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## Our Notarization Process

OnlineNotary.net is a Virginia Based Notarization firm. Following document has been notarized by us. The Commonwealth of Virginia signed into law SB 827 and HB 2318. These billsauthorize and allow for approved, certified Virginia Notaries to legally notarize any signature within anyUS State by using audio-video capturing technology. We use highest standard Personal identityValidation, UETA and ESIGN ACT during our notarization process and have fully vetted signers in thisdocument. We also keep video recordings of each notarization in an event if needed by court of law.You may also scan the QR code on the right to validate this document instantly.



Amgen Exhibit 1058
Amgen v. BMS




# AFFIDAVIT OF NATHANIEL E FRANK-WHITE

1. I am a Records Request Processor at the Internet Archive. I make this declaration of my own personal knowledge.

2. The Internet Archive is a website that provides access to a digital library of Internet sites and other cultural artifacts in digital form. Like a paper library, we provide free access to researchers, historians, scholars, and the general public. The Internet Archive has partnered with and receives support from various institutions, including the Library of Congress.

3. The Internet Archive has created a service known as the Wayback Machine. The Wayback Machine makes it possible to browse more than 450 billion pages stored in the Internet Archive's web archive. Visitors to the Wayback Machine can search archives by URL (i.e., a website address). If archived records for a URL are available, the visitor will be presented with a display of available dates. The visitor may select one of those dates, and begin browsing an archived version of the Web. Links on archived files in the Wayback Machine point to other archived files (whether HTML pages or other file types), if any are found for the URL indicated by a given link. For instance, the Wayback Machine is designed such that when a visitor clicks on a hyperlink on an archived page that points to another URL, the visitor will be served the archived file found for the hyperlink's URL with the closest available date to the initial file containing the hyperlink.

4. The archived data made viewable and browsable by the Wayback Machine is obtained by use of web archiving software that automatically stores copies of files available via the Internet, each file preserved as it existed at a particular point in time.

5. The Internet Archive assigns a URL on its site to the archived files in the format http://web.archive.org/web/[Year in yyyy][Month in mm][Day in dd][Time code in hh:mm:ss]/[Archived URL] aka an "extended URL". Thus, the extended URL http://web.archive.org/web/19970126045828/http://www.archive.org/ would be the URL for the record of the Internet Archive home page HTML file (http://www.archive.org/) archived on January 26, 1997 at 4:58 a.m. and 28 seconds (1997/01/26 at 04:58:28). The date indicated by an extended URL applies to a preserved instance of a file for a given URL, but not necessarily to any other files linked therein. Thus, in the case of a page constituted by a primary HTML file and other separate files (e.g., files with images, audio, multimedia, design elements, or other embedded content) linked within that primary HTML file, the primary HTML file and the other files will each have their own respective extended URLs and may not have been archived on the same dates.

6. Attached hereto as Exhibit A are true and accurate copies of browser screenshots of the Internet Archive's records of the archived files for the URLs and the dates specified in the attached coversheet of each printout.




7. Attached hereto as Exhibit B are true and accurate copies of printouts of the Internet Archive's records of the archived files for the URLs and the dates specified in the attached coversheet of each printout.

8. I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

DATE: 09/26/2024

Nathaniel Frank-White

Nathaniel E Frank-White

Please see attached
All Purpose
Jurat form
for additional
Notary Events

# JURAT ATTACHMENT

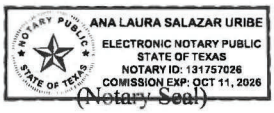
A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

STATE OF Texas }

COUNTY OF Harris }

The foregoing instrument was subscribed and sworn before me this date of 09/26/2024, by Nathaniel Frank-White

This notarial act was an online notarization.



(Notary Seal)

Notary's Signature Ana Laura Salazar Uribe

Registration No.: 131757026

Commission Expiration Date: October 11, 2026

# EXHIBIT A

https://web.archive.org/web/20151005230003/https://clinicaltrials.gov/ct2/search

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# Basic Search

Example: "Heart attack" AND "Los Angeles"
Search for studies: Search
Advanced Search | Help

## Search Tips and Examples

- You can enter a word or a phrase, such as the name of a medical condition or an intervention.
- Use AND (in uppercase) to search for multiple terms.
- For more information, see How to Search.

Click on the links below to practice some sample searches:

heart disease AND stroke AND California
melanoma
lung cancer AND risk factors
prostate cancer AND radiation
veterans affairs medical center
aspirin AND prevention

## Learn More

- How to Use Search Results: Learn how to change the search results display.
- How to Find Results of Studies: Learn about the results information available for some studies.
- How to Read a Study Record: Learn about the information found in a study record.

This page last reviewed in April 2015

TO TOP

For Patients and Families | For Researchers | For Study Record Managers

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About this capture



# FAQ: ClinicalTrials.gov - Submission and Review of Information

Printer-friendly Version

**Question: Who submits information on clinical studies and what review takes place before information is posted on *ClinicalTrials.gov*?**

**Answer:**

- Organizations that sponsor and implement clinical studies are responsible for ensuring that accurate and timely information about their studies is submitted to *ClinicalTrials.gov*.
- All clinical study information submitted to *ClinicalTrials.gov* is reviewed by the National Library of Medicine (NLM). The *ClinicalTrials.gov* database is updated daily.
- Additional Resource Information on clinical trials can be found at *http://clinicaltrials.gov/info/resources*

**Related Questions:**

*ClinicalTrials.gov* questions

Return to the top | Return to the list of FAQs
*http://www.nlm.nih.gov/services/ctmaintain.html*

**Last reviewed:** 21 April 2008
**Last updated:** 21 April 2008
**First published:** 01 January 2001
**Metadata| Permanence level:** Permanence Not Guaranteed

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# ClinicalTrials.gov Protocol Data Element Definitions (DRAFT)

August 20, 2008

| | |
|---|---|
| * | 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

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**

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

**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 Label** * (FDAAA) - the short name used to identify the arm.
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.

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 Label** * - the short name used to identify the group.
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.

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)

- 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

https://web.archive.org/web/20090826144918/http://clinicaltrials.gov:80/ct2/info/results

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# About the ClinicalTrials.gov Results Database

## Overview

The ClinicalTrials.gov Results Database allows data providers to report summary results of registered clinical trials and observational studies. Results are reported in a standard, tabular format that consists of the following:

- Participant Flow
- Baseline Characteristics
- Outcome Measures and Statistical Analyses
- Adverse Events Information
- Administrative Information

ClinicalTrials.gov reviews results submissions to ensure that they are clear and informative prior to public posting (review criteria). However, ClinicalTrials.gov cannot ensure scientific accuracy. Each data provider is responsible for ensuring that the information is accurate and complete.

To search and find posted results information, use the Advanced Search page and set the Study Results search field to "Studies With Results."

## Results Reporting Requirements Under U.S. Federal Law

### Scope

While results information may be submitted for any registered study, US Public Law 110-85 (Food and Drug Administration Amendments Act of 2007 or FDAAA), Title VIII, Section 801 mandates that a "responsible party" (i.e., the study sponsor or designated principal investigator) register and report results of certain "applicable clinical trials" that were initiated or ongoing as of September 27, 2007:

- Trials of Drugs and Biologics: Controlled, clinical investigations, other than Phase I investigations, of a product subject to FDA regulation
- Trials of Devices: Controlled trials with health outcomes of a product subject to FDA regulation (other than small feasibility studies) and pediatric postmarket surveillance studies.

"Applicable clinical trials" generally include interventional studies (with one or more arms) of drugs, biological products, or devices that are subject to FDA regulation, meaning that the trial has one or more sites in the U.S, involves a drug, biologic, or device that is manufactured in the US (or its territories), or is conducted under an investigational new drug application (IND) or investigational device exemption (IDE).

### Timing

In general, a responsible party is required to submit "basic results" information not later than one year after the "primary completion date" or 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. (Note that, if submitted by the data provider, the "primary completion date" is listed in the study protocol record.)

### Delayed Submission

The law allows for delayed submission of results information with certification. A responsible party may submit a certification for delayed submission of results information for an applicable clinical trial that is:

- Completed before the drug or device is initially approved, licensed, or cleared by the FDA ("seeking initial approval")
- Studying a new use of an FDA-approved drug or device (i.e., a use not included in the labeling) for which the manufacturer of a drug or device is the sponsor of the trial and has filed or will file within a year an application to the FDA for approval or clearance of that use ("seeking approval of a new use")

The law also allows the NIH to provide an extension of the deadline for submission of results information for an applicable clinical trial if the responsible party submits a written request that demonstrates good cause for the extension and provides an estimate of the date on which the results information will be submitted. Pending publication is not considered a good cause for an extension.

## Displaying Results Records

ClinicalTrials.gov organizes information for each registered study as an integrated unit, displaying the study protocol record and, if available, the corresponding results record under different tabs on the same page to facilitate cross-referencing.

### No Study Results Posted

When results are not available for a study, the results record tab is labeled, "No Study Results Posted." Results may not be posted for any of the following reasons:

- The study is still ongoing
- The study may not be subject to the Federal results reporting requirements
- The study is completed, but the deadline for results reporting has not been reached
- The results have been submitted, but have not yet been posted (e.g., pending review by ClinicalTrials.gov)
- Submission of results information has been delayed with certification
- A request for extending the submission deadline has been submitted to NIH

### Has Study Results

When results are available publicly for a study, the status column in the "List Results" tab (search results list) is annotated, "Has Results," and the results record tab is labeled, "Study Results." The summary results will be displayed in the tabular format, a s described above.

## More Information

### Publications

- "Basic Results" Database and Information on US Public Law 110-85
- Tse T, Williams RJ, Zarin DA. Reporting "Basic Results" in ClinicalTrials.gov. Chest. 2009 Jul;136(1):295-303.
- Tse T, Williams RJ. ClinicalTrials.gov to Include Basic Results Data. NLM Tech Bull. 2008 Sep-Oct;(364):e15.

Background Information

Last Updated: August 4th, 2009





https://web.archive.org/web/20081013222556/http://www.clinicaltrials.gov:80/ct2/info/about

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# About ClinicalTrials.gov

ClinicalTrials.gov offers up-to-date information for locating federally and privately supported clinical trials for a wide range of diseases and conditions. A clinical trial (also clinical research) is a research study in human volunteers to answer specific health questions. Interventional trials determine whether experimental treatments or new ways of using known therapies are safe and effective under controlled environments. Observational trials address health issues in large groups of people or populations in natural settings.

ClinicalTrials.gov currently contains 63,054 trials sponsored by the National Institutes of Health, other federal agencies, and private industry. Studies listed in the database are conducted in all 50 States and in 158 countries ClinicalTrials.gov receives over 40 million page views per month 50,000 visitors daily.

The U.S. National Institutes of Health (NIH), through its National Library of Medicine (NLM), has developed this site in collaboration with the Food and Drug Administration (FDA), as a result of the FDA Modernization Act, which was passed into law in November 1997. See the FDA document - Guidance for Industry: Information Program on Clinical Trials for Serious or Life-Threatening Diseases and Conditions (March 2002).

You can learn more about this site from its Frequently Asked Questions and Factsheet.

We subscribe to the HONcode principles. Verify here.

## Information for Investigators

For information on submitting studies to ClinicalTrials.gov, please see the information at http://prsinfo.clinicaltrials.gov.

## Information for Webmasters

There is information available on linking to ClinicalTrials.gov from your web page.

Please read our Terms and Conditions regarding use of ClinicalTrials.gov data.

**Background Information**

Last Updated: 2008-04-01

https://web.archive.org/web/20090812224128/http://clinicaltrials.gov/ct2/help/help

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# Help for Searching ClinicalTrials.gov

## Help Topics:

Basic Search
Advanced Search
Refine Search
Search Expressions

## Basic Search:

On the Basic Search page, enter a word or word(s) that you want to use to find studies. These may include diseases, interventions, and/or locations.

Medical terms are often several words long, such as Percutaneous Coronary Intervention. To only find studies where the words are together as a phrase, put the term in quotes (e.g., "Percutaneous Coronary Intervention"). If you search for a multi-word term without quotes, studies with all words together as a phrase will appear higher in the results list than studies where the words are separated and spread throughout the document. For example, a search for **Heart Attack** will list a study about,

Use of a Pacemaker Following a **Heart Attack**.

higher than the study,

**Heart** Defects and Transient Ischemic **Attacks**

A search for **"Heart Attack"** would not find the second study. Synonyms are known for some terms and are used where possible. For example, a search for Heart Attack will also find occurrences of **Myocardial Infarction**.

## Advanced Search:

Many searches are a single term and can be performed with a few words in the search box. But, sometimes you need more control. Click on the Advanced Search tab (if starting a new search) or Refine Search tab (if modifying an existing search) to show additional search fields.

The additional search fields can be used to limit your search results. Note that it is not necessary to fill in all the fields, only those that are needed for your search. If you are finding too few studies, consider clearing a field and searching again.

**Search Terms:**

Performs a general search in all sections of the study record, including title, description, conditions, interventions, locations, etc. Terms in this field are searched the same as Basic Search.

**Recruitment:**

Limits search results to studies that are open or closed. New volunteers may be able to participate in open studies, but not closed studies.

Open recruitment status values:
**Recruiting**,
**Not yet recruiting**, or
**Available for expanded access**.

Closed recruitment status values:
**Active, not recruiting**,
**Completed**,
**Terminated**,
**Suspended**,
**Withdrawn**,
**Enrolling by invitation**,
**Temporarily not available for expanded access**,
**No longer available for expanded access**, or
**Approved for marketing**.

Values are color coded (as shown) in the search results.

**Study Results:**

Limits search results based on whether the study has results or not:
All Studies,
Studies With Results, or
Studies Without Results
The inclusion of Study Results is a new feature of ClinicalTrials.gov. Only a few studies have results available.

**Study Type:**

Limits search results to any of the following study types:
Interventional,
Observational, or
Expanded Access

**Conditions:**

Performs a search on fields describing the diseases or conditions being studied.

**Interventions:**

Performs a search on fields listing the drugs or interventions being studied.

**Outcomes Measures:**

Performs a search on fields listing the outcome measures used to quantify study results.

**Lead Sponsors:**

Performs a search on fields listing the lead sponsor of a study.

It is common for several sponsors to collaborate by providing funding, facilities, experimental treatments, etc. Which sponsor is considered the lead sponsor is decided by the data provider.

When the **Exact Match** checkbox is checked, the lead sponsor name in the study must exactly match the lead sponsor name in the search. For example, if unchecked, a search for Merck in the lead sponsor field will find Merck, Merck KGaA, Dupont Merck, and Merck Sharp & Dohme. When checked, only Merck, with no other words in the name, will be found.

**Sponsors:**

Performs a search on fields listing the sponsors of a study.

When the **Exact Match** checkbox is checked, the sponsor name in the study must exactly match the sponsor name in the search. For example, if unchecked, a search for Merck in the sponsor field will find Merck, Merck KGaA, Dupont Merck, and Merck Sharp & Dohme. When checked, only Merck, with no other words in the name, will be found.

**Study IDs:**

Performs a search on fields listing ID numbers.

**Country/State:**

Trials are often conducted at many locations around the world. Select up to three locations to find trials conducted in specific countries. Some countries (currently limited to the United States, Canada, and Australia), locations can be narrowed further by selecting a state (e.g., United States, Alabama).

**Location Terms:**

Finds studies in specific locations such as a city (Los Angeles) or facility (Mayo Clinic). Not all studies include this level of detail, but if they do, this will find them.

**Gender:**

Limits search results to those studies that accept female or male participants.

**Age Group:**

Limits search results to those studies that include at least one of the specified age ranges. More than one age group can be selected.

**Phase:**

Limits search results to studies that are labeled with at least one of the specified phases. More than one Phase can be selected.

**Funded By:**

Limits search results to studies that have at least one sponsor of the specified types. More than one sponsor type can be selected.

**Safety Issue:**

Limits search results to studies that have at least one outcome measure designated as a safety issue.

**First Received:**

Limits search results to studies that were received by ClinicalTrials.gov within a specified date range. The "From" or "To" field can be left blank.

**Last Updated:**

Limits search results to studies that were modified within a specified date range. The "From" or "To" field can be left blank.

## Refine Search:

Searches display a list of studies found (List Results tab). If you are not content with the search results, click on the Refine Search tab at the top of the list to modify your search.

Add terms to empty fields to search within your current result. You can also add terms to fields that contain terms. For best results, use an AND (all upper case) as a separator between terms in the same field.

For example:

heart attack
heart attack AND aspirin
heart attack AND aspirin AND older adults
heart attack AND aspirin AND older adults AND California

When you are done making changes, click Search to display the new results.

## Search Expressions:

Use AND (all upper case) to find study records that contain all terms connected by AND.
For example:

prostate cancer AND radiation
heart disease AND stroke AND California

Use OR (all upper case) to find study records that contain either term connected by OR.
For example:

Aspirin OR ibuprofen
heart disease OR heart attack

Use NOT (all upper case) to find study records that do not contain the term following NOT.
For example:

Immunodeficiency NOT AIDS

Likewise, AND, OR, NOT, and parentheses can be used to create more complicated search expressions.
For example:

prostate cancer AND NOT ( radiation OR homeopathic remedies )
( heart disease OR heart attack ) AND ( stroke OR clot )

Note that the use of AND and OR as logical operators can be confusing.
An appropriate search for a list such as,

Ear, Nose, and Throat Conditions

is the expression

( Ear OR Nose OR Throat ) AND Conditions

Fortunately, search will do a pretty good job of finding the right studies either way.

To search for AND as a word, instead of using it as an operator, put it in quotes.
Likewise, you can quote OR, NOT, and parentheses.

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**Fill in any or all of the fields below.**

Click on a label to the left for further explanation or read the **Help**.

Search Terms: Search Help
Recruitment: All Studies
Study Results: All Studies
Study Type: All Studies

Targeted Search:

Conditions:
Interventions:
Outcome Measures:
Lead Sponsors: Exact Match
Sponsors: Exact Match
Study IDs:

Locations:

State 1: --- Optional ---
Country 1: --- Optional ---
State 2: --- Optional ---
Country 2: --- Optional ---
State 3: --- Optional ---
Country 3: --- Optional ---
Location Terms:

Additional Criteria:

Gender: All Studies
Age Group: Child (birth-17) Adult (18-65) Senior (66+)
Phase: Phase I Phase II Phase III Phase IV
Funded By: NIH Other U.S. Federal Agency Industry University/Organization
Safety Issue: Has an outcome measure designated as a safety issue.
First Received: From To (MM/DD/YYYY)
Last Updated: From To (MM/DD/YYYY)

Search Help





https://web.archive.org/web/20090812223843/http://clinicaltrials.gov/ct2/search

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A service of the U.S. National Institutes of Health



Basic Search | Advanced Search | Studies by Topic | Studies on Map

**Enter a word or phrase, such as the name of a medical condition or intervention.**

**Example: Heart Attack AND Los Angeles**

Search

Advanced Search Help

**Search Tips:**

Use AND (all upper case) to search for multiple terms. For example:
prostate cancer AND radiation
heart disease AND stroke AND California

Contact Help Desk
Lister Hill National Center for Biomedical Communications, U.S. National Library of Medicine,
U.S. National Institutes of Health, U.S. Department of Health & Human Services,
USA.gov, Copyright, Privacy, Accessibility, Freedom of Information Act



# EXHIBIT B

https://web.archive.org/web/20090410230211/http://prsinfo.clinicaltrials.gov/registering.pdf

## How do I register my trial?

- **Does the trial sponsor have an existing account with the Protocol Registration System (PRS)?** The PRS is a Web-based data system that allows sponsors to submit, maintain, and update information about their trials free of charge. To find out if the sponsor already has a PRS account, check the list at: http://prsinfo.clinicaltrials.gov/prs_organizations.html.
  - **If "yes,"** obtain contact information at: http://prsinfo.clinicaltrials.gov/contactRequest.html.
  - **If "no,"** apply for an account at: http://prsinfo.clinicaltrials.gov/application.html.
- **After you receive login information,** log into the PRS system. (See http://prsinfo.clinicaltrials.gov/intro.html for a guided tour.)
- **View the "Quick Start Guide."** All the features required to enter data about a trial are available through the "Standard Functions" menu.
- **Complete all ClinicalTrials.gov data elements,** providing as much accurate, up-to-date information as possible.
- **After you enter the data,** a PRS administrator will review the record before releasing it for publication on the ClinicalTrials.gov site.
- **You can view a record,** including its unique identifier (NCT number), at ClinicalTrials.gov within 2–5 business days after it is released.

For more information about registering a clinical trial at ClinicalTrials.gov, see the FAQs at http://prsinfo.clinicaltrials.gov or send e-mail to register@clinicaltrials.gov.



## *Resources*

**Information on Registering Clinical Trials**
http://prsinfo.ClinicalTrials.gov

**ClinicalTrials.gov Web Site**
http://www.ClinicalTrials.gov

**The International Committee of Medical Journal Editors (ICMJE) policy on trial registration**
http://www.icmje.org/clin_trialup.htm

**Food and Drug Administration's Guidance for Industry: Information Program on Clinical Trials for Serious or Life-Threatening Diseases and Conditions**
http://www.fda.gov/cder/guidance/4856fnl.htm

# Registering Clinical Trials

## *with ClinicalTrials.gov*



*Linking Patients to Medical Research*



**prsinfo.ClinicalTrials.gov**







## What is ClinicalTrials.gov?

**ClinicalTrials.gov is a directory of federally and privately supported research trials conducted in the United States and around the world to test the effect of experimental drugs, devices, and procedures for many diseases and conditions.**

**Each entry includes a summary of the trial protocol, including the purpose, recruitment status, and criteria for patient participation. Trial locations and specific contact information are provided to assist enrollment.**

**The Web site is a free service of the U.S. National Institutes of Health (NIH), developed by the National Library of Medicine.**

*Linking Patients to Medical Research*

## Why register?

- **Required by law.** Section 113 of the FDA Modernization Act mandates registration with ClinicalTrials.gov of investigational new drug (IND) efficacy trials for serious diseases or conditions.
- **Required for journal publication.** The International Committee of Medical Journal Editors (ICMJE) requires trial registration as a condition for publication of research results generated by a clinical trial (*N Engl J Med* 2004;351:1250–1).
- **NIH commitment.** The NIH is committed to providing information to increase public awareness and access to clinical trials sponsored federally and by industry and foundations.

## Which of my trials should be registered?

- ClinicalTrials.gov accepts registration of all clinical trials (1) approved by a human subject review board and (2) conforming to the regulations of the appropriate national health authorities. Both interventional and observational trials are accepted.
- Sponsors, funders, reviewers, ethics board members, and coordinators and investigators of clinical research anywhere in the world should be familiar with ClinicalTrials.gov registration policies.
- Trials can be registered at any time, but many policies require registration prior to the enrollment of the first participant.

Information about these policies and background materials are available at http://prsinfo.ClinicalTrials.gov.

https://web.archive.org/web/20090902185232/http:/prsinfo.clinicaltrials.gov/s801-fact-sheet.pdf

# FACT SHEET (Available at http://prsinfo.clinicaltrials.gov/)

# Registration at ClinicalTrials.gov: As required by Public Law 110-85, Title VIII

On September 27, 2007, a U.S. law was enacted that expands the types of clinical trials that must be registered in ClinicalTrials.gov, increases the number of data elements that must be submitted, and also requires submission of results data. There are penalties for non-compliance with the law. This fact sheet addresses the new registration requirements, some of which have reporting deadlines beginning on **December 26, 2007.** Information about the requirement to submit results data will be forthcoming.

## 1. General Requirements for Registration

### A. Clinical Trials That Must be Registered at ClinicalTrials.gov ("Applicable Clinical Trials")

- Trials of Drugs and Biologics: controlled clinical investigations, other than Phase 1 investigations, of a product subject to FDA regulation [1]
- Trials of Devices: Controlled trials with heath outcomes of devices subject to FDA regulation, other than small feasibility studies, and pediatric postmarket surveillance [2]

### B. Who is Responsible for Trial Registration? ("Responsible Party") [3]

1. The sponsor of the clinical trial [4]; - *OR* -
2. The principal investigator (PI) of such clinical trial if so designated by a sponsor, grantee, contractor, or awardee, so long as the PI is responsible for conducting the trial and has sufficient data rights.

### C. Required Data Elements -

The Responsible Party must submit descriptive, recruitment, location, contact, and administrative information when registering an applicable clinical trial [5]. More data elements are required than under prior U.S. law, and these new requirements include primary and secondary outcome measures, start date, and target number of subjects.

## 2. Timing of Registration at ClinicalTrials.gov

In general, the Responsible Party for an applicable clinical trial must submit required information by the later of 12/26/**2007** or 21 days after the first patient is enrolled [6].

*Exceptions:* (a) data for trials "ongoing" as of 9/27/2007 that do ***not*** involve a "serious or life threatening disease or condition" must be submitted by 9/27/**2008** [7], [8];
(b) trials that involve a "serious or life threatening disease or condition", are initiated before 9/27/07, and have a "completion date" prior to 12/26/2007 [9] are not subject to the new requirements, although they may be subject to other laws.

## 3. Penalties for Failure to Register

Penalties for responsible parties who fail to register applicable clinical trials are significant and may include civil monetary penalties [10] and, for federally-funded trials, the withholding or recovery of grant funds [11]. Starting December 26, 2007, any application or report submitted to FDA under sections 505, 510(k), 515, or 520(m) of the Federal Food, Drug, and Cosmetic Act or under section 351 of the Public Health Service Act will need to include certification of compliance with any applicable provisions [12].

# FACT SHEET

## Registration at ClinicalTrials.gov:
## As required by Public Law 110-85, Title VIII

### ENDNOTES

1. "`(iii) APPLICABLE DRUG CLINICAL TRIAL-

`(I) IN GENERAL- The term `applicable drug clinical trial' means a controlled clinical investigation, other than a phase I clinical investigation, of a drug subject to section 505 of the Federal Food, Drug, and Cosmetic Act or to section 351 of this Act. [The Public Health Service Act]

`(II) CLINICAL INVESTIGATION- For purposes of subclause (I), the term `clinical investigation' has the meaning given that term in section 312.3 of title 21, Code of Federal Regulations (or any successor regulation).

`(III) PHASE I- For purposes of subclause (I), the term `phase I' has the meaning given that term in section 312.21 of title 21, Code of Federal Regulations (or any successor regulation)."

*[PL 110-85, Section 801(a), adding new 42 U.S.C. 282(j)(1)(A)(iii)]*

2. "`(ii) APPLICABLE DEVICE CLINICAL TRIAL- The term `applicable device clinical trial' means--

`(I) a prospective clinical study of health outcomes comparing an intervention with a device subject to section 510(k), 515, or 520(m) of the Federal Food, Drug, and Cosmetic Act against a control in human subjects (other than a small clinical trial to determine the feasibility of a device, or a clinical trial to test prototype devices where the primary outcome measure relates to feasibility and not to health outcomes); and

`(II) a pediatric postmarket surveillance as required under section 522 of the Federal Food, Drug, and Cosmetic Act."

*[PL 110-85, Section 801(a), adding new 42 U.S.C. 282(j)(1)(A)(ii)]*

3. "`(ix) RESPONSIBLE PARTY- The term `responsible party', with respect to a clinical trial of a drug or device, means--

`(I) the sponsor of the clinical trial (as defined in section 50.3 of title 21, Code of Federal Regulations (or any successor regulation)); or

"`(II) 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 under this subsection for the submission of clinical trial information."

*[PL 110-85, Section 801(a), adding new 42 U.S.C. 282(j)(1)(A)(ix)]*

4. Under 21 C.F.R. 50.3, "Sponsor" is defined as "a person who initiates a clinical investigation, but who does not actually conduct the investigation, i.e., the test article is administered or dispensed to or used involving, a subject under the immediate direction of another individual. A person other than an individual (e.g., corporation or agency) that uses one or more of its own employees to conduct a clinical investigation it has initiated is considered to be a sponsor (not a sponsor-investigator), and the employees are considered to be investigators."

5. "`(ii) CONTENT- The clinical trial information required to be submitted under this paragraph for an applicable clinical trial shall include--

`(I) descriptive information, including--
`(aa) a brief title, intended for the lay public;
`(bb) a brief summary, intended for the lay public;
`(cc) the primary purpose;
`(dd) the study design;
`(ee) for an applicable drug clinical trial, the study phase;
`(ff) study type;
`(gg) the primary disease or condition being studied, or the focus of the study;
`(hh) the intervention name and intervention type;
`(ii) the study start date;
`(jj) the expected completion date;
`(kk) the target number of subjects; and
`(ll) outcomes, including primary and secondary outcome measures;

`(II) recruitment information, including--
`(aa) eligibility criteria;
`(bb) gender;
`(cc) age limits;
`(dd) whether the trial accepts healthy volunteers;
`(ee) overall recruitment status;
`(ff) individual site status; and
`(gg) in the case of an applicable drug clinical trial, if the drug is not approved under section 505 of the Federal Food, Drug, and Cosmetic Act or licensed under section 351 of this Act, specify whether or not there is expanded access to the drug under section 561 of the Federal Food, Drug, and Cosmetic Act for those who do not qualify for enrollment in the clinical trial and how to obtain information about such access;

`(III) location and contact information, including--
`(aa) the name of the sponsor;
`(bb) the responsible party, by official title; and
`(cc) the facility name and facility contact information (including the city, State, and zip code for each clinical trial location, or a toll-free number through which such location information may be accessed); and

`(IV) administrative data (which the Secretary may make publicly available as necessary), including--
`(aa) the unique protocol identification number;
`(bb) other protocol identification numbers, if any; and
`(cc) the Food and Drug Administration IND/IDE protocol number and the record verification date."

*[PL 110-85, Section 801(a), (adding new 42 U.S.C. 282(j)(2)(A)(ii))]*

6. "`(C) DATA SUBMISSION- The responsible party for an applicable clinical trial, including an applicable drug clinical trial for a serious or life-threatening disease or condition, that is initiated after, or is ongoing on the date that is 90 days after, the date of the enactment of the Food and Drug Administration Amendments Act of 2007, shall submit to the Director of NIH for inclusion in the registry data bank the clinical trial information described in of subparagraph (A)(ii) not later than the later of--

`(i) 90 days after such date of enactment;

`(ii) 21 days after the first patient is enrolled in such clinical trial; or

`(iii) in the case of a clinical trial that is not for a serious or life-threatening disease or condition and that is ongoing on such date of enactment, 1 year after such date of enactment."

*[PL 110-85, Section 801(a), (adding new 42 U.S.C. 282(j)(2)(C))]*

7. "`(viii) ONGOING.—The term 'ongoing' means, with respect to a clinical trial of a drug or a device and to a date, that—

`(I) 1 or more patients is enrolled in the clinical trial; and

`(II) the date is before the completion date of the clinical trial.

*[PL 110-85, Section 801(a), (adding new 42 U.S.C. 282(j)(1)(A)(viii))]*

8. Consistent with current FDA and ClinicalTrials.gov guidance, the NIH interprets "serious and life-threatening disease or condition to mean: (1) diseases or conditions where the likelihood of death is high unless the course of the disease is interrupted and (2) diseases or conditions with potentially fatal outcomes, where the endpoint of clinical trial analysis is survival.

The seriousness of a disease is a matter of judgment, but generally is based on such factors as survival, day-to-day functioning, and the likelihood that the disease, if left untreated, will progress from a less severe condition to a more serious one. For example, acquired immunodeficiency syndrome (AIDS), all other stages of human immunodeficiency virus (HIV) infection, Alzheimer's disease, angina pectoris, heart failure, cancer, and many other diseases are clearly serious in their full manifestations. Furthermore, many chronic illnesses that are generally well managed by available therapy can have serious outcomes. For example, inflammatory bowel disease, asthma, rheumatoid arthritis, diabetes mellitus, systemic lupus erythematosus, depression, psychoses, and many other diseases can be serious in some or all of their phases or for certain populations.

Any investigational drug that has received fast track designation by the FDA is considered a drug to treat a serious disease or condition.

9. "(v) COMPLETION DATE.—The term 'completion date' means, 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.

*[PL 110-85, Section 801(a), adding new 42 U.S.C. 282(j)(1)(A)(v)]*

10. "`(1) PROHIBITED ACTS- Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amended by adding at the end the following:

`(jj)(1) The failure to submit the certification required by section 402(j)(5)(B) of the Public Health Service Act, or knowingly submitting a false certification under such section.

`(2) The failure to submit clinical trial information required under subsection (j) of section 402 of the Public Health Service Act.

`(3) The submission of clinical trial information under subsection (j) of section 402 of the Public Health Service Act that is false or misleading in any particular under paragraph (5)(D) of such subsection (j).'

(2) CIVIL MONEY PENALTIES- Subsection (f) of section 303 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333), as redesignated by section 226, is amended--

(A) by redesignating paragraphs (3), (4), and (5) as paragraphs (5), (6), and (7), respectively;

(B) by inserting after paragraph (2) the following:

`(3)(A) Any person who violates section 301(jj) shall be subject to a civil monetary penalty of not more than $10,000 for all violations adjudicated in a single proceeding.

`(B) If a violation of section 301(jj) is not corrected within the 30-day period following notification under section 402(j)(5)(C)(ii), the person shall, in addition to any penalty under subparagraph (A), be subject to a civil monetary penalty of not more than $10,000 for each day of the violation after such period until the violation is corrected.';

(C) in paragraph (2)(C), by striking `paragraph (3)(A)' and inserting `paragraph (5)(A)';

(D) in paragraph (5), as so redesignated, by striking `paragraph (1) or (2)' each place it appears and inserting `paragraph (1), (2),or (3)';

(E) in paragraph (6), as so redesignated, by striking `paragraph (3)(A)' and inserting `paragraph (5)(A)'; and

(F) in paragraph (7), as so redesignated, by striking `paragraph (4)' each place it appears and inserting `paragraph (6)'.

*[PL 110-85, Section 801(b), adding new section 21 U.S.C. 331(jj)]*

11. `(i) GRANTS FROM CERTAIN FEDERAL AGENCIES- If an applicable clinical trial is funded in whole or in part by a grant from any agency of the Department of Health and Human Services, including the Food and Drug Administration, the National Institutes of Health, or the Agency for Healthcare Research and Quality, any grant or progress report forms required under such grant shall include a certification that the responsible party has made all required submissions to the Director of NIH under paragraph (2) and (3).

`(ii) VERIFICATION BY FEDERAL AGENCIES- The heads of the agencies referred to in clause (i), as applicable, shall verify that the clinical trial information for each applicable clinical trial for which a grantee is the responsible party has been submitted under paragraph (2) and (3) before releasing any remaining funding for a grant or funding for a future grant to such grantee.

*[PL 110-85, Section 801(a), adding new 42 U.S.C. 282(j)(5)(A)(i) and (ii)]*

12. ‘‘(B) CERTIFICATION TO ACCOMPANY DRUG, BIOLOGICAL PRODUCT, AND DEVICE SUBMISSIONS.—At the time of submission of an application under section 505 of the Federal Food, Drug, and Cosmetic Act, section 515 of such Act, section 520(m) of such Act, or section 351 of this Act, or submission of a report under section 510(k) of such Act, such application or submission shall be accompanied by a certification that all applicable requirements of this subsection have been met. Where available, such certification shall include the appropriate National Clinical Trial control numbers.

*[PL 110-85, Section 801(a), adding new 42 U.S.C. 282(j)(5)(B)]*