Clinical Trial Visualization Redesign | Section and Field Definitions (ClinicalTrials.gov)

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Fields containing an " * " are required for the Clinical Trial Visualization Redesign Challenge. Other fields may be included based on patient feedback/needs, but are not required.*

1. Titles and Background Information

Organization's Unique Protocol ID

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 *

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)

Brief Summary *
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).

Disease Conditions or Focus of Study *
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.

Study Type *

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.

Study Phase *

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

2. Status

Record Verification Date

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 * *[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)

Timeline *

Study Start Date

Definition: Date that enrollment to the protocol begins.

Primary Completion Date [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. Sponsors

Responsible Party 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)

Sponsor *

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

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

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. 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.

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 nameExamples:United States: Institutional Review BoardUnited States: Food and Drug AdministrationGermany: Federal Institute for Drugs and Medical DevicesAustralia: Therapeutic Goods Administration

5. Site Location(s)

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

Facility *

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

Facility Contact * (or Central Contact required)

- First Name
- Middle Initial
- Last Name
- Degree
- Phone (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 (or Phone required) electronic mail address of the facility contact person

Site Recruitment Status * - 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".

Investigators * (at the protocol location)

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

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

6. 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 *

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

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

Exclusion Criteria: *
  - Insulin dependent diabetes
  - Thyroid disease
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Other fields from Inclusion criteria that should be separated for ease of identification

Gender *

Definition: Physical gender of individuals who may participate in the protocol. Select one. (separate field from Inclusion criteria)

- 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 * (separate field from Inclusion criteria)

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.

Ethnicity * (separate field from Inclusion criteria)

Create a field to include the ethnicity of patients being enrolled in the trial (e.g. Chinese, East Indian, Japanese, etc.)

Genetic Mutation Type * (separate field from Inclusion criteria)

Create a field to include the type of genetic mutation type that will be used to include participants (e.g. CYP 2C19 poor metabolizers, etc.)

Biomarker(s) * (separate field from Inclusion criteria)

Create a field to include the type of biomarkers that will be used to include participants (e.g. KRAS mutation, etc.)

Accepts Healthy Volunteers?

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.

7. Design Elements

Two types: Arms (interventional) or Groups (Observational)

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). [See Section 7 for more insight]

Arm Type* - select one

- Experimental
- Active Comparator
- Placebo Comparator
- Sham Comparator
- No intervention
- Other

Arm Label* - the short name used to identify the arm. (Limit: 62 characters)

Examples:

- Metformin
- Lifestyle counseling
- Sugar pill

Arm Description - 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). [See Section 7 for more insight]

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* - 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* - 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* - 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)

Mechanism of Action: *

Provide details of how the intervention works (e.g. blocks X receptor site, etc.)

Route of Administration *

Provide details of how the intervention will be administered (e.g. orally, subcutaneous injection, intramuscular injection, etc)

Frequency of dose *

Provide details on how often the intervention is taken and at what dose. Example:

50 mg/m2, IV (in the vein) on day 5 of each 28 day cycle.

Timeline/Schedule of Events *

Discuss the timeline in which various scheduled events take place (e.g. vitals, labs, etc to be drawn on X date)

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 - 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.

8. Study Design

Interventional Study Design

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 - 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.

Intervention Model (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

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

Masking (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 (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.

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* [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** [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?** - 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*

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. 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

CitationDefinition: 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.

URL

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

11. Patient Considerations *

Risk/Benefit of study participation*

Describe or show the key elements for patient consideration of risk/benefit. An example could be an adverse event risk score. Another example could be the probability of being in active treatment arm.

Study logistics*

Describe logistics of the study such as handling of expenses, frequency and types of visits, other relevant patient information.

Post Study Plans*

Describe how the patient will be cared for after their participation in the study is complete. Examples could include: access to study data, study drug, study results, etc.