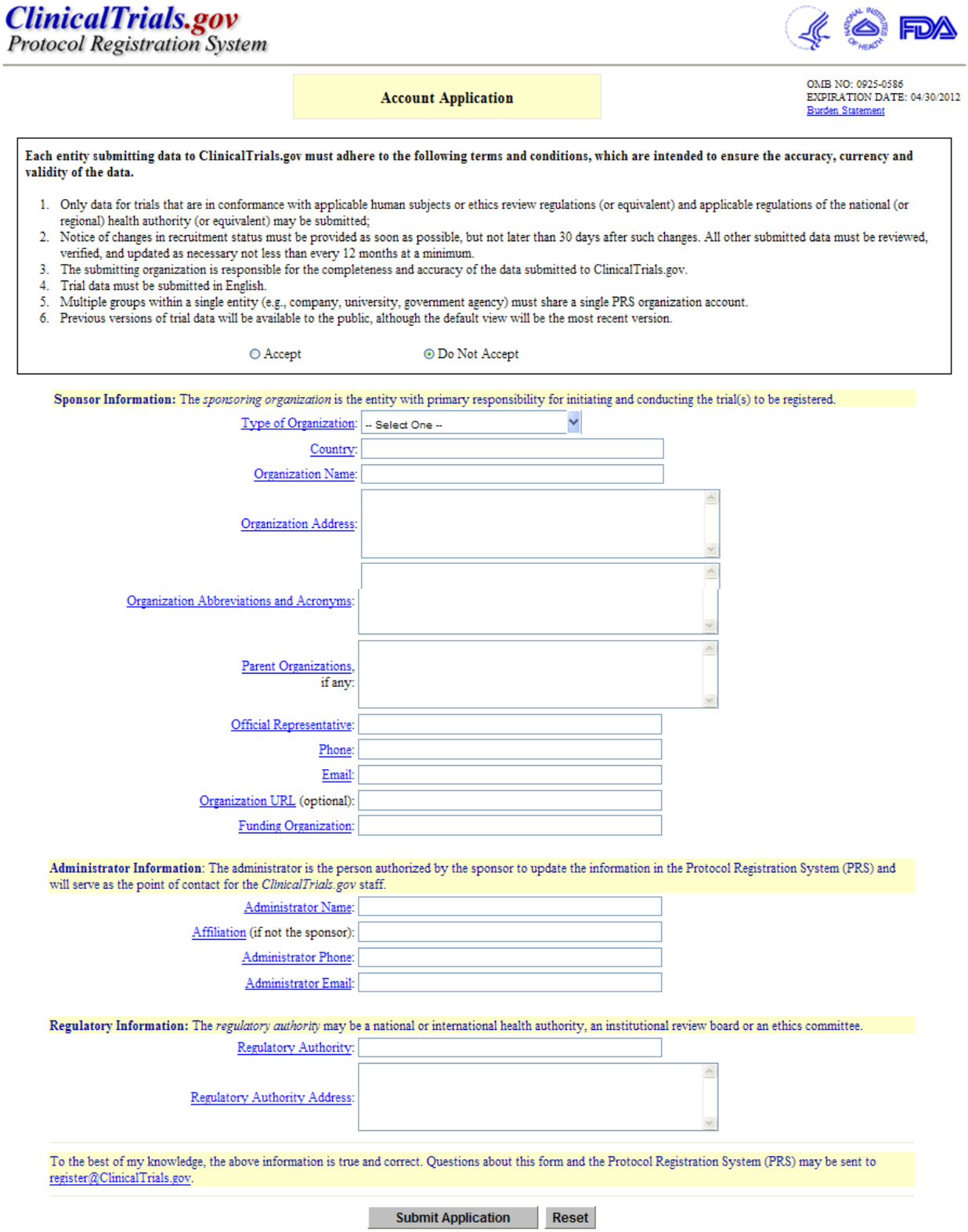
Attachment 3 - ClinicalTrials.gov Registration Data Entry Screen Shots



ClinicalTrials.gov
Protocol Registration System

Account Application

OMB NO: 0925-0586
EXPIRATION DATE: 04/30/2012
Burden Statement

Each entity submitting data to ClinicalTrials.gov must adhere to the following terms and conditions, which are intended to ensure the accuracy, currency and validity of the data.

1. Only data for trials that are in conformance with applicable human subjects or ethics review regulations (or equivalent) and applicable regulations of the national (or regional) health authority (or equivalent) may be submitted;
2. Notice of changes in recruitment status must be provided as soon as possible, but not later than 30 days after such changes. All other submitted data must be reviewed, verified, and updated as necessary not less than every 12 months at a minimum.
3. The submitting organization is responsible for the completeness and accuracy of the data submitted to ClinicalTrials.gov.
4. Trial data must be submitted in English.
5. Multiple groups within a single entity (e.g., company, university, government agency) must share a single PRS organization account.
6. Previous versions of trial data will be available to the public, although the default view will be the most recent version.

○ Accept ◉ Do Not Accept

Sponsor Information: The *sponsoring organization* is the entity with primary responsibility for initiating and conducting the trial(s) to be registered.

Type of Organization: -- Select One --
Country:
Organization Name:
Organization Address:
Organization Abbreviations and Acronyms:
Parent Organizations, if any:
Official Representative:
Phone:
Email:
Organization URL (optional):
Funding Organization:

Administrator Information: The administrator is the person authorized by the sponsor to update the information in the Protocol Registration System (PRS) and will serve as the point of contact for the *ClinicalTrials.gov* staff.

Administrator Name:
Affiliation (if not the sponsor):
Administrator Phone:
Administrator Email:

Regulatory Information: The *regulatory authority* may be a national or international health authority, an institutional review board or an ethics committee.

Regulatory Authority:
Regulatory Authority Address:

To the best of my knowledge, the above information is true and correct. Questions about this form and the Protocol Registration System (PRS) may be sent to register@ClinicalTrials.gov.

Submit Application Reset

Login

Welcome to the ClinicalTrials.gov Protocol Registration System (PRS).

OMB NO: 0925-0586
EXPIRATION DATE: 04/30/2012
Burden Statement

Organization:
Username:
Password: Forgot password

Login

PRS account registration information

Send email to ClinicalTrials.gov Administration

OMB NO: 0925-0586
EXPIRATION DATE: 04/30/2012
Burden Statement

Public reporting burden for this collection of information is estimated to average 7.0 hours per response for initial registration, 2.0 hours for each of 8 updates to the registration information during the course of the trial, 10.0 hours per response for initial results reporting, and 5.0 hours for two substantive updates to the results information. These estimates include the time for reviewing instructions, searching existing data sources, gathering the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0586). Do not return the completed form to this address.

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Protocol Registration System

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Create New Protocol Record

To avoid duplicate or invalid registration of your study, check the following before proceeding with registration:

1. **Section 801 studies may only be registered by the Responsible Party.** If this is an applicable clinical trial as defined by US Public Law 110-85, Title VIII, Section 801, ensure that your organization is the Responsible Party as defined by the law before registering the study.
2. **IND/IDE studies may only be registered by the IND/IDE holder.** If the study is subject to US Food and Drug Administration regulations, under an Investigational New Drug (IND) Application or Investigational Device Exemption (IDE), ensure that your organization is the IND/IDE holder before registering the study.
3. **For NIH-funded studies, coordinate with the relevant Institute or Center.** If this is a US National Institutes of Health (NIH) funded study, registration should be coordinated with the sponsoring NIH Institute or Center to avoid duplicate registration.
4. **Multi-site studies are NOT registered by individual sites.** If this is a multi-site study it must be registered only once, by the sponsor (primary organization that oversees implementation of study and is responsible for data analysis) or its designated principal investigator (PI).
5. **Coordinate with all collaborators before registering.** If the study has multiple collaborators, contact the other organizations to confirm that the study has not already been registered and to notify them that your organization, as sponsor or its designated PI, is registering the study.
6. **Refer to the ClinicalTrials.gov Review of Protocol Submissions document** for a description of items evaluated by ClinicalTrials.gov after protocol information is submitted.

Unique Protocol ID: *	
Brief Title: *	

Continue Cancel

* 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

ClinicalTrials.gov
Protocol Registration System

Send message to PRS

Title Oversight Sponsor Summary Status Design Interventions Conditions Eligibility Locations Citations Links

Title: Sample Clinical Trial Org: NLM ID: 654321

Unique Protocol ID: * FDAAA	Enter sponsoring organization's unique identifier. 654321
Brief Title: * FDAAA (Special characters)	Use lay language. Example: Safety Study of Recombinant Vaccinia Virus Vaccine to Treat Prostate Cancer Sample Clinical Trial
Acronym:	If there is an acronym or abbreviation used to identify this study, enter it here.
Official Title:	Example: Phase 1 Study of Recombinant Vaccinia Virus That Expresses Prostate Specific Antigen in Metastatic Adenocarcinoma of the Prostate
Study Type: * FDAAA	○ Interventional ○ Observational ○ Expanded Access About expanded access records
FDA Regulated Intervention? (FDAAA)	Indicate whether this trial includes an intervention subject to US Food and Drug Administration regulations. --Select--
IND/IDE Protocol? * (FDAAA)	Indicate whether the protocol is subject to US Food and Drug Administration regulations, under an Investigational New Drug (IND) Application or Investigational Device Exemption (IDE). --Select--

Continue Quit

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Title **FDA** Oversight Sponsor Summary Status Design Interventions Conditions Eligibility Locations Citations Links
Title: Study of Investigational New Device for Heart Disease Org: TestOrg ID: 11110000

NOTE: The information entered on this screen is required for administrative purposes and will not be made public in ClinicalTrials.gov.

Section 801 Clinical Trial?: (FDAAA)	Indicate whether this is an "applicable clinical trial" as defined by US Public Law 110-85, Title VIII, Section 801. --Select--
Delayed Protocol Posting?: (FDAAA)	Indicate whether this is an **unapproved or uncleared device trial** for which posting to ClinicalTrials.gov should be delayed in accordance with US Public Law 110-85, Title VIII, Section 801. --Select--
IND/IDE Grantor: * (FDAAA)	--Select--
IND/IDE Number: * (FDAAA)	
IND/IDE Serial Number: (FDAAA)	
Has Expanded Access?: FDAAA	Indicate whether any protocol exceptions are to be granted for the investigational drug or device. --Select-- About expanded access records
Expanded Access Record: FDAAA	If applicable, enter the ClinicalTrials.gov identifier (NCT number) for the associated Expanded Access record.

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Title Oversight Sponsor Summary Status Design Interventions Conditions Eligibility Locations Citations Links
Title: Sample Clinical Trial Org: NLM ID: 654321

Secondary ID Type:	**Select one ID Type** and fill in the additional information, if any, for that type. ○ US NIH Grant/Contract Award Number — For grant numbers, include activity code, institute code and 6 digit serial number. Examples: R01DA013131, UO1HL066582, 5R01HL123451-01A2 ○ Other Grant/Funding Number **Grantor or Funder:** ○ Registry Identifier **Registry Name:** ○ EudraCT Number — European Union Drug Regulatory Authorities Clinical Trial System ○ Other Identifier **Issuing Organization:**
Secondary ID: FDAAA	

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Title **Oversight** Sponsor Summary Status Design Interventions Conditions Eligibility Locations Citations Links

Title: Sample Clinical Trial Org: NLM ID: 654321

Provide information for the human subjects review board, such as an Institutional Review Board (IRB), ethics committee or equivalent group, that is responsible for the review and monitoring of this protocol. For studies involving multiple review boards, provide information only for a single board.

Board Approval: *
If review board approval has been granted, enter the approval number below. If the board does not assign numbers, enter date i
Please send a signed board approval letter to ClinicalTrials.gov (address and instructions).
Status: --Select-- Approval Number:

Board Name: *

Board Affiliation: *

Board Contact: *
(Not made public)
NOTE: Incomplete review board information may delay publication of the trial on ClinicalTrials.gov.
Business Phone: Extension:
Business Email:
Business Address:

Data Monitoring Committee?
Has a group been appointed to monitor safety and scientific integrity of the study?
--Select--

Oversight Authorities: *
(One per line)
Enter, in English, country followed by organization name. [List of oversight authorities]
Examples:
United States: Food and Drug Administration
Germany: Federal Institute for Drugs and Medicinal Devices

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Title Oversight **Sponsor** Summary Status Design Interventions Conditions Eligibility Locations Citations Links

Title: Sample Clinical Trial Org: NLM ID: 654321

Responsible Party: FDAAA
NOTE: The **Sponsor** option should be selected, unless the Investigator has been designated as Responsible Party as permitted under US Public Law 110-85, the FDA Amendments Act (FDAAA).
Sponsor About Responsible Party...

Sponsor: * FDAAA
National Library of Medicine

Collaborators:
(One per line)
Include all additional funding sources.
Enter only the organization names, one per line (no numbers, dashes, bullets, etc.).

Continue Quit

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(FDAAA) May be required to comply with US Public Law 110-85, Section 801

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Title Oversight Sponsor **Summary** Status Design Interventions Conditions Eligibility Locations Citations Links

Title: Sample Clinical Trial Org: NLM ID: 654321

Brief Summary: * FDAAA (Formatting tips)	Use lay language. Include a statement of the study hypothesis.
Detailed Description: (Formatting tips)	Provide a more extensive description, if desired. **Avoid duplication of information to be recorded elsewhere**, such as eligibility criteria or outcome measures.

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Title Oversight Sponsor Summary **Status** Design Interventions Conditions Eligibility Locations Citations Links

Title: Sample Clinical Trial Org: NLM ID: 654321

Record Verification Date: * FDAAA	--Select-- Year:
Overall Recruitment Status: * FDAAA	Tip: Before selecting Suspended, Terminated or Withdrawn, consult the Data Element Definition for Overall Recruitment Status. --Select--
Why Study Stopped:	For suspended, terminated or withdrawn studies, briefly explain why the study was stopped.
Key Trial Dates	
Study Start Date: FDAAA	--Select-- Year:
Primary Completion Date: FDAAA	Final data collection date for primary outcome measure. --Select-- Year: Type: --Select--
Study Completion Date:	Final data collection date for the study. --Select-- Year: Type: --Select--

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Title Oversight Sponsor Summary Status **Design** Interventions Conditions Eligibility Locations Citations Links

Title: Sample Clinical Trial Org: NLM ID: 654321

NOTE: These attributes apply to an "Interventional" study. If desired, change the study type to "Observational".

Primary Purpose: (FDAAA)	--Select--
Study Phase: * (FDAAA)	--Select--
Intervention Model: (FDAAA)	Formerly referred to as Study Design or Assignment. --Select--
Number of Arms: (FDAAA)	
Masking: (FDAAA)	--Select-- Masked Roles: ☐ Subject ☐ Caregiver ☐ Investigator ☐ Outcomes Assessor
Allocation: (FDAAA)	--Select--
Study Endpoint Classification:	--Select--
Enrollment: (FDAAA)	Number of Subjects: Type: --Select--

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Title: Sample Clinical Trial Org: NLM ID: 654321

Primary Outcome Measure

Tip: Refer to the Protocol Review Criteria to avoid problems with specification of Outcome Measures.

Title: *	Enter only one distinct outcome measure.
Time Frame: (FDAAA)	
Description:	
Safety Issue? (FDAAA)	Does this outcome measure assess a safety issue? --Select--

Continue Quit

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(FDAAA) May be required to comply with US Public Law 110-85, Section 801


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Title Oversight Sponsor Summary Status Design Interventions Conditions Eligibility Locations Citations Links
Title: Sample Clinical Trial
Org: NLM
ID: 654321
Secondary Outcome Measure
Tip: Refer to the Protocol Review Criteria to avoid problems with specification of Outcome Measures.
Title: *
Enter only one distinct outcome measure.
Time Frame: (FDAAA)
Description:
Safety Issue? (FDAAA)
Does this outcome measure assess a safety issue?
--Select--


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Title Oversight Sponsor Summary Status Design Interventions Conditions Eligibility Locations Citations Links
Title: Sample Clinical Trial
Org: NLM
ID: 654321
Intervention Type: * FDAAA
--Select--
Intervention Name: * FDAAA
Enter the specific name of the intervention.
For a drug, use the generic equivalent name if it has been established.
Intervention Description: (FDAAA)
Key details, e.g., for drugs include dosage form, dosage, frequency and duration.
Other Names:
(One per line)
Include brand names, serial numbers and code names, if applicable.
Other names are used to improve search results on the ClinicalTrials.gov web site.
Continue
Quit
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Title Oversight Sponsor Summary Status Design Interventions **Conditions** Eligibility Locations Citations Links

Title: Sample Clinical Trial Org: NLM ID: 654321

Conditions are checked against terminology sources such as the National Library of Medicine's Medical Subject Headings (MeSH). Search MeSH for a specific condition term.

Conditions or Focus of Study: * FDAAA (Enter 1 to 5 items)	**Enter only conditions** (no numbers, dashes, bullets, etc.), **one per line.** If there are no conditions under study, enter focus of study instead.
Keywords:	Enter only Keywords (no numbers, dashes, bullets, etc.), one per line.

Continue Quit

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Title Oversight Sponsor Summary Status Design Interventions Conditions **Eligibility** Locations Citations Links

Title: Sample Clinical Trial Org: NLM ID: 654321

Eligibility Criteria: * FDAAA	For best results use the preferred format. (Formatting tips) (Special characters) Inclusion Criteria: - Exclusion Criteria: -
Gender: * FDAAA	--Select--
Age Limits: * FDAAA	Minimum: --Select-- Maximum: --Select--
Accepts Healthy Volunteers? FDAAA	--Select--

Continue Quit

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(FDAAA) May be required to comply with US Public Law 110-85, Section 801

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Title Oversight Sponsor Summary Status Design Interventions Conditions Eligibility **Locations** Citations Links

Title: Sample Clinical Trial Org: NLM ID: 654321

Facility: * (FDAAA)
(Special characters)

Name:
City:
State/Province: Postal Code:
Country:

Recruitment Status: * FDAAA

Location recruitment status is required when Overall Status is "Recruiting".
If Overall Status is anything other than Recruiting, location status is not displayed on ClinicalTrials.gov.

--Select--

Facility Contact: * (FDAAA)

Facility contact is required for locations that are recruiting, but may be ommitted if a Central Contact is provided for the trial. At a minimum, last name and either phone or email are required.
If Overall Status is anything other than Recruiting, facility contact information is not displayed on ClinicalTrials.gov.

First: MI: Last: Degree:
Phone: Ext: Email:

Facility Contact Backup:

First: MI: Last: Degree:
Phone: Ext: Email:

Continue Cancel

* Required

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Title Oversight Sponsor Summary Status Design Interventions Conditions Eligibility **Locations** Citations Links

Title: Sample Clinical Trial Org: NLM ID: 654321

Central Contact is the person with overall recruitment responsibility for this study.
If contact information is provided for all recruiting locations, Central Contact may be left blank.

Central Contact: * (FDAAA)

First: MI: Last: Degree:
Phone: Ext: Email:

Central Contact Backup:

First: MI: Last: Degree:
Phone: Ext: Email:

Continue Quit

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(FDAAA) May be required to comply with US Public Law 110-85, Section 801

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Title Oversight Sponsor Summary Status Design Interventions Conditions Eligibility **Locations** Citations Links
Title: Sample Clinical Trial Org: NLM ID: 654321

Study Official's Name:	First: MI: Last: Degree:
Official's Role:	--Select--
Organizational Affiliation:	

OK Cancel

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

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Title Oversight Sponsor Summary Status Design Interventions Conditions Eligibility Locations **Citations** Links
Title: Sample Clinical Trial Org: NLM ID: 654321

Provide the unique PubMed Identifier (PMID) for the citation.

Search for a citation in MEDLINE, using the PubMed browser.

MEDLINE Identifier:	Enter PubMed Identifier (PMID)
Results Reference?	Does the publication report on results of this study? --Select--

If the publication was not found in MEDLINE, enter the citation text.

OK Cancel

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Send message to PRS

Title Oversight Sponsor Summary Status Design Interventions Conditions Eligibility Locations **Citations** Links
Title: Sample Clinical Trial Org: NLM ID: 654321

You may provide the PMID instead of entering the citation.

Citation:	**Example:** Kelly DP, Strauss AW. Inherited cardiomyopathies. New England Journal of Medicine 330(13): 913-919, 1994.
Results Reference?	Does the publication report on results of this study? --Select--

Search MEDLINE Cancel