
19 Feb 2013 (date data were downloaded from ClinicalTrials.gov)

This readme file describes the data file accompanying the above publication. For any further queries please contact williamsre@mail.nih.gov.

The following variables are included:

A - Terminated Results Sample NCT # - ClinicalTrials.gov Unique Identifier (NCT Number) for all trials in the Terminated Results Sample (n=905).

B - Target Enrollment Sample (1=included; 0=excluded) - Indicator for whether a trial in the Terminated Results Sample was included (1) or excluded (0) from the Target Enrollment Sample (n=827).

C - Brief Title - Protocol title intended for the lay public. (ClinicalTrials.gov Protocol Data Element Definitions (DRAFT) January 2013)

D - Primary Purpose - Reason for the protocol. (ClinicalTrials.gov Protocol Data Element Definitions (DRAFT) January 2013)

E - Intervention Model - Intervention assignments. (ClinicalTrials.gov Protocol Data Element Definitions (DRAFT) January 2013)

F - Blinding - Knowledge of intervention assignments. (“Masking” data element in ClinicalTrials.gov Protocol Data Element Definitions (DRAFT) January 2013)

G - Allocation - Participant assignment to intervention. (ClinicalTrials.gov Protocol Data Element Definitions (DRAFT) January 2013)

H - Intervention Type - Select one per intervention. (ClinicalTrials.gov Protocol Data Element Definitions (DRAFT) January 2013)

I - Study Phase - Phase of investigation, as defined by the US FDA for trials involving investigational new drugs. (ClinicalTrials.gov Protocol Data Element Definitions (DRAFT) January 2013)

J - Condition Category - Categories assigned by ClinicalTrials.gov based on National Library of Medicine Medical Subject Headings (MeSH) controlled vocabulary.

K - Lead Sponsor Type – Categories assigned by ClinicalTrials.gov based on information provided by the organization that is the Sponsor of the study. (For information on “Sponsor” data element see ClinicalTrials.gov Protocol Data Element Definitions (DRAFT) January 2013)

L - DMC (y/n) [Not available to the public - data removed] - Whether a data monitoring committee has been appointed for this study. Data are excluded because they were not available to public at time of analysis. (“Data Monitoring Committee?” data element in ClinicalTrials.gov Protocol Data Element Definitions (DRAFT) January 2013)
M - Single Site/Multiple Site - Whether the trial is conducted at a single location (single) or more than one location (multiple). (Derived by ClinicalTrials.gov from the “Facility” protocol data element in ClinicalTrials.gov Protocol Data Element Definitions (DRAFT) January 2013)

N - Location Countries - Countries in which trial facilities are located. (“Facility Country” data element in ClinicalTrials.gov Protocol Data Element Definitions (DRAFT) January 2013)

O - Study Start Date - Date that enrollment to the protocol begins. (ClinicalTrials.gov Protocol Data Element Definitions (DRAFT) January 2013)

P - First Received Date - Date that summary clinical study protocol information was first submitted to ClinicalTrials.gov. (https://clinicaltrials.gov/ct2/about-studies/glossary#first-received-date)

Q - Primary Completion Date - 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 prespecified protocol or was terminated. (ClinicalTrials.gov Protocol Data Element Definitions (DRAFT) January 2013)

R - Study Completion Date - Final date on which data was (or is expected to be) collected. (ClinicalTrials.gov Protocol Data Element Definitions (DRAFT) January 2013)

S – Results First Received Date - Date that summary results information was first submitted to ClinicalTrials.gov. (https://clinicaltrials.gov/ct2/about-studies/glossary#results-first-received-date)

T - Why Study Stopped - For suspended, terminated or withdrawn studies, provide a brief explanation of why the study has been halted or terminated. (ClinicalTrials.gov Protocol Data Element Definitions (DRAFT) January 2013)

U - Why Study Stopped - Detailed Description Text (if any) - If the Why Study Stopped explanation (Column T) referenced the Detailed Description, the relevant text was abstracted from Detailed Description.

V - Termination Category - Assigned by reviewers: (1) Funding issues; (2) Insufficient accrual rate; (3) Drug supply issues; (4) Trial Administration or Conduct (issues with protocol, investigators, site); (5) Safety/toxicity issues; (6) Interim results (positive, negative, inconclusive); (7) External information; (8) Sponsor decision/business decision/strategic reasons; (9) blank; (10) uninformative response; (11) misuse of website categories or statuses; (12) IRB issues; (16) product withdrawal

W - Enrollment (Protocol) – Target or actual number of subjects in the trial. (ClinicalTrials.gov Protocol Data Element Definitions (DRAFT) January 2013)

X - Enrollment (Protocol) Type – Whether the number of subjects entered for Enrollment is Anticipated or Actual. (ClinicalTrials.gov Protocol Data Element Definitions (DRAFT) January 2013)

Y - First Enrollment (Protocol) - The value first specified for Enrollment. (Derived from “Enrollment” data element in ClinicalTrials.gov Protocol Data Element Definitions (DRAFT) January 2013)
Z - First Enrollment (Protocol) Type – The value first specified for Enrollment Type; whether the number of subjects entered for First Enrollment (Column Y) is Anticipated or Actual. (Derived from “Enrollment” data element in ClinicalTrials.gov Protocol Data Element Definitions (DRAFT) January 2013)

AA - Enrollment = n part started Part Flow (Column W = AC) - Whether the Enrollment (Protocol) (Column W) is the same as the total number of participants started in the results Participant Flow (Column AC).

AB - For adjudicated enrollment, which value was determined to be correct, E= protocol, F=participant flow - If Column AA=FALSE, reviewer assessment of whether the total number of participants enrolled in trial should be based on Enrollment (Protocol) (Column W) or total number of participants started in the results Participant Flow (Column AC).

AC - Total Number of Participants Started Part Flow - Value calculated from the sum of the participants in each arm of the trial that started the trial per results participant flow. (Derived from “Milestone - STARTED” data element in ClinicalTrials.gov “Basic Results” Data Element Definitions (DRAFT) January 2013)

AD - ADJUDICATED N Participants Enrolled in Trial (use for all analyses) - Number of participants enrolled in trial incorporating determination from Column AB.

AE - Max N participants Analyzed Any POM - The sum of participants analyzed in each arm of the trial was calculated for each primary outcome measure. The total number of participants analyzed for the primary outcome measure with the highest value is recorded here. (Derived from “Outcome Measures – Number of Participants Analyzed” data element in ClinicalTrials.gov “Basic Results” Data Element Definitions (DRAFT) January 2013)

AF - # participants enrolled/first enrollment [Column AD/Y] - Proportion of target enrollment achieved.

AG - SeriousAENAffected - Sum of participants in each Arm/Group Affected by Serious Adverse Events (total). (Derived from “Adverse Events – Total Number Affected by Any Serious Adverse Event” data element in ClinicalTrials.gov “Basic Results” Data Element Definitions (DRAFT) January 2013)

AH - SeriousAENAtRisk - Sum of participants in each Arm/Group At Risk for Serious Adverse Events (total). (Derived from “Adverse Events – Total Number of Participants at Risk for Serious Adverse Event” data element in ClinicalTrials.gov “Basic Results” Data Element Definitions (DRAFT) January 2013)

AI - PUBMED LISTING INFO as of 31 Dec 2013 (0=no, 1=yes) - Whether a PubMed citation for a primary publication was available for the trial.

AJ - PMID as of 31 Dec 2013 - PubMed Identifier (PMID) for the primary publication.

AK - Termination Categories [Column V] - Aggregated termination categories based on Column V (Termination Category): 1 - Scientific Data (coded 5 or 6 in (V)); 2 - No Scientific Data (Not coded 5, 6, or 9 in (V)); 3 - No Reason Provided (coded 9 in (V))
ClinicalTrials.gov Protocol Data Element Definitions (DRAFT)

January 2013

1. Titles and Background Information

Organization's Unique Protocol ID * FDAAA
Definition: Unique identification assigned to the protocol by the sponsoring organization, usually an accession number or a variation of a grant number. Multiple studies conducted under the same grant must each have a unique number.
(Limit: 30 characters)
Examples:
ABT-1233-RV
Merck-023
ACTG 021

Secondary IDs FDAAA
Definition: Other identification numbers assigned to the protocol, including unique identifiers from other registries and NIH grant numbers, if applicable. (Limit: 30 characters)

ID Type Select one. Provide additional information, depending upon selected ID Type, as noted below. (Limit: 119 characters)
- US NIH Grant/Contract Award Number - in the Secondary ID field, include activity code, institute code and 6-digit serial number. Other components of the full award number (type code, support year and suffix, if applicable) are optional.
  Examples: R01DA013131, UO1HL066582, 5R01HL123451-01A2
- Other Grant/Funding Number - also provide name of grantor.
- Registry Identifier - also provide name of clinical trials registry.
- EudraCT Number - from European Union Drug Regulatory Authorities Clinical Trial System.
- Other Identifier - also provide brief description (i.e., what organization issued the ID).

Brief Title * FDAAA
Definition: Protocol title intended for the lay public. (Limit: 300 characters)
Example: Safety Study of Recombinant Vaccinia Virus Vaccine to Treat Prostate Cancer

Acronym
Definition: Acronym or initials used to identify this study, if applicable. Enter only the acronym. If supplied, the acronym is automatically displayed in parentheses following the brief title. (Limit: 14 characters)
Example:
  Brief Title: Women's Health Initiative
  Acronym: WHI
  Displayed on ClinicalTrials.gov as: Women's Health Initiative (WHI)

Official Title
Definition: Official name of the protocol provided by the study principal investigator or sponsor.
Example: Phase 1 Study of Recombinant Vaccinia Virus That Expresses Prostate Specific Antigen in Metastatic Adenocarcinoma of the Prostate (Limit: 600 characters)

Study Type * FDAAA
Definition: Nature of the investigation. Select one.
- Interventional: studies in human beings in which individuals are assigned by an investigator based on a protocol to receive specific interventions. Subjects may receive diagnostic, therapeutic or other types of interventions. The assignment of the intervention may or may not be random. The individuals are then followed and biomedical and/or health outcomes are assessed.
- Observational: studies in human beings in which biomedical and/or health outcomes are assessed in pre-defined groups of individuals. Subjects in the study may receive diagnostic, therapeutic, or other interventions, but the investigator does not assign specific interventions to the subjects of the study.
Patient Registry
Definition: For observational studies only, check the Patient Registry box if this record describes a study that is also considered to be a Patient Registry. This type of study should only be registered once in the PRS, by the sponsor responsible for the primary data collection and analysis.

The Agency for Healthcare Research and Quality (AHRQ) defines a Patient Registry as including an organized system that uses observational methods to collect uniform data (clinical and other) prospectively for a population defined by a particular disorder/disease, condition (including susceptibility to a disorder), or exposure (including products, health care services, and/or procedures) and that serves a predetermined scientific, clinical, or policy purpose. Patient registries may be single purpose or on-going data collection programs that address one or more questions.

Expanded Access: records describing the procedure for obtaining an experimental drug or device for patients who are not adequately treated by existing therapy, who do not meet the eligibility criteria for enrollment, or who are otherwise unable to participate in a controlled clinical study. Expanded Access records are used to register all types of non-protocol access to experimental treatments, including protocol exception, single-patient IND, treatment IND, compassionate use, emergency use, continued access and parallel track.

2. US Food and Drug Administration (FDA) Information

Applicable Clinical Trial

FDA Regulated Intervention? (FDAAA)
Definition: Indicate whether this trial includes an intervention subject to US Food and Drug Administration regulation under section 351 of the Public Health Service Act or any of the following sections of the Federal Food, Drug and Cosmetic Act: 505, 510(k), 515, 520(m), and 522. Select Yes/No.

Section 801 Clinical Trial? (FDAAA)
Definition: If this trial includes an FDA regulated intervention, indicate whether this is an "applicable clinical trial" as defined in US Public Law 110-85, Title VIII, Section 801. Briefly, applicable drug trials include controlled clinical investigations, other than Phase I investigations, of a drug or biologic subject to US FDA regulation. Applicable device clinical trials are controlled trials with health outcomes of devices subject to FDA regulation, other than small feasibility studies, and pediatric postmarket surveillance. Select Yes/No.

Delayed Posting? (FDAAA)
Definition: If this is a Section 801 applicable clinical trial, indicate whether this trial includes a device NOT previously approved or cleared by the US FDA for any use, as specified in US Public Law 110-85, Title VIII, Section 801. Select Yes/No. If "Yes" is selected, full posting of the trial information on ClinicalTrials.gov will be delayed until after the device has been approved or cleared. At that time, it is the registrant's responsibility to change this selection to "No" and release the record for full publication.

Investigational New Drug Application (IND)/Investigational Device Exemption (IDE) Information: Complete the following only if the protocol involves an Investigational New Drug Application (IND) or Investigational Device Exemption (IDE) under US Food and Drug Administration regulations.

IND/IDE Protocol? * (FDAAA)
Definition: Indicate if the protocol involves an Investigational New Drug Application (IND) or Investigational Device Exemption (IDE) under US Food and Drug Administration regulations (Will not be made public - for administrative purposes only.)

IND/IDE Grantor * (FDAAA)
Definition: FDA center to which the IND or IDE was submitted, i.e., Center for Drug Evaluation and Research (CDER) or Center for Biologics Evaluation and Research (CBER) for INDs; Center for Devices and Radiological Health (CDRH) for IDEs. Select one. (Will not be made public - for administrative purposes only.)

IND/IDE Number * (FDAAA)
Definition: Number assigned to an Investigational New Drug Application (IND) or Investigational Device Exemption (IDE). (Will not be made public - for administrative purposes only.) Examples: 22,333; BB1234

IND/IDE Serial Number (FDAAA)
Definition: Use the serial number from the first submission of the protocol to the IND or IDE. *(Will not be made public -
for administrative purposes only.)*

**Has Expanded Access?**
FDAAA
Definition: Indicate whether any non-protocol access is to be provided for the investigational drug or device. If so, an
Expanded Access record should also be created for this IND/IDE.

**Expanded Access Record**
FDAAA
Definition: The ClinicalTrials.gov identifier (NCT number) for the Expanded Access record associated with this study,
specified if and only if "Yes" is specified for Has Expanded Access.

### 3. Human Subjects Review
Submitted studies must have approval from a human subjects review board prior to the recruitment of the first
patient. Appropriate review boards include an Institutional Review Board, an ethics committee or an equivalent group that is responsible for
review and monitoring of this protocol to protect the rights and welfare of human research subjects. A study may be submitted for
registration prior to approval of the review board so long as the study is not yet recruiting patients.

Review board information is desired but not required for trials associated with U.S. FDA Investigational New Drug (IND) or Investigational
Device Exemption (IDE) applications.

*Review board information is required for internal administrative use and is not revealed to the public.*

**Board Approval** * - provide information for only one review board, even for studies involving multiple boards

**Board Approval Status** *
Definition: Human subjects review board approval status. Select one.
- Request not yet submitted: review board approval is required but has not yet been requested
- Submitted, pending: review board approval has been requested but not yet granted
- Submitted, approved: review board approval has been requested and obtained
- Submitted, exempt: review board has granted an exemption in response to the approval request
- Submitted, denied: review board has denied the approval request
- Submission not required: the study does not require human subjects review

**Board Approval Number** *(required only if status is "Submitted, approved")
Definition: Number assigned by the human subjects review board upon approval of the protocol. May be omitted if status is
anything other than approved. If the human subjects review board does not assign numbers, please enter the date of approval in
mm/dd/yyyy format.

**Board Name** *(required unless status is "Submission not required")
Definition: Full name of the approving human subjects review board.
Example: National Institutes of Health - NCI - IRB #1

**Board Affiliation** *(required only if status is "Submitted, approved" or "Submitted, exempt")
Definition: Official name of organizational affiliation of the approving human subjects review board. (Limit: 255 characters)
Example: US National Institutes of Health

**Board Contact** *(required only if status is "Submitted, approved" or "Submitted, exempt")
Definition: Contact information for the human subjects review board.
- Phone (or Email required): * Use the format 123-456-7890 within the United States and Canada. Otherwise, provide the country
code.
- Ext: Phone extension, if needed
- Email (or Phone required): * Electronic mail address.
- Address: Mailing address for the board, including street address, city, state or province, postal code, and country.

**Data Monitoring Committee?**
Definition: Indicate whether a data monitoring committee has been appointed for this study. The data monitoring committee (board) is
a group of independent scientists who are appointed to monitor the safety and scientific integrity of a human research intervention, and
to make recommendations to the sponsor regarding the stopping of the trial for efficacy, for harms or for futility. The composition of
the committee is dependent upon the scientific skills and knowledge required for monitoring the particular study.
Oversight authority information is displayed on ClinicalTrials.gov. For IND/IDE protocols, Oversight Authority is filled in automatically with "United States: Food and Drug Administration."

**Oversight Authorities**

Definition: The name of each national or international health organization with authority over the protocol. Use the following format for each authority:

country: organization name

Examples:
- United States: Institutional Review Board
- United States: Food and Drug Administration
- Germany: Federal Institute for Drugs and Medical Devices
- Australia: Therapeutic Goods Administration

4. Sponsors

**Responsible Party** [FDAAA] *

Definition: As defined in US Public Law 110-85, Title VIII, Section 801, the term "responsible party," with respect to a clinical trial, means

1. the sponsor of the clinical trial (as defined in 21 CFR 50.3) or
2. the principal investigator of such clinical trial if so designated by a sponsor, grantee, contractor, or awardee, so long as the principal investigator is responsible for conducting the trial, has access to and control over the data from the clinical trial, has the right to publish the results of the trial, and has the ability to meet all of the requirements for the submission of clinical trial information.

Select one:
- Sponsor: the entity (e.g., corporation or agency) that initiates the study
- Principal Investigator: the individual who serves as the principal investigator and is designated as responsible party, consistent with the conditions described in the statute
- Sponsor-Investigator: the individual who both initiates and conducts the study

**Investigator Information**

If either Principal Investigator or Sponsor-Investigator is selected, the following is required:

- **Investigator Name**: select from the list of PRS users/administrators; if the investigator does not have an account, one must be created. The Full Name for the selected PRS account must be the name of a person and include first and last name, and may include any relevant degrees.
- **Investigator Official Title**: title of the investigator, at the primary organizational affiliation (Limit: 254 characters)
- **Investigator Affiliation**: primary organizational affiliation of the investigator; typically will be the same as sponsor's full name, as recorded in the PRS (Limit: 160 characters)

**Sponsor** [FDAAA]

Definition: Name of primary organization that oversees implementation of study and is responsible for data analysis. For applicable clinical trials, sponsor is defined in 21 CFR 50.3. (Limit: 160 characters)

Examples: National Institute of Allergy and Infectious Diseases, Bristol-Myers Squibb

**Collaborators**

Definition: Other organizations (if any) providing support, including funding, design, implementation, data analysis and reporting. The data provider is responsible for confirming all collaborators before listing them. Provide up to 10 full names of collaborating organizations. (Limit: 160 characters per name)

5. Study Description

**Brief Summary** [FDAAA]

Definition: Short description of the protocol intended for the lay public. Include a brief statement of the study hypothesis. (Limit: 5000 characters)

Example: The purpose of this study is to determine whether prednisone, methotrexate, and cyclophosphamide are effective in the
treatment of rapidly progressive hearing loss in both ears due to autoimmune inner ear disease (AIED).

**Detailed Description**

**Definition:** Extended description of the protocol, including more technical information (as compared to the Brief Summary) if desired. Do not include the entire protocol; do not duplicate information recorded in other data elements, such as eligibility criteria or outcome measures. (Limit: 32,000 characters)

For Patient Registries: Also describe the applicable (1) registry procedures and (2) other quality factors (e.g., third party certification, on-site audit). In particular, summarize any procedures implemented as part of the patient registry, including, but not limited to the following:

- Quality assurance plan that addresses data validation and registry procedures, including any plans for site monitoring and auditing.
- Data checks to compare data entered into the registry against predefined rules for range or consistency with other data fields in the registry.
- Source data verification to assess the accuracy, completeness, or representativeness of registry data by comparing the data to external data sources (e.g., medical records, paper or electronic case report forms, or interactive voice response systems).
- Data dictionary that contains detailed descriptions of each variable used by the registry, including the source of the variable, coding information if used (e.g., World Health Organization Drug Dictionary, MedDRA), and normal ranges if relevant.
- Standard Operating Procedures to address registry operations and analysis activities, such as patient recruitment, data collection, data management, data analysis, reporting for adverse events, and change management.
- Sample size assessment to specify the number of participants or participant years necessary to demonstrate an effect.
- Plan for missing data to address situations where variables are reported as missing, unavailable, "non-reported," uninterpretable, or considered missing because of data inconsistency or out-of-range results.
- Statistical analysis plan describing the analytical principles and statistical techniques to be employed in order to address the primary and secondary objectives, as specified in the study protocol or plan.

### 6. Status

**Record Verification Date** *FDAAA*

**Definition:** Date the protocol information was last verified. Verification date is shown along with organization name on ClinicalTrials.gov to indicate to the public whether the information is being kept current, particularly recruiting status and contact information. **Update verification date when reviewing the record for accuracy and completeness, even if no other changes are made.**

**Overall Recruitment Status** *FDAAA* [Required when Study Type is "Interventional" or "Observational"].

**Definition:** Overall accrual activity for the protocol. Select one.

- Not yet recruiting: participants are not yet being recruited
- Recruiting: participants are currently being recruited
- Enrolling by invitation: participants are being (or will be) selected from a predetermined population
- Active, not recruiting: study is ongoing (i.e., patients are being treated or examined), but participants are not currently being recruited or enrolled
- Completed: the study has concluded normally; participants are no longer being examined or treated (i.e., last patient's last visit has occurred)
- Suspended: recruiting or enrolling participants has halted prematurely but potentially will resume
- Terminated: recruiting or enrolling participants has halted prematurely and will not resume; participants are no longer being examined or treated
- Withdrawn: study halted prematurely, prior to enrollment of first participant

**NOTE:** Contact information is shown on ClinicalTrials.gov only when overall status is "Recruiting" or "Not yet recruiting".

**Why Study Stopped?**

**Definition:** For suspended, terminated or withdrawn studies, provide a brief explanation of why the study has been halted or terminated. If desired, use brief summary or detailed description to provide additional information. (Limit: 160 characters)

**Study Start Date** *FDAAA*

**Definition:** Date that enrollment to the protocol begins.

**Primary Completion Date** *FDAAA* [* Required by ClinicalTrials.gov for records first released on or after December 1, 2012*]

**Definition:** As specified in US Public Law 110-85, Title VIII, Section 801, with respect to an applicable clinical trial, 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 prespecified protocol or was terminated. A "Type" menu is also included, with options
Anticipated and Actual. For active studies, set Type to Anticipated and specify the expected completion date, updating the date as needed over the course of the study. Upon study completion, change Type to Actual and update the date if necessary.

**Study Completion Date**

Definition: Final date on which data was (or is expected to be) collected. Use the Type menu (Anticipated/Actual) as described above.

**Expanded Access Status** *

Definition: Status indicating availability of an experimental drug or device outside any clinical trial protocol. This data element is only applicable for Expanded Access records (see Expanded Access under Study Type). Select one.

- Available: expanded access is currently available for this treatment.
- No longer available: expanded access was available for this treatment previously but is not currently available and will not be available in the future.
- Temporarily not available: expanded access is not currently available for this treatment, but is expected to be available in the future.
- Approved for marketing: this treatment has been approved for sale to the public.

7. Study Design

**Interventional Study Design** *(FDAAA)*

Definition: Primary investigative techniques used in the protocol. Select the most appropriate term describing the protocol from each of the following data elements.

**Primary Purpose** *(FDAAA)* - reason for the protocol

- Treatment: protocol designed to evaluate one or more interventions for treating a disease, syndrome or condition
- Prevention: protocol designed to assess one or more interventions aimed at preventing the development of a specific disease or health condition
- Diagnostic: protocol designed to evaluate one or more interventions aimed at identifying a disease or health condition
- Supportive Care: protocol designed to evaluate one or more interventions where the primary intent is to maximize comfort, minimize side effects or mitigate against a decline in the subject's health or function. In general, supportive care interventions are not intended to cure a disease.
- Screening: protocol designed to assess or examine methods of identifying a condition (or risk factors for a condition) in people who are not yet known to have the condition (or risk factor).
- Health Services Research: protocol designed to evaluate the delivery, processes, management, organization or financing of health care.
- Basic Science: protocol designed to examine the basic mechanism of action (e.g., physiology, biomechanics) of an intervention.
- Other: describe in Detailed Description.

**Study Phase** *(FDAAA)*

Definition: Phase of investigation, as defined by the US FDA for trials involving investigational new drugs. Use "N/A" for trials that do not involve drug or biologic products. Select only one.

- N/A: for trials without phases (e.g., trials of devices or behavioral interventions)
- **Phase 0**: exploratory trials, involving very limited human exposure, with no therapeutic or diagnostic intent (e.g., screening studies, microdose studies). See [FDA guidance on exploratory IND studies](https://www.fda.gov) for more information.
- **Phase 1**: includes initial studies to determine the metabolism and pharmacologic actions of drugs in humans, the side effects associated with increasing doses, and to gain early evidence of effectiveness; may include healthy participants and/or patients
- **Phase 1/Phase 2**: for trials that are a combination of phases 1 and 2
- **Phase 2**: includes controlled clinical studies conducted to evaluate the effectiveness of the drug for a particular indication or indications in patients with the disease or condition under study and to determine the common short-term side effects and risks
- **Phase 2/Phase 3**: for trials that are a combination of phases 2 and 3
- **Phase 3**: includes expanded controlled and uncontrolled trials after preliminary evidence suggesting effectiveness of the drug has been obtained, and are intended to gather additional information to evaluate the overall benefit-risk relationship of the drug and provide an adequate basis for physician labeling
Phase 4: studies of FDA-approved drugs to delineate additional information including the drug's risks, benefits, and optimal use

Intervention Model (FDAAA) (at least one of the following required: Intervention Model, Masking, Allocation. All may be required as part of Study Design under PL 110-85, Section 801) - intervention assignments

- Single Group: single arm study
- Parallel: participants are assigned to one of two or more groups in parallel for the duration of the study
- Cross-over: participants receive one of two alternative interventions during the initial phase of the study and receive the other intervention during the second phase of the study
- Factorial: two or more interventions, each alone and in combination, are evaluated in parallel against a control group

Number of Arms (FDAAA)
Definition: Number of intervention groups (enter 1 for single-arm study).

Masking (FDAAA) (at least one of the following required: Intervention Model, Masking, Allocation. All may be required as part of Study Design under PL 110-85, Section 801) - knowledge of intervention assignments

- Open: no masking is used. All involved know the identity of the intervention assignment.
- Single Blind: one party, either the investigator or participant, is unaware of the intervention assignment; also called single-masked study.
- Double Blind: two or more parties are unaware of the intervention assignment

If Single Blind or Double Blind is selected, check the role(s) that are to be masked: Subject, Caregiver, Investigator or Outcomes Assessor.

Allocation (FDAAA) (at least one of the following required: Intervention Model, Masking, Allocation. All may be required as part of Study Design under PL 110-85, Section 801) - participant assignment to intervention group

- N/A: single arm study
- Randomized Controlled Trial: participants are assigned to intervention groups by chance
- Nonrandomized Trial: participants are expressly assigned to intervention groups through a non-random method, such as physician choice

Study Classification (formerly Endpoint) - type of primary outcome or endpoint that the protocol is designed to evaluate. Select one.

- N/A: not applicable
- Safety: show if the drug is safe under conditions of proposed use
- Efficacy: measure of an intervention's influence on a disease or health condition
- Safety/Efficacy
- Bio-equivalence: scientific basis for comparing generic and brand name drugs
- Bio-availability: rate and extent to which a drug is absorbed or otherwise available to the treatment site in the body
- Pharmacokinetics: the action of a drug in the body over a period of time including the process of absorption, distribution and localization in tissue, biotransformation, and excretion of the compound
- Pharmacodynamics: action of drugs in living systems
- Pharmacokinetics/dynamics

Enrollment (Target or Actual Number of Subjects) FDAAA
Definition: Number of subjects in the trial. A “Type” menu is also included, with options Anticipated and Actual. For active studies, set Type to Anticipated and specify the expected enrollment, updating the number as needed over the course of the study. Upon study completion, change Type to Actual and update the enrollment if necessary.

Observational Study Design

Observational Study Model * - primary strategy for subject identification and follow-up. Select one.

- Cohort: group of individuals, initially defined and composed, with common characteristics (e.g., condition, birth year), who are examined or traced over a given time period
- Case-control: group of individuals with specific characteristics (e.g., conditions or exposures) compared to group(s) with different characteristics, but otherwise similar
- Case-only: single group of individuals with specific characteristics
Case-crossover: characteristics of case immediately prior to disease onset (sometimes called the hazard period) compared to characteristics of same case at a prior time (i.e., control period)

Ecologic or community studies: geographically defined populations, such as countries or regions within a country, compared on a variety of environmental (e.g., air pollution intensity, hours of sunlight) and/or global measures not reducible to individual level characteristics (e.g., health care system, laws or policies median income, average fat intake, disease rate)

Family-based: studies conducted among family members, such as genetic studies within families or twin studies and studies of family environment

Other - explain in Detailed Description

**Time Perspective** * - temporal relationship of observation period to time of subject enrollment. Select one.

- Prospective: look forward using periodic observations collected predominantly following subject enrollment
- Retrospective: look back using observations collected predominantly prior to subject selection and enrollment
- Cross-sectional: observations or measurements made at a single point in time, usually at subject enrollment
- Other - explain in Detailed Description

**Biospecimen Retention** - select one

- None Retained - no samples retained
- Samples With DNA - samples retained, with potential for extraction of DNA from at least one of the types of samples retained (e.g., frozen tissue, whole blood)
- Samples Without DNA - samples retained, with no potential for DNA extraction from any retained samples (e.g., fixed tissue, plasma)

**Biospecimen Description**

Definition: Specify all types of biospecimens to be retained (e.g., whole blood, serum, white cells, urine, tissue). (Limit: 1000 characters)

**Enrollment** *

Definition: (see above)

**Target Follow-Up Duration** *

Definition: For Patient Registries, the anticipated time period over which each participant is to be followed. Provide a number and select a unit of time (years, months, weeks, days).

**Number of Groups/Cohorts** *

Definition: Number of study groups/cohorts. Enter 1 for a single-group study. Many observational studies have one group/cohort; case control studies typically have two.

**Outcome Measures**

**Primary Outcome Measure** *(FDAAA)* Required by ClinicalTrials.gov for records first released on or after December 1, 2012

Definition: Specific key measurement(s) or observation(s) used to measure the effect of experimental variables in a study, or for observational studies, to describe patterns of diseases or traits or associations with exposures, risk factors or treatment.

- **Title** * - A concise name for the specific measure that will be used to determine the effect of the intervention(s) or, for observational studies, related to core objectives of the study and receiving the most emphasis in assessment. (Limit: 254 characters)
- **Time Frame** *(FDAAA)* [ ] Required by ClinicalTrials.gov for records first released on or after December 1, 2012 - Time point(s) at which outcome measure is assessed. (Limit: 254 characters)
- **Description** - Additional information about the outcome measure, if needed for clarification. (Limit: 999 characters)
- **Safety Issue?** *(FDAAA)* - Is this outcome measure assessing a safety issue? Select: Yes/No

Examples:

Title: all cause mortality
Time Frame: one year
Safety Issue: No
Title: Evidence of clinically definite ischemic stroke (focal neurological deficits persisting for more than 24 hours) confirmed by non-investigational CT or MRI
Time Frame: within the first 30 days (plus or minus 3 days) after surgery
Safety Issue: Yes

Secondary Outcome Measures **FDAAA**
Definition: Secondary measurements that will be used to evaluate the intervention(s) or, for observational studies, that are a focus of the study. Specify Title, Time Frame, Description (if needed) and Safety Issue as described above.

Other Pre-specified Outcome Measures
Definition: Any other measurements, excluding post-hoc measures, that will be used to evaluate the intervention(s) or, for observational studies, that are a focus of the study. Specify Title, Time Frame, Description (if needed) and Safety Issue.

8. Arms, Groups and Interventions

For interventional studies specify the arms, corresponding to Number of Arms specified under Study Design (for single-arm studies, the following data elements are optional).

**Arm Label** *(FDAAA)* - the short name used to identify the arm. (Limit: 62 characters)
Examples:
- Metformin
- Lifestyle counseling
- Sugar pill

**Arm Type** *(FDAAA)* - select one
- Experimental
- Active Comparator
- Placebo Comparator
- Sham Comparator
- No intervention
- Other

**Arm Description** *(FDAAA)* - brief description of the arm. This element may not be necessary if the associated intervention descriptions contain sufficient information to describe the arm. (Limit: 999 characters)

For observational studies specify the predefined participant groups (cohorts) to be studied, corresponding to Number of Groups specified under Study Design (for single-group studies, the following data elements are optional). Do not use this section to specify strata (Detailed Description can be used for that purpose, if desired).

**Group/Cohort Label** * - the short name used to identify the group. (Limit: 62 characters)
Examples:
- Statin dose titration
- Chronic kidney disease, no anemia
- No treatment

**Group/Cohort Description** Definition: Explanation of the nature of the study group (e.g., those with a condition and those without a condition; those with an exposure and those without an exposure). Note that the overall study population should be described under Eligibility. (Limit: 1000 characters)

For all studies, and for expanded access records, specify the associated intervention(s). For interventional studies, at least one intervention must be specified. For observational studies, specify the intervention(s)/exposure(s) of interest, if any.

**Intervention Type** *(FDAAA)* - select one per intervention
- Drug (including placebo)
- Device (including sham)
- Biological/Vaccine
- Procedure/Surgery
- Radiation
- Behavioral (e.g., Psychotherapy, Lifestyle Counseling)
- Genetic (including gene transfer, stem cell and recombinant DNA)
- Dietary Supplement (e.g., vitamins, minerals)
- Other

**Intervention Name** [FDAAA] - for drugs use generic name; for other types of interventions provide a brief descriptive name. (Limit: 160 characters)

For investigational new drugs that do not yet have a generic name, a chemical name, company code or serial number may be used on a temporary basis. As soon as the generic name has been established, update the associated protocol records accordingly.

For non-drug intervention types, provide an intervention name with sufficient detail so that it can be distinguished from other similar interventions.

**Intervention Description** [FDAAA] - cover key details of the intervention. Must be sufficiently detailed to distinguish between arms of a study (e.g., comparison of different dosages of drug) and/or among similar interventions (e.g., comparison of multiple implantable cardiac defibrillators). For example, interventions involving drugs may include dosage form, dosage, frequency and duration. (Limit: 1000 characters)

Example:
50 mg/m², IV (in the vein) on day 5 of each 28 day cycle. Number of Cycles: until progression or unacceptable toxicity develops.

**Other Names** - list other names used to identify the intervention, past or present (e.g., brand name for a drug). These names will be used to improve search results in ClinicalTrials.gov. (Limit: 160 characters per name)

**Arms/Groups** [FDAAA] - if multiple Arms/Groups have been specified for the study, edit the Cross-Reference, checking boxes to indicate which of the Interventions are to be administered under each Arm/Group of the study.

9. **Conditions and Keywords**

**Conditions or Focus of Study** [FDAAA]
Definition: Primary disease or condition being studied, or focus of the study. Diseases or conditions should use the National Library of Medicine's Medical Subject Headings (MeSH) controlled vocabulary when possible.

**Keywords**
Definition: Words or phrases that best describe the protocol. Keywords help users find studies in the database. Use NLM's Medical Subject Heading (MeSH) controlled vocabulary terms where appropriate. Be as specific and precise as possible. Avoid acronyms and abbreviations.

10. **Eligibility**

**Study Population Description**
Definition: For observational studies only, a description of the population from which the groups or cohorts will be selected (e.g., primary care clinic, community sample, residents of a certain town). (Limit: 1000 characters)

**Sampling Method** - For observational studies only, select one and explain in Detailed Description.
- Probability Sample: exclusively random process to guarantee that each participant or population has specified chance of selection, such as simple random sampling, systematic sampling, stratified random sampling, cluster sampling, and consecutive patient sampling
- Non-Probability Sample: any of a variety of other sampling processes, such as convenience sampling or invitation to volunteer

**Eligibility Criteria** [FDAAA]
Definition: Summary criteria for participant selection. The preferred format includes lists of inclusion and exclusion criteria as shown below. (Limit: 15,000 characters)
Example:

**Inclusion Criteria:**
- Clinical diagnosis of Alzheimer's Disease
- Must be able to swallow tablets

**Exclusion Criteria:**
Gender * FDAAA
Definition: Physical gender of individuals who may participate in the protocol. Select one.
- Both: both female and male participants are being studied
- Female: only female participants are being studied
- Male: only male participants are being studied

Age Limits * FDAAA
Minimum Age
Definition: Minimum age of participants. Provide a number and select a unit of time (years, months, weeks, days, hours or minutes). Select "N/A (No limit)" if no minimum age is indicated.

Maximum Age
Definition: Maximum age of participants. Provide a number and a unit of time (years, months, weeks, days, hours or minutes). Select "N/A (No limit)" if no maximum age is indicated.

Accepts Healthy Volunteers? * FDAAA
Definition: Indicate if persons who have not had the condition(s) being studied or otherwise related conditions or symptoms, as specified in the eligibility requirements, may participate in the study. Select Yes/No.

11. Protocol Location, Contact and Investigator Information
Multiple locations may be specified. Location is composed of the following fields.

Facility * (FDAAA)
- Name: Full name of the organization where the protocol is being conducted. (Limit: 254 characters)
  Examples: UCLA Eye Institute; Springfield Memorial Hospital
- City * (FDAAA)
- State/Province * (FDAAA)
- Postal Code
- Country * (FDAAA)

Recruitment Status * FDAAA - protocol accrual activity at a facility. Select one.
- Not yet recruiting: participants are not yet being recruited
- Recruiting: participants are currently being recruited
- Enrolling by invitation: participants are being (or will be) selected from a predetermined population
- Active, not recruiting: study is ongoing (i.e., patients are being treated or examined), but participants are not currently being recruited or enrolled
- Completed: the study has concluded normally; participants are no longer being examined or treated (i.e., last patient's last visit has occurred)
- Suspended: recruiting or enrolling participants has halted prematurely but potentially will resume
- Terminated: recruiting or enrolling participants has halted prematurely and will not resume; participants are no longer being examined or treated
- Withdrawn: study halted prematurely, prior to enrollment of first participant

NOTE: Contact information is shown on ClinicalTrials.gov only for locations with status set to "Recruiting" or "Not yet recruiting".

Tip: When a trial's overall status changes to "Active, not recruiting," it is not necessary to change recruitment status for each location. Location recruitment status is only shown on ClinicalTrials.gov when Overall Status is "Recruiting".

Facility Contact * (FDAAA) (or Central Contact required)
- First Name
- Middle Initial
Facility Contact Backup
Person to contact if Facility Contact is not available (i.e., a second contact person).

Investigators (at the protocol location)

- First Name
- Middle Initial
- Last Name
- Degrees
- Role: Site Principal Investigator or Site Sub-Investigator (pick one)

Central Contact (or Facility Contact required)
Definition: Person providing centralized, coordinated recruitment information for the entire study.

- First Name
- Middle Initial
- Last Name
- Degree
- Phone: Toll free phone number of the central contact person. Use the format 800-555-5555 within the United States and Canada. Otherwise, provide the country code.
- Ext: phone extension, if needed
- Email: electronic mail address of the central contact person

Central Contact Backup
Person to contact if Central Contact is not available.

Overall Study Officials
Definition: Person(s) responsible for the overall scientific leadership of the protocol, including study principal investigator.

- First Name
- Middle Initial
- Last Name
- Degree
- Official's Role: Position or function of the official. Select one (Study Chair/Study Director/Study Principal Investigator).
- Organizational Affiliation: Full name of the official's organization. If none, specify Unaffiliated.
  (Limit: 255 characters)

If Overall Status is "Recruiting":
- At least one location must be specified.
- At least one location must have status set to "Recruiting".
- All locations must have status specified.
- Either any location that is recruiting must have Contact specified, or Overall Contact must be specified.

Contact information limits:
- First Name: 62 characters
- Last Name: 62 characters
- Degrees: 30 characters
- Phone: 30 characters
- Phone Ext: 14 characters
- Email: 254 characters
- Affiliation: 160 characters

12. Related Information
References
Definition: Citations to publications related to the protocol: background and/or results. Provide either the unique PubMed Identifier (PMID) of an article or enter the full bibliographic citation.

MEDLINE Identifier
Definition: unique PubMed Identifier (PMID) for the citation in MEDLINE
Example: PMID: 10987815

Citation
Definition: bibliographic reference in NLM's MEDLINE format (Limit: 2000 characters)
Example: Barza M; Pavan PR; Doft BH; Wisniewski SR; Wilson LA; Han DP; Kelsey SF. Evaluation of microbiological diagnostic techniques in postoperative endophthalmitis in the Endophthalmitis Vitrectomy Study. Arch Ophthalmol 1997 Sep;115(9):1142-50

Results Reference?
Definition: Indicate if the reference provided reports on results from this clinical research study.

Links
Definition: A Web site directly relevant to the protocol may be entered, if desired. Do not include sites whose primary goal is to advertise or sell commercial products or services. Links to educational, research, government, and other non-profit Web pages are acceptable. All submitted links are subject to review by ClinicalTrials.gov.

URL
Definition: complete URL, including http:// (Limit: 254 characters)
Example: http://www.alzheimers.org/

Description
Definition: title or brief description of the linked page. If the page being linked is the protocol's home page on the sponsor's Web site, include the words "Click here for more information about this study:" and provide the name of the protocol. (Limit: 254 characters)
Examples:

Click here for more information about this study: Clinical Trial of Eye Prophylaxis in the Newborn

The Alzheimer's Disease Education and Referral (ADEAR) Center is a service of the National Institute on Aging
ClinicalTrials.gov "Basic Results" Data Element Definitions (DRAFT)  

January 2013

The "basic results" data element definitions and requirements currently included in ClinicalTrials.gov represent the National Institutes of Health's (NIH's) current thinking on this topic, and were developed in response to the provision contained within FDAAA that required the Agency to develop a "basic results" databank within one year of enactment. They do not create or confer any rights for or on any person and do not operate to bind NIH, the Department of Health and Human Services or the public. NIH will interpret these "basic results" reporting requirements in regulations or guidance to be issued at a later date. Prior to the issuance of draft regulations or guidance for comment, comments on the existing ClinicalTrials.gov "basic results" data element definitions and requirements are welcome and will be considered by the Agency in drafting a Notice of Proposed Rulemaking. Comments should be addressed to register@clinicaltrials.gov. Please include "Comments on ClinicalTrials.gov Results Requirements" in the subject line.

* 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. (i.e., the **Study Completion Date** from the Protocol Data Elements)

     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 you will have the option to copy arm and/or intervention information from the protocol section into the results section when the Participant Flow module is "posted". After that, copied 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.

Minimum length is 4 characters. Titles shorter than the minimum are unlikely to sufficiently describe the arm or comparison group.

Examples: fluoxetine; sertraline; drug-eluting stent; placebo

(Limit: >=4 and <=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. Minimum length is 4 characters. Titles shorter than the minimum are unlikely to sufficiently describe the arm or comparison group.

Examples: fluoxetine; sertraline; drug-eluting stent; placebo
(Limit: >=4 and <=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 Analysis Population Description**

Definition: Explanation of how the number of participants for analysis was determined.

(Limit: 350 characters)

**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, 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: 600 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.

**NA (Not Available) Explanation [*]** - required when NA is reported.: Explain why baseline measure data (i.e., any "Number" or "Descriptive Statistics" value) are Not Available.
(Limit: 250 characters)

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.

Minimum length is 4 characters. Titles shorter than the minimum are unlikely to sufficiently describe the arm or comparison group.

Examples: fluoxetine; sertraline; drug-eluting stent; placebo

(Limit: >=4 and <=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

**Number of Units Analyzed ["] - required when "Type of Units Analyzed" is reported**

(per outcome measure, per arm/group)

For the outcome data reported, the number of units analyzed when analysis is not based on participants; see **Type of Units Analyzed**.

**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, secondary and other pre-specified 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 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: 999 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/Precision** *: Select one.
- Not Applicable (only when Measure Type is "Number")
- Standard Deviation
- Inter-Quartile Range
- Full Range
- Standard Error
- 95% Confidence Interval
- 90% Confidence Interval
- Geometric Coefficient of Variation (only when Measure Type is "Geometric Mean")

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

**Type of Units Analyzed [†] - required when "Number of Units Analyzed" are reported:** If analysis is not based on participants, specify the type of units analyzed (e.g., eyes, lesions, implants); see [Number of Units Analyzed](#).  
(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, 95% confidence interval, or 90% confidence interval

NA (Not Available) Explanation [*] - required when NA is reported: Explain why outcome data (i.e., any "Number" or "Descriptive Statistics" value) are Not Available.
Example: (Time-to-event outcome) The upper limit of the 95% confidence interval was not calculable because an insufficient number of participants reached the event at the final time point for assessment.
(Limit: 250 characters)

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.

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)

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

Confidence Interval [*] (if applicable, provide the following sub-elements):

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

Number of Sides: Select 1-sided or 2-sided (default).

Lower Limit [*]: (required if confidence interval is 2-sided or if confidence interval is 1-sided and no Upper Limit is entered.)

Upper Limit [*]: (required if confidence interval is 2-sided or if confidence interval is 1-sided and no Lower Limit is entered.)

NA (Not Available) Explanation [*]: (required when NA is reported as upper-limit of 2-sided confidence interval.) Explain why the upper limit data are Not Available.
Example: (Time-to-event outcome) The upper limit of the 95% confidence interval was not calculable because an insufficient number of participants reached the event at the final time point for assessment.
(Limit: 250 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)
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**: 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. (See Adverse Events definition below).

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.

**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. Minimum length is 4 characters. Titles shorter than the minimum are unlikely to sufficiently describe the arm or comparison group. Examples: fluoxetine; sertraline; drug-eluting stent; placebo (Limit: >=4 and <=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)

**Time Frame for Adverse Event Reporting**
Definition: Period in which the reported adverse event data were collected (e.g., 1 year, 6 months) (Limit: 255 characters)

**Adverse Event Reporting Additional Description**
Definition: Additional relevant information about adverse event collection, including details about the method of systematic assessment (e.g., daily questionnaire) (Limit: 350 characters)

**Source Vocabulary Name for Table Default**
Definition: Default value for Source Vocabulary Name to be applied to all adverse event terms entered in the "Serious" and "Other" adverse event tables, unless otherwise specified (e.g., SNOMED CT, MedDRA 10.0). (Limit: 20 characters)

**Assessment Type for Table Default**
Definition: Default value for Adverse Event Assessment Type (Systematic or Non-Systematic Assessment Type) to be applied to all adverse event terms entered in the "Serious" or "Other" adverse event tables, unless otherwise specified.

**Adverse Events**
Definition: Unfavorable changes in health, 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.

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

2. 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: 100 characters)

**Source Vocabulary Name**: Standard terminology, controlled vocabulary, or classification and version from which adverse event terms are drawn, if any (e.g., SNOMED CT, MedDRA 10.0). Leave blank to indicate that the value specified as the Source Vocabulary for Table Default should be used.

(Limit: 20 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
- Investigations
- 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
- Social circumstances
- Surgical and medical procedures
- Vascular disorders

**Assessment Type**: Method used to assess the adverse event. Select one or leave blank to indicate that the value specified as the Assessment Type for Table Default should be used.

- 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
- Non-systematic Assessment: Any non-systematic method for determining whether or not adverse events have occurred, such as self-reporting by participants or occasional assessment/testing

**Adverse Event Term Additional Description**: Additional relevant information about the adverse event, including any deviation from the Time Frame for Adverse Event Reporting.

(Limit: 250 characters)

**Total Number Affected by Any Serious Adverse Event**: Overall number of participants affected by one or
more Serious Adverse Events.

**Total Number of Participants at Risk for Serious Adverse Event** *(or Number of Participants at Risk for each Serious Adverse Event Term required)*
(per arm/group) : Overall number of participants included in the assessment of serious adverse events during the trial (i.e., the denominator for calculating frequency of serious adverse events)

**Frequency Threshold for Reporting Other (Not Including Serious) Adverse Event** *

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. The number must be less than or equal to the allowed maximum (5%), and must not include any symbols (e.g., >= , %).
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 above the Frequency Threshold** *(per arm/group):* Overall number of participants affected by one or more Other (Not Including Serious) Adverse Events above the specified Frequency Threshold (e.g., 5%) reported in the table.

**Total Number of Participants at Risk for Other (Not Including Serious) Adverse Event** *(or Number of Participants at Risk for each Other, Not Including Serious, Adverse Event Term required)*
(per arm/group) : Overall number of participants included in the assessment of other, not including serious, adverse events during the trial (i.e., the denominator for calculating frequency of other, not including serious, adverse events).

**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). Leave blank to indicate that the value specified as the total at risk in the arm/group for the table should be used. Note, when the number at risk in the arm/group is blank, the total at risk in the arm/group for the table must be entered.

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**Delayed Results** - OPTIONAL: A responsible party may delay the deadline for submitting results information under Section 801 of the Food and Drug Administration Amendments Act if one of the two certification conditions below applies to the applicable clinical trial. Alternatively, the responsible party may request an extension of the results submission deadline for good cause. The extension must be granted by the NIH Director. To delay the results submission deadline using either of these mechanisms, all [*]-marked data elements are required, except as noted below.

**Delay Results Type** [*] : Select one

- **Certify Initial Approval** - trial completed before a drug, biologic or device studied in the trial is initially approved, licensed or cleared by the FDA (for any use)
- **Certify New Use** - the manufacturer of a drug, biologic or device is the sponsor of the trial and has filed or will file within one year, an application seeking FDA approval, licensure, or clearance of the new use (i.e., use not included in the labeling of the approved drug, biologic or device) studied in the trial
- **Extension** - request, for good cause, an extension of the deadline for the submission of results

**Note:** If a manufacturer (who is the responsible party) makes a certification under "Certify New Use" the manufacturer shall make such a certification with respect to each applicable clinical trial that is required to be submitted in an application or report to the FDA for licensure, approval, or clearance of the use studied in the clinical trial. [42 U.S.C. 282 (j)(3)(E)(v)(II)]
**Intervention Name(s) [*]**: Required when Delay Results Type is "Certify Initial Approval" or "Certify New Use."
Provide the name of one or more drugs, biological products or devices to which the certification applies. For drugs use generic name; for other types of interventions provide a brief descriptive name. The name(s) entered should match Intervention Name(s) provided in the protocol record.

**FDA Application Number(s):**
Provide at least one FDA application number (e.g., NDA, BLA, or PMA number), if available, when Delay Results Type is "Certify Initial Approval" or "Certify New Use."

**Requested Submission Date [*]**: Required when Delay Results Type is "Extension."
Provide the month and year when results are expected to be submitted.

**Explanation [*]**: Required when Delay Results Type is "Extension."
Provide a written explanation that demonstrates good cause for the extension. Provide sufficient information to allow for evaluation of the request. Note that "pending publication" is not considered "good cause" for an extension. (Limit: 600 characters)