

ClinicalTrials.gov Results Quality Control Review Criteria: Introduction and Overview

This document provides an overview of the ClinicalTrials.gov Results Quality Control (QC) review process, along with specific criteria intended to help responsible parties prepare study records with results. ClinicalTrials.gov results information includes four scientific modules: Participant Flow, Baseline Characteristics, Outcome Measures and Statistical Analyses, and Adverse Event Information. Results information also includes Limitations and Caveats, Certain Agreements, and the Results Point of Contact for scientific information about the results. Results information submitted for studies with a primary completion date on or after January 18, 2017 also includes a copy of the study protocol and statistical analysis plan. After a record with results is released by the responsible party in the Protocol Registration and Results System (also called the PRS), the record is reviewed by National Library of Medicine (NLM) reviewers before it is posted on ClinicalTrials.gov.

As part of the QC review process, the reviewer provides the responsible party with comments noting Major Issues and Advisory Issues. Each Major Issue must be corrected or addressed; Advisory Issues are suggestions for improving the clarity of the record. The QC review process ends when all Major Issues noted in PRS Review Comments have been corrected or addressed by the responsible party. However, NLM may notify responsible parties of issues with a record and request revisions after results information has been posted publicly.

The responsible party is responsible for ensuring that the study follows all applicable laws and regulations and that the study record is consistent with these criteria and with the [Protocol Registration Quality Control Review Criteria](#). The posting of results information following the QC review process does not necessarily mean that the information complies with Section 801 of the Food and Drug Administration Amendments Act (FDAAA 801) and the Final Rule for Clinical Trials Registration and Results Information Submission (42 CFR Part 11). The QC review process is intended to help identify apparent errors, deficiencies, and/or inconsistencies in the submitted information; however, it does not assess the appropriateness of the scientific design and analytic approach and cannot ensure that the information is “truthful and non-misleading” under the relevant regulatory standards. Additional information about FDAAA 801 and the Final Rule is available at <https://prsinfo.clinicaltrials.gov>.

ClinicalTrials.gov Results Quality Control Review Criteria: General Preferred Formatting

General Preferred Formatting Overview

These instructions are intended as a style guide, and results information should be provided in the format described below. However, the QC review focuses on substantive issues, so the review comments may not note every formatting issue within the results information.

General Preferred Formatting Review Criteria

1. The study record is written in the third person.
2. Free-text fields are blank if there is no information to report, and they do not contain text such as “TBD,” “Pending,” “N/A,” “None,” or similar.
3. Acronyms and abbreviations are spelled out, with the acronym or abbreviation provided in parentheses immediately after, at least the first time they are used in the Protocol and Results sections of the study record (e.g., myocardial infarction (MI), major adverse cardiac events (MACE)).
4. There are no spelling or typographical errors.
5. Numerical values use a period for the decimal point and either a comma for the thousands separator or no separator (e.g., 1,234,567.89 or 1234567.89).
6. Symbols are spelled out (e.g., “percentage” for the % symbol, “number” for the # symbol).
7. A caret (^) is used to indicate exponents (e.g., kg/m²).
8. “Participants” is the preferred term, rather than “subjects” or “patients.”
9. Interventions are referred to by the same name throughout the study record.
10. If more than one name is used for the same drug (e.g., a generic name and a brand name), the study record clearly indicates that the drugs are the same.
11. Intervention names are the nonproprietary (i.e., generic) names instead of internal company serial numbers, if possible.
12. The same Arm/Group Titles and Arm/Group Descriptions are used in each module, if appropriate.
13. Baseline Measure Titles and Outcome Measure Titles do not end with a period.

ClinicalTrials.gov Results Quality Control Review Criteria: Participant Flow Module

Participant Flow Overview

The Participant Flow module is a tabular summary of the progress of participants through each stage of the study, by assignment group. It includes the numbers of participants who were assigned to each intervention strategy or sequence of intervention strategies and the number who started, completed, and dropped out of each stage. The Participant Flow module is identical in purpose to a [CONSORT flow diagram](#) but is presented as tables. The module accommodates a wide range of study designs and allows for the description of key events prior to group assignment (i.e., Recruitment Details and Pre-assignment Details).

Generally, each arm or comparison group (column) is used to represent the unique experience of a group of participants by describing all the interventions (or “exposures” in observational studies) that participants received while progressing through the study. The tabular presentation may be separated into Periods, each of which indicates a stage or interval of study activity. Each Period consists of Milestones (rows) used to report the numbers of participants at particular points in time or the numbers of participants who met certain criteria within that Period. Time is represented vertically, so participants “flow” downward from earlier to later Periods, generally within the same Arm/Group.

Participant Flow Review Criteria

I. General

1. Written results or conclusions are not presented in any free-text field as the only means of reporting data.
2. Information provided is consistent with relevant data element definitions. Information is also consistent between data elements.

II. Recruitment Details and Pre-assignment Details

1. The information provided for Recruitment Details and Pre-assignment Details is consistent with the data element definitions and the information provided in the Protocol Section of the study record.

III. Arm/Group Information

1. Results are presented separately for each arm of the study (i.e., “per arm”), or a valid explanation is provided for why results for each arm cannot be presented separately, as consistent with the study design.
2. Arm/Group Titles are brief and informative; Arm/Group Descriptions include details about the intervention strategies administered (e.g., dosage, dosage form, frequency of administration, duration of administration) or groups evaluated.

IV. Periods

1. The number of Periods is consistent with the number of discrete stages of the study.
2. Each Period Title is unique, is descriptive, and preferably includes the duration of the Period.

V. Milestones and Milestone Data

1. The data include only participants enrolled in the registered study protocol.
2. The unit of assignment (participants or units other than participants) is represented only once per Milestone (row).
3. The numbers of participants overall and for each Arm/Group have face validity and are logical.
4. The Type of Units Assigned is provided when the unit of assignment is a unit other than participants (e.g., eyes, lesions, implants).
5. The number of participants in the Started milestone is consistent with the Enrollment provided in the Protocol Section. If these numbers are inconsistent, a valid explanation is provided (e.g., in the Pre-assignment Details).
6. If there is more than one Period, the number of participants in the Started milestone in a subsequent Period matches the number of participants in the Completed milestone in the preceding Period, or a valid explanation is provided for the inconsistency.
7. Information describing a study milestone is included as a structured Milestone row in the Participant Flow table, not in a free-text field.

VI. Reason Not Completed and Reason Not Completed Data

1. If "Other" is selected as the Reason Not Completed Type, any entries for Other Reason are unique and do not duplicate a selection from the Reason Not Completed Type dropdown menu.

ClinicalTrials.gov Results Quality Control Review Criteria: Baseline Characteristics Module

Baseline Characteristics Overview

The Baseline Characteristics module is a tabular summary of each baseline or demographic characteristic for the entire study population and for each arm or comparison group (similar to Table 1 in a journal article). At a minimum, Baseline Measure Information includes Age, Sex/Gender, Race and Ethnicity (if collected under the study protocol), and any other measures that were assessed at baseline and used in the analysis of the Primary Outcome Measures. The Baseline Characteristics module allows for the submission of information describing an unlimited number of Baseline Measures, which are added by selecting prestructured measures (Age, Sex/Gender, Race and Ethnicity, and Region of Enrollment) and/or by specifying one or more Study-Specific Measures.

Each Baseline Measure includes a Baseline Measure Title and Baseline Measure Description that provide enough information for a general reader of the medical literature to understand the reported data, including any relevant definitions and/or assessment criteria. The data for each Baseline Measure are presented in a table. Columns in the table represent the groups of participants for which baseline measures are reported (each arm/group and overall). Rows represent numerical summary data for each Arm/Group and the entire study population (total), using a summary statistic (e.g., count, mean, median) and a specific Unit of Measure (e.g., mg/dL, participants).

Baseline Characteristics Review Criteria

I. General

1. Written results or conclusions are not presented in any free-text field as the only means of reporting data.
2. Information provided is consistent with relevant data element definitions. Information is also consistent between data elements.
3. Baseline Measures include only baseline data (i.e., do not include Outcome Measure data).
4. Each Baseline Measure is unique and does not duplicate another Baseline Measure.
5. Each Baseline Measure contains sufficient information to be understood on its own, independent of other Baseline Measures or information in other parts of the study record.

II. Arm/Group Information, Baseline Analysis Population Information, Number of Baseline Participants, and Number of Units Analyzed

1. Results are presented separately for each arm of the study (i.e., “per arm”), or a valid explanation is provided for why results for each arm cannot be presented separately, as consistent with the study design and the numbers of participants in the Participant Flow module.
2. The Arms/Groups include only participants enrolled in the registered study.
3. No participants appear for first time in the study record in the Baseline Characteristics module.
4. The Overall Number of Baseline Participants, the Number of Baseline Participants in Baseline Measures, and any free-text descriptions of the analysis population are consistent.
5. The Type of Units Analyzed, Overall Number of Units Analyzed and Number of Units Analyzed are provided when the unit of analysis for a Baseline Measure is a unit other than participants (e.g., eyes, lesions, implants).

6. Arm/Group Titles are brief and informative; Arm/Group Descriptions include details about the intervention strategies administered (e.g., dosage, dosage form, frequency of administration, duration of administration) or groups evaluated.
7. The Overall Number of Baseline Participants and Overall Number of Units Analyzed (if provided) are consistent with a Milestone (row) or logical combination of Milestones from the Participant Flow module; if not, a valid explanation for this inconsistency is provided in the Baseline Analysis Population Description.

III. Baseline Measure Title and Baseline Measure Description

1. Each Baseline Measure Title and Baseline Measure Description includes sufficient information to understand the reported values in the data table.
2. A Baseline Measure using a scale, grading, or staging approach includes sufficient information about the approach to understand the data in the data table. That is, the Baseline Measure Descriptions for scale, grade, and stage measures include the range of possible scores, specify whether higher numbers indicate better or worse outcomes, and provide brief descriptions of any categories reported.
3. Each Baseline Measure includes descriptive information about the methods and/or criteria used (e.g., a measure of “normal weight” should include the weight criteria used to define “normal”).
4. The Baseline Measure Title accurately indicates what was measured and is reported as Baseline Measure Data with the specific Unit of Measure.
5. Baseline Measure data that can be included in a prestructured Baseline Measure (Age, Sex/Gender, Race and Ethnicity, Region of Enrollment) are not included in a Study-Specific Measure.
6. The prestructured Baseline Measures are only used to present the data for which they were intended (e.g., the prestructured Age Baseline Measure is only used to report the ages of the enrolled participants).

IV. Categories and Rows

1. The number of participants analyzed per row accurately indicates the analysis population in each row.
2. Category Titles and Row Titles are unique, brief, and informative.
3. Categories are used instead of Rows when the dataset consists of exhaustive and mutually exclusive categories.

V. Measure Type and Measure of Dispersion

1. Continuous data are summarized using a Measure Type of central tendency (e.g., Mean, Median, Geometric Mean) and an appropriate Measure of Dispersion (e.g., Standard Deviation, Full Range).
2. “Count of Participants” or “Count of Units” is selected as the Measure Type when appropriate (e.g., with a Unit of Measure such as participants or eyes, respectively).
3. “Number” is selected as the Measure Type only if no other Measure Type applies.

VI. Baseline Measure Data

1. Baseline Measure Data are provided separately for each Arm/Group and for the entire study population (total).
2. Only values that represent collected data are provided in the data table. That is, placeholder or nonmeaningful values are not included (e.g., do not enter “0” or “999” to indicate that data are not available; use “NA” instead).

3. Data have face validity and are consistent with other information provided in the study record.
4. The units of analysis (participants or units other than participants) are not represented more than once in any row.
5. Any NA (Not Available) Explanation (i.e., the explanation provided when “NA” is used to indicate that data are not available) includes sufficient information to understand why one or more values are not available.

VII. Unit of Measure

1. The Unit of Measure is valid and consistent with the Baseline Measure Title and Baseline Measure Description.
2. The Unit of Measure consists of only one unit that applies to all the data in the data table.
3. The Unit of Measure is clear and self-explanatory.

ClinicalTrials.gov Results Quality Control Review Criteria: Outcome Measures and Statistical Analyses Module

Outcome Measures Overview

The Outcome Measures section of the Outcome Measures and Statistical Analyses module includes a tabular summary of each outcome measure, by arm or comparison group. At a minimum, all pre-specified primary outcome measures and secondary outcome measures are included. Other pre-specified outcome measures and post-hoc outcome measures may also be submitted.

Each Outcome Measure includes an Outcome Measure Title, Outcome Measure Description, and Outcome Measure Time Frame that provide enough information for a general reader of the medical literature to understand the reported data, including any relevant definitions, assessment criteria, and the time point(s) at which the measurement was assessed. The data for each Outcome Measure are presented in a table. Columns in the table represent the arms or comparison groups of participants for which outcome measures are reported. Rows in the table are used to describe the numbers of participants analyzed and to provide the numerical summary data for each Arm/Group using a summary statistic (e.g., count, mean, median) and a specific Unit of Measure (e.g., mg/dL, participants).

Outcome Measures Review Criteria

I. General

1. Written results or conclusions are not presented in any free-text field as the only means of reporting data.
2. Information provided is consistent with relevant data element definitions. Information is also consistent between data elements.
3. Outcome Measure Data are complete for each Outcome Measure and do not consist of a partial dataset (e.g., data summarized before participants reach the pre-specified Outcome Measure Time Frame).
4. All collected data for pre-specified Primary Outcome Measures are reported, or a valid explanation is provided for why data are not available.
5. All collected data for pre-specified Secondary Outcome Measures are reported, or a valid explanation is provided for why data are not available.
6. Each Outcome Measure Title, Outcome Measure Description, and Outcome Measure Time Frame combination is unique and does not duplicate a Baseline Measure or another Outcome Measure.
7. Each Outcome Measure contains sufficient information to be understood on its own, independent of other Outcome Measures or information in other parts of the study record.
8. For Outcome Measures that do not have reported data, the Anticipated Reporting Date should be provided.

II. Outcome Measure Title and Outcome Measure Description

1. Each Outcome Measure Title and Outcome Measure Description includes sufficient information necessary to understand the reported values in the data table.
2. An Outcome Measure using a scale, grading, or staging approach includes sufficient information about the approach to understand the data in the data table. That is, the Outcome Measure Descriptions for scale, grade, and stage measures include the range of possible scores, specify

whether higher numbers indicate better or worse outcomes, and provide brief descriptions of any categories reported.

3. Each Outcome Measure includes descriptive information about the methods and/or criteria used (e.g., a measure of “participants with response” should include a brief, informative description of the criteria for “response”).
4. The Outcome Measure Title accurately indicates what was measured and is reported in the Outcome Measure Data Table with the specific Unit of Measure.
5. The Outcome Measure Title is “outcome neutral” when possible, especially when reporting a change in a continuous variable (e.g., use “Change in Systolic Blood Pressure” not “Decrease in Systolic Blood Pressure”).
6. The Outcome Measure Title and Outcome Measure Description contain only information relevant to the associated Outcome Measure.

III. Outcome Measure Time Frame

1. The Outcome Measure Time Frame is understandable, indicates the time point(s) or duration of time over which Outcome Measure Data were assessed, and is expressed from the participants’ perspective (e.g., use “from enrollment to end of treatment at 8 weeks” not “until end of study”).
2. The time points in the Outcome Measure Time Frame are consistent with the Outcome Measure Data reported in the table.
3. The Outcome Measure Time Frame is specific and represents the time point(s) in the study at which each participant was assessed (e.g., use “from enrollment to end of follow-up at 12 weeks” and not “from enrollment to end of follow-up”).

IV. Arm/Group Information, Analysis Population Information, Number of Participants Analyzed, and Number of Units Analyzed

1. Results are presented separately for each arm of the study (i.e., “per arm”), or a valid explanation is provided for why results for each arm cannot be presented separately, as consistent with the study design and the numbers of participants in the Participant Flow module.
2. The Arms/Groups include only participants enrolled in the registered study protocol.
3. No participants appear for the first time in the study record in an outcome measure.
4. If the Overall Number of Participants Analyzed equals zero, there is a clear and valid reason for why data will never be reported (e.g., data were not collected).
5. The Overall Number of Participants Analyzed, Numbers of Participants Analyzed in the rows of the Outcome Measure Data Table and free-text descriptions of the analysis population are consistent.
6. The Type of Units Analyzed, Overall Number of Units Analyzed, and Number of Units Analyzed in each row are provided when the unit of analysis is a unit other than participants (e.g., eyes, lesions, implants).
7. Arm/Group Titles are brief and informative; Arm/Group Descriptions include details about the intervention strategies administered (e.g., dosage, dosage form, frequency of administration, duration of administration) or groups evaluated.
8. The Overall Number of Participants Analyzed and Overall Number of Units Analyzed (if provided) are consistent with a Milestone (row) or logical combination of Milestones from the Participant Flow module; if not, a valid explanation for the inconsistency is provided in the Analysis Population Description.

V. Categories and Rows

1. The Number of Participants Analyzed accurately indicates the analysis population in each row.
2. Category Titles and Row Titles are unique, brief, and informative.
3. Categories are used instead of Rows when the dataset consists of exhaustive and mutually exclusive categories.

VI. Measure Type and Measure of Dispersion/Precision

1. Continuous data are summarized with a Measure Type of central tendency (e.g., Mean, Median, Geometric Mean) and an appropriate Measure of Dispersion/Precision (e.g., Standard Deviation, Full Range, Confidence Interval).
2. "Count of Participants" or "Count of Units" is selected as the Measure Type when appropriate (e.g., with a Unit of Measure such as participants or eyes, respectively).
3. "Number" is selected as the Measure Type only if no other Measure Type applies.

VII. Outcome Measure Data

1. Outcome Measure Data are provided separately for each Arm/Group.
2. Only values that represent collected data are provided in the data table. That is, placeholder or nonmeaningful values are not included (e.g., do not enter "0" or "999" to indicate that data are not available; use "NA" instead).
3. Data have face validity and are consistent with other information provided in the study record.
4. Any NA (Not Available) Explanation (i.e., the explanation provided when "NA" is used to indicate that data are not available) includes sufficient information to understand why one or more values are not available.

VIII. Unit of Measure

1. The Unit of Measure is valid and consistent with the Outcome Measure Title and Outcome Measure Description.
2. The Unit of Measure consists of only one unit that applies to all the data in the data table.
3. The Unit of Measure is clear and self-explanatory.

Statistical Analyses Overview

The Statistical Analyses section of the Outcome Measures and Statistical Analyses module summarizes the results of any scientifically appropriate tests of statistical significance in a tabular format. Each Statistical Analysis is linked to an Outcome Measure. There is no limit to the number of Statistical Analyses that can be submitted for each Outcome Measure, but only statistical analyses that rely on submitted outcome measure information should be included in the study record.

Statistical results are summarized in the Statistical Analyses section using dropdown menus and free-text fields, including:

- The Statistical Analysis Overview, which identifies the arms or comparison groups compared in the statistical analysis (by selecting the Arms/Groups defined for the Outcome Measure) and specifies the type of analysis conducted. If “Non-inferiority” or “Equivalence” is selected for Type of Statistical Test, a free-text description of the key parameters of the statistical analysis is required.
- One or more of the following:
 - The Statistical Test of Hypothesis, which consists of the P-Value and the Method used to calculate the reported p-value.
 - The Method of Estimation, which consists of the Estimation Parameter (e.g., Odds Ratio, Mean Difference), Estimated Value, Confidence Interval (if calculated), and Parameter Dispersion Type with Dispersion Value (if calculated).
 - The Other Statistical Analysis, which consists of a free-text field to provide a description of the statistical analysis and the results of any other scientifically appropriate tests of statistical significance when the statistical analysis cannot be reported using the Statistical Test of Hypothesis or Method of Estimation options.

Statistical Analyses Review Criteria

I. General

1. Written results or conclusions are not presented in any free-text field as the only means of reporting data.
2. Information provided is consistent with relevant data element definitions. Information is also consistent between data elements.
3. If “Other” is selected from the Method or Estimation Parameter dropdown menu, the Other Method Name or Other Parameter Name is unique and does not duplicate a selection from the dropdown menu.

II. Arms/Groups

1. The Comparison Group Selection includes all the Outcome Measure Arms/Groups that were involved in the Statistical Analysis.

III. Statistical Analysis Data

1. Statistical Analyses results have face validity and are understandable.
2. Only values that represent calculated statistical results are provided in the data table. That is, placeholder or nonmeaningful values are not included (e.g., do not enter the *a priori* threshold for statistical significance as the P-Value; enter the calculated p-value instead).
3. Any NA (Not Available) Explanation (i.e., the explanation provided when “NA” is used to indicate that data are not available) includes sufficient information to understand why one or more values are not available.

4. If a Method is specified for the Statistical Test of Hypothesis that typically calculates a p-value, the P-Value is reported or a valid explanation is provided for why no P-Value is reported for that Method.
5. Statistical Analyses results are consistent with the Outcome Measure Data.
6. The Method for the Statistical Test of Hypothesis is consistent with the type of Outcome Measure data collected.
7. Each Statistical Analysis is unique and does not duplicate another Statistical Analysis.

ClinicalTrials.gov Results Quality Control Review Criteria: Adverse Event Information Module

Adverse Event Information Overview

The Adverse Event Information module summarizes adverse events that were collected during the study. This information is submitted in three tables, described below:

- All-Cause Mortality: A table of all anticipated and unanticipated deaths due to any cause, with the number and frequency of such events by arm or comparison group
- Serious Adverse Events: A table of all anticipated and unanticipated serious adverse events, grouped by organ system, with the number and frequency of each event by arm or comparison group
- Other (Not Including Serious) Adverse Events: A table of the anticipated and unanticipated adverse events not included in the Serious Adverse Events table that exceed a frequency threshold (e.g., 5 percent) within any arm of the study, grouped by organ system, with the number and frequency of each event by arm or comparison group

The Adverse Event Information tables include columns representing the arms or comparison groups of participants for which adverse events are reported. Rows present adverse event data for each Adverse Event Term and overall for each Arm/Group. Information describing the approach to adverse event data collection is provided using the following:

- The Time Frame is the specific period of time over which adverse event data were collected.
- The Adverse Event Reporting Description includes information about adverse event definitions (as needed), details about methods for adverse event data collection, or information about how the analysis population was determined.
- The Source Vocabulary Name is the standard terminology, controlled vocabulary, or classification and version from which adverse event terms are drawn, if any (e.g., SNOMED CT, MedDRA 10.0).
- The Collection Approach is the type of approach taken to collect adverse event information, either Systematic Assessment or Non-Systematic Assessment.

Adverse Event Information Review Criteria

I. General

1. Written results or conclusions are not presented in any free-text field as the only means of reporting data.
2. Serious adverse events and other adverse events are reported in separate tables. They are not presented together in either the Serious Adverse Events table or the Other (Not Including Serious) Adverse Events table.
3. Information provided is consistent with relevant data element definitions. Information is also consistent between data elements.
4. All collected Serious Adverse Events and all collected Other (Not Including Serious) Adverse Events that exceed the specified frequency threshold are reported in the Adverse Event Information module, regardless of whether these events were anticipated or attributed to the intervention.

II. Time Frame

1. The Time Frame is understandable and indicates the time point(s) or duration of time over which adverse events were collected (e.g., “up to 2 years”) expressed from the participants’ perspective (e.g., use “from enrollment to end of treatment at 8 weeks” not “until end of study”).
2. The Time Frame specifically indicates each time point in the study or the duration of time for which participants were assessed for adverse events (e.g., use “assessed every visit (every 2 weeks) from enrollment until end of follow-up (at 12 weeks)” not “assessed every visit until the end of follow-up”).

III. Arm/Group Information

1. Results are presented separately for each arm of the study (i.e., “per arm”), or a valid explanation is provided for why results for each arm cannot be presented separately, as consistent with the study design and the numbers of participants in the Participant Flow module.
2. Arm/Group Titles are brief and informative; Arm/Group Descriptions include details about the intervention strategies administered (e.g., dosage, dosage form, frequency of administration, duration of administration) or groups evaluated.

IV. Total Number of Participants at Risk

1. If All-Cause Mortality, Serious Adverse Events, or Other (Not Including Serious) Adverse Events has zero entered for total number of participants at risk (“0” as the denominator) in any arm, a valid explanation is provided for why adverse events were not assessed (e.g., in the Adverse Event Reporting Description).
2. The Arms/Groups include only participants enrolled in the registered study protocol.
3. No participants appear for the first time in the study record in the Adverse Event Information module.
4. The total numbers of participants at risk for All-Cause Mortality, Serious Adverse Events, and Other (Not Including Serious) Adverse Events are consistent with a Milestone (row) or logical combination of Milestones from the Participant Flow module; if not, a valid explanation for this inconsistency is provided in the Adverse Event Reporting Description or Arm/Group Description.

V. Number of Participants at Risk (for each Adverse Event Term)

1. The Number of Participants at Risk (the denominator) for each Adverse Event Term is the same as the total number of participants at risk unless a valid explanation is provided for the inconsistency.

VI. Adverse Event Term, Organ System and Adverse Event Data

1. A serious adverse event (such as death) is not reported as an Adverse Event Term in the Other (Not Including Serious) Adverse Events table.
2. Data reported in the Adverse Event Information module are consistent with any similar data reported in the Outcome Measures and Statistical Analyses module.
3. Each Adverse Event Term is a specific, descriptive word or phrase for the adverse event (e.g., use “atrial fibrillation” not “cardiac disorders”) and is listed under the appropriate Organ System.
4. Each Adverse Event Term is listed only once in each table, or the difference between seemingly identical terms is clarified (e.g., in the description of the Adverse Event Term itself or in the Adverse Event Term Additional Description).

ClinicalTrials.gov Quality Control Review Criteria: Document Upload Information

Document Upload Information Overview

This document provides the ClinicalTrials.gov Document Upload Information Quality Control (QC) Review Criteria to help responsible parties prepare study documents for upload. The full study protocol and statistical analysis plan (SAP) must be uploaded as part of results information submission for studies with a Primary Completion Date on or after January 18, 2017. The study protocol and statistical analysis plan may be uploaded before results information is submitted and then updated, as needed, by uploading new versions. Informed consent forms may optionally be uploaded at any time.

Uploaded study documents must be in Portable Document Format Archival (PDF/A) file format, and each document must include a cover page with the study's Official Title, its NCT Number (if available), and the date of the document. Each uploaded document should be the most recent version reviewed by the human subjects protection review board (if applicable). **Note:** Uploaded study documents will be posted on the ClinicalTrials.gov public website after a quality control review.

Document Upload Information Review Criteria

1. The Document must be in English.
2. The cover page includes the information needed to confirm that the Document is related to the study described in the study record, specifically, the study's Official Title, its NCT Number (if available), and the date of the Document.
3. The Document Date data element in the study record is consistent with the latest version date in the uploaded document.
4. The Document Type data element in the study record accurately reflects the content in the uploaded document (e.g., "Study Protocol with SAP" is selected for an uploaded study protocol that includes a statistical analysis plan).
5. The Document does not include any tracked changes or comments that do not appear to be part of a version that would be reviewed or approved by the human subjects protection review board.
6. The Document does not include the name, address, or other personally identifiable information (PII) of any study participant.
7. The Document does not include redactions of information that is required to be submitted and posted on ClinicalTrials.gov. Only PII, trade secret, or confidential commercial information may be redacted.