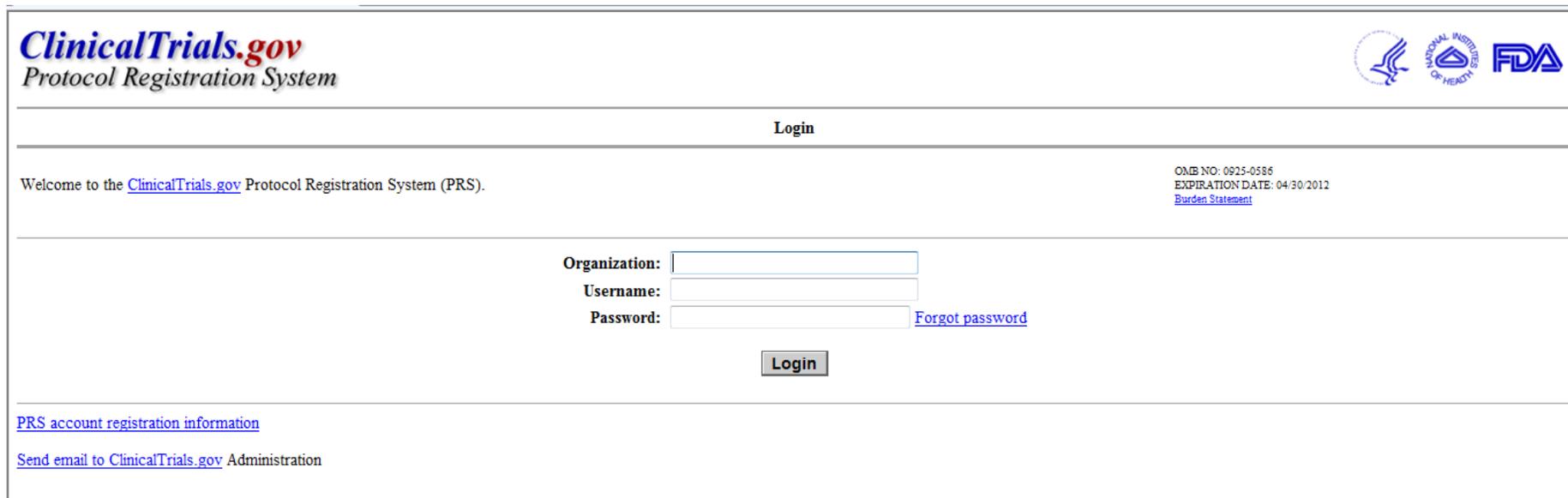


OVERVIEW

The ClinicalTrials.gov Protocol Registration System (PRS) is a web-based tool developed for submitting clinical trials information to ClinicalTrials.gov. This document provides step-by-step instructions for entering, modifying, and releasing protocol records using the PRS. Records submitted through the PRS (<http://register.clinicaltrials.gov>) are available to the public at ClinicalTrials.gov (<http://clinicaltrials.gov>). A guided tour of the PRS and account application information are available at <http://prsinfo.clinicaltrials.gov/>

The screen shots provided below for your review and assistance are step by step guidance to enter a protocol record.



ClinicalTrials.gov
Protocol Registration System

[PRs account registration information](#)
[Send email to ClinicalTrials.gov Administration](#)

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

Color Key Code used on subsequent pages:

-  **Green = Text explanation**
-  **Orange = Highlighted information on form**
-  **RED = Please take note**



Create New Protocol Record

This "send message" shows on all screens, however it's better to consult your Organizational contact prior to sending emails to this external group.

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.

Sponsor provided protocol number. This is not the IRB number. If you do not have one, contact your administrator.

Unique Protocol ID: *

Brief Title: *

Enter the Study "Short Title"; the full title is entered later. The Brief Title put here is to be in lay language and include the condition and intervention evaluated in the study. 300 character limit.

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

Look for the asterisks as you go through the various screens.

Choose Continue when ready to advance to each next screen. The site will allow you to go forward with incomplete entries as long as all applicable required fields are completed. At the end the system will stop you from filing and will give you an error report that includes anything missing. You will see notes or symbols where there is missing information.

Form section headers are useful for navigation.
The section where you are is in **Blue** font.

[Send message to PRS](#)



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

Title: Short Title of Study

ID: _____

Unique Protocol ID: * FDAAA

Enter sponsoring organization's unique identifier.

Brief Title: * FDAAA
(Special characters)

Use lay language.

Example: Safety Study of Recombinant Vaccinia Virus Vaccine to Treat Prostate Cancer

Short Title of Study

These should be prepopulated.

Acronym:

If there is an acronym or abbreviation used to identify this study, enter it here.

Limit: 14 characters. If you add an acronym, it will be appended to the brief title in parentheses.

Official Title:

Example: Phase 1 Study of Recombinant Vaccinia Virus That Expresses Prostate Specific Antigen in Metastatic Adenocarcinoma of the Prostate

Full title here. Limit 600 characters.

Study Type: * FDAAA

- [Interventional](#)
 [Observational](#)
 [Expanded Access](#) [About expanded access records](#)

Choose the button that applies to your study. For help click on the Study Types link to the left (in the blue box) or on any of the choices. See note below on this page concerning Expanded Access.

FDA Regulated Intervention? (FDAAA)

Indicate whether this trial includes an intervention subject to US Food and Drug Administration regulations

Choose Yes or No from drop-down list.

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).

Choose Yes or No from drop-down list.

[Continue](#)

[Quit](#)

* 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

Study Type Expanded Access includes all types of non-protocol access to experimental treatments: protocol exception, single-patient IND, treatment IND, compassionate use, emergency use, continued access and parallel track.

This is a smart form - the choices you made on previous screens affect future screens.

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

Title: Short Title of Study

ID: _____

Controlled clinical investigations other than Phase 1 of an FDA regulated drug or biologic, or controlled trial of FDA regulated device with health outcomes other than small feasibility studies and pediatric post-market surveillance.

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--

If you answered Yes above, does this study include a device not previously approved or cleared by US FDA for any use? "Yes" here will delay full posting of the study and the registrant will have to change this selection to "No" to release the record for full publication.

IND/IDE Grantor: * (FDAAA)

--Select--

CDER,
CBER or
CDRH

IND/IDE Number: * (FDAAA)

IND/IDE Number is assigned by FDA. Serial Number is of the submission in which the protocol for this study was added to the IND or IDE.

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](#)

If you answer "Yes", an Expanded Access Record should be created for it.

Expanded Access Record: (FDAAA)

If applicable, enter the ClinicalTrials.gov identifier (NCT number) for the associated Expanded Access record.

Continue **Quit**

* 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

FDA screen comes up if you say Yes.

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.

If you have multiple IRBs, enter the information for the IRB of Record.

Board Approval: *

If review board approval has been granted, enter the approval number below. If the board does not assign numbers, enter date in mm/dd/yyyy format. Please send a signed board approval letter to ClinicalTrials.gov ([address and instructions](#)).

(or date) is required only if Status is Submitted, approved

Board Name: *

Board Affiliation: *

Board Contact: *
(Not made public)

Status: Approval Number:

Request not yet submitted
 Submitted, pending
 Submitted, approved
 Submitted, exempt
 Submitted, denied
 Submission not required

IRB Approval is required for interventional studies. If Overall Recruitment status is Not Yet Recruiting at the time of registration, here the acceptable choices are Submitted, Pending or Request Not Yet Submitted. **FOLLOW UP**

NOTE 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?

Choose "Yes" or "no" from the drop down.

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
United States: Food and Drug Administration

If the study has a Medical Monitor but no DMC, the answer is No.

Choose Continue when ready to advance to each next screen. The site will allow you to go forward with incomplete entries as long as all applicable required fields are completed. At the end the system will stop you from filing and will give you an error report that includes anything missing. You will see notes or symbols where there is missing information.



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...](#)

Three choices: Sponsor, Sponsor-Investigator or Principal Investigator. If not the Sponsor, additional information will be asked for.

Sponsor: * ^{FDAAA}

Include all additional funding sources.

Enter only the organization names, one per line (no numbers, dashes, bullets, etc.).

Name of primary organization that oversees implementation of the study and is responsible for data analysis. For applicable trials, Sponsor is defined in 21 CFR 50.3.
Limit: 160 characters.

Collaborators:

(One per line)

[Continue](#)

[Quit](#)

* 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

Up to 10 names if applicable to the study. The person who fills in this field is responsible for confirming any Collaborator before listing them here.
Limit 160 characters per name.

Brief Summary: * FDAAA

[\(Formatting tips\)](#)

Use lay language. Include a statement of the study hypothesis.

Can cut and paste into this field from a study document. Suggest in from the Informed Consent Form as must use lay language.

5000 character limit.

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.

This field is NOT asterisked in red, so is optional. May be left blank.

Extended description of the protocol including more technical information as compared to the Brief Summary. Do not include the entire protocol or duplicate information recorded in other data elements of the submission form (such as eligibility criteria or outcome measures). Limit 32,000 characters.

[Continue](#)

[Quit](#)

* 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

Update this date when reviewing the record for accuracy and completeness, even when no other changes (besides this date) are made.

[Send message to PRS](#)



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

Title: Short Title of Study ID: _____

Record Verification Date: * FDAAA
January Year: 2012

Overall Recruitment Status: * FDAAA
Tip: Before selecting Suspended, Terminated or Withdrawn, consult the Data Element Definition for [Overall Recruitment Status](#).
Not yet recruiting

Choose from the 8 choices on pick-list.

Why Study Stopped:
For suspended, terminated or withdrawn studies, briefly explain why the study was stopped.
Limit 160 characters

Key Trial Dates

Study Start Date: FDAAA
April Year: 2012
Date when first participant is enrolled. **DEFINE**

Primary Completion Date: FDAAA
Final data collection date for primary outcome measure.
April Year: 2015 Type: --Select--

Date the final Subject was examined or received an intervention for the purposes of final collection of data for the **primary outcome**. Choose from: Anticipated and Actual.

Study Completion Date:
Final data collection date for the study.
--Select-- Year: Type: --Select--

[Continue](#) [Quit](#)

* Required by ClinicalTrials.gov
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Final date on which study data was (or is expected to be) collected. Choose from: Anticipated and Actual.

Title FDA Oversight Sponsor Summary Status **Design** Interventions Conditions Eligibility Locations Citations Links
Title: Short Title of Study ID: _____

Following this link will provide screens that are specific for Observational.

NOTE: These attributes apply to an "Interventional" study. If desired, [change the study type to "Observational"](#).

Choose from the 8 choices on pick-list. If you choose Other, provide a description in the Detailed Description data field.

Primary Purpose: ^{FDAAA} --Select--

Study Phase: * ^{FDAAA} --Select--

Intervention Model: ^{FDAAA} Formerly referred to as Study Design or Assignment.
--Select--

Choices are N/A (for trials without Phases), 0, 1, 1/2, 2, 2/3, 3, and 4.

Number of Arms: ^{FDAAA}

Number of interventional groups.
Enter 1 for single-arm study.

Masking: ^{FDAAA} --Select-- Masked Roles: Subject
 Caregiver
 Investigator
 Outcomes Assessor

At least one of the following is required: Intervention Model, Masking or Allocation. All may be required for some studies.

Allocation: ^{FDAAA} --Select--

Choices are Open, Single-Blind, Double Blind. If there is a blind, also check among Masked Roles boxes, which roles will be blinded.

Study Endpoint Classification: --Select--

Enrollment: ^{FDAAA} Number of Subjects: Type: --Select--

Continue **Quit**

Choose from the 9 choices on pick-list. N/A is an allowed choice. "Other" is not.

* 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

Target or Actual Number of Subjects, you specify by selecting Anticipated or Actual in the accompanying Type menu. Upon study completion, you must update this to reflect actual and final total enrollment.

Title: Short Title of Study

ID: _____
Choices are Cohort, Case-Control, Case-only, Case-crossover, Ecologic or community study, Family-based or Other. .

NOTE: These attributes apply to an "Observational" study. If desired, [change the study type to "Interventional"](#).

Observational Study Model: *

Formerly referred to as Study Design.

--Select--

Temporal relationship of observation period to time of subject enrollment. Choices are Prospective, Retrospective, Cross-sectional, and Other.

Time Perspective: *

--Select--

Biospecimen Retention:

--Select--

May be left blank if no biospecimens are to be retained

Pick list choices are: None Retained, Samples With DNA; Samples Without DNA. If the samples have the potential, then "With DNA" is required.

Biospecimen Description:

Specify all types of bio specimens if any are to be retained. Limit: 1000 characters.

Enrollment: ^{FDAAA}

Number of Subjects: Type: --Select--

Target or Actual Number of Subjects, you specify by selecting Anticipated or Actual in the accompanying Type menu. Upon study completion, update is required.

Number of Groups/Cohorts: *

Continue **Quit**

* 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

Enter 1 for a single-group study. Many observational studies have 1 group; case-control studies often have 2.

This screen comes next for either study type: Interventional or Observational.

[Send message to PRS](#)



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

Title: Short Title of Study

ID: _____

Provide the primary and secondary outcome measures associated with the protocol, along with the associated time frames.

Continue

Quit

[Add a primary outcome](#) measure to this study.

[Add a secondary outcome](#) measure to this study.

Tip: Refer to the [Protocol Review Criteria](#) to avoid problems with specification of Outcome Measures.

This is a link to the Tip they are trying to offer you.

Proceed through steps per each outcome measure

Primary Outcome Measure

Primary Outcomes: There is no primary outcome measure specified for this study.

Once you make additions, the two Outcomes highlighted areas will become populated. The system will enter these items in the results sections when you begin to access the results section of the registration.

Specific key measurement(s) or observation(s) used to measure the effect of study experimental variables OR for Observational studies, to describe patterns of diseases, traits or associations with exposures, risk factors or treatment.

Secondary Outcome Measures

Secondary Outcomes: There are no secondary outcome measures specified for this study.

Other key measures that will be used to evaluate the intervention(s) OR, for observational studies, that are a focus of the study.

- * 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

Once all Outcomes have been entered, then you will select continue to move on.

The next two pages demonstrate screens you will see once Outcomes Measures has been chosen.

Title: Short Title of Study

This is a link to additional information that the site is offering you.

ID: _____

Primary Outcome Measure

Tip: Refer to the [Protocol Review Criteria](#) to avoid problems with specification of Outcome Measures.

Title is a concise name for the specific measure. Limit, 254 characters. First one listed for observational studies should be the one that receives the most emphasis in assessment.

Title: * Enter only one distinct outcome measure.

Time Frame: (FDAAA) Time Points where measurement will be made

Or, over what span of time, see example below. (orange box) Limit 254 characters.

Description: What the measurement is.

Note this is an optional field, available to hold additional information about the outcome measure, if needed for clarification. Limit: 600 characters.

Safety Issue? (FDAAA) Does this outcome measure assess a safety issue?
--Select--
--Select--
Yes
No

Continue

Quit

* 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

No asterisk to signal that this is a required field, but strongly suggest that either Yes or No be selected.

Two examples offered by clinicaltrials.gov:

Title: All-cause mortality
Time Frame: one year
Safety Issue: No

Title: Evidence of clinically definite ischemic stroke (focal neurological deficits persisting for more than 234 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

Interventional studies have Arms:

Arm Label: * (FDAAA)	Arm Label should be descriptive, yet concise, especially for later use in results posting. Examples: Metformin, Lifestyle counseling, Sugar pill <input type="text"/>
Arm Type: * (FDAAA)	--Select-- <input type="text"/>
Arm Description: (FDAAA)	<input type="text"/>

Short name used to identify the arm. Limit: 62 characters.

5 item Pick list: Experimental, Active Comparator, Placebo Comparator, Sham Comparator, No intervention, Other.

* 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

May not be needed, if the Arm Label says all that's needed. If you use it, Limit is 999 characters.

For each Arm, specify the Intervention, see next page.

9 item Pick List, select one per intervention:

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.

Generic name for drugs, descriptive name for others.
Limit: 1000 characters.

Intervention Description: (FDAAA)

Key details, e.g., for drugs include dosage form, dosage, frequency and duration.

Limit: 1000 characters.

There are as many boxes here, with the labels you entered, as you told the system the number of arms your protocol has. You'll be filling in a screen for each study Intervention, indicating which Arms receive it.

Arms: * (FDAAA)

:
 :
 :

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.

Other names used to identify the intervention, past or present.
These names will be used to improve search results. Limit: 160 characters per name.

Continue

Quit

* 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

For a single group study, both of these items are optional.

Group/Cohort Label: *

Group Label should be descriptive, yet concise, especially for later use in results posting. Examples: Metformin, Lifestyle counseling, Sugar pill

Note relationship to later posting of results. Limit: 62 characters.

Group/Cohort Description:

Explanation of the nature of the study group, e.g. those with a condition or those without a condition; those with an exposure or those without an exposure. Note that the overall population is described under Eligibility; here put the specifics that cause eligible participants to be in the indicated study group. Limit: 1000 characters.

[Continue](#) [Quit](#)

* 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

Group/Cohort Label Notes and examples from clinicaltrials.gov:

If the Number of Groups/Cohorts field on the Study Characteristics page is specified as 2 or greater and no groups have yet been defined, that number of groups is created automatically.

IMPORTANT: A single intervention can be assigned to multiple groups, so that the intervention need not be specified redundantly. If the same intervention applies to multiple groups, but with different dosages or other differences, the group descriptions can be used to indicate those differences.

For all studies and for expanded access-related registrations, specify the associated interventions in the group label and description. Describe the nature of the group or cohort. Note that for observational studies where interventions are specified, intervention information will be displayed with the associated group(s).

Examples:

- Statin dose titration
- Chronic kidney disease, no anemia
- No treatment

Title: Short Title of Study

ID: _____

Be sure to use standardized terms here.

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: *FDA
(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.

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.

Avoid dashes and bullets, or risk being tripped up at final automated data check.

Keywords:

Enter only Keywords (no numbers, dashes, bullets, etc.), one per line.

Words or phrases that best possible describe the protocol. Keywords help users find studies in the database. Use MeSH controlled vocabulary terms where appropriate. Be as specific and precise as possible. Avoid acronyms and abbreviations.

Continue

Quit

* Required by ClinicalTrials.gov

FDA Required to comply with US Public Law 110-85, Section 801

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

Observational studies have Groups/Cohorts

Study Population Description: *

Definition: For observational studies only, a description of the population from which the groups or cohorts will be selected (e.g., primary care clinic, community sample, residents of a certain town). (Limit: 1000 characters)

Sampling Method selection is for Observational studies only. Pick list choices are Probability Sample and Non-Probability Sample.

Sampling Method: *

--Select--

Eligibility Criteria: * FDAAA

For best results use the preferred format. (Formatting tips) (Special characters)

Inclusion Criteria:
-
Exclusion Criteria:
-

Limit 15,000 characters. List criteria with Hyphen, then space, then text in words, phrases or sentences.

Gender: * FDAAA

--Select--

Physical Gender. Choices are Male, Female, Both

Age Limits: * FDAAA

Minimum: --Select-- Maximum: --Select--

Accepts Healthy Volunteers? FDAAA

--Select--

Yes or No

If there is a limit, provide a number and select the corresponding unit. Age unit choices are minutes, hours, days, weeks, months, years. Blank with selection of N/A (No Limit) is allowed for minimum, maximum or both.

Continue **Quit**

* 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

This section begins illustration for completing Contact/Facility Information, next 7 pages.



[Specify the Central Contact](#) * (FDAAA) with overall recruiting responsibility for this study.
[Specify the Study Officials/Investigators](#) with overall scientific responsibility for this study.
[Add a location](#) * (FDAAA) to this Study.
[Copy locations](#) from a master list, extracted from this organization's records.

Locations: * There are no Locations currently listed for this study.

* 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

Study officials, including the principal investigator, are the persons responsible for the overall scientific leadership of the protocol.

OK

[Add](#) a Study Official to this study.

Study Official is the person with overall scientific leadership of the study. Select this and you get the next page.

Study Officials:

There are no Study Officials currently listed for this study.

NOTE: Study Official is required by the WHO and ICMJE.

- * 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

ICJME: International Council of Medical Journal Editors. This item relates to your ability to publish the study results.



Title: Required

ID: Test2

Study Official's Name:

First: MI: Last: Degree:

Official's Role:

--Select--

Organizational Affiliation:

Pick list choices are: Study Chair, Study Director, Principal Investigator.

* 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

Once OK is selected here, the system will return you to the first Locations page. If "Add Location" is chosen the next screen shot will appear.

Title: Short Title of Study

ID: _____

Facility: * (FDAAA)
(Special characters)

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

Full name and street address of the organization where the protocol is being conducted. Name field limit: 254 characters.

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--
- Not yet recruiting
- Recruiting
- Active, not recruiting
- Enrolling by invitation
- Completed
- Suspended
- Terminated (Halted Prematurely)
- Withdrawn (No Participants Enrolled)

These are the picklist choices for Recruitment Status.

Facility Contact information on this page is required only for locations with status of Recruiting or Not Yet Recruiting.

Facility Contact: * (FDAAA)

that are recruiting, but may be
Recruiting, facility contact inform

Last: Degree:
Phone: Ext: Email:

Facility Contact Backup:

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

Facility Contact back up person.

* Required

Tip from Clinicaltrials.gov:

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 shown on clinicaltrials.gov only when Overall Status is "Recruiting".

Repeat of previous page, to illustrate boxes covered by the pick list.

Facility: * (FDA) (Special characters)

Name:

City:

State/Province: Postal Code:

Country:

Multiple locations may be specified by invoking this page more than once.

Recruitment Status: * (FDA)

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: * (FDA)

Facility contact is required for locations that are recruiting, but may be omitted 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:

Office phone **OR** email is required. In the US and Canada, phone number should include area code and be in the format 123-555-5555. Otherwise, include the country code. Extension can be left blank if not needed.

Facility Contact Backup:

First: MI: Last: Degree:

Phone: Ext: Email:

A Backup for the Facility Contact is not required.

* Required

After you fill in Location you then have the opportunity to Add one or multiple Investigator(s) at this location. (See next page).

Location:

The Facility name and address that you added is brought into this area for you.

[Add an Investigator to this Location.](#)

Choose this Add button and the following screen comes up.

[Investigators:](#)

There are no Investigators currently listed for this location.



Title: Required

ID: Test2

Investigator Name: First: MI: Last: Degrees:

Role:

This OK brings up the screen illustrated on the next page.

2 Pick list choices: Site PI or Site Sub-I.

Multiple Investigators may be specified by invoking this page more than once.

Continue **Quit**

[Specify the Central Contact](#) * (FDAAA) with overall recruiting responsibility for this study.
[Specify the Study Officials/Investigators](#) with overall scientific responsibility for this study.
[Add a location](#) * (FDAAA) to this Study.
[Copy locations](#) from a master list, extracted from this organization's records.

You can attach additional Investigators or additional Locations from here. Choose Continue button to the left if you are finished adding both Investigators and Locations for the study.

[Edit](#)

[Delete](#)

[Edit Investigators](#)

Facility:	Information you previously added populates here for you to review. The system provides Edit and Delete links for your convenience just to the left of these entries.
Recruitment Status: Contact: Contact Backup:	
Investigators:	Francisco K Fermata , MD Role: Site Sub-Investigator

* 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

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

* 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

Phone if given for Central Contact (and Central Contact Backup if one is entered), must be a toll-free number. Phone format in the US and Canada to be used is 800-555-5555. Otherwise, provide the country code. Extension may be left blank.

Provide Citations of publications related to the protocol, background or results.

Continue **Quit** [Add](#) a Citation to this study, if applicable.

Choose this Add link and the screen on the next page comes up.

Citations: There are no Citations currently listed for this study.

Once a citation is added, it will show here when you are brought back to this screen to be able to add more.

As always select Continue to leave this screen (when you have added as many citations as you wish to). Adding Citations is encouraged.

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?

Yes or No.

If the publication was not found in MEDLINE, [enter the citation text](#).

OK Cancel

This OK will take you back to the screen on the previous page, where you confirm that you are done adding citations by choosing Continue.

Use this screen to provide pointers to web pages directly relevant to the protocol. Provide up to 5 suggested links.

Continue

Quit

[Add](#) a Link to a related web page to this study, if applicable.

If you choose this Add link and the screen on the next page comes

Links to educational, research, government, and other non-profit Web pages are acceptable. All submitted links are subject to review by ClinicalTrials.gov.

Links:

There are no Links to related web pages currently listed for this study.

Once one is added, it will show here and you are brought back to this screen to be able to add more, up to 5 allowed.

Cautionary Tip from Clinicaltrials.gov:

Do not include sites whose primary goal is to advertise or sell commercial products or services.

Title: Required

ID: Test2

URL:

http://

Complete URL, Limit 254 characters, includes the http://.

Description:

Enter desired link text. Default: Related Info

OK

Cancel

Limit: 254 characters.

Typographical errors may be easily picked up at this review stage. There is a spelling tool on the View Protocol Record page.

Protocol Record Completed

Title: Short Title of Study

ID: _____

You have reached the last data entry screen. Proceed to the next screen (Edit Protocol) to review the entire record.

Note that the data that you have entered are automatically validated by the system. Messages describing problems of varying severity (Errors, Alerts, or Notes) are included on the Edit Protocol screen, beneath the relevant fields. Review each message and take the appropriate action.

Once the record is ready for review by your administrator, click on the "Complete" link near the top of the Edit Protocol Record screen to mark the record as completed. Your administrator must then "Approve" and "Release" the record, in order for the record to be submitted for final Quality Assurance review and publication on the ClinicalTrials.gov web site.

OK

The OK button invokes an automated check of the registration form fields. The system will return errors to be corrected and omissions where it recognizes that additions are needed. The programming indicates what is needed based on the entries you have made.

On your final pass, when the automated checks indicate all is well, selecting this OK means your Administrator will be notified and will be required to do a QC check prior to releasing your registration for posting into the system. Your Administrator is ClinicalTrials.gov's UC contact person of record. **Even after your Administrator has approved and released, the QA review done by clinicaltrials.gov personnel may return additional questions to be resolved before your study actually becomes posted.**

Holding off on enrollment start until after you see your study fully posted on ClinicalTrials.gov assures your ability to publish the study results.