ClinicalTrials.gov Protocol Data Element Definitions (DRAFT)

September 2014

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* Required by ClinicalTrials.gov

FDAAA Required to comply with Food and Drug Administration Amendments Act (FDAAA), Section 801

(FDAAA) May be required to comply with FDAAA, Section 801

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1. Study Identification

- **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

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)

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, U01HL066582, 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).

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. Study 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.

3. Sponsor/Collaborators

- **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

Responsible Party FDAAA [* Required by ClinicalTrials.gov for records first released on or after December 1, 2012]
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)

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)

4. Oversight

- **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.

- **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 ommitted 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

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. 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.

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 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** (Target or Actual Number of Subjects) *
  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.

- **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.

8. Arms, Groups and Interventions

- **Arms:** 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)

Groups: 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)

Interventions: 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: 200 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.

  - **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: 200 characters per name)

- **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.

- **[Arm or Group]/Intervention Cross-Reference** * (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. Outcome Measures

- NOTE: When Results are added to a record, outcome measures are transferred from the protocol section to the results section.
- **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.

10. Eligibility

- **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.

- **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:
    - - Insulin dependent diabetes
    - - Thyroid disease

- **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

11. Contacts, Locations, and Investigator Information

- Multiple locations may be specified. Location is composed of the following fields.

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

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

- **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
- Last Name * (FDAAA)
- Degree
- Phone * (FDAAA): (or Email required) office phone of the facility contact person. Use the format 123-456-7890 within the United States and Canada. Otherwise, provide the country code.
- Ext: phone extension, if needed

- Email * (FDAAA): (or Phone required) electronic mail address of the facility contact person

- **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
  - Degree
  - Role: Site Principal Investigator or Site Sub-Investigator (pick one)

  Contact information character limits:

  - First Name: 62 characters
  - Last Name: 62 characters
  - Degree: 30 characters
  - Phone: 30 characters
  - Phone Ext: 14 characters
  - Email: 254 characters
  - Affiliation: 160 characters

12. References

- **Citations**
  Definition: Citations to publications related to the protocol: background and/or results. Provide either the PubMed Unique Identifier (PMID) of an article or enter the full bibliographic citation.

  - **PubMed Identifier**
    Definition: PubMed Unique Identifier (PMID) for the citation in MEDLINE
    Example: 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