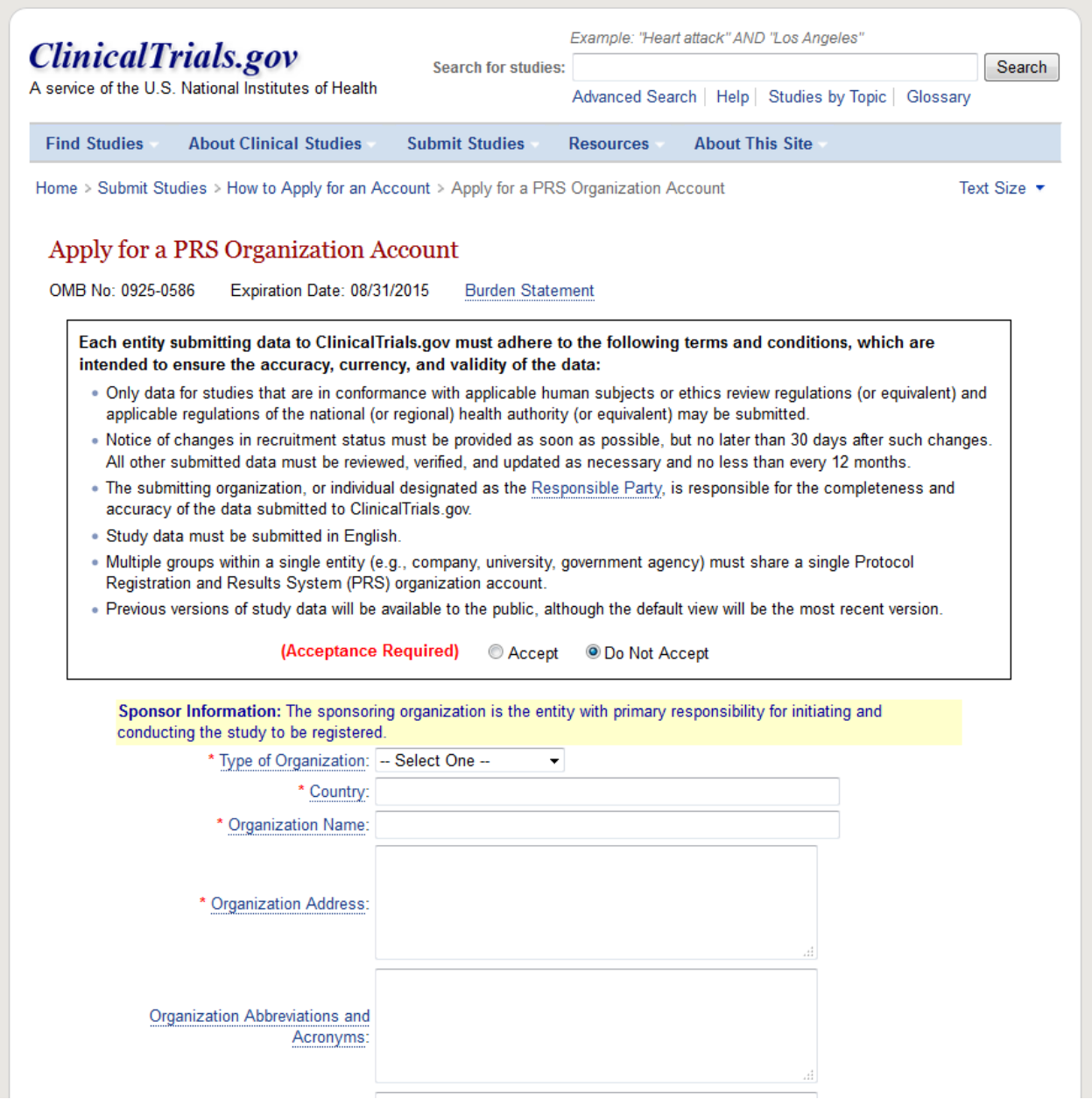
Attachment 3 - ClinicalTrials.gov Registration Data Entry Screen Shots



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

Example: "Heart attack" AND "Los Angeles"
Search for studies: Search
Advanced Search | Help | Studies by Topic | Glossary

Find Studies | About Clinical Studies | Submit Studies | Resources | About This Site

Home > Submit Studies > How to Apply for an Account > Apply for a PRS Organization Account Text Size

Apply for a PRS Organization Account

OMB No: 0925-0586 Expiration Date: 08/31/2015 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:

- Only data for studies 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.
- Notice of changes in recruitment status must be provided as soon as possible, but no later than 30 days after such changes. All other submitted data must be reviewed, verified, and updated as necessary and no less than every 12 months.
- The submitting organization, or individual designated as the Responsible Party, is responsible for the completeness and accuracy of the data submitted to ClinicalTrials.gov.
- Study data must be submitted in English.
- Multiple groups within a single entity (e.g., company, university, government agency) must share a single Protocol Registration and Results System (PRS) organization account.
- Previous versions of study data will be available to the public, although the default view will be the most recent version.

(Acceptance Required) Accept Do Not Accept

Sponsor Information: The sponsoring organization is the entity with primary responsibility for initiating and conducting the study to be registered.

* Type of Organization: -- Select One --
* Country:
* Organization Name:
* Organization Address:
Organization Abbreviations and Acronyms:

Parent Organizations, if any:

* Official Representative:

Please enter a valid phone number, including area code.
* Phone:

* Email:

Organization URL (optional):

Funding Organization:

PRS Administrator Information: The PRS Administrator is the person authorized by the sponsor to update the information in the PRS will serve as the point of contact for ClinicalTrials.gov staff.

* Administrator Name:

Affiliation (if not the sponsor):

Please enter a valid phone number, including area code.
* Administrator Phone:

* Administrator Email:

Regulatory Information: The regulatory authority can 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 PRS may be sent to register@ClinicalTrials.gov.

* Required

Submit Application Reset

This page last reviewed in December 2014

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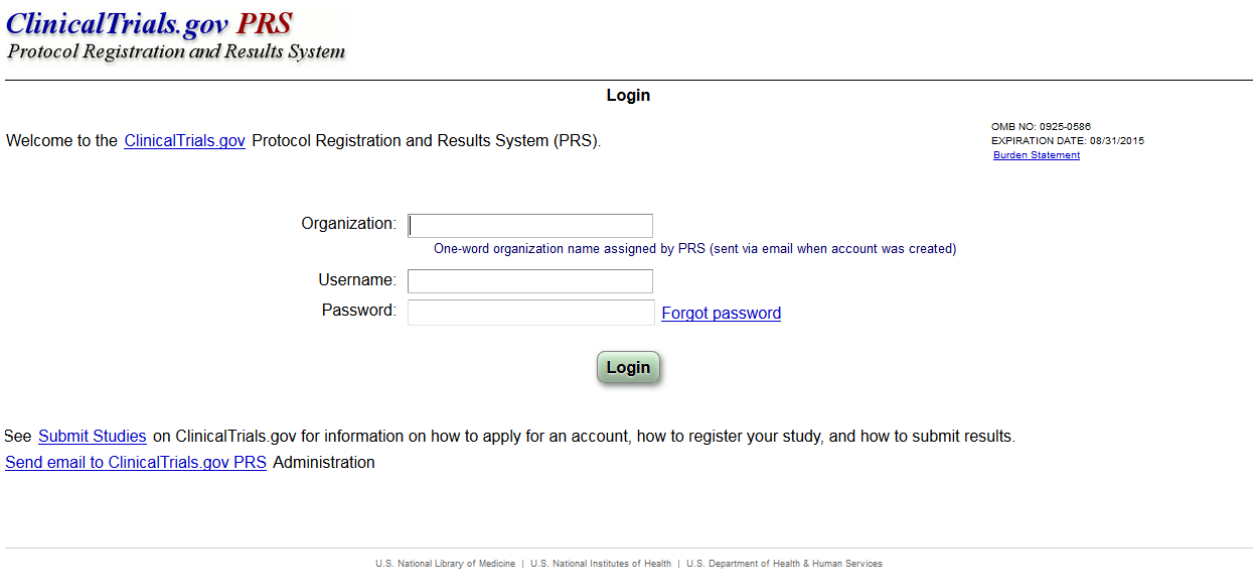
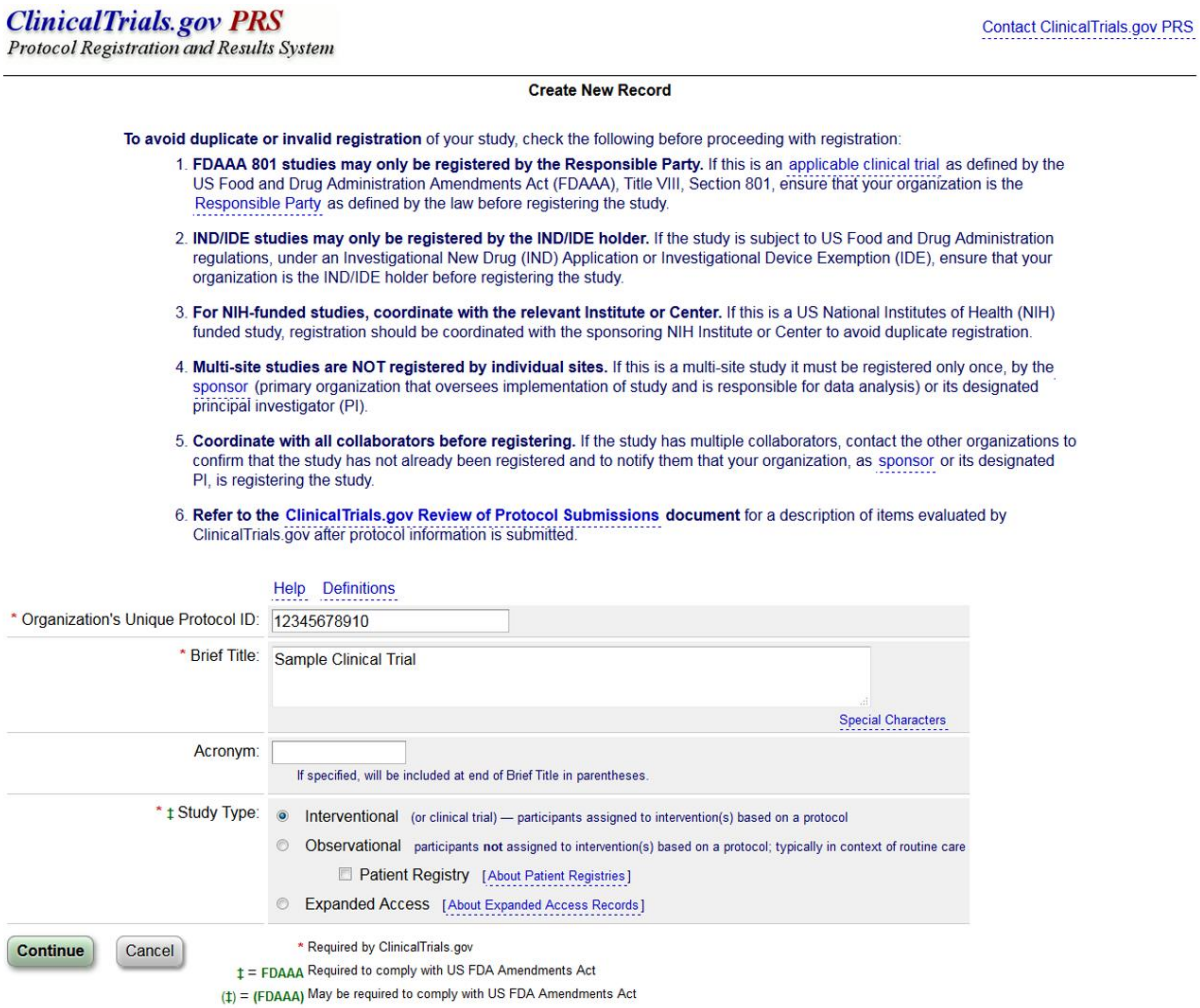


OMB NO: 0925-0586
EXPIRATION DATE: 08/31/2015
Burden Statement

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, 25.0 hours per response for initial results submission, 8.0 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



ClinicalTrials.gov PRS
Protocol Registration and Results System

Contact ClinicalTrials.gov PRS

Create New Record

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

1. **FDAAA 801 studies may only be registered by the Responsible Party.** If this is an applicable clinical trial as defined by the US Food and Drug Administration Amendments Act (FDAAA), 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.

Help Definitions

* Organization's Unique Protocol ID: 12345678910

* Brief Title: Sample Clinical Trial

Special Characters

Acronym:

If specified, will be included at end of Brief Title in parentheses.

* ‡ Study Type:
- Interventional (or clinical trial) — participants assigned to intervention(s) based on a protocol
- Observational participants **not** assigned to intervention(s) based on a protocol; typically in context of routine care
  - Patient Registry [About Patient Registries]
- Expanded Access [About Expanded Access Records]

Continue Cancel

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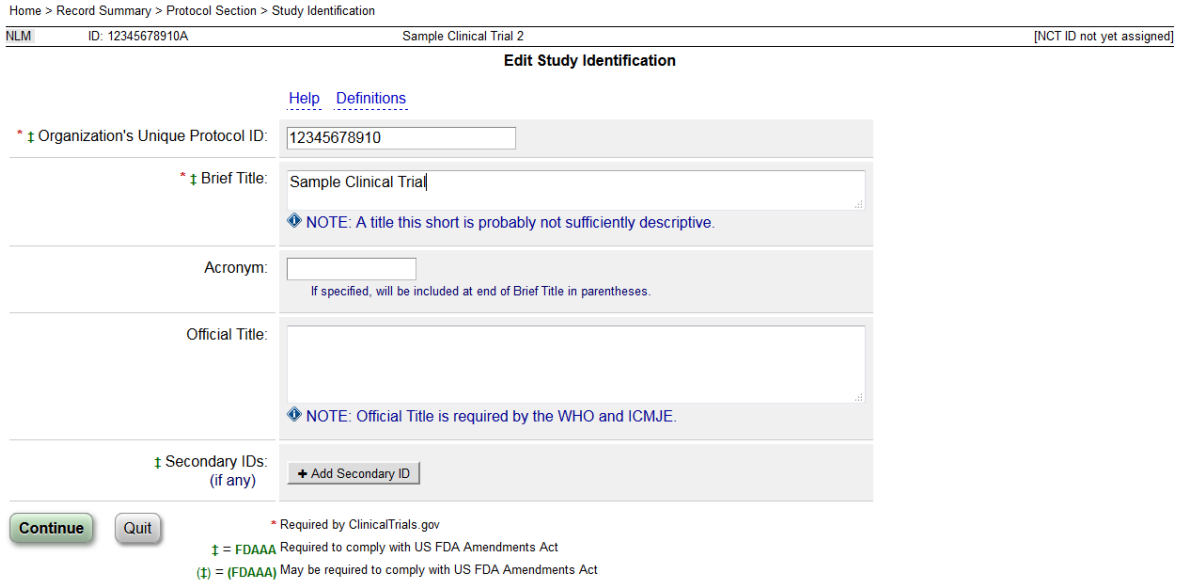
(‡) = (FDAAA) May be required to comply with US FDA Amendments Act



Home > Record Summary > Protocol Section > Study Identification

NLM ID: 12345678910A Sample Clinical Trial 2 [NCT ID not yet assigned]

Edit Study Identification

Help Definitions

* ‡ Organization's Unique Protocol ID: 12345678910

* ‡ Brief Title: Sample Clinical Trial

NOTE: A title this short is probably not sufficiently descriptive.

Acronym:

If specified, will be included at end of Brief Title in parentheses.

Official Title:

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

‡ Secondary IDs: (if any) + Add Secondary ID

Continue Quit

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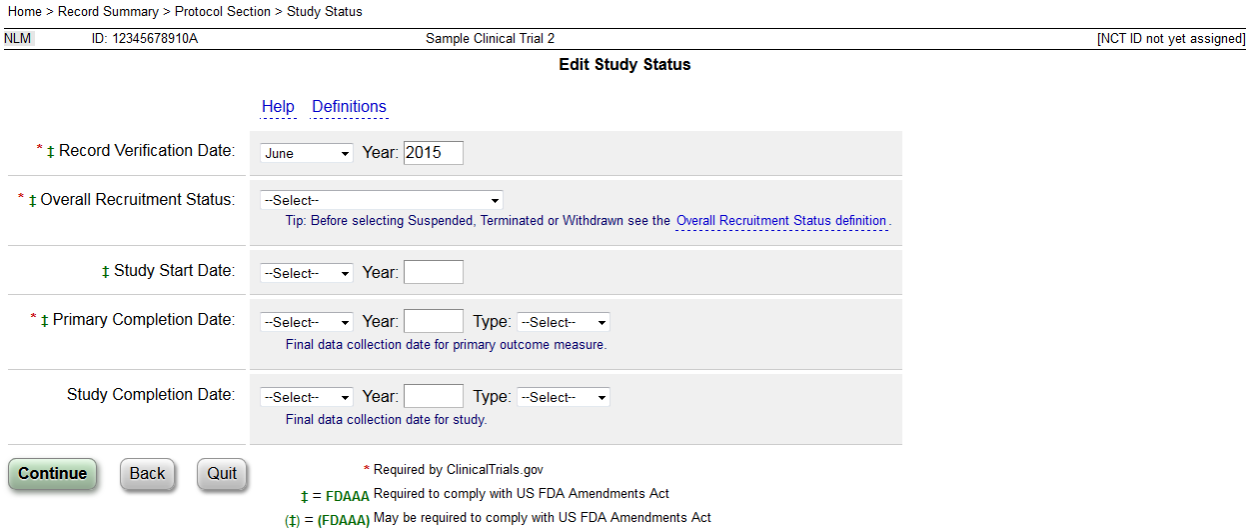

Home > Record Summary > Protocol Section > Study Status

NLM ID: 12345678910A Sample Clinical Trial 2 [NCT ID not yet assigned]

Edit Study Status

Help Definitions

* ‡ Record Verification Date: June Year: 2015

* ‡ Overall Recruitment Status: --Select--

Tip: Before selecting Suspended, Terminated or Withdrawn see the Overall Recruitment Status definition.

‡ Study Start Date: --Select-- Year:

* ‡ Primary Completion Date: --Select-- Year: Type: --Select--

Final data collection date for primary outcome measure.

Study Completion Date: --Select-- Year: Type: --Select--

Final data collection date for study.

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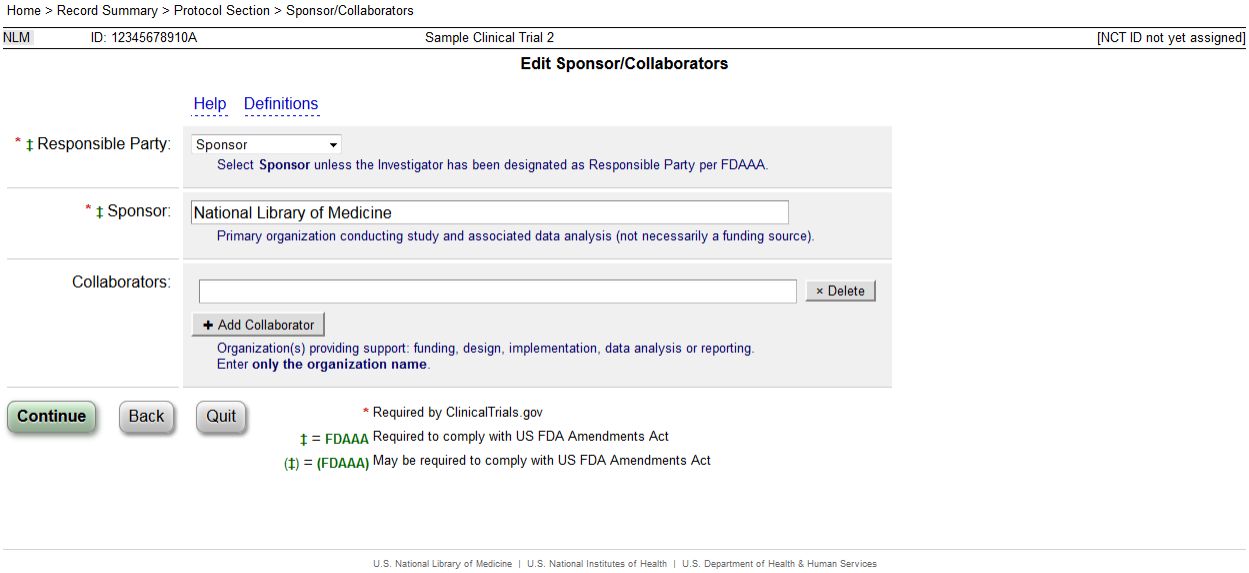

Home > Record Summary > Protocol Section > Sponsor/Collaborators

NLM ID: 12345678910A Sample Clinical Trial 2 [NCT ID not yet assigned]

Edit Sponsor/Collaborators

Help Definitions

* ‡ Responsible Party: Sponsor

Select **Sponsor** unless the Investigator has been designated as Responsible Party per FDAAA.

* ‡ Sponsor: National Library of Medicine

Primary organization conducting study and associated data analysis (not necessarily a funding source).

Collaborators: × Delete

+ Add Collaborator

Organization(s) providing support: funding, design, implementation, data analysis or reporting.
Enter **only the organization name**.

Continue Back Quit

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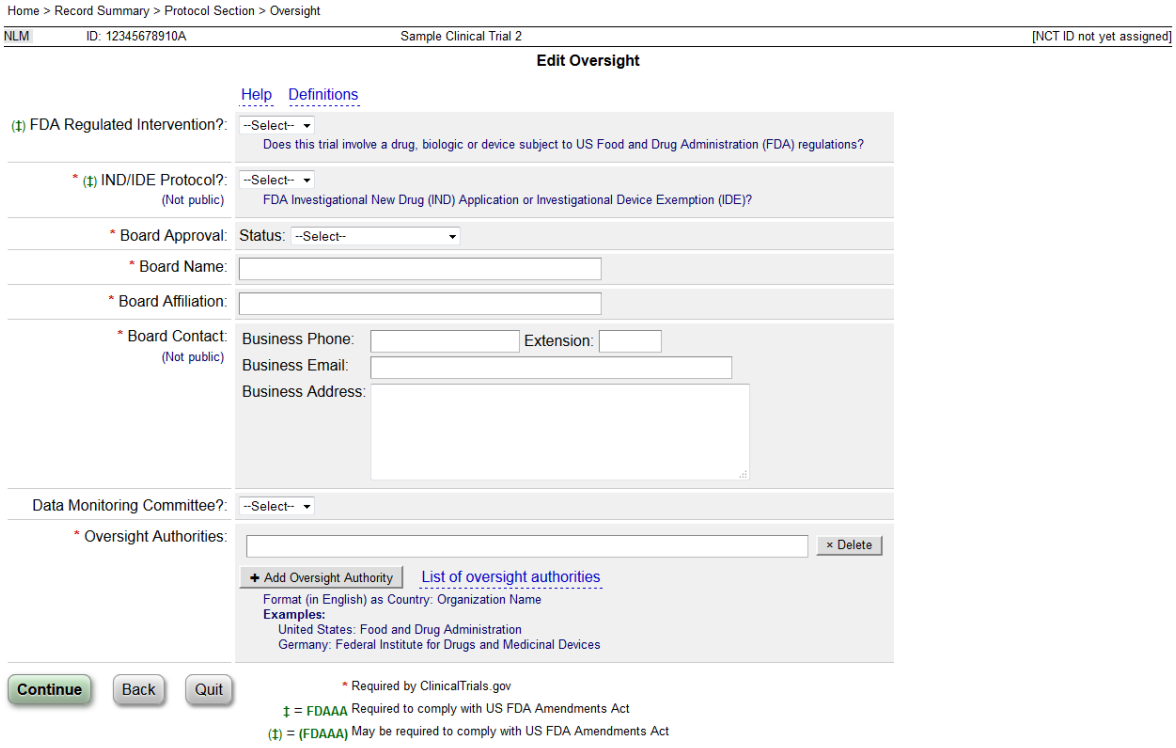

Home > Record Summary > Protocol Section > Oversight

NLM ID: 12345678910A Sample Clinical Trial 2 [NCT ID not yet assigned]

Edit Oversight

Help Definitions

(‡) FDA Regulated Intervention?: --Select--
Does this trial involve a drug, biologic or device subject to US Food and Drug Administration (FDA) regulations?

* (‡) IND/IDE Protocol?: --Select--
(Not public)
FDA Investigational New Drug (IND) Application or Investigational Device Exemption (IDE)?

* Board Approval: Status: --Select--

* Board Name:

* Board Affiliation:

* Board Contact: Business Phone: Extension:
(Not public)
Business Email:
Business Address:

Data Monitoring Committee?: --Select--

* Oversight Authorities: × Delete

+ Add Oversight Authority List of oversight authorities

Format (in English) as Country: Organization Name
Examples:
United States: Food and Drug Administration
Germany: Federal Institute for Drugs and Medicinal Devices

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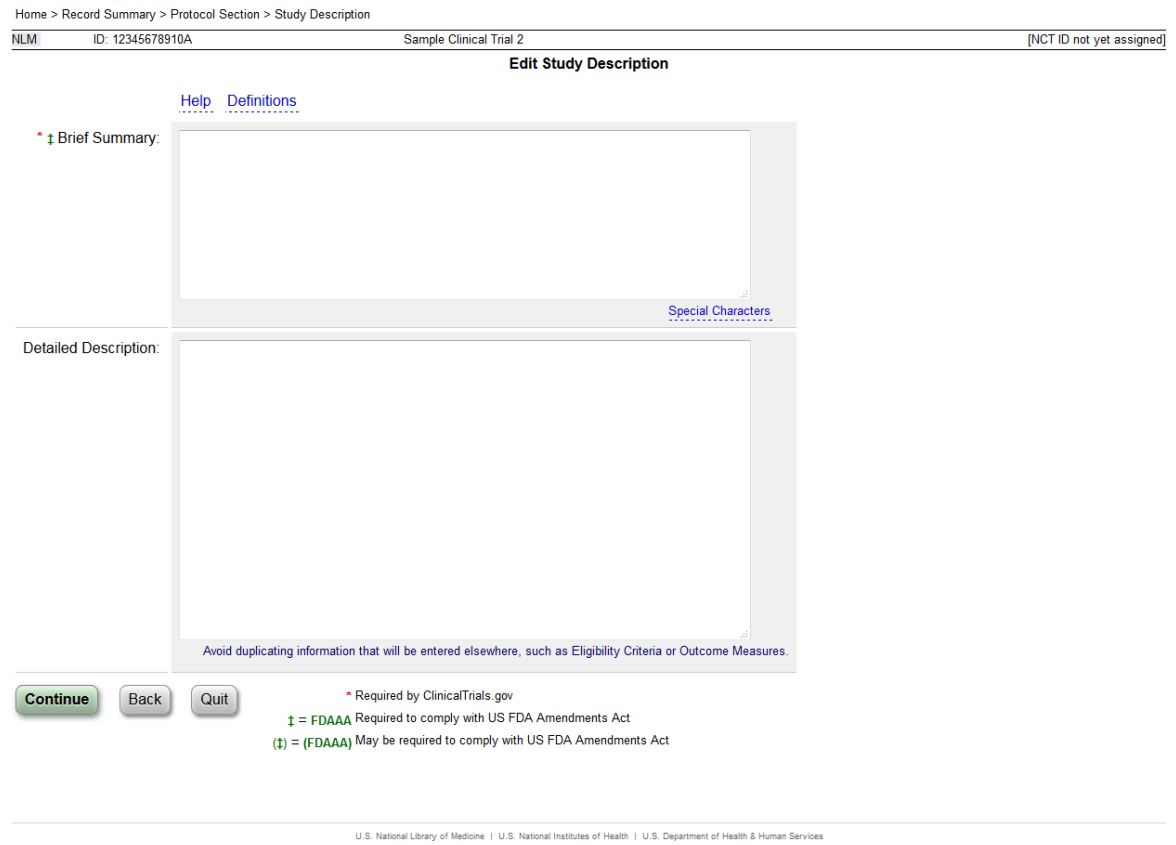

Home > Record Summary > Protocol Section > Study Description

NLM ID: 12345678910A Sample Clinical Trial 2 [NCT ID not yet assigned]

Edit Study Description

Help Definitions

* ‡ Brief Summary:

Special Characters

Detailed Description:

Avoid duplicating information that will be entered elsewhere, such as Eligibility Criteria or Outcome Measures.

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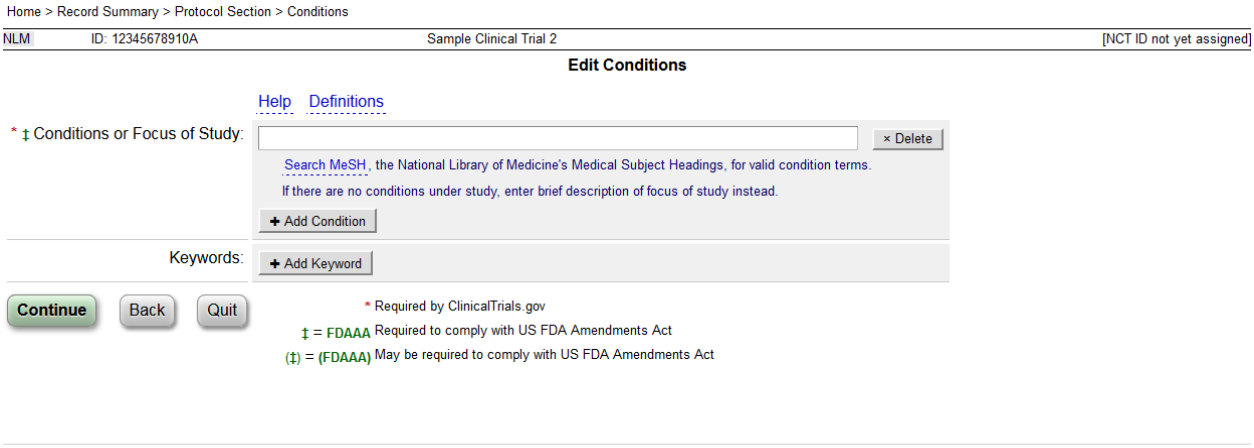

Home > Record Summary > Protocol Section > Conditions

NLM ID: 12345678910A Sample Clinical Trial 2 [NCT ID not yet assigned]

Edit Conditions

Help Definitions

* ‡ Conditions or Focus of Study: × Delete

Search MeSH, the National Library of Medicine's Medical Subject Headings, for valid condition terms.

If there are no conditions under study, enter brief description of focus of study instead.

+ Add Condition

Keywords: + Add Keyword

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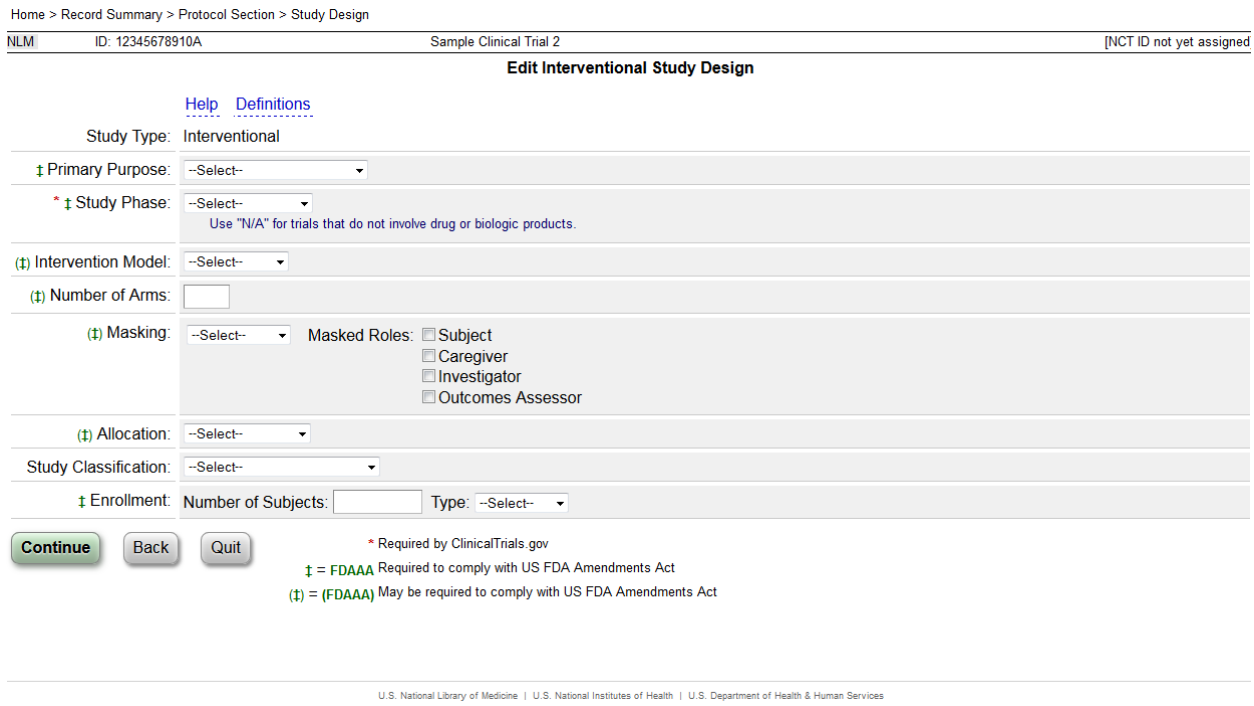

Home > Record Summary > Protocol Section > Study Design

NLM ID: 12345678910A Sample Clinical Trial 2 [NCT ID not yet assigned

Edit Interventional Study Design

Help Definitions

Study Type: Interventional

‡ Primary Purpose: --Select--

* ‡ Study Phase: --Select--

Use "N/A" for trials that do not involve drug or biologic products.

(‡) Intervention Model: --Select--

(‡) Number of Arms:

(‡) Masking: --Select-- Masked Roles: Subject, Caregiver, Investigator, Outcomes Assessor

(‡) Allocation: --Select--

Study Classification: --Select--

‡ Enrollment: Number of Subjects: Type: --Select--

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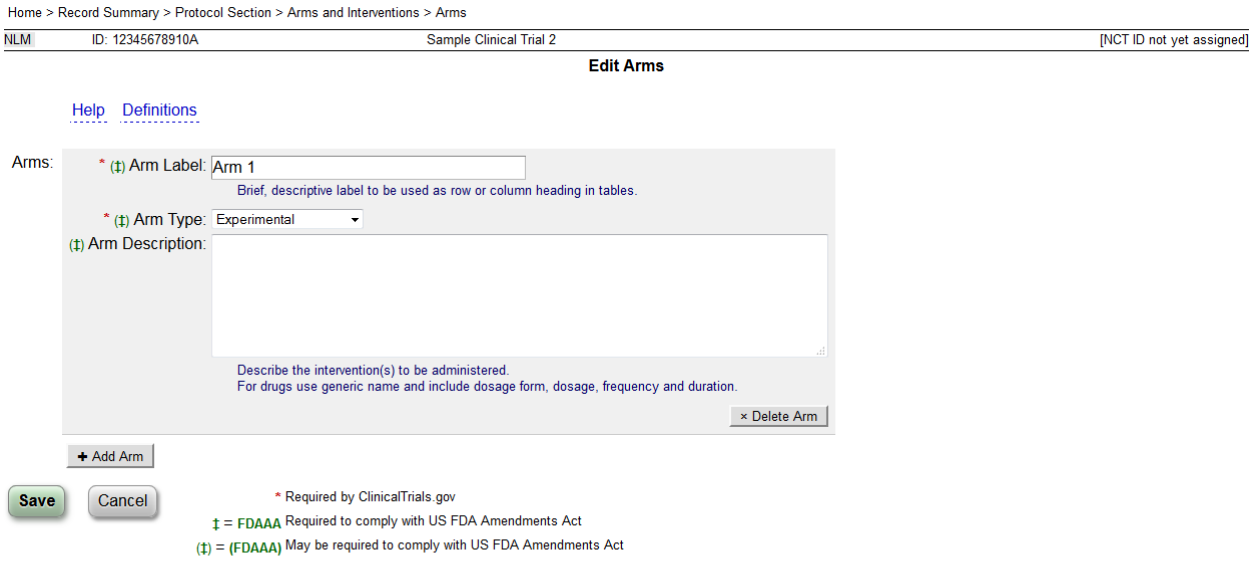
Home > Record Summary > Protocol Section > Arms and Interventions > Arms
NLM ID: 12345678910A Sample Clinical Trial 2 [NCT ID not yet assigned]
Edit Arms
Help Definitions
Arms:
* (‡) Arm Label: Arm 1
Brief, descriptive label to be used as row or column heading in tables.
* (‡) Arm Type: Experimental
(‡) Arm Description:
Describe the intervention(s) to be administered.
For drugs use generic name and include dosage form, dosage, frequency and duration.
× Delete Arm
+ Add Arm
Save Cancel
* Required by ClinicalTrials.gov
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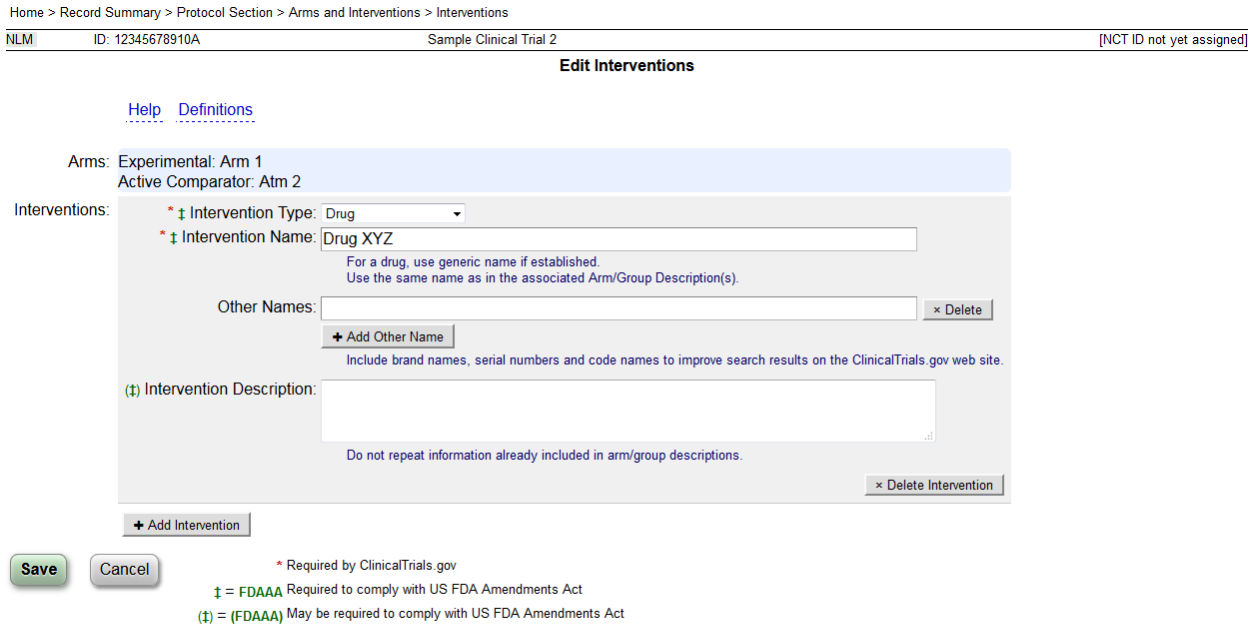
Home > Record Summary > Protocol Section > Arms and Interventions > Interventions
NLM ID: 12345678910A Sample Clinical Trial 2 [NCT ID not yet assigned]
Edit Interventions
Help Definitions
Arms: Experimental: Arm 1
Active Comparator: Atm 2
Interventions:
* ‡ Intervention Type: Drug
* ‡ Intervention Name: Drug XYZ
For a drug, use generic name if established.
Use the same name as in the associated Arm/Group Description(s).
Other Names:
× Delete
+ Add Other Name
Include brand names, serial numbers and code names to improve search results on the ClinicalTrials.gov web site.
(‡) Intervention Description:
Do not repeat information already included in arm/group descriptions.
× Delete Intervention
+ Add Intervention
Save Cancel
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Home > Record Summary > Protocol Section > Arms and Interventions > Cross-Reference

NLM ID: 12345678910A Sample Clinical Trial 2 [NCT ID not yet assigned]

Edit Arm/Intervention Cross-Reference

Help Definitions

* (‡) Cross-Reference:

Arms	Interventions	
	Drug: Drug XYZ	Drug: Drug ABC
Experimental: Arm 1	☐	☐
Active Comparator: Atm 2	☐	☐

Check boxes for Interventions associated with each Arm in the study.

Save Cancel

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Home > Record Summary > Protocol Section > Outcome Measures

NLM ID: 12345678910A Sample Clinical Trial 2 [NCT ID not yet assigned]

Edit Outcome Measures

Help Definitions

* ‡ Primary Outcome Measure:

Outcome 1

* Title:

* Time Frame:

Description:

(‡) Safety Issue? --Select--

× Delete Outcome

+ Add Primary Outcome

‡ Secondary Outcome Measures:

+ Add Secondary Outcome

Other Pre-specified Outcomes:

+ Add Other Outcome

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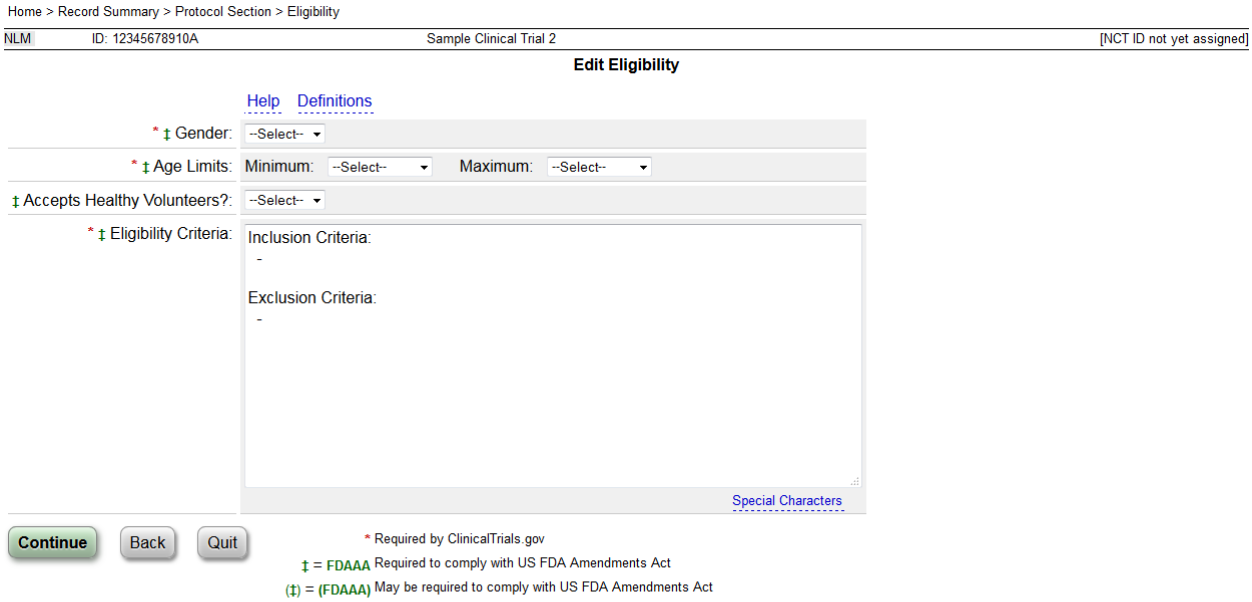

Home > Record Summary > Protocol Section > Eligibility

NLM ID: 12345678910A Sample Clinical Trial 2 [NCT ID not yet assigned]

Edit Eligibility

Help Definitions

* ‡ Gender: --Select--

* ‡ Age Limits: Minimum: --Select-- Maximum: --Select--

‡ Accepts Healthy Volunteers?: --Select--

* ‡ Eligibility Criteria:

Inclusion Criteria:
-

Exclusion Criteria:
-

Special Characters

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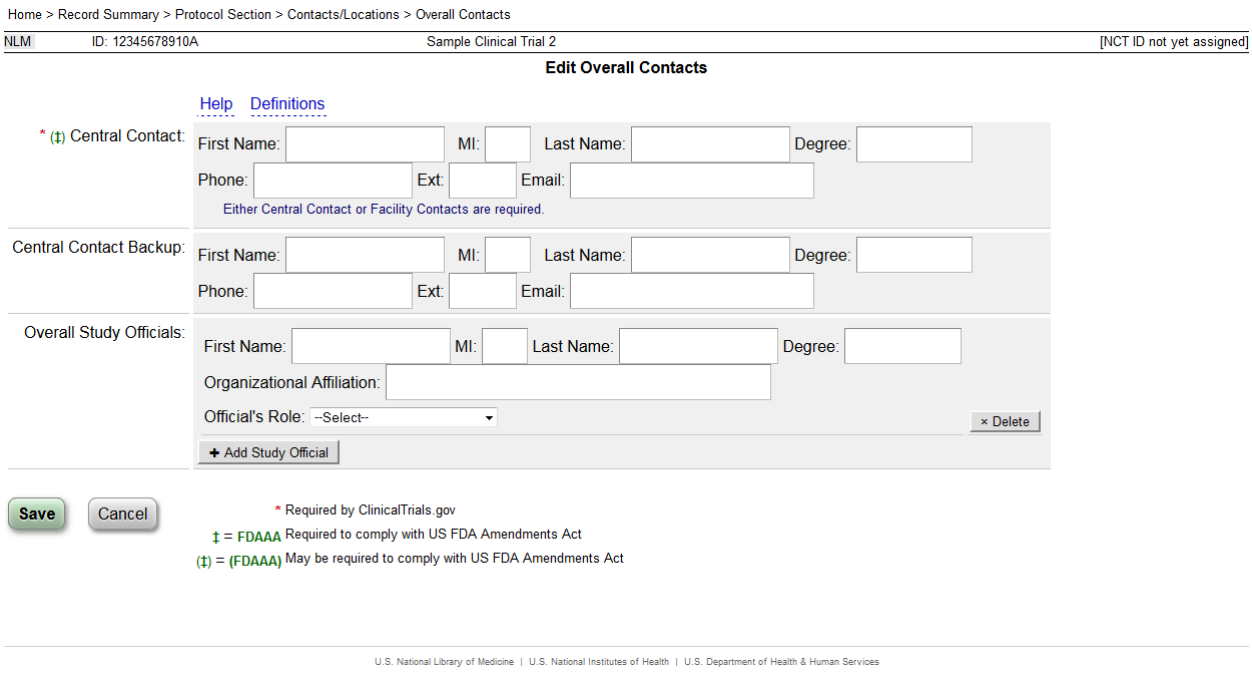

Home > Record Summary > Protocol Section > Contacts/Locations > Overall Contacts

NLM ID: 12345678910A Sample Clinical Trial 2 [NCT ID not yet assigned]

Edit Overall Contacts

Help Definitions

* (‡) Central Contact: First Name: MI: Last Name: Degree:
Phone: Ext: Email:
Either Central Contact or Facility Contacts are required.

Central Contact Backup: First Name: MI: Last Name: Degree:
Phone: Ext: Email:

Overall Study Officials: First Name: MI: Last Name: Degree:
Organizational Affiliation:
Official's Role: --Select-- × Delete
+ Add Study Official

Save Cancel

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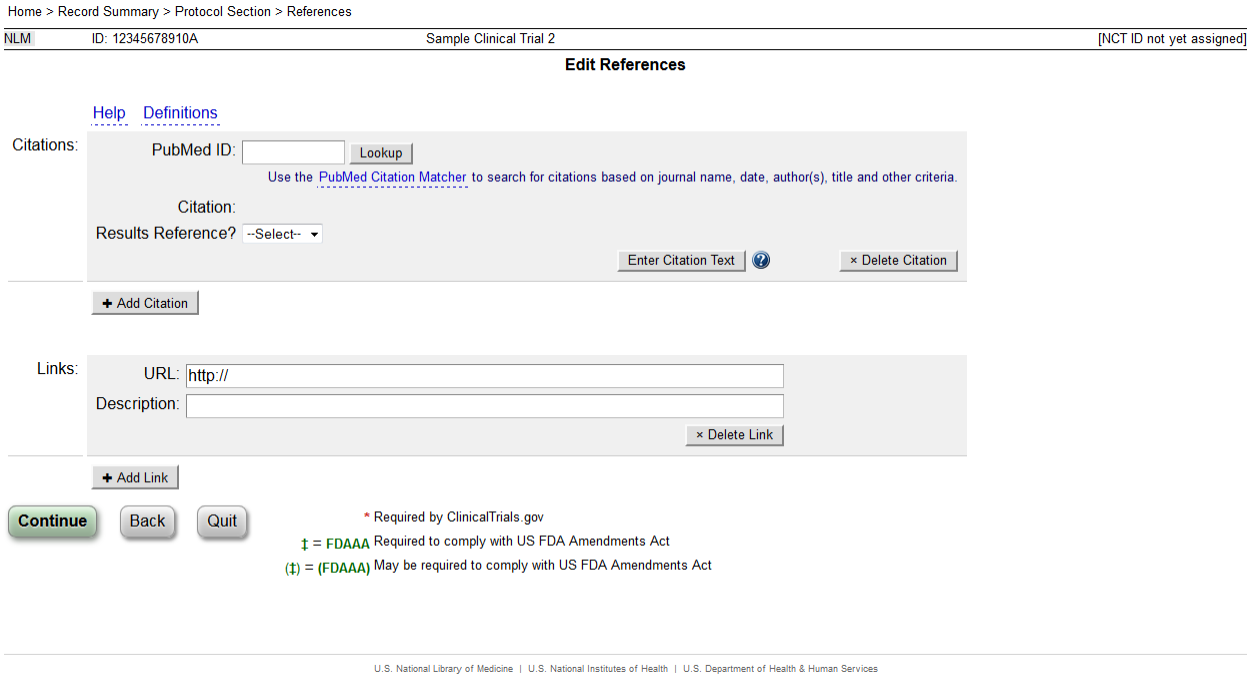

Home > Record Summary > Protocol Section > References

NLM | ID: 12345678910A | Sample Clinical Trial 2 | [NCT ID not yet assigned]

Edit References

Help Definitions

Citations:

PubMed ID: Lookup

Use the PubMed Citation Matcher to search for citations based on journal name, date, author(s), title and other criteria.

Citation:

Results Reference? --Select--

Enter Citation Text × Delete Citation

+ Add Citation

Links:

URL: http://

Description:

× Delete Link

+ Add Link

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