ClinicalTrials.gov "Basic Results"
Data Element Definitions

November 5, 2008

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*	Required by ClinicalTrials.gov
[*]	Conditionally required by ClinicalTrials.gov
(FDAAA)	May be required to comply with US Public Law 110-85, Section 801

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1. Results Point of Contact * : Point of contact for scientific information about the posted clinical trial results.

Name or Official Title * : For the designated individual. Note that this may be a specific person's name (e.g., Dr. Jane Smith) or a position title (e.g., Director of Clinical Trials)

Organization Name * : Full name of the designated individual's organizational affiliation.

Phone * : (or "Email" required) Office phone of the designated individual. Use the format 123-456-7890 within the United States and Canada. Otherwise, provide the country code and phone number.

ext. : Phone extension, if needed

Email * : (or "Phone" required) Electronic mail address of the designated individual.

2. Certain Agreements * : Information certifying whether there exists an agreement between the sponsor or its agent and the principal investigators (unless the sponsor is an employer of the principal investigators) that restricts in any manner the ability of the principal investigators (PIs), after the completion of the trial, to discuss the results of the trial at a scientific meeting or any other public or private forum, or to publish in a scientific or academic journal information concerning the results of the trial. This does not include an agreement solely to comply with applicable provisions of law protecting the privacy of participants.

Are all PIs Employees of Sponsor? (Y/N) *: If all principal investigators are employees of the sponsor, select "Yes" and skip the remaining questions. If any principal investigator (PI) is not an employee of the sponsor, select "No" and answer the remaining questions.

Results Disclosure Restriction on PI(s)? (Y/N) [*] If there is an agreement between the sponsor (or its agent) and any non-employee PI(s) that restricts the PI's rights to discuss or publish trial results after the trial is completed, select "Yes" and select a "Restriction Type." Trial completion is defined as the final date on which data were collected (see Study Completion Date definition).

If there are agreements with multiple non-employee PIs and there is a disclosure restriction on at least one PI, select "Yes" and answer the remaining question. If there are varying agreements with PIs, choose the type below that represents the most restrictive of the agreements (e.g., the agreement with the greatest embargo time period).

PI Disclosure Restriction Type : Select one

- The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **less than or equal to 60 days** from the time submitted to the sponsor for review. The sponsor cannot require changes to the communication and cannot extend the embargo.
- The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **more than 60 days but less than or equal to 180 days** from the time submitted to the sponsor for review. The sponsor cannot require changes to the communication and cannot extend the embargo.
- Other disclosure agreement that restricts the right of the PI to discuss or publish trial results after the trial is completed

Other Disclosure Restriction Type : If "Other disclosure agreement..." is selected, please describe the type of agreement including any provisions allowing the sponsor to require changes, ban the communication, or extend an embargo.
(Limit: 500 characters)

3. Participant Flow * : Progress of research participants through each stage of a trial in a tabular format, including the number of participants who dropped out of the clinical trial. (Identical in purpose to a CONSORT flow diagram, but represented as tables.)

The tabular presentation may be separated into "periods," each of which comprises an interval of trial activity. Each period consists of "milestones" for reporting numbers of participants at particular points in time within that period.

Recruitment Details
Definition: Key information relevant to the recruitment process for the overall study, such as dates of the recruitment period and types of location (e.g., medical clinic), to provide context.
(Limit: 350 characters)

Pre-assignment Details
Definition: Description of any significant events and approaches for the overall study (e.g., wash out, run-in, transition) following participant enrollment, but prior to group assignment. For example, an explanation of why enrolled participants were excluded from the trial before assignment to groups.
(Limit: 350 characters)

Arm/Group *

Definition: Arms or comparison groups in a trial

(Note that arm information from the protocol section will be copied into the results section the *first time* results are created. After that, such information may be changed in the results section at any time. However, any changes in the results section will not be reflected in the protocol section - you will also need to update the protocol section, as appropriate.)

Arm/Group Title * : Label used to identify the arm or comparison group.
Examples: fluoxetine; sertraline; drug-eluting stent; placebo
(Limit: 62 characters)

Arm/Group Description : Brief description of the arm or comparison group to distinguish it from other arms/groups in the trial.
Examples: fluoxetine, 20mg qhs; Sirolimus-eluting stent (SES) implanted using standard percutaneous coronary intervention (PCI) technique via the femoral approach.
(Limit: 999 characters)

Period(s) *

Definition: Discrete stages of a clinical trial during which numbers of participants at specific significant events or points of time are reported. If only one period, use *Overall Study* for "Period Title."

There is no limit to the number of periods that may be used to describe a single trial. Each subsequent period represents a trial stage following the previous period. That is,

participants "flow" from earlier to later periods. All results sections must cover participant flow from initial assignment to arms/groups to completion of the trial.

Period Title *

Definition: Title describing a stage of the trial. If only one period is defined, the default title is "Overall Study." When a trial has more than one period, none of the period titles should be "Overall Study." Example of two periods: sertraline then placebo; placebo then sertraline;
(Limit: 40 characters)

Milestone(s) *

Definition: Specific events or time points in the trial when the numbers of participants are reported. While there is no limit to the number of milestones that may be used in a single period, data are required for two milestones, STARTED and COMPLETED, within each period.

STARTED * : Number of participants at the beginning of the period.

Comments : Additional information about the STARTED milestone.
(Limit: 100 characters)

COMPLETED * : Number of participants at the end of the period.

Comments : Additional information about the COMPLETED milestone.
(Limit: 100 characters)

[**Not Completed** : Number of participants that did not complete the period. *Calculated automatically* by subtracting COMPLETED from STARTED]

Additional Milestone(s) : Any number of milestones may be added between the two required milestones, STARTED and COMPLETED.

Milestone Title: * : Label describing milestone
(Limit: 40 characters)

Milestone Data * (per milestone, per arm/group): Number of participants to reach the milestone.

Comments : Additional information about the milestone.
(Limit: 100 characters)

Reason Not Completed : Additional information about participants who did not complete the period. If any are provided, the total number of participants accounted for by all reasons must equal the number of participants listed under "Not Completed."

Reason Not Completed Type [*] : Select one for each reason not completed

- Adverse Event
- Death
- Lack of Efficacy
- Lost to Follow-up
- Physician Decision
- Pregnancy
- Protocol Violation
- Withdrawal by Subject
- Other

Other Reason [*] : If "Other" is selected, provide label
(Limit: 40 characters)

Reason Not Completed Data * (per reason, per arm/group): Number of participants for each arm or comparison group.

4. Baseline Characteristics * : A table of demographic and baseline data for the entire trial population and for each arm or comparison group. Note that only baseline measures for **Age** and **Gender** are required; all other baseline measures are optional. The table cells accommodate different types of data:

- Categorical - create customized categories and then report a count or a measure of central tendency and a measure of dispersion for each category by arm or comparison group
- Continuous - report a measure of central tendency and a measure of dispersion for each arm or comparison group
- Time-to-Event Data - report as either (1) continuous data (e.g., mean time to event with measure of dispersion) or (2) categorical data at different time points by arm or comparison group

Arm/Group *
Definition: Arms or comparison groups in a trial

(Note that arm information from the protocol section will be copied into the results section the *first time* results are created. After that, such information may be changed in

the results section at any time. However, any changes in the results section will not be reflected in the protocol section - you will also need to update the protocol section, as appropriate.)

Arm/Group Title * : Label used to identify the arm or comparison group.
Examples: fluoxetine; sertraline; drug-eluting stent; placebo
(Limit: 62 characters)

Arm/Group Description : Brief description of the arm or comparison group to distinguish it from other arms/groups in the trial.
Examples: fluoxetine, 20mg qhs; Sirolimus-eluting stent (SES) implanted using standard percutaneous coronary intervention (PCI) technique via the femoral approach.
(Limit: 999 characters)

Overall Number of Baseline Participants * (per arm/group) : Overall number of participants for which baseline characteristics were measured for all baseline measures reported. Note that if the participant population differs for a particular baseline measure, the number of participants should be included in the Baseline Measure Description.

Baseline Measure(s) *
Definition: Name and description of a characteristic measured at the beginning of the trial. Note that baseline measure data for "Age" (at least one of the three types) and "Gender" are required. There is no limit to the number of additional "Study-Specific Measures" that may be provided.

Baseline Measure Title * : Select one. Note that baseline measures for at least one "Age" and "Gender" title are required.

- Study-Specific Measure (as many as needed)
- Age * (at least one of the following):
  - Age, Continuous: example - mean age in years
  - Age, Categorical:
    - <=18 years
    - >18 and <65 years
    - >=65 years
  - Age, Customized: example - number in each category (birth-10 years, 11-20 years, 21-30 years, etc.)
- Gender * (one of the following):
  - Gender, female, male
  - Gender, Customized

- Race (NIH/OMB): U.S. National Institutes of Health and U.S. Office of Management and Budget Classification Categories
- Race, Customized
- Ethnicity (NIH/OMB): U.S. National Institutes of Health and U.S. Office of Management and Budget Classification Categories
- Ethnicity, Customized
- Region of Enrollment

Study-Specific Baseline Measure Title(s) **[*]** : If "Study-Specific Measure" is chosen, provide the name of the measure. Examples: Systolic blood pressure; Prior anti-depressant treatment.
(Limit: 100 characters)

Baseline Measure Description : Additional information about the measure, such as details about the collection method or participant population, if different from Overall Number of Baseline Participants.
(Limit: 350 characters)

Measure Type * : Select one

- Number (e.g., number of participants)
- Measure of Central Tendency, if a continuous measure is reported
  - Mean
  - Median
  - Least Squares Mean
  - Geometric Mean
  - Log Mean

Measure of Dispersion * : Select one. Please select "Not Applicable" if the Measure Type is "Number". Please do NOT select "Not Applicable" for other measure types.

- Not Applicable
- Standard Deviation
- Inter-Quartile Range
- Full Range

Unit of Measure * : e.g., participants, mm Hg
(Limit: 40 characters)

Category Title * : (required for categorical data)
Definition: Name of distinct category for a baseline measure, if reporting categorical data.
(Limit: 50 characters)

Baseline Measure Data * : (per baseline measure and per arm/group)
Definition: Baseline measure data (either "Number" or "Descriptive Statistics").

Number * : (or Descriptive Statistics): e.g., number of participants

Descriptive Statistics * : (or Number)

Central Tendency Value : mean, median, least squares mean, geometric mean, or log mean.

Dispersion Value(s) : standard deviation, inter-quartile range, or full range.

5. Outcome Measures * : A table of values for each of the outcome measures by arm (i.e., initial assignment of groups to interventions) or comparison group (i.e., groups receiving interventions regardless of initial assignment). The table cells accommodate different types of data:

- Categorical - create customized categories and then report a count or a measure of central tendency and a measure of dispersion for each category by arm or comparison group
- Continuous - report a measure of central tendency and a measure of dispersion for each arm or comparison group
- Time-to-Event Data - report as either (1) continuous data (e.g., mean time to event with measure of dispersion) or (2) categorical data at different time points by arm or comparison group

Note that data reported for each outcome measure will be displayed as a separate table. All statistical analyses on those data will be associated with that table.

Arm/Group *
Definition: Arms or comparison groups in a trial

(Note that arm information from the protocol section will be copied into the results section the *first time* results are created. After that, such information may be changed in the results section at any time. However, any changes in the results section will not be

reflected in the protocol section - you will also need to update the protocol section, as appropriate.)

Arm/Group Title * : Label used to identify the arm or comparison group.
Examples: fluoxetine; sertraline; drug-eluting stent; placebo
(Limit: 62 characters)

Arm/Group Description : Brief description of the arm or comparison group to distinguish it from other arms/groups in the trial.
Examples: fluoxetine, 20mg qhs; Sirolimus-eluting stent (SES) implanted using standard percutaneous coronary intervention (PCI) technique via the femoral approach.
(Limit: 999 characters)

Number of Participants Analyzed * (per outcome measure, per arm/group)
For the outcome reported

Analysis Population Description
Definition: Explanation of how the number of participants for analysis was determined. Indicate whether the analysis was "per protocol", "intention to treat (ITT)", or another method. Also provide relevant details such as imputation technique (e.g., Last Observational Carried Forward [LOCF]), as appropriate.
(Limit: 350 characters)

Outcome Measure *
Definition: Name and description of the measure used to assess the effect of experimental variables in the trial

(Note that primary and secondary outcome measure information from the protocol section of the record will be copied into the results section the first time results are created. After that, "Outcome Measure Type," "Outcome Measure Title," "Outcome Measure Time Frame" and "Outcome Measure Safety Issue? (Y/N)" for primary or secondary outcome measures may only be changed in the results section.)

Outcome Measure Type * : Select one

- Primary Outcome Measure (from Protocol section)
- Secondary Outcome Measure (from Protocol section)
- Other Pre-specified Outcome Measure
- Post-Hoc Outcome Measure

Outcome Measure Reporting Status * : Indicate whether posting results data for this outcome measure. Note that each record is required to have "Posted" data for at least one outcome measure.

- Posted: Results data included
- Not Posted: Results data not included

Anticipated Posting Date : If "Outcome Measure Reporting Status" is "Not Posted", then indicate the expected month and year it will be "Posted."

Outcome Measure Title * : Name of outcome measure
(Limit: 255 characters)

Outcome Measure Time Frame * : Time point(s) at which outcome measure was assessed.
(Limit: 255 characters)

Outcome Measure Description : Additional information about outcome measure.
(Limit: 350 characters)

Outcome Measure Safety Issue? (Y/N) (FDAAA) : Is this outcome measure assessing a safety issue? Select: Yes/No

Measure Type * : Select one

- Number (e.g., number of participants)
- Measure of Central Tendency, if a continuous measure is reported
  - Mean
  - Median
  - Least Squares Mean
  - Geometric Mean
  - Log Mean

Measure of Dispersion * : Select one. Please select "Not Applicable" if the Measure Type is "Number". Please do NOT select "Not Applicable" for other Measure Types.

- Not Applicable
- Standard Deviation

- Inter-Quartile Range
- Full Range
- Standard Error
- 95% Confidence Interval

Unit of Measure * : e.g., participants, mm Hg
(Limit: 40 characters)

Category Title * : (required for categorical data, as many as needed)
Definition: Name of distinct category used to measure outcome, if reporting categorical data.
(Limit: 50 characters)

Outcome Data * : (per category, per arm/group)
Definition: Outcome measure summary data (either "Number" or "Descriptive Statistics").

Number * : (or Descriptive Statistics): e.g., number of participants

Descriptive Statistics * : (or Number)

Central Tendency Value : mean, median, least squares mean, geometric mean, or log mean

Dispersion Value(s) : standard deviation, inter-quartile range, full range, standard error, or 95% confidence interval

Statistical Analyses - OPTIONAL; if statistical analysis information is provided, then [*]-marked data elements are required.
Definition: One or more statistical analyses conducted on the outcome data.

If a statistical analysis is reported, the following data elements are required: "Comparison Group Selection," "Non-inferiority or Equivalence Analysis," and at least "P-Value" or "Confidence Interval" with the associated information.
Statistical Analysis Overview : Summary description of the analysis performed.

Comparison Group Selection [*] : Identifies the arms or comparison groups involved in the statistical analysis (check all to indicate an "omnibus" analysis)

Comments : Additional details about the statistical analysis, such as null hypothesis and description of power calculation
(Limit: 500 characters)

Non-inferiority or Equivalence Analysis? (Y/N) **[*]** : Identifies whether the analysis is a test of non-inferiority or equivalence (Choose "Yes") or superiority (Choose "No").

Comments : If, "Yes", provide additional details, including details of the power calculation (if not previously provided), definition of non-inferiority margin, and other key parameters
(Limit: 500 characters)

Statistical Test of Hypothesis : Procedure used for statistical analysis of outcome data and calculated p-value.

P-Value **[*]** : (if applicable): Calculated p-value given the null-hypothesis

Comments : Additional information, such as whether or not the p-value is adjusted for multiple comparisons and the a priori threshold for statistical significance
(Limit: 250 characters)

Method **[*]** : (required if "P-Value" is reported): Select a statistical test.

- 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

Other Method Name [*] : If "Other" is selected, provide name of statistical test.
(Limit: 40 characters)

Comments : Any other relevant information, such as adjustments or degrees of freedom
(Limit: 150 characters)

Method of Estimation : Procedure used to estimate effect of intervention.

Confidence Interval [*] : (if applicable, provide all five of the following sub-elements)
If the confidence interval is one-sided, also provide the Estimated Value in either the Lower Limit or Upper Limit.

Level [*] : Expressed as a percentage. (Default "95").

Lower Limit [*]

Upper Limit [*]

Estimated Value [*] (if provided, Estimation Parameter required)

Estimation Parameter [*] : 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

Other Parameter Name [*] : If "Other" is selected, provide name
(Limit: 40 characters)

Dispersion of Confidence Interval

Parameter Dispersion Type : Select one.

- Standard Deviation
- Standard Error of the Mean

Dispersion Value

Estimation Comments : Any other relevant estimation information, including the direction of the comparison (e.g., describe which arm or comparison group represents the numerator and denominator for relative risk)
(Limit 250 characters)

6. Overall Limitations and Caveats : If appropriate, describe significant limitations of the trial. Examples: Early termination leading to small number of subjects analyzed; Technical problems with measurement leading to unreliable or uninterpretable data.
(Limit 250 characters)

7. Adverse Events - OPTIONAL; if adverse events information is provided, then all [*]-marked data elements are required.

Two types of adverse event data are to be reported

1. Serious Adverse Events: A table of *all* anticipated and unanticipated serious adverse events, grouped by organ system, with number and frequency of such events in each arm of the clinical trial
2. Other (Not Including Serious) Adverse Events: A table of anticipated and unanticipated events (not included in the serious adverse event table) that exceed a frequency *threshold* within any arm of the clinical trial, grouped by organ system, with number and frequency of such events in each arm of the clinical trial.

Adverse events are unfavorable changes in health (or side effects), including abnormal laboratory findings, that occur in trial participants during the clinical trial or within a specified period following the trial.

Serious Adverse Events include adverse events that result in death, require either inpatient hospitalization or the prolongation of hospitalization, are life-threatening, a persistent or significant disability/incapacity or a congenital anomaly/birth defect. Other important medical events, based upon appropriate medical judgment, may also be considered Serious Adverse Events if a trial participants' health is at risk and intervention is required to prevent an outcome mentioned.

Arm/Group [*]
Definition: Arms or comparison groups in a trial

(Note that arm information from the protocol section will be copied into the results section the *first time* results are created. After that, such information may be changed in

the results section at any time. However, any changes in the results section will not be reflected in the protocol section - you will also need to update the protocol section, as appropriate.)

Arm/Group Title [*] Label used to identify the arm or comparison group.
Examples: fluoxetine; sertraline; drug-eluting stent; placebo
(Limit: 62 characters)

Arm/Group Description: Brief description of the arm or comparison group to distinguish it from other arms/groups in the trial.
Examples: fluoxetine, 20mg qhs; Sirolimus-eluting stent (SES) implanted using standard percutaneous coronary intervention (PCI) technique via the femoral approach.
(Limit: 999 characters)

Adverse Events
Definition: Unfavorable changes in health (or side effects), including abnormal laboratory findings, that occur in trial participants during the clinical trial or within a specified period following the trial.

Two types of adverse event data are to be reported: "Serious" and "Other (Not Including Serious)" adverse events.

Serious Adverse Events include adverse events that result in death, require either inpatient hospitalization or the prolongation of hospitalization, are life-threatening, a persistent or significant disability/incapacity or a congenital anomaly/birth defect. Other important medical events, based upon appropriate medical judgment, may also be considered Serious Adverse Events if a trial participants' health is at risk and intervention is required to prevent an outcome mentioned.

Other (Not Including Serious) Adverse Events are those that are not Serious Adverse Events that exceed a frequency threshold.

Adverse Event Term [*] : Word or phrase describing an adverse event.
(Limit: 62 characters)

Source Vocabulary Name : Standard terminology, controlled vocabulary, or classification and version from which adverse event terms are drawn, if any (e.g., MeSH 2007, SNOMED CT 2007, ICD9CM_2007, MedDRA 10.0)
(Limit: 14 characters)

Organ System [*] : High-level categories used to group adverse event terms by body or organ system. Select one. Adverse events that affect multiple systems should be classified as "General disorders."

- Blood and lymphatic system disorders

- Cardiac disorders
- Congenital, familial and genetic disorders
- Ear and labyrinth disorders
- Endocrine disorders
- Eye disorders
- Gastrointestinal disorders
- General disorders
- Hepatobiliary disorders
- Immune system disorders
- Infections and infestations
- Injury, poisoning and procedural complications
- Metabolism and nutrition disorders
- Musculoskeletal and connective tissue disorders
- Neoplasms benign, malignant and unspecified (including cysts and polyps)
- Nervous system disorders
- Pregnancy, puerperium and perinatal conditions
- Psychiatric disorders
- Renal and urinary disorders
- Reproductive system and breast disorders
- Respiratory, thoracic and mediastinal disorders
- Skin and subcutaneous tissue disorders
- Vascular disorders

Assessment Type [*] : Method used to assess the adverse event. Select one.

- Systematic Assessment: Any method of routinely determining whether or not certain adverse events have occurred, for example through a standard questionnaire, regular investigator assessment, regular laboratory testing, or other method
- Spontaneous Report: Any non-systematic method for determining whether or not adverse events have occurred, such as self-reporting by participants or occasional assessment/testing

Total Number Affected by Any Serious Adverse Event [*] (per arm/group): Overall number of participants affected by one or more Serious Adverse Events.

Frequency Threshold for Reporting Other (Not Including Serious) Adverse Event [*]
Definition: The frequency of Other (Not Including Serious) Adverse Events that, when exceeded within any arm or comparison group, are reported in the results database for all arms or comparison groups.
Expressed as a percentage

For example, a threshold of 5 percent indicates that all Other (Not Including Serious) Adverse Events with a frequency greater than 5 percent within at least one arm or comparison group are reported.

Total Number Affected by Any Other (Not Including Serious) Adverse Event [*] (per arm/group): Overall number of participants affected by one or more Not Including Serious Adverse Events reported in the table.

Adverse Event Data [*] (per adverse event, per arm/group)

Number of Affected Participants [*] : Number of participants experiencing at least one event being reported

Number of Events: Number of occurrences of the adverse event being reported

Number of Participants at Risk [*] : Number of participants assessed for adverse events during the trial (i.e., the denominator for calculating frequency of adverse events)