READ THIS BEFORE SUBMITTING RESULTS DATA!

Serious errors of logic are occurring during results data entry. To learn how to avoid these errors, please consult the resources listed below, including Detailed Review Items (pdf) (DRAFT) - (http://prsinfo.clinicaltrials.gov/ResultsDetailedReviewItems.pdf) . DO NOT SUBMIT your data prior to reviewing these materials and inspecting your data tables for the following items:

Results Display

The Basic Results data tables will be seen by the public as "stand alone" tables. They must be meaningful to people who are not already familiar with the study.

General (relates to all data tables)

- ☐ Spell out all abbreviations and acronyms when first used (and include in parentheses) in the results section.
- ☐ Provide brief, but descriptive, Arm/Group Titles. These will be displayed as column headings. "Arm 1" is an example of an uninformative title.
- ☐ Use absolute numbers rather than percentages when possible (e.g. "participants" instead of "percentage of participants").
- ☐ Data based on a scale will only be informative to a reader if basic information about the scale is available. Provide the following:
  - Name of scale in "Measure Title;"
  - Best and worst scores in the "Outcome Measure Description" (e.g., "0 is worst and 10 is best"); and
  - "Unit of Measure" ("*units on a scale*" if no other unit).
- ☐ "Category Titles" are only appropriate if more than one category is described.

Participant Flow

- ☐ Number of participants "STARTED" should match "Enrollment, **Actual**" (in protocol section).

Baseline Characteristics

- ☐ For categorical data, if "Measure Type" is "Number" (e.g., "*Participants*") and the total for each Arm/Group does not match the "Overall Number of Baseline Participants," provide an explanation in "Baseline Measure Description."

Outcome Measures

- ☐ Provide a complete and meaningful description of the Outcome Measure
  - Ensure consistency among "Outcome Measure Title," "Outcome Measure Description," and "Units of Measure" (e.g., do not name the measure "response rate" and then report data for "number of participants").
  - Specify two or more time points for measures of change (in the "Time Frame" field).
  - A measure of change should be described as "Change from baseline in measure at time t." Explain any relevant calculation in the "Outcome Measure Description" (e.g., "percent change = [(measure at time t - measure at baseline)/measure at baseline]*100%").

- ☐ Provide specific "Time Frame" when possible (e.g., "24 weeks" **not** "at end of study").
- ☐ Be precise with terms. For example:
  - Only use "*proportion*" in the "Outcome Measure Title" when a ratio of two numbers is being presented (as a fraction or as a decimal).
  - Do not use words such as "rate," "frequency," and "incidence" if simply the number of participants with a certain outcome is being presented.

Statistical Analysis

- ☐ If more than one category in Outcome Measure, explain which category the Statistical Analysis applies to.

Adverse Events - Starting on September 27, 2009, data providers will be required to report two tables of summary adverse event information: one table for all serious adverse events and one table for other (not including serious) adverse events that exceed a frequency threshold of 5 percent in any arm. A threshold of lower than 5 percent may be used voluntarily.

- ☐ "Number of Participants at Risk" should be consistent with the information provided in the Participant Flow module.
- ☐ The same adverse event should not appear 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.

Other Situations

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

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)
- **"Basic Results" Data Element Definitions (DRAFT)** - details on the information that is entered about results, including adverse events, via the PRS. (http://prsinfo.clinicaltrials.gov/results_definitions.html)
- **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)
- **Detailed Review Items (pdf) (DRAFT)** - describes items evaluated by ClinicalTrials.gov after results have been submitted. (http://prsinfo.clinicaltrials.gov/ResultsDetailedReviewItems.pdf)
- **Common Errors (pdf) (DRAFT)** - overview of common types of errors identified in submitted records with "basic results" (http://prsinfo.clinicaltrials.gov/CommonErrors.pdf)