# ClinicalTrials.gov Data Element Definitions (DRAFT)

February 5, 2008

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

## 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.
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. Provide up to 5 Secondary ID Numbers, one per line.
Examples:
ISRCTN12345678
NCI-793-0115D
R01-123456-1

### Brief Title * FDAAA

Definition: Protocol title intended for the lay public.
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.
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

**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.
- 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.

**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 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 only if status is "Submitted, approved" or "Submitted, exempt")

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.
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

**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.
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.

**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.

Provide the following information for the designated responsible party:

- Name/Official Title FDAAA - for either the principal investigator or sponsor contact
- Organization FDAAA - the sponsor or the principal investigator's organizational affiliation
- Contact Information FDAAA - *[required for internal administrative use only; not revealed to public]* provide telephone number and/or email address

## 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.

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.

Example:
Sudden out-of-hospital cardiac arrest (OOH-CA) remains a significant cause of death, in

spite of recent declines in overall mortality from cardiovascular disease. Existing methods of emergency resuscitation are inadequate due to time delays inherent in the transport of a trained responder with defibrillation capabilities to the side of the OOH-CA victim. Existing Emergency Medical Services (EMS) systems typically combine paramedic Emergency Medical Technician (EMT) services with some level of community involvement, such as bystander cardiopulmonary resuscitation (CPR) training. Some communities include automated external defibrillators (AEDs) at isolated sites or in mobile police or fire vehicles. A comprehensive, integrated community approach to treatment with AEDs would have community units served by these volunteer non-medical responders who can quickly identify and treat a patient with OOH-CA. Such an approach is termed Public Access Defibrillation (PAD).

## 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

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.

**Study Start Date** FDAAA
Definition: Date that enrollment to the protocol begins.

**Primary Completion Date** FDAAA
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** FDAAA
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. Select only one.

**N/A**: for trials without phases

**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).

**Enrollment** *
Definition: (see above)

**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.

## Primary and Secondary Outcome Measures

**Primary Outcome Measure** FDAAA
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.

- **Outcome Measure** FDAAA - 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.
- **Time Frame** (FDAAA) - Time point(s) at which outcome measure is assessed.
- **Safety Issue?** (FDAAA) - Is this outcome measure assessing a safety issue? Select: Yes/No

Examples:

Outcome Measure: all cause mortality
Time Frame: one year
Safety Issue: No

Outcome Measure: 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: Other key measures that will be used to evaluate the intervention(s) or, for observational studies, that are a focus of the study. Specify Outcome Measure, Time Frame and Safety Issue (see above).

## 8. Arms, Groups and Interventions

For interventional studies specify the arms:

**Arm Number or Label** * (FDAAA) - the number, letter or name used to identify the arm. Examples: A, 2, III

**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.

For observational studies specify the predefined participant groups (cohorts) to be studied. Do not use this section to specify strata (Detailed Design can be used for that purpose, if desired).

**Group/Cohort Number or Label** * - the number, letter or name used to identify the group. Examples: A, 2, III, Surgical, Observation

**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.

For all studies, and for expanded access records, specify the associated intervention(s).

**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.

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.
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.

**Arms/Groups** * (FDAAA) - if arms or groups have been specified for the protocol, select the ones for which the intervention is to be administered. For interventional studies with arms specified, all arms must have at least one intervention (unless arm type is "No Intervention") and each intervention must be assigned to at least one arm. For observational studies with groups specified, each intervention (if any) must be assigned to at least one group.

**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.

## 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).

**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.
Example:

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

Exclusion Criteria:
  - Insulin dependent diabetes
  - Thyroid disease
```

**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. 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
- Degrees

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

**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
- 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.

## 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

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://

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.

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