClinicalTrials.gov reviews results information for apparent validity, meaningful entries, logic and internal consistency, and formatting. All results submissions undergo two levels of review. This document outlines some specific items that are evaluated by the QA/QC staff during a detailed review only after the results submission has passed a more general, high level review. This document is not comprehensive, but is intended to provide an overview to help data providers ensure that records meet these review criteria prior to submission to ClinicalTrials.gov. Additional explanatory documents, “Helpful Hints” and “Common Errors,” are also available at <http://prsinfo.clinicaltrials.gov/fdaaa.html>.

### General

- Acronyms and abbreviations are spelled out fully (with acronym in parentheses) at least the first time they are used in the Protocol and Results Sections.
- No spelling errors exist.
- No formatting problems exist, including no unreadable characters or symbols.

### Protocol Section

#### ADMINISTRATIVE INFORMATION

- “Overall Study Status” is **not** “Recruiting” or “Not Yet Recruiting.”
- “Primary Completion Date” is “Actual” and in the past.

#### ENROLLMENT (NUMBER OF SUBJECTS)

- “Enrollment” is “Actual” and consistent with Number “STARTED” in Participant Flow.

#### INTERVENTIONS AND ARMS/GROUPS

- “Intervention Names” are consistent with information provided in Results Section.
  - If a “company serial number” (e.g., V501) was used and another name is now available, each section includes the new name.
- Arms/Groups in Protocol Section are consistent with Arms/Groups in Results Section.

### Results Section

#### GENERAL

- Decimal separator – All numbers with a decimal, use a decimal point [“.”] rather than a comma [“,”] for the decimal separator symbol.
- Comma separator – All numbers of “thousands” use a comma [“,”] rather than a decimal point [“.”] for the separator symbol (e.g., 10,200).

#### TITLE AND DESCRIPTION INFORMATION

- The Title (e.g. “Arm/Group Title,” “Period Title”) and Description (e.g., “Arm/Group Description) are comprehensible and descriptive (e.g., Arm A, B, C or Period 1, 2, 3 is not acceptable).

- The Title (e.g., “Arm/Group Title”) is generally shorter than the Description (e.g., “Arm/Group Description.”)
- Abbreviations or symbols used in Titles (e.g., “Baseline Measure Title”) due to space limitations are explained in the relevant Description data element (e.g., “Baseline Measure Description.”)

#### MEASURE INFORMATION

- For measures obtained using a scale:
  - Name of scale is provided in “Measure Title.”
  - Range and direction of scores (0 = worst; 10 = best) are indicated in “Measure Description.”
  - “Unit of Measure” is “units on a scale” if no other unit.
- Symbols used for “Unit of Measure” are spelled out (e.g., “percentage” for “%”; “number” for “#”).

#### Participant Flow

##### GENERAL

- Number “STARTED” first Period matches “Enrollment, Actual” in Protocol Section.
  - If Number “STARTED” does not match, reasons are explained in “Pre-Assignment Details.”

##### PERIODS

- Single Period
  - “Period Title” is “Overall Study.”
- Multiple Periods
  - Number “STARTED” in a Period is the same as the Number “COMPLETED” in the previous Period.
  - If the Number “STARTED” in a Period is not the same as the Number “COMPLETED” in the previous period, discrepancy is explained in the “Comments” data element.

##### MILESTONES

- Number in a Milestone is greater than or equal to the Number “COMPLETED” the Period.
- Multiple Milestones
  - Number in “Milestone Data” for a Milestone is not greater than the Number in “Milestone Data” for the previous Milestone.

#### Baseline Characteristics

##### DATA

- “Overall Number of Baseline Participants” is consistent with the Number “STARTED” in the Participant Flow Module.
  - If not consistent, explanatory comments are provided in “Baseline Measure Description.”
- Age – Data provided are consistent with the Minimum and Maximum Ages provided for “Age Limits” in Protocol Section.
- For categorical data using “Number” and participants as the “Unit of Measure,” the total number of participants in each arm/group matches “Overall Number of Baseline Participants” in each arm/group.
  - If not matching, explanatory comments are provided in “Baseline Measure Description.”

- For Continuous Measures (e.g., Mean, Median), the Total column is completed. Zeros may not be entered unless the actual value of the measure is zero.

#### Outcome Measures

##### OUTCOME MEASURE INFORMATION

- The Outcome Measure Information should be comprehensible.
  - “Outcome Measure Title and Description,” “Units of Measure” and scale information are logical for each Outcome Measure.
  - Measures evaluating change specify two or more points in time (e.g., baseline and 12 weeks).
  - If “Category Titles” are used, any ancillary information regarding numbers of participants in each category and the respective arm/group is clear and complete. This may be described in “Analysis Population Description” and as part of the “Category Title” (e.g., Category Title [n=23, 24, 26] where “n” refers to the number of participants in each of the 3 arms/groups for that category).
- “Outcome Measure Time Frame” is as specific as possible (e.g., 24 weeks or 4 weeks after hospital discharge).

##### DATA

- “Number of Participants Analyzed” may not be zero unless explanatory comments are provided in “Analysis Population Description.”

#### Statistical Analyses

- Each Statistical Analysis clearly describes which groups and categories are being compared in the analysis.
- If “Non-inferiority or Equivalence Analysis? (Y/N)” is “Yes,” explanatory comments are provided in “Comments.”
- “=” in “P-Value” is not present.
- If Statistical “Method” Type is “Other,” “Other Method Name” is not redundant with a method listed in the drop-down menu.

#### Adverse Events

- “Number of Participants at Risk” is consistent with the information provided in the Participant Flow Module.