Tip #1: Results entry is required for all Applicable Clinical Trials (ACTs) within one year of the primary completion date (the date that the final subject was examined or received an intervention for the purposes of final collection of data for the primary outcome, whether the clinical trial concluded according to the pre-specified protocol or was terminated).

Tip #2: For detailed information, please review the following document:
http://prsinfo.clinicaltrials.gov/ResultsDetailedReviewItems.pdf

Tip #3: Results Display
- The Basic Results data tables will be seen by the public as “stand alone” tables.
- All tables must be meaningful to people who are not already familiar with the study.

Tip #4: Basic Entry Tips
- 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.

Tip #5: Participant Flow Module
- Number of participants “STARTED” should match “Enrollment, Actual” (in protocol section).

Tip #6: Baseline Characteristics Module
- 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.”
**Tip #7: Outcome Measures Module**
- 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%”).

**Tip #8: Statistical Analysis**
- If there is more than one category in Outcome Measure, explain the category to which the Statistical Analysis applies.

**Tip #9: Adverse Event Entry**
- Effective September 27, 2009, data providers are 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.
  - When entering adverse events, add all the events FIRST, then go back and enter in the actual numbers. This will save a lot of “clicking” and screen transfer.

For more information, go to [http://www.ucdenver.edu/academics/research/AboutUs/regcomp/Pages/Regulatory-Compliance.aspx](http://www.ucdenver.edu/academics/research/AboutUs/regcomp/Pages/Regulatory-Compliance.aspx) or call the Clinical Research Support Center at 303.724.1111.