

ClinicalTrials.gov Review of Results Submissions

Background

Protocol and results information must be clear and informative. Prior to submission of results, a record must have summary protocol information and an assigned NCT Number (ClinicalTrials.gov unique identifier). ClinicalTrials.gov reviews protocol and results information for apparent validity, meaningful entries, logic and internal consistency, and formatting. The review focuses on assessing whether the entered data could be understood by a reader of the medical literature who is not already familiar with the study.

This document is intended to assist data providers in preparing results records by providing an overview of ClinicalTrials.gov review criteria. This document is not comprehensive. It is the responsibility of the data provider to ensure that records are consistent with these criteria. The public posting of a results record by ClinicalTrials.gov does not necessarily mean that all of these criteria have been met. At times, ClinicalTrials.gov may note problems and request revisions after results have been posted publicly. Additional explanatory user documents are also available at <http://prsinfo.clinicaltrials.gov/fdaaa.html>.

Results Review Criteria

General

- Records are in English (with possible exception for the Official Title).
- 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. Note: The Spelling Tool on the “View Protocol Record” page may be used to identify possible spelling errors.
- No formatting problems exist, including any unreadable characters or symbols.
 - Unicode, UTF-8 format, is the standard for ClinicalTrials.gov

Consistency with Protocol Section (at the time of results submission, the protocol section is re-reviewed).

ADMINISTRATIVE INFORMATION

- Overall Study Status is consistent with Study Start and Study Completion Dates.
- “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 a generic name is now available, the “Intervention Name” is updated and each section includes the new name(s).
- Arms/Groups in Protocol Section are consistent with Arms/Groups in Results Section.

- Interventional Study Model (e.g., “Single Group Assignment” or “Cross-Over”) is consistent with Arms/Groups in Results Section.

Results Section

Summary results information may be submitted once data are available for one or more primary outcome measures and for each arm of the study.

GENERAL

- All information is entered in the relevant and appropriate fields. For example, information relevant to the analysis population should be entered in “Analysis Population Description,” not in the Measure Description.
- Results, including study or outcome conclusions, are not provided in narrative form.
- Data elements that are optional are left blank if there is no relevant information to provide. Note: Do not use terms such as N/A or None.
- If a pull-down menu option is specified as “other,” a description of “other” is provided and it is not redundant with an option listed in the pull-down menu.
- 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.

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 is not informative).
- The Title (e.g., “Arm/Group Title”) is generally shorter than the Description (e.g., “Arm/Group Description.”) Note: The “Arm/Group Description” should be used to provide additional details about the interventions administered (e.g., dosage, dosage form, frequency of administration) or groups evaluated.
- 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

The Participant Flow module summarizes the number of participants starting and completing each period of the study in a tabular format. The arms/groups (columns of the table) are used to explain how interventions were assigned to participants and how participants “flow” through the study (and each period within the study). In general, participants are followed through a single arm/group (column) and

each participant is represented once per period (total number of participants STARTED the period is not greater than the actual number of participants enrolled in the study from the protocol section). Note: Particular attention should be paid to the table structure for cross-over studies. Please see Helpful Hints (<http://prsinfo.clinicaltrials.gov/ResultsExamples.pdf>) for a specific example of an acceptable structure for a crossover study.

GENERAL

- Number “STARTED” in 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 subsequent Period is the same as the Number “COMPLETED” in the previous Period.
 - If the Number “STARTED” in a subsequent Period is not the same as the Number “COMPLETED” in the previous period, discrepancy is explained in the “Comments” data element.
 - For “Reasons Not Completed,” reasons are only included when applicable. For example, a reason should not be included when “0” participants are entered in all data fields across that specific row.

MILESTONES

- In general, number in a Milestone is greater than or equal to the Number “COMPLETED” the Period.
- In general, if multiple Milestones, number in “Milestone Data” for a Milestone is not greater than the Number in “Milestone Data” for the previous Milestone.
- Note: there may be acceptable exceptions to the above.

Baseline Characteristics

The Baseline Characteristics module summarizes the demographic and other baseline characteristics of the participants in the study, overall and by arm/group. At a minimum, age and gender must be provided. An unlimited number of other characteristics relevant to the study may also be entered.

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.
- Preferred formatting for “Unit of Measure” of study participants is “participants” (e.g., instead of “number of participants” or “subjects”).
- Categorical data do not have categories that overlap and all possible categories are presented.

- For categorical data using “Number” as the “Measure Type” 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.”
 - Units of Measure are specified in the Category Title (e.g., “years” for categories of age).
- 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

The Outcome Measures module summarizes data for prespecified primary and secondary outcomes as well as other prespecified outcomes, *post hoc* outcomes and statistical analyses. The combination of the Outcome Measure Title, Description and Units of Measure must be sufficiently descriptive to allow a reader not familiar with the study to understand what was assessed.

OUTCOME MEASURE INFORMATION

- The Outcome Measure Information is comprehensible and describes WHAT was measured, not why it was measured. Note: Generally, verbs should not be included in the Measure Title.
- “Outcome Measure Title, Description,” and “Units of Measure” are logical for each Outcome Measure when used together. The Outcome Measure is specific and measurable by the Units of Measure provided. Outcome Measure Titles and Descriptions that are identical are not necessary. If the Outcome Measure Title is sufficiently descriptive, the Outcome Measure Description may be left blank.
- Outcome Measure 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.
- Outcome Measure of Change
 - Two time points are specified (e.g., baseline and 6 months) in the Time Frame and Measure Title. Example of preferred formatting for Measure Title is: "Change from baseline in blood pressure at 6 months"
 - Details of change calculation are provided in Measure Description.
 - Note: No calculation details are necessary if the change is calculated as the later time point minus the earlier time point (eg., 6 months minus baseline). If different, describe calculation details.
 - Change calculation details are specified in Outcome Measure Description if more than two time points.
- Category Titles are not used if there is only one category.
- 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” specifies the specific time point(s) at which the outcome measure was assessed and for which data are presented. For example, “1 year or “up to 24 weeks.”
- For Outcome Measures that have not yet been posted, the Anticipated Posting Dates are included.

DATA

- “Number of Participants Analyzed” does not include zero for any Arm unless explanatory comments are provided in “Analysis Population Description.”
- “Number of Participants Analyzed” is consistent with Participant Flow Module. If not consistent, any discrepancy is explained in the Analysis Population Description.
- Units of Measure are specific. Absolute numbers are preferred (e.g., participants), although percentages are accepted. If the Unit of Measure is a percentage, what the percentage refers to is specified (e.g., Percentage of Participants) and “%” is spelled out as “percentage.”

STATISTICAL ANALYSES

- Each Statistical Analysis clearly describes which groups and categories are being compared in the analysis. **Note:** If more than one category (“row”) in Outcome Measure, explain which category the Statistical Analysis applies to.
- Statistical Analysis is consistent with reported data for the associated Outcome Measure (e.g. a mean difference is consistent with the two Arm/Groups from which the difference is calculated).
- If “Non-inferiority or Equivalence Analysis? (Y/N)” is “Yes,” explanatory comments which include the margin of non-inferiority are provided in “Comments.”
- “=” in “P-Value” is not present.
- If a P-Value is not provided, “Method” data element is left blank.
- If a “Confidence Interval” is provided, the “Estimation Parameter” field is complete.

Adverse Events

The Adverse Events module summarizes adverse event information in two tables: one table for all serious adverse events and one table for other (not including serious) adverse events. Starting on September 27, 2009, data providers will be required to report all serious adverse events and other (not including serious) adverse events that exceed a frequency threshold of 5 percent in any arm. Data providers may voluntarily use a threshold that is lower than 5 percent, if they so desire.

- “Number of Participants at Risk” is consistent with the information provided in the Participant Flow Module.
- The same adverse event is not represented in both the serious and other (not including serious) tables. Note: It may be acceptable for the same “Adverse Event Term” to appear in both tables, however, the “Adverse Event Term” or “Adverse Event Term Additional Description” can be used to differentiate between the two events.

For Assistance

- If you require assistance with a specific situation, please contact register@clinicaltrials.gov.

Additional Results Resources (available at <http://prsinfo.clinicaltrials.gov/fdaaa.html>):

- Guide to Results Data Entry - (CHEST, 2009 Jul;136(1):295-303) – article includes summary results reporting requirements, brief descriptions of the results database modules, and suggestions for preparing results submissions. (<http://www.chestjournal.org/content/136/1/295.full>)
- Pre-Submission Checklist (pdf) (DRAFT) - a short reminder checklist to assist in results data entry. (<http://prsinfo.clinicaltrials.gov/pre-submission-checklist.pdf>)
- Common errors (pdf) (DRAFT) - overview of common types of errors identified in submitted records with "basic results." (<http://prsinfo.clinicaltrials.gov/CommonErrors.pdf>)
- Helpful hints (pdf) - tips on entering results data, including three examples of common study models (parallel design, crossover design, and diagnostic accuracy studies), reporting measure types, including information on reporting outcomes measured with a scale. (<http://prsinfo.clinicaltrials.gov/ResultsExamples.pdf>)
- "Basic Results" Data Element Definitions (DRAFT) - details on the information that is entered about results via the PRS. (http://prsinfo.clinicaltrials.gov/results_definitions.html)