NCI Clinical Trials Reporting Program Registration Site

User's Guide v. 2.0

NATIONAL® CANCER INSTITUTE

Center for Biomedical Informatics and Information Technology

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About This Guide

This chapter introduces you to the NCI Clinical Trials Reporting Program Registration Site User's Guide. It includes the following topics:

- *Purpose* on this page
- *Audience* on this page
- *Topics Covered* on this page
- *Text Conventions Used* on page 2
- *Credits and Resources* on page 3

Purpose

This guide provides an overview of the NCI Clinical Trials Reporting Program Trial Registration Site (CTRP Registration Site) and instructions for using its tools and resources to search for and view details of existing clinical trials. Additionally, registered users can submit new clinical trials and amend those currently registered and verified in the CTRP.

Audience

This guide is designed for members of the NCI clinical research community, who, in their role as submitters and/or principal investigators, register details about clinical trials for use by the broader scientific community.

Topics Covered

If you are new to the CTRP Registration Site, read this brief overview, which explains what you will find in each chapter.

- *Chapter 1, Getting Started,* on page 7 introduces you to the CTRP Registration Site and provides instructions for registering for an account and for logging in to the system.
- *Chapter 2, Searching For Trials,* on page 15 describes how to search for, submit, and view trials in the CTRP Registration Site.

- *Chapter 3, Registering New Trials,* on page 23 describes how to submit, or register, trials using the CTRP Registration Site.
- *Chapter 4, Amending Registered Trials,* on page 53 describes how to submit amendments to trials currently registered and verified in the CTRP.
- *Chapter 5, Managing Your Account,* on page 63 provides instructions for modifying your CTRP Registration Site account.
- *Appendix A, Metadata Definitions*, on page 65 defines the metadata associated with trials and provides examples of valid values for trial details.
- *Appendix B, Batch Upload Data Specifications*, on page 75 describes how to prepare your trial data and documents. It also provides data specifications for the trial data.
- *Appendix C, Participating Sites Document Specifications*, on page 79 provides the specifications—rules, formats, requirements, etc.—for Participating Sites documents.
- *Glossary* provides definitions of acronyms, abbreviations, and terminology used in this guide.

Text Conventions Used

This section explains conventions used in this guide. The various typefaces represent interface components, keyboard shortcuts, toolbar buttons, dialog box options, and text that you type.

Convention	***Description***	***Example***
Bold	Highlights names of option buttons, check boxes, drop-down menus, menu commands, command buttons, or icons.	Click **Search**.
URL	Indicates a Web address.	http://domain.com
text in SMALL CAPS	Indicates a keyboard shortcut.	Press ENTER.
text in SMALL CAPS + text in SMALL CAPS	Indicates keys that are pressed simultaneously.	Press SHIFT + CTRL.
Italics	Highlights references to other documents, sections, figures, and tables.	See *Figure 4.5*.
Italic boldface monospace type	Represents text that you type.	In the **New Subset** text box, enter ***Proprietary Proteins.***
Note:	Highlights information of particular importance	**Note:** This concept is used throughout the document.
{ }	Surrounds replaceable items.	Replace {last name, first name} with the Principal Investigator's name.

Credits and Resources

The following people contributed to the development of this document.

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References	
Protocol definitions	• http://clinicaltrials.gov • http://www.cancer.gov/dictionary/db_alpha.aspx?expand • http://prsinfo.clinicaltrials.gov/fdaaa.html • http://www.cancer.gov/ncictrp • http://www.cancer.gov/clinicaltrials/ctrp/page12

Application Support

For technical assistance when registering your trials with CTRP, or for any general information about the application, application support, or to report a bug, contact National Cancer Institute Center for Biomedical Informatics and Information Technology (NCI-CBIIT) (formerly, NCICB) Application Support.

Email: ncicb@pop.nci.nih.gov (mailto:ncicb@pop.nci.nih.gov)	When submitting support requests via email, please include: • Your contact information, including your telephone number. • The name of the application/tool you are using • The URL if it is a Web-based application • A description of the problem and steps to recreate it. • The text of any error messages you have received
Application Support URL	http://ncicb.nci.nih.gov/NCICB/support
Telephone: 301-451-4384 Toll free: 888-478-4423	Telephone support is available: Monday to Friday, 8 am – 8 pm Eastern Time, excluding government holidays.

For business, process, and other general questions about CTRP, send an email to ncictrp@mail.nih.gov (mailto:ncictrp@mail.nih.gov).

CHAPTER 1
GETTING STARTED

This chapter introduces you to the NCI Clinical Trials Reporting Program Trial Registration Site (CTRP Registration Site) and provides instructions for registering for an account and for logging in to the system.

This section includes the following topics:

- *About the CTRP Registration Site* on this page
- *Creating an Account* on page 8
- *Logging In to the CTRP Registration Site* on page 10
- *Using CTRP Trial Registration Templates and Resources* on page 11

About the CTRP Registration Site

The CTRP Registration Site provides researchers with access to cancer clinical trials. It enables users to search for clinical trials submitted by members of the cancer research community and to view details of existing trials. Additionally, users who create an account with the CTRP can submit new clinical trial protocol details and amend those currently registered and verified in the CTRP.

The CTRP Registration Site enables users to register trials one-at-a-time, or in batches consisting of multiple trials. For information on registering single trials, see *Chapter 3, Registering New Trials,* on page 23. For information on registering multiple trials, see *Registering Multiple Trials in a Batch* on page 49.

Currently you can register *interventional trials*. Future releases of this produce will enable you to register *observational* trials as well.

Note: CTRP Registration Site supports Internet Explorer 7 (IE 7.0.5730.13 and 7.0.5730.11), IE 8 (8.0.6001.18702), and FireFox 3 (3.0.10) browsers.

Creating an Account

To search for and submit individual clinical trial protocol details, create an account with the CTRP using the account feature in the CTRP Registration Site. Additionally, you can request authorization from the CTRP to use the batch upload feature to register multiple new trials that were conducted at a given site. Follow instructions in *Registering Multiple Trials in a Batch* on page 49

Note: You must provide, and have access to, a valid email address to create an account.

How to Register as a New User

1. Navigate to the CTRP Registration Site home page at: http://trials.nci.nih.gov/registration
2. On the navigation pane on the left side of the page (*Figure 1.1*), click **Create Account**.

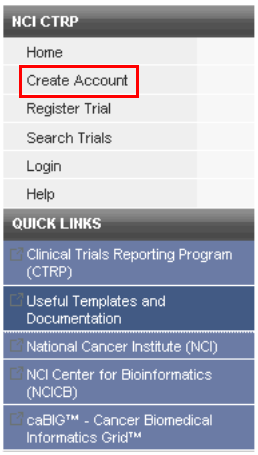


Figure 1.1 Navigation Pane

The Create Account page appears (*Figure 1.2*).

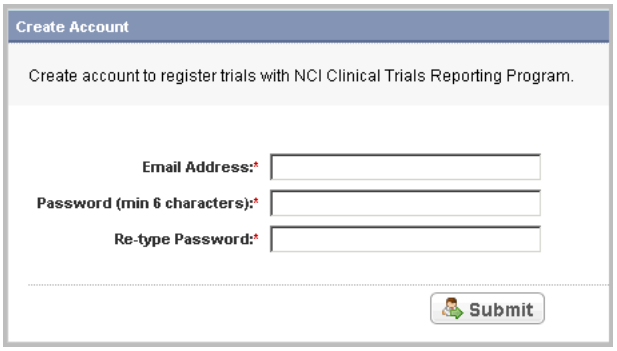


Figure 1.2 CTRP Registration Site – Create Account Page

3. Type a valid email address and password in the fields provided. Passwords must contain a minimum of the following characters:
   - Six characters

- One numeric character (e.g. 1,2,3)

4. Re-type your password in the field provided.
5. Click **Submit**.

   A message appears indicating that the system has sent a confirmation email to the email address you provided.

6. Open the confirmation email and click the embedded link to confirm your registration.

   The My Account page appears. The Email Address, Password, and Re-type Password fields are pre-populated with the information you provided.

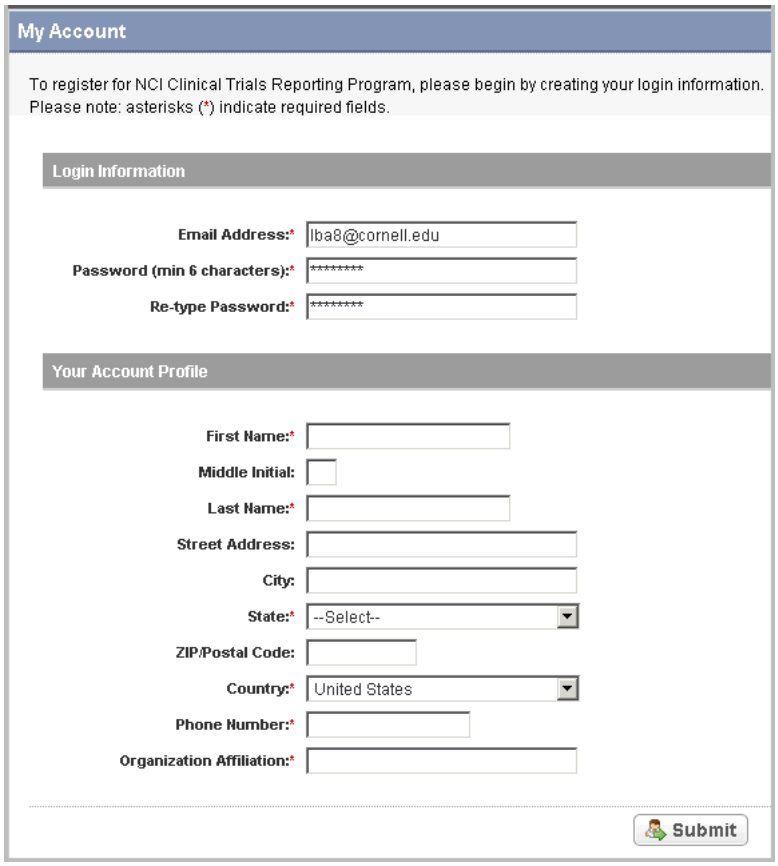


Figure 1.3 My Account page

7. Complete the remaining personal information fields. An asterisk (*) beside a field indicates that the information is required.

   Note: If the address you provide is outside of the United States, select the zip code "None."

8. In the **Organization Affiliation** field**,** type the name of the organization you are affiliated with.
9. Click **Submit**.

Logging In to the CTRP Registration Site

Once you have created a CTRP Registration Site account, you can log in to search for and submit clinical trial details.

Tip: Gather all the protocol data you need before you begin. The system logs you out if it detects that you have not used the application for 90 minutes.

How to Log In to the CTRP Registration Site

1. Navigate to the CTRP Registration Site home page at: http://trials.nci.nih.gov/registration
2. Do one of the following to access the login page:
   - On the navigation pane on the left side of the page (*Figure 1.4*), click **Login**.

   - **or** -

   - On the banner at the top of the page on the right side, click **Login**.

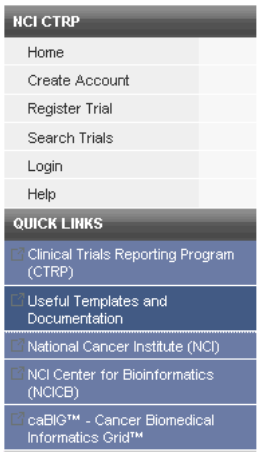


Figure 1.4 Navigation Pane

The Login page appears (*Figure 1.5*).

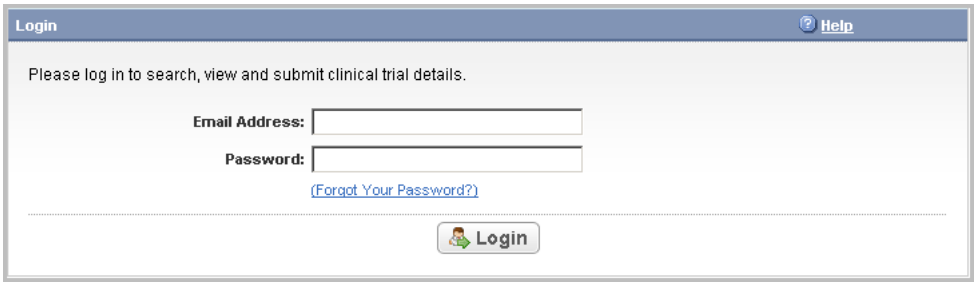


Figure 1.5 CTRP Registration Site – Login page

3. Type the email address and password you registered earlier. See *Creating an Account* for more information on creating a user account.

Note: If you have forgotten your password, see the instructions in *Resetting Your Password* on page 32.

4. Click **Login**.

   The **Search Trials** page appears.

After you have logged in to CTRP Registration Site, you can proceed to search for and/or add clinical trials in the system.

Related topics:

- *Editing User Information*
- *Resetting Your Password*
- *Searching For Trials*
- *Viewing Trial Details*
- *Adding New Trials*
- *About the CTRP Registration Site*

Using CTRP Trial Registration Templates and Resources

The CTRP provides templates and other resources on their website that you can use to facilitate trial information gathering, registration, and amendment. Additionally, a template is available to guide you through the process of registering multiple trials at one time using the CTRP Registration Site's batch upload feature. CTRO staff use the information you provide in these documents to abstract your trials.

Instructions, rules, valid values, and specifications for using each of the templates are provided in the template files.

Tip: Refer to the glossary of CTRP terms at http://www.cancer.gov/clinicaltrials/ctrp/page12, or the *Glossary* in this guide to help you to understand all the data elements required.

Downloading Trial Registration Templates

You can download the following templates from the CTRP website:

- `Registry_Proprietary_Trial_Template.xls` – Use this template to record proprietary trial data for non-NCI trials for which there are no protocol documents.
- `CTRP_Participating_Sites_Template.xls` – Use this template to record participating site data, especially if site-specific data is not included in the trial protocol, or if you need to make changes to the original participating sites information.
- `CTRP_Registry_Batch_Upload.xls` – Use this template as a guide to record trial data required for registering multiple trials in batches.

How to Download CTRP Templates

1. Navigate the CTRP website at http://www.cancer.gov/clinicaltrials/ctrp.

Tip: Click the Resources and Templates quick link on the CTRP Registration Site navigation pane to jump to the template download page.

2. Click the link for the document you want to download.
3. Save the file to your local hard drive.

Note: If you have difficulty locating or downloading the templates, send a request for the files to application support at http://ncicb.nci.nih.gov/NCICB/support.

Using the Proprietary Trial Template

The proprietary trial template is designed primarily for industry-lead or other trials that are not supported by the NCI, which cannot supply a protocol document.

The CTRP Registration Site contains some data fields that are mandatory for registration of NCI-supported trials but which are not applicable to proprietary trial registrations.

In order to satisfy system requirements, use the following work-arounds when entering proprietary trial data through the CTRP Registration Site:

- Leave non-applicable optional fields blank (e.g., grant information)
- Upload protocol and other related documents
- If you are not able to provide a trial protocol document, complete the CTRP Proprietary Trial Worksheet tab
- If the trial has already been registered in ClinicalTrials.gov, include the Clinical Trials ID (NCT number) on the worksheet
- Upload the CTRP Proprietary Trial Data Entry Template in place of the protocol

Using the Participating Sites Template

The participating sites template is designed for recording participating site data, especially if site-specific data is not included in the trial protocol. The participating site document includes participating site information and collaborator information. See *Participating Sites Document Specifications* on page 79.

Rules for completing participating site documents are as follows:

- The collaborators information is optional.
- Participating site information must include the following data elements:
  - Study participating site data
  - At least one study site investigator's information
  - Participating site primary contact information
- Participating site data must include the following data elements:
  - Organization attribute
  - Current recruitment status
  - Status date

- Target accrual. This is mandatory if the target accrual is for a study at a participating site or if the lead organization is a Cancer Center.

- Study site investigator's information must include the following data elements:
  - Study site investigator data with person's attributes
  - Investigator's role in the study at the site

  Note: When registering multiple investigators for a single trial, create one line per investigator/site, using the participating site number as reference.

- Participating site contact information is optional if the contact person is the investigator
- If the contact person is the investigator, the participating site data and study site investigator's information are mandatory

Using the Batch Upload Template

The Batch Upload Template contains the trial elements required for registration, provided in the order in which you should list them. It also contains instructions for preparing the trial documents for submission, valid values for key data elements, and an example of a completed batch upload file.

CHAPTER

2

SEARCHING FOR TRIALS

This chapter describes how to search for existing trials in the CTRP Registration Site.

This chapter includes the following topics:

- *About Clinical Trial Metadata* on this page
- *Searching For Trials* on page 15
- *Working with Search Results* on page 18
- *Viewing Trial Details* on page 20

About Clinical Trial Metadata

The CTRP Registration Site captures trial details, or metadata, as entered by a trial protocol submitter. This metadata enables the research community to share common elements. *Appendix A, Metadata Definitions*, on page 65 describes the metadata associated with trials and provides examples of valid values.

As a CTRP account holder, you can search for and review a subset of registered data that has been submitted and validated.

Searching For Trials

You can retrieve existing trials through the CTRP Registration Site once you have registered for an account. See *Creating an Account* on page 8.

Note: You can search the registration information for all trials registered with the CTRP from all organizations/accounts, or, you can limit your search to the trials that you have submitted by using the Search My Trials feature. For details, see step 3 on page 17All registered users can search trials with the "Validated" processing status. Additionally, you can search trials that you registered, but not validated. These trials are indicated by the "Submitted" status.

How to Search For Existing Trials

1. On the navigation pane on the left side of the page, click **Search Trials**.

   The Search Trials page appears (*Figure 2.1*).

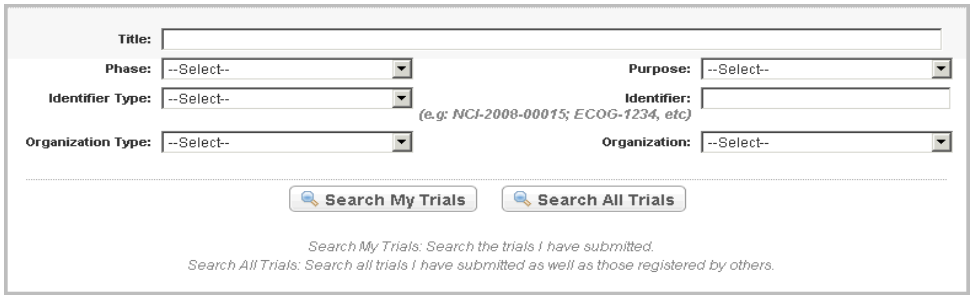


Figure 2.1 Search Trials Page

2. Provide one or more search criteria for the trials you want to retrieve, or, to display a list of all trials that have been submitted, leave all fields blank and click **Search All Trials**.

   Table 2.3 lists the available search criteria. When viewing this guide online, click a hyperlinked term to see its definition.

To search by this...	***Do this...***
Title	Type one or more words from the long title or name of the trial provided by the principal investigator or sponsor.
Phase	Select the trial *phase* from the drop-down menu. • *Phase 0* • *Phase I* • *Phase I/II* • *Phase II* • *Phase II/III* • *Phase III* • *Phase IV* • *Pilot* • *N/A* • *Other*

Table 2.1 Trial Search Criteria

To search by this...	*Do this...*
Purpose	Select the *primary purpose* of the trial from the drop-down menu. • *Treatment* • *Prevention* • *Diagnostic* • *Early Detection* • *Supportive Care* • *Epidemiologic* • *Screening* • *Health Services Research* • *Basic Science* • *Observational* • *Outcome* • *Ancillary* • *Correlative* • *Interventional* • Other – Any other type of trial not included in this list
Identifier Type	Select the *type of trial identifier* from the drop-down list. • NCI – National Cancer Institute • NCT – National Clinical Trial identifier (NCT Number) • Lead Organization
Identifier	Type the unique identifier assigned to the trial by the NCI, NCT, PRS, or the identifier assigned to it by the lead organization. For Inter-Group trials, type the Lead Group's trial number.
Organization Type	Select either Lead or Participating Site from the drop-down list.
Organization	Type the initial letter(s) of your organization and then select the name of your organization from the drop-down list.

Table 2.1 Trial Search Criteria (Continued)

3. Do one of the following:

   - To search all registered trials in the system, click **Search All Trials**.

   -**or** -

   - To search only the trials that you submitted previously, click **Search My Trials**.

   -**or** -

   - To clear all search criteria and begin a new search, click **Reset**.

   The Search Trials page refreshes and displays a list of search results. For more information on navigating and working with search results, see *Working with Search Results*.

4. To view the trial, click the link corresponding to the *NCI Trial Identifier*.

   The Trial Details page appears. For more information on viewing trial details, see *Viewing Trial Details*.

Working with Search Results

The Clinical Trials Reporting Office (CTRO) reviews, or validates each trial submitted to the system. During the validation process, these reviewers check for duplicate records and ensure that the submitter has provided all required information. If all data is complete and accurate, the reviewers assign the trial a status of "accepted," otherwise they assign the status "rejected." In the event that your submission is "rejected," the CTRP sends you an email message indicating the status and reason for the rejection.

Note: If notified about a rejected trial, trial submitters review the accuracy of their submissions, make adjustments, and re-submit the trial, if applicable. Submitters may also contact NCICB Application Support for additional assistance, as necessary. See *Application Support* on page 4.

The search returns results and displays them according to the following criteria:

- Processing status of the trial at the time of the search
- User's role with respect to the trial
- Trial ownership

User roles include the following:

- Submitter – User who submitted the trial
- Other user – Any user other than the submitter

Trial ownership categories are as follows:

- Private trials – Trials submitted by the user who is currently logged in to the CTRP Registration Site
- Public trials – Trials submitted by other registered users

Table 2.2 provides definitions for each of the processing statuses and indicates which ones will be displayed for different user roles.

Note: Only trials that you submitted display a status in the search results list.

Processing Status	***Definition***	***Which roles can see this trial in the list?***	***Listed in "My Trials?"***
Submitted	Trial submitted but not validated	Submitter	Yes
Rejected	Trial did not pass validation	No one	No
Accepted	Trial passed validation	• Submitter • Other users	Yes

Table 2.2 Processing statuses of trials in the CTRP Registration Site

Processing Status	***Definition***	***Which roles can see this trial in the list?***	***Listed in "My Trials?"***
Abstracted	Trial has been abstracted	• Submitter • Other users	Yes
Abstraction Verified Response	Submitter has verified the abstraction as per the TSR, and has returned feedback to the CTRO within the allowed time frame	• Submitter • Other users	Yes
Abstraction Verified No Response	Submitter has not returned verification feedback to the CTRO within the allowed time frame	• Submitter • Other users	Yes

Table 2.2 Processing statuses of trials in the CTRP Registration Site

Navigating Through the Search Results List

After you search for trials, a list of search results and their associated trial details appears at the bottom of the Search Trials page (*Figure 2.2*).

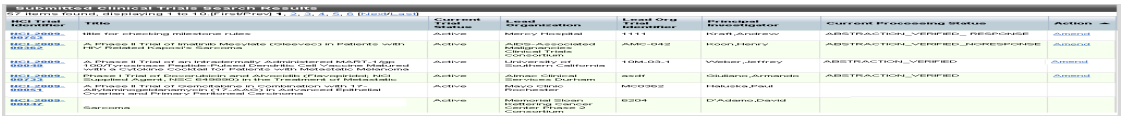


Figure 2.2 Search Results List

Search results display the following information about each trial:

- NCI Trial Identifier – Unique identifier assigned to the trial by the CTRP.
- Title
- Current Trial Status – Code that represents the status of a trial in relation to the ability to enroll participants/patients.
- Lead Organization – Organization responsible for the overall scientific and administrative coordination, study monitoring, and data management activities of a given clinical trial
- Lead Organization Trial Identifier – Unique identification assigned to the protocol by the lead 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.
- Principal Investigator – Appointed investigator responsible for conducting clinical trial, or for multi-site trials, the study chair
- Current Processing Status – Position of the trial with respect to the abstraction process life cycle.
- Action – When "Amend" appears in this column, an amendment to the trial can be submitted.

You can navigate through the search results in several ways, as detailed in *Table 2.3*.

To do this...	*Do this...*	*Additional Notes*
Sort your results by column	Click the column heading.	By default, results are sorted by *NCI Trial Identifier*.
Move to the next page of results	Click **Next** or click the next page number above or below the list of results.	The **Next** link is not active on the last page of results.
Move to the previous page of results	Click **Prev** or click the preceding page number above or below the list of results.	The **Prev** link is not active on the first page of results.
Move to a specific page of results	Click the specific page number above or below the list of results.	None
Move to the first page of results	Click **First** above or below the list of results.	The **First** link is not active on the first page of results.
Move to the last page of results	Click **Last** above or below the list of results.	The **Last** link is not active on the last page of results.
View details for a trial	Click the *NCI Trial Identifier* for the trial of interest. The Trial Details page appears.	As a registered user, you can view details for accepted trials that have been submitted by others. Additionally, you can view all trials that you have submitted that have not been rejected during the validation process.
Download trial-related documents	Click the name of the trial document.	Only submitters can view/ download trial-related documents.

Table 2.3 Methods for viewing search results and trial details

Viewing Trial Details

To view details for a given clinical trial listed on a search results page, click its associated *NCI Trial Identifier* hypertext link.

The Trial Details page displays the metadata as entered by a trial submitter. Refer to *Appendix A, Metadata Definitions*, on page 65 for a description of the metadata.

Note: Responsible party, IND/IDE, NIH grant information and trial-related documents are only displayed for the private trials.

Viewing Trial-Related Documents

Only submitters can view/download trial-related documents.

How to Download Trial-Related Documents

1. Click the **NCI Trial Identifier** hypertext link associated with the trial of interest.

The metadata for the selected trial is displayed in a new page.

2. In the **Trial Related Documents** section at the bottom of the page, click hypertext link associated with the document of interest.

   A dialog box appears in which you are given the option to open the document or save it to location of your choice.

3. Follow the instructions for your browser and operating system to view or save the document.

CHAPTER 3

REGISTERING NEW TRIALS

This chapter describes how to register trials using the CTRP Registration Site.

This chapter includes the following topics:

- *Registering Trials in the CTRP Registration Site* on this page
- *Registering Organizations* on page 41
- *Registering Persons* on page 45
- *Registering Multiple Trials in a Batch* on page 49

Registering Trials in the CTRP Registration Site

The CTRP Registration Site provides a user-friendly interface through which you can register new and amended trials in the CTRP system. Additionally, when your registration is verified, you will receive a Trial Summary Report—a system-generated report that contains all your abstracted data—in both MS Word and XML formats. The later is formatted to facilitate the registration of your trials with the Library of Medicine's ClinicalTrials.gov database.

Tip: Before you begin to register a trial, ensure that the trial does not exist in the system already. You can do this by searching for trials using any of the criteria as per the instructions in *Searching For Trials* on page 15.

Note: You are required to provide information for all fields marked with an asterisk (*).

See the following topics for more detailed instructions and definitions:

- *Completing the Trial Details Section* on page 25
- *Completing the Lead Organization/Principal Investigator Section* on page 28
- *Completing the Sponsor/Responsible Party Section* on page 28

- *Completing the Summary 4 Information Section* on page 29
- *Completing the NIH Grant Information Section* on page 30
- *Completing the Trial Status/Dates Section* on page 35
- *Completing the IND/IDE Information Section* on page 36
- *Completing the Trial Related Documents Section* on page 40

How to Submit a Trial

1. On the navigation pane on the left side of the page, click **Register Trial**.

   The Register Trial page appears (*Figure 3.1*).

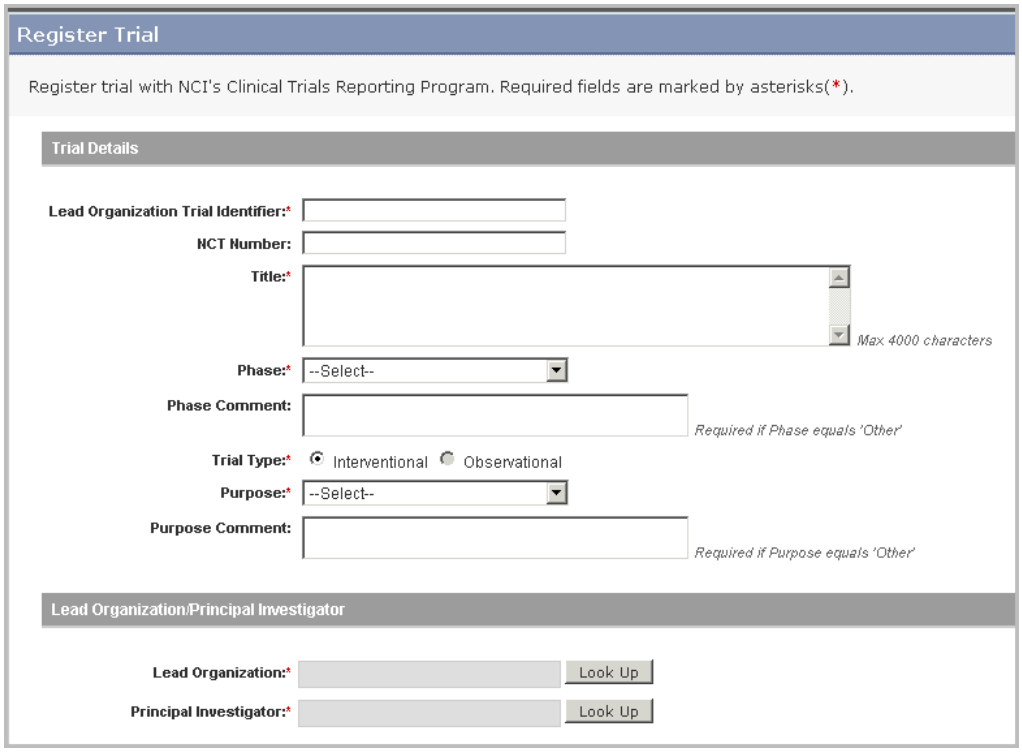


Figure 3.1 Register Trial Page – Upper Section

2. Type the appropriate information in the text fields, or select options from the drop-down lists as appropriate.
3. Scroll to the bottom of the **Register Trial** page, and click **Review Trial**.

   The system checks for errors and missing information and displays the results in a message at the top of the Review Trial Details page. Indicators mark specific fields that you must complete or correct in order to submit the trial.
4. Correct any errors if indicated, and repeat the previous step as many times as necessary until the trial is error-free.

   Note: The Review Trial Details page is read-only. To edit information that you have reviewed, see *Editing Amendment Details* on page 60.
5. Click **Submit**.

The system sends you an email message to acknowledge that the trial has been submitted. After submission, no other users can see the trial information you provided until the information has been validated. If the trial is rejected at validation, the system alerts you via a rejection message. Once validated, the trial you submitted is ready for abstraction by an NCI Clinical Trials Reporting Office (CTRO) specialist.

Completing the Trial Details Section

You must complete all fields in the Trial Details section (*Figure 3.2*).

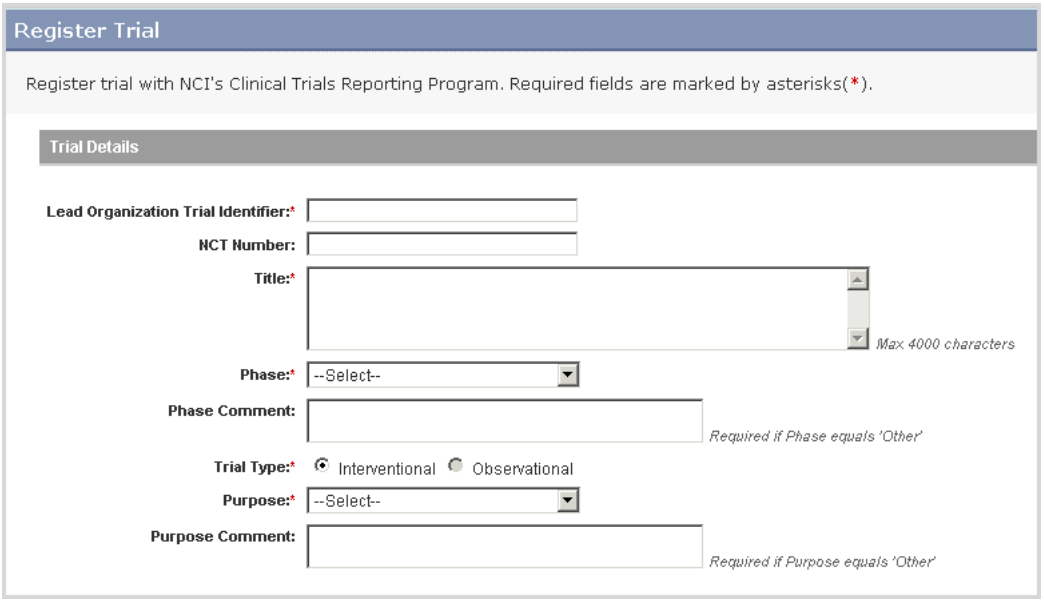


Figure 3.2 Add Trial Page – Trial Details Section

How to Complete the Trial Details Section

1. Type the *Lead Organization Trial Identifier* in the field provided, or for Inter-Group trials, type the Lead Group's trial number.

   Note: The Trial Identifier must be exactly the same as it appears in the protocol document.

   For example:

   `NSABP-B-40`

   Note: For multi-site trials that have no assigned single center, use the protocol ID.

2. Type the *Title* in the field provided. You can use a maximum of 4000 characters.

   For example:

   "Study of Recombinant Vaccinia Virus That Expresses Prostate Specific Antigen in Metastatic Adenocarcinoma of the Prostate"

3. Select the Trial *Phase* from the drop-down list. *Table 3.1* lists valid trial phases:

Phase #	Definition
0	Tests a new treatment that is available only in very limited quantities and which has never previously given to humans or for which there is extremely limited human experience to enable researchers to understand the path of the drug in the body and its efficacy.
I	The first step in testing a new treatment in humans. These studies test the best way to administer a new treatment (e.g., by mouth, intravenous infusion, or injection) and the best dose. The dose is usually increased a little at a time in order to find the highest dose that does not cause harmful side effects. Because little is known about the possible risks and benefits of the treatments being tested, phase I trials usually include only a small number of patients who have not been helped by other treatments
I/II	A clinical research protocol designed to study the safety, dosage levels and response to new treatment. Phase I/II trials combine a Phase I and a Phase II trial of the same treatment into a single protocol.
II	A study to test whether a new treatment has an anticancer effect (for example, whether it shrinks a tumor or improves blood test results) and whether it works against a certain type of cancer.
II/III	A trial to study response to a new treatment and the effectiveness of the treatment compared with the standard treatment regimen.
III	A study to compare the results of people taking a new treatment with the results of people taking the standard treatment (for example, which group has better survival rates or fewer side effects). In most cases, studies move into phase III only after a treatment seems to work in phases I and II. Phase III trials may include hundreds of people.
IV	Evaluates the long-term safety and efficacy of a treatment for a given indication and studies side effects that may have become apparent after the phase III study was completed
Pilot	Initial study examining a new method or treatment.
N/A	Not applicable
Other	Any phase not listed above

Table 3.1 Trial phase definitions

4. If you selected Other in Step 3, in the **Phase Comment** field, type a description about the phase of the trial.
5. The *Interventional Trial Type* is pre-selected.

   Note: Currently you can register *interventional* trials only. Future releases of this produce will enable you to register *observational* trials as well.

6. From the **Purpose** drop-down list, select the purpose of the trial.

Table 3.2 lists valid values:

Trial Purpose	***Definition***
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.
Early Detection	Clinical trials directly testing the efficacy of devices, techniques, procedures; or tests for earlier detection or diagnosis of efficacy of devices, techniques, procedures; or tests for earlier or more accurate detection or diagnosis of disease.
Basic Science	Protocol designed to examine the basic mechanism of action (e.g., physiology, biomechanics) of an intervention.
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).
Epidemiologic	Studies among cancer patients and healthy populations that involve no intervention or alteration in the status of the participants, e.g., surveillance, risk assessment, outcome, environmental, and behavioral studies.
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
Outcome	Studies among cancer patients and healthy populations that involve no intervention or alteration in the status of the participants, e.g., surveillance, risk assessment, outcome, environmental, and behavioral studies.
Ancillary	Auxiliary studies that are stimulated by, but are not a required part of, a main clinical trial/study, and that utilize patient or other resources of the main trial/study to generate information relevant to it. Ancillary studies included must be linked to an active trial or epidemiologic or other study and should include only patients accrued to that trial or study. Only studies that can be linked to individual patient or participant data should be reported.

Table 3.2 Trial purpose definitions

Trial Purpose	Definition
Correlative	Laboratory based studies using specimens to assess cancer risk, clinical outcomes, response to therapies, etc. Only studies that can be linked to individual patient or participant data should be reported.
Health Services Research	Protocol designed to evaluate the delivery, processes, management, organization or financing of health care.
Other	Any trial type not included in this list.

Table 3.2 Trial purpose definitions (Continued)

7. If you selected **Other** in Step 6, in the **Purpose Comment** field, describe the purpose of the trial.

Completing the Lead Organization/Principal Investigator Section

You must complete both fields in the Lead Organization/Principal Investigator section (*Figure 3.3*).

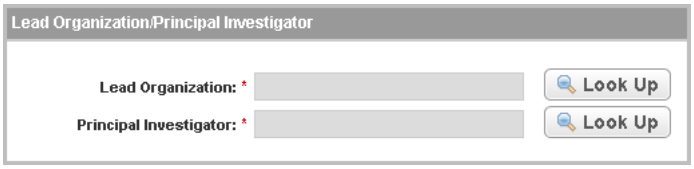


Figure 3.3 Add Trial Page – Lead Organization/Principal Investigator Section

How to Complete the Lead Organization/Principal Investigator Section

1. Look up the *Lead Organization* and select the appropriate organization from the list of search results. If your trial's lead organization is not listed, you can register it in the system at this point. To search for and register an organization, follow the instructions in *Searching for Registered Organizations* on page 42 and *Adding Organizations* on page 44.

2. Look up the *Principal Investigator* and select the appropriate name from the list of search results. If your trial's principal investigator's name is not listed, you can register it in the system at this point. To search for and register an investigator, follow the instructions in *Searching for Principal Investigators* on page 45 and *Adding Principal Investigators* on page 47.

Completing the Sponsor/Responsible Party Section

You must complete all fields in the Sponsor/Responsible Party section (*Figure 3.4*).

Figure 3.4 Add Trial Page – Sponsor/Responsible Party Section

How to Complete the Sponsor/Responsible Party Section

1. Look up the *Sponsor* and select the appropriate sponsor organization from the list of search results. If your trial's sponsor is not listed, you can register it in the system at this point. To search for and register a sponsor, follow the instructions in *Searching for Registered Organizations* on page 42 and *Adding Organizations* on page 44.

2. Indicate the party who is responsible for the trial. Select one of the following options:

   - *PI* (principal investigator) – Primary medical researcher in charge of carrying out a clinical trial's protocol.

   - or-

   - *Sponsor* – Name of primary organization that oversees implementation of study and is responsible for data analysis.

3. If you selected Sponsor in the previous step, the **Sponsor/Responsible Party** section (*Figure 3.5*) expands to display the **Responsible Party Contact**. Follow the instructions in *Looking Up Registered Persons* on page 123 to record the responsible party contact person information.

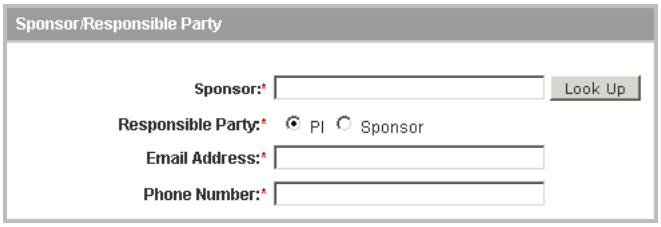


Figure 3.5 Add Trial Page – Sponsor Section, Expanded

4. In the **Email Address** and **Phone Number** fields, type the responsible party's contact email address and phone number. You can use spaces or dashes, or no separators at all in the **Phone Number** fields. Include numbers only for phone number extensions where applicable.

   Caution: Do not add spaces in the phone number.

Completing the Summary 4 Information Section

If the lead organization or at least one participating site is a NCI designated cancer center, complete both fields in the Summary 4 Information section (*Figure 3.6*).

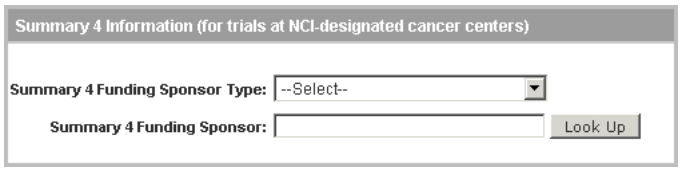


Figure 3.6 Add Trial Page – Summary 4 Information Section

How to Complete the Summary 4 Information Section

1. Select the *Summary 4 Funding Category* from the drop-down list. *Table 3.3* lists valid categories:

Funding Category	***Definition (For clinical trials involving an agent or device or other intervention)***
National	National Cooperative Group Trials
Externally Peer-Reviewed	*R01s* and *P01s* or other trial mechanisms funded by NIH or supported by other peer-reviewed funding organizations.
Institutional	In-house, internally reviewed trials, including those collaborative studies conducted with industry sponsorship in which the center is a primary contributor to the design, implementation, and monitoring of the trial, or participation in a multi-site trial initiated by an investigator at another center.
Industrial	Design and implementation of the study is controlled by the pharmaceutical company

Table 3.3 Summary 4 funding categories definitions

2. Look up the *Summary 4 Funding Sponsor/Source* and select the appropriate organization from the list of search results. If your trial's lead organization is not listed, you can register it in the system at this point. To search for an organization, follow the instructions in *Searching for Registered Organizations* on page 42. To register an organization, follow the instructions in *Adding Organizations* on page 44.

Completing the NIH Grant Information Section

If your trial includes an NIH grant, record the funding mechanism, institute code, serial number, and NCI division/program for this grant (*Figure 3.7*). You can add multiple NIH grants.

An NIH grant identification number consists of several parts, each having a distinct meaning.

For example:

```
1R01CA009999-08A1S2
```

where,

1 is the single-digit code identifying the type of application received and processed

R01 (position 2 - 4) is the three-digit code identifying a specific category of extramural activity. It corresponds to Funding Mechanism element in the NIH grant information section.

CA (position 5 - 6)is the two-letter code identifying the assignment or funding NIH Institute or Center. It corresponds to Institute Code element in the NIH grant information section.

009999 (position 7 - the dash) is the five- or six-digit number generally assigned sequentially to a series within an Institute, Center, or Division. It corresponds to the Serial Number element in the NIH grant information section.

- (dash) separates the serial number from the grant year

08 is the two-digit number indicating the actual segment or budget period of a project The grant year is preceded by a dash to separate it from the serial number.

A1 is the letter code for a resubmitted application, (commonly referred to as an Amendment) and related number that identifies a particular amendment record

S2 is the letter code for Revision (for Supplemental funding) and related number identifing a particular supplemental record.

Note: The Grant Identification Number is also commonly referred to as Assignment Number, Application Number, or the Award Identification Number, depending upon its processing status.

For a complete guide to NIH grant information, see the following web pages:

- http://ocga3.ucsd.edu/Proposal_Preparation/Federal/NIH/Grants/Basics/NIH_Grants_Grant_Identification_Numbering_System.htm
- http://grants1.nih.gov/grants/funding/ac.pdf
- http://deais.nci.nih.gov/Query/search/

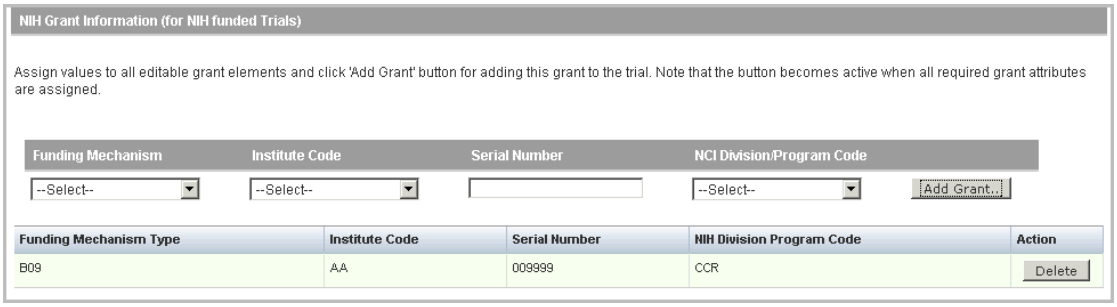


Figure 3.7 Add Trial Page – NIH Grant Information Section

How to Complete the NIH Grant Information Section

1. Type the initial letter(s) and or number(s) in the *Funding Mechanism* field and then select the funding mechanism code from the drop-down list.

   Tip: Click the down arrow in the field, and then use the up and down arrow keys on your keyboard to scroll up and down the drop-down list. When you arrive at the appropriate code, press the ENTER key.

Table 3.4 lists examples of valid codes:

Funding Mechanism	Definition
B09	Mental Health Services Block Grant
C06	Research Facilities Construction Grant
DP1	NIH Director's Pioneer Award (NDPA)
DP2	NIH Director's New Innovator Awards
D43	International Training Grants in Epidemiology
D71	International Training Program Planning Grant
X02	Pre-application

Table 3.4 NIH grant funding mechanisms definitions

2. Type the initial letter(s) of the name of the primary organization responsible for funding the trial in the **Institute Code** field and then select the institute code from the drop-down list.

   Table 3.5 lists examples of valid codes:

Institute Code	Definition
AA	National Institute on Alcohol Abuse and Alcoholism
AG	National Institute on Aging
AI	National Institute of Allergy and Infectious Diseases
AO	NIAID Research Support
AR	National Institute of Arthritis and Musculoskeletal and Skin Disease
AT	National Center for Complementary and Alternative Medicine

Table 3.5 NIH institute code definitions

3. Type the six-digit number generally assigned sequentially to a series within an Institute, Center, or Division, for example, 009999, in the **Serial Number** field.

4. Type the initial letter(s) of the division or program code in the **NCI Division/ Program Code** field and then select the code from the drop-down list.

Table 3.6 lists examples of valid codes:

Division/ Program Code	***Definition***
CCR	Center for Cancer Research
CTEP	Cancer Therapy Evaluation Program
DCB	Division of Cancer Biology
DCCPS	Division of Cancer Control and Population Sciences
DCEG	Division of Cancer Epidemiology and Genetics
DTP	Developmental Therapeutics Program
DCP	Division of Cancer Prevention
DEA	Division of Extramural Activities
OD	Office of the Director, NCI, NIH
OSB/SPORE	Organ Systems Branch/ Specialized Programs of Research Excellence
CIP	Cancer Imaging Program
CDP	Cancer Diagnosis Program
TRP	Translational Research
RRP	Radiation Research Program
N/A	Not applicable

Table 3.6 NCI Division/Program code definitions

5. Click **Add Grant**.

   Note: The **Add Grant** button is operable only after you have provided the grant information in all fields.

   The grant is displayed and added to the trial and the Grant fields are reset.

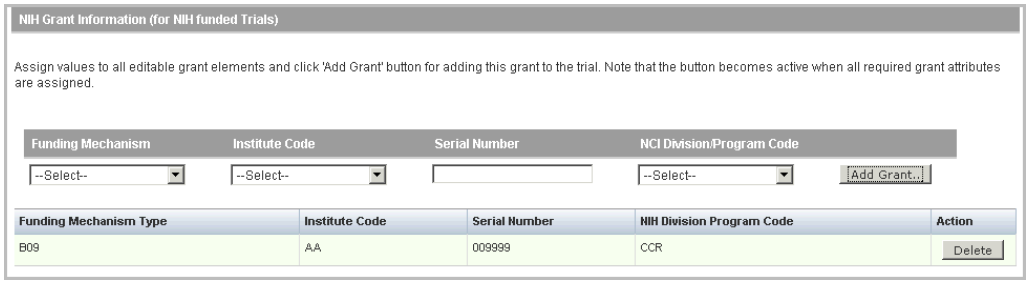


Figure 3.8 Grant Information Section – Registered Grant

6. If your trial is funded by more than one grant, repeat the steps above, and then click **Add Grant**.

Another grant record appears.

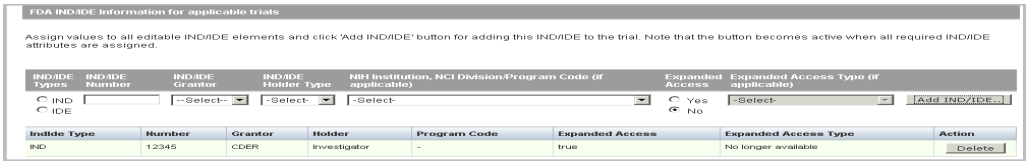


Figure 3.9 Grant Information Section – Additional Grant

7. To unlink a grant from a trial, in the **Action** column, click **Delete**.

Completing the Trial Status/Dates Section

You must complete all fields in the Status/Dates section. Valid dates for a given trial status depend on the other values you have entered, and whether those dates are actual or anticipated. The following table provides the rules for trial status dates.

If this is true...	***Follow this rule***
Trial Start Date is “Actual”	Trial Start Date must be current or in the past
Trial Start Date is “Anticipated”	Trial Start Date must be in the future
If the Primary Completion Date is “Actual”	Trial Start Date must be current or in the past
If the Primary Completion Date is “Anticipated”	Trial Start Date must be in the future
Current Trial Status Date	Date must be current or in the past
Current Trial Status is “Approved”	Trial Start Date must be “Anticipated”
Current Trial Status is *not* “Approved”	Trial Start Date must be “Actual”
Current Trial Status is “Completed”	• Trial Status Date must be “Actual” • Primary Completion Date must be the same as Current Trial Status Date
Current Trial Status is “Completed”	Primary Completion Date must be “Actual”
Current Trial Status is “Administratively Completed”	Primary Completion must be “Actual”
Current Trial Status is neither of the following: • “Administratively Completed” • “Completed”	Primary Completion Date must be “Anticipated”

Table 3.7 Rules for Status/Dates relationships

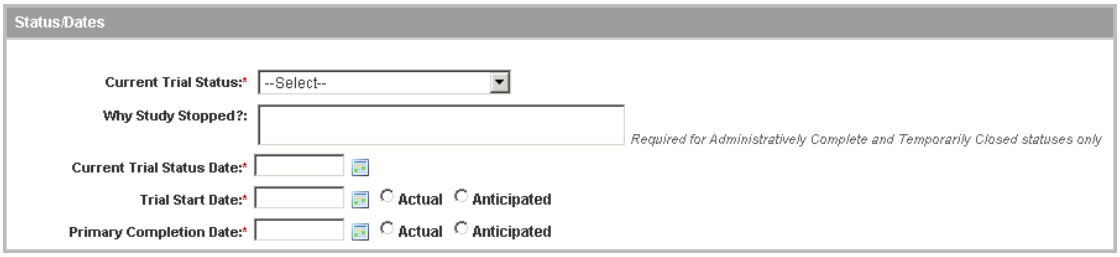


Figure 3.10 Add Trial Page – Status/Dates Section

How to Complete the Status/Dates Section

1. Select the trial’s current *status* from the **Current Trial Status** drop-down list. *Table 3.8* lists valid categories.

Status	***Definition***
Approved	Trial has been approved
Active	Trial is open for *accrual*

Table 3.8 Current trial status definitions

Status	*Definition*
Closed to Accrual	Trial has been closed to participant accrual. Participants are still receiving treatment/intervention.
Closed to Accrual and Intervention	Trial has been closed to participant accrual. No participants are receiving treatment/intervention, but participants are still being followed according to the primary objectives of the study.
Temporarily Closed to Accrual	Trial is temporarily not accruing.
Temporarily Closed to Accrual and Intervention	Trial is temporarily not accruing. Participants are not receiving intervention.
Administratively Complete	Trial has been completed prematurely (for example, due to poor accrual, insufficient drug supply, IND closure, etc.)
Complete	Trial has been closed to accrual; participants have completed treatment/intervention, and the study has met its primary objectives.

Table 3.8 Current trial status definitions

2. If you selected the **Administratively Complete** or **Temporarily Closed to Accrual** status, in the **Why Study Stopped** field, type the reason why the study has ended or not currently accruing.
3. Type the date on which the current trial status became effective in the *Current Trial Status Date* field using the mm/dd/yyyy format, or, click the calendar icon () and select the date from the calendar.
4. Type the date on which the trial started, or is expected to start, in the **Trial Start Date** field using the mm/dd/yyyy format, or, click the calendar icon () and select the date from the calendar.
5. Indicate whether the start date is the one on which you expect the trial to start, or the date on which it actually started, by selecting either **Anticipated** or **Actual**.
6. Type the date on which the trial ended, or is expected to end, in the **Primary Completion Date** field using the mm/dd/yyyy format, or, click the calendar icon () and select the date from the calendar.
7. Indicate whether the completion date is the one on which you expect the trial to end, or the date on which the trial actually ended by selecting either **Anticipated** or **Actual**.

Completing the IND/IDE Information Section

Complete the IND/IDE number and grantor fields only if your trial is/was conducted in the United States. You must indicate whether your trial qualifies as an Investigational New Drug Application (IND) or Investigational Device Exemption (IDE) protocol.

To register IND trials, see *Registering IND Trials* on page 37.

To register IDE trials, see *Registering IDE Trials* on page 38.

Registering IND Trials

There are several dependencies between elements in the IND/IDE section (*Figure 3.11*). Follow the instructions below in the order in which they are presented.

How to Register IND Trials

1. In the **IND/IDE Types** column, select the **IND**.

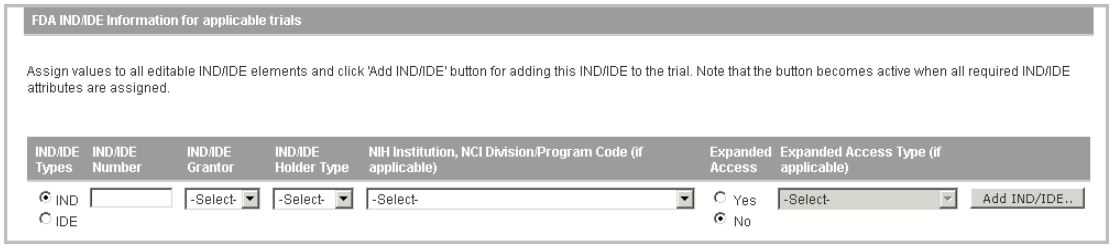


Figure 3.11 Add Trial Page – IND/IDE Section

2. In the **IND/IDE Number** field, type the *IND number* associated with the trial.
3. From the **IND/IDE Grantor** drop-down list, select the IND grantor.

   Note: The list of grantors varies depending on the selected IND/IDE type. *Table 3.9* lists valid grantors.

Valid Grantors
CDER – Center for Drug Evaluation and Research
CBER – Center for Biologics Evaluation and Research
CDRH – Center for Devices and Radiological Health

Table 3.9 Valid grantors

4. From the **IND/IDE Holder Type** drop-down list, select the holder type from the **IND/IDE Holder Type** drop-down list.

   Table 3.10 lists valid holder types.

Valid Holder Types
Investigator
Organization
Industry
NIH
NCI

Table 3.10 Valid holder types

   Note: If you select either NCI or NIH, you must select the **NIH or NCI Division/ Program** code.

5. If you selected either NIH or NCI, from the **NIH Institution, NCI Division/ Program Code** drop-down list, select the appropriate *institute code*.

6. In the **Expanded Access** column, indicate whether or not an experimental drug or device is available outside any clinical trial protocol by selecting either **Yes** or **No**.

7. Do one of the following:

   - If you selected **No**, click **Add IND/IDE**.

   - **or**-

   - If you selected **Yes**, select the status of the drug or device access from the **Expanded Access Status** field, and then click **Add IND/IDE**.

     Table 3.11 lists valid states.

Status	***Definition***
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

Table 3.11 Valid values for expanded access status

8. Optionally, to add another IND/IDE, repeat the steps above.

Registering IDE Trials

Due to several IND/IDE element dependencies, follow the instructions below in the order in which they are presented.

How to Register IDE Trials

1. In the **IND/IDE Types** column, select the **IDE** (*Figure 3.12*).

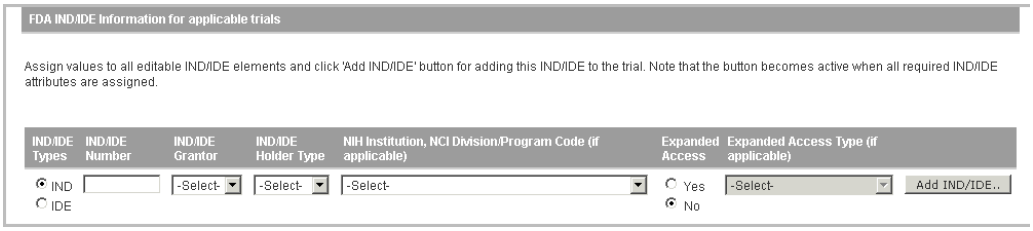


Figure 3.12 Add Trial Page – IND/IDE Section

2. In the **IND/IDE Number** field, type the *IDE number* associated with the grant.

3. From the **IND/IDE Grantor** drop-down list, select **CDRH** (CDRH – Center for Devices and Radiological Health).

4. From the **IND/IDE Holder Type** drop-down list, select the holder type from the **IND/IDE Holder Type** drop-down list.

Table 3.12 lists valid holder types.

Valid Holder Types
Investigator
Organization
Industry
NIH
NCI

Table 3.12 Valid holder types

Note: If you select either NCI or NIH, you must select the **NIH or NCI Division/ Program** code.

5. If you selected either NIH or NCI, from the **NIH Institution, NCI Division/ Program Code** drop-down list, select the appropriate *institute code*. See *Appendix A, Metadata Definitions*, on page 65 for valid Institute codes.
6. Indicate whether or not an experimental drug or device is available outside any clinical trial protocol by selecting either **Yes** or **No**.
7. Do one of the following:

   - If you selected **No**, proceed to Step 8.

   - **or**-

   - If you selected **Yes**, select the status of the drug or device access from the **Expanded Access Status** field, and then click **Add IND/IDE**.

     Table 3.13 lists valid states.

Status	*Definition*
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

Table 3.13 Valid values for expanded access status

8. To add the IND/IDE information to the trial, click **Add IND/IDE**.

   Note: The **Add IND/IDE** button is operable only after you have provided information in all fields.

   The IND/IDE record is displayed and added to the trial.

   Tip: If the IND/IDE information is incorrect, delete the record and add it again with the correct information.

9. If your trial is includes more than one IND/IDE, repeat the steps above, and then click **Add IND/IDE**.

   Another IND/IDE record appears (*Figure 3.13*).

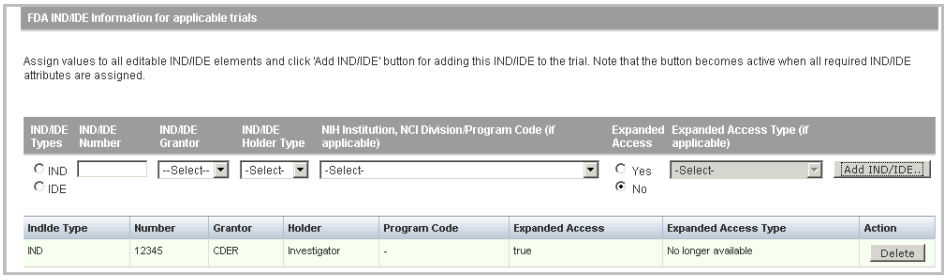


Figure 3.13 Grant Information Section – Additional Grant

10. To delete an IND/IDE record from a trial, in the **Action** column, click **Delete**.

Completing the Trial Related Documents Section

You must include each of the following types of documents in order to register your trial:

- For non-industry trials only: Complete protocol
- For industrial trials only: Summary of the proprietary protocol
- *IRB* approval
- Informed Consent (if not included in the protocol document)
- Participating sites (if not included in the protocol document)

Note: If the Informed Consent and Participating Sites documents are not included as part of the protocol document, upload them separately as "Trial Related Documents."

Currently you are required to supply your documents as Microsoft Word (`.doc`, `.docx`, or `.docm`), Adobe PDF, Microsoft Excel (`.xls`, `.xlsx`, `.xlsm`, or `.xlsb`), and/or WordPerfect files.

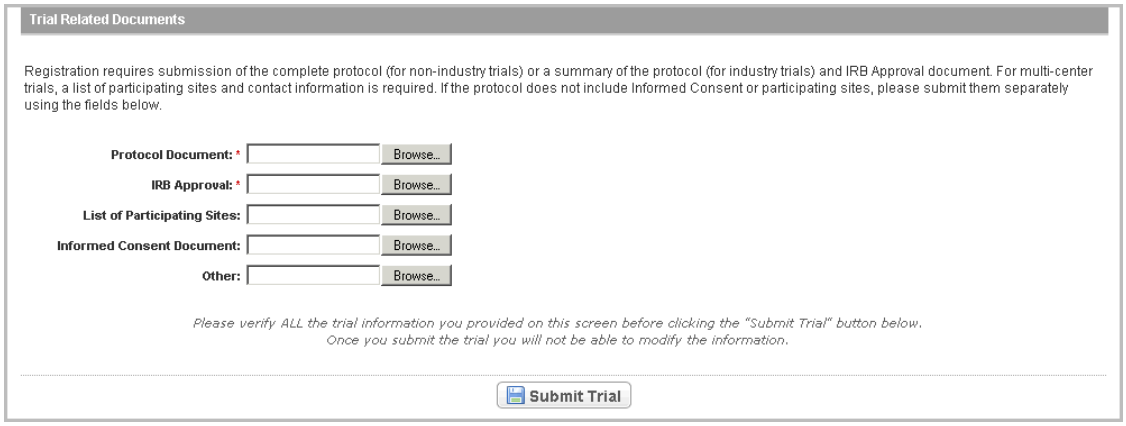


Figure 3.14 Add Trial Page – Trial Related Documents

Note: The procedure for uploading documents is the same for all document types.

How to Submit Trial Related Documents

1. Click the Browse button beside the **Protocol Document** field.
2. Navigate to, and select, the appropriate document, and then click **Open**.

   Note: Depending on your operating system, you may see a different command name for "Open."
3. Repeat these steps above for each type of document.
4. When you have completed all fields, click **Submit Trial**.

   The Trial Details page appears. It contains a message that you have created your trial successfully (if appropriate), and lists the details of the trial you just submitted. It also provides the assigned NCI Identification number. In case of incomplete submission, the message prompts you to complete required fields.

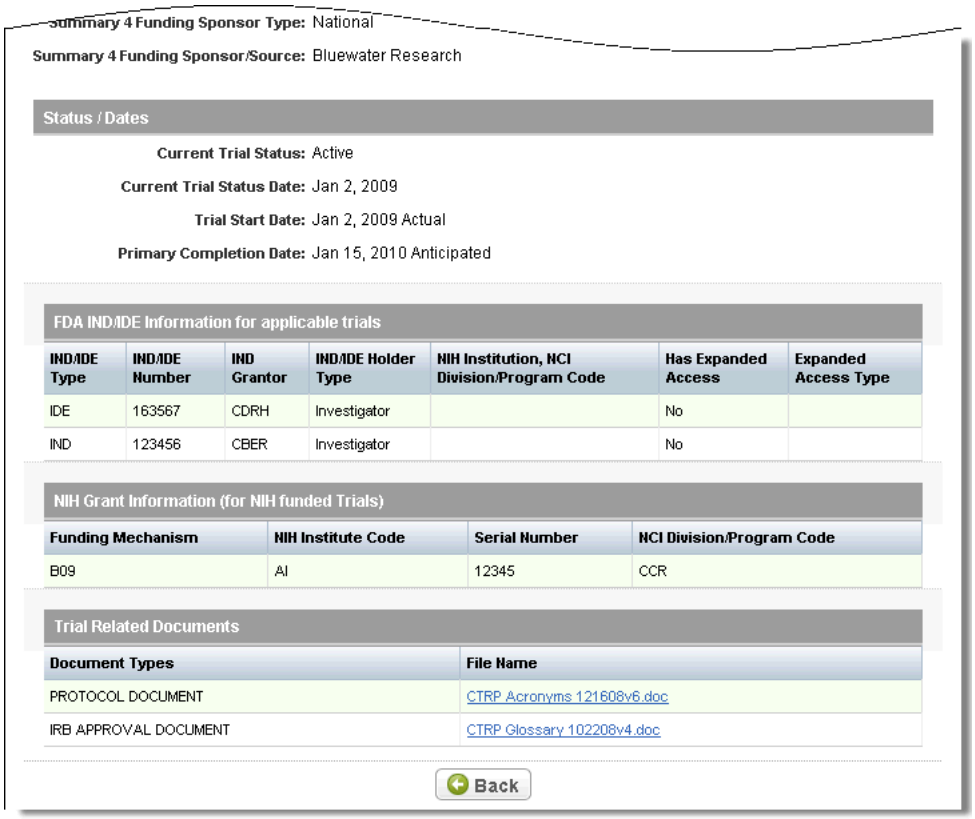


Figure 3.15 Trial Details Page After Successful Submission – Lower Sections

5. Optionally, to view the trial related documents, click the document links.

Registering Organizations

You can register an organization if you are unable to find your organization listed in the system. Before you register an organization, be sure to search the system's registered organizations to ensure that you do not create a duplicate record. (See *Searching for*

Registered Organizations on page 42.) If your search results do not contain the name of your organization, you can register a new one. (See *Adding Organizations* on page 44.)

Searching for Registered Organizations

If you are unsure of the name of the lead organization for a trial that you are registering, you can search for organizations in the system and select the correct one from a list of search results.

Note: The instructions provided below are for searching for a Lead Organization. Use the same instructions for searching for Sponsors and Summary 4 Funding Sponsor/ Sources.

How to Search for Registered Organizations

1. On the navigation pane, click **Register Trial**, and then navigate to the **Lead Organization/Principal Investigator** section.

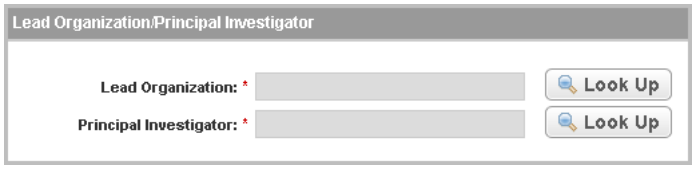


Figure 3.16 Lead Organization/Principal Investigator Section

2. Next to the **Lead Organization** field, click **Look Up**.

   The Search Organizations window appears.

Figure 3.17 Search Organizations Window

3. Provide as much information as you can about your organization. For example, if you know just the city location, type it in the **City** field. If you search by **CTEP** Identifier, you must provide the entire identifier.

   Tip: You can type the initial character, or series of characters in the **Name**, **City**, or **Zip** fields to narrow the search results, but do not use wildcard symbols (*). For example, to search for organizations in Rockville only, type ***R***, S***o***, or ***Roc*** in the **City** field.

Note: You must enter search criteria in at least one field.

4. Click **Search**.

   The Search Organizations window displays the results of your search.

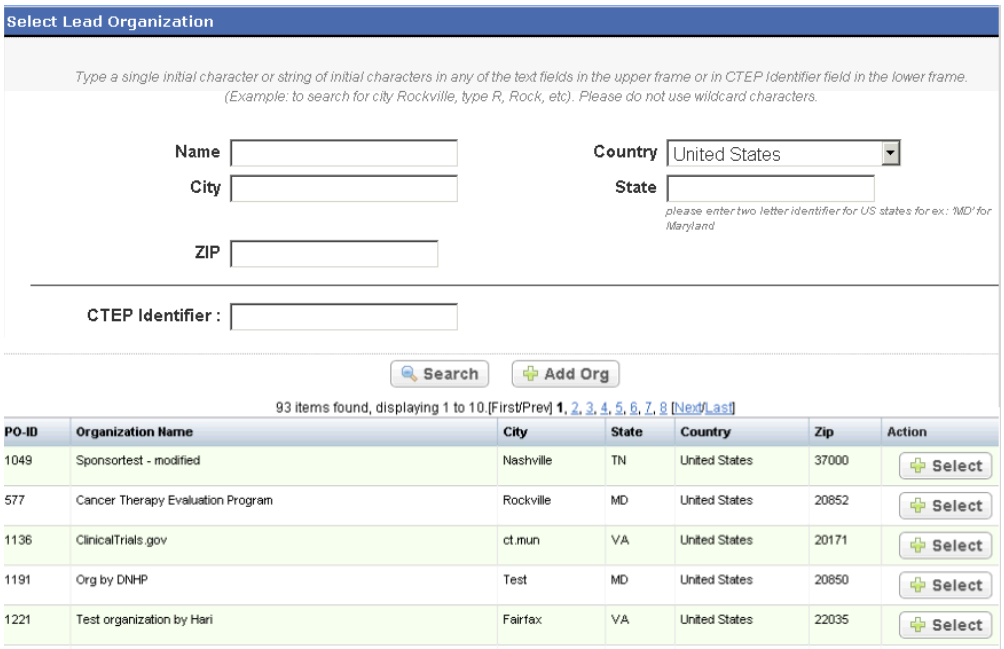


Figure 3.18 Search Organizations Window – Search Results

Tip: If your organization is not listed, you may have searched too narrowly (that is, you may have provided too much information about the organization). If the list of results is very long and contains many organizations that are similar to yours, you can narrow your search by providing more information. Refer to Step 5 for instructions.

5. If your organization was not listed, do one of the following to modify your search:

   - To broaden your search so that more organizations are listed in the search results, delete one or more of your criteria. For example, if you searched by part of the organization's name, city, state, and zip code in your original search, you may want to search by state alone.

   - or -

   - To narrow your search so that fewer organizations are listed in the search results, provide more about your organization. For example, if you searched by organization name only in your original search, you may want to search by city in addition to the name.

6. Click **Search**.

   The Search Organizations window displays the results of your new search. See *Figure 3.18, Search Organizations Window – Search Results,* on page 43.

7. Scroll through the results list until you locate your organization, and then click **Select**.

The organization name you selected appears in the **Lead Organization** field in the **Lead Organization/Principal Investigator** section.

If you don't find your organization in the system, you can register it as a new one. For instructions, see *Adding Organizations* on page 44.

Adding Organizations

If your organization is not currently registered in the system, you can register it at the same time you register your trial. Be sure to search the system's registered organizations first before you register a new one. This will ensure that you do not create a duplicate record in the system.

Note: The instructions provided below are for registering a Lead Organization. Use the same instructions for registering Sponsors and Summary 4 Funding Sponsor/Sources.

How to Register an Organization

1. On the navigation pane, click **Register Trial**, and then navigate to the **Lead Organization/Principal Investigator** section.

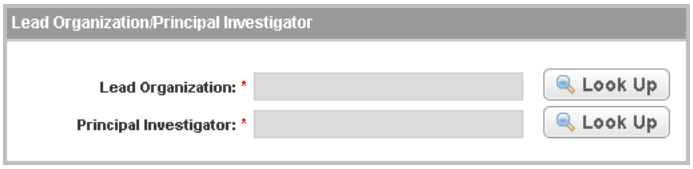


Figure 3.19 Lead Organization/Principal Investigator Section

2. Next to the **Lead Organization** field, click **Look Up**.

   The Organization Lookup page appears.

Figure 3.20 Organization Lookup Page – Search for an Organization

3. Click **Add Org**.

   The Add Organization window appears.

Figure 3.21 Add Organization Window

4. In the **Organization Name** field, type the full name of your organization.
5. Provide information in all required fields—those marked with an asterisk (*), and then click **Save**.

   Your new organization is saved in the system and appears below the information you provided.
6. Click **Select**.

   The **Organization Name** field is populated with the name you just registered.

Registering Persons

You can register an investigator if you are unable to find the person listed in the system. Before you register an investigator, be sure to search the system's registered investigators to ensure that you do not create a duplicate record. (See *Searching for Principal Investigators* on page 45.) If your search results do not contain the name of your investigator, you can register a new one. (See *Adding Principal Investigators* on page 47.)

Searching for Principal Investigators

If you are unsure of the name of the principal investigator for the trial that you are registering, you can search for one in the system and select the correct one from a list of search results.

Tip: If you don't find your investigator in the system, you can register it as a new one. For instructions, see *Adding Principal Investigators* on page 47.

How to Search For Principal Investigators

1. On the navigation pane, click **Register a Trial**, and then navigate to the **Lead Organization/Principal Investigator** section.

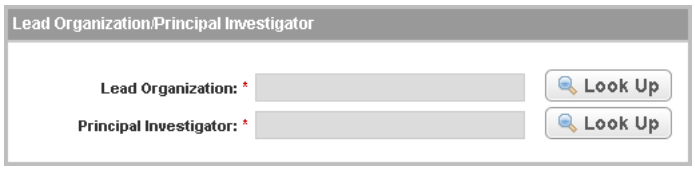


Figure 3.22 Lead Organization/Principal Investigator Section

2. Next to the **Principal Investigator** field, click **Look Up**.

   The Select Principal Investigator page appears.

Figure 3.23 Select Principal Investigator Page – Search Persons

3. Provide as much information as you can about your investigator.

   Tip: You can type the initial character, or series of characters in either of the **Name** fields to narrow the search results, but do not use wildcard symbols (*). For example, to search for an investigator whose last name is Slocum, type ***S***, ***Sl***, or ***Slo*** in the **Last Name** field.

   Note: You must enter search criteria in at least one field.

4. Click **Search**.

   The Select Principal Investigator page displays the results of your search.

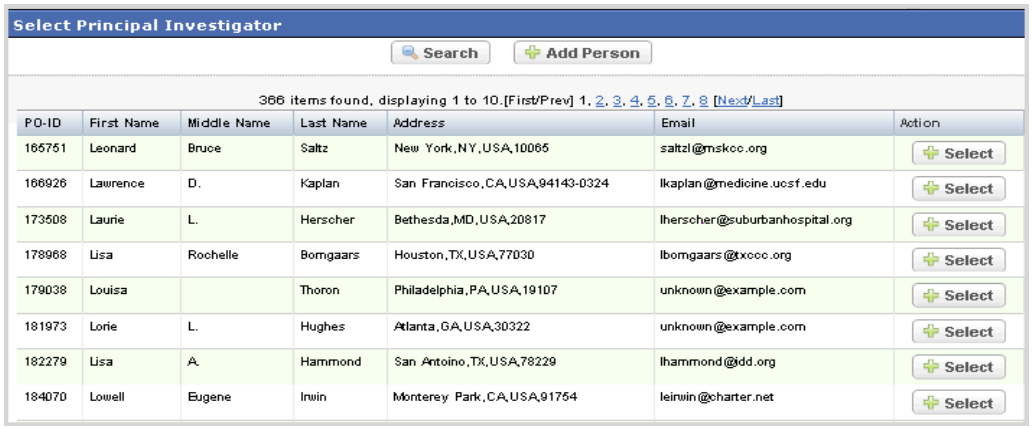


Figure 3.24 Principal Investigator Lookup Page – Search Results (partially redacted)

Tip: If your principal investigator is not listed, you may have searched too narrowly (i.e. you may have provided too much information about the person). If the list of results is very long and contains many names that are similar to yours, you can narrow your search by providing more information. Refer to Step 5 for instructions.

5. Scroll through the results list until you locate your principal investigator, and then click **Select**. The investigator's name you selected appears in the **Principal Investigator** field in the **Lead Organization/Principal Investigator** section.

6. If your investigator was not listed, modify your search as follows:

   - To broaden your search so that more names are listed in the search results, delete one or more of your criteria. For example, if you searched by part of the person's names, email address, and CTEP Identifier in your original search, you may want to search by last name alone.

   - **or** -

   - To narrow your search so that fewer names are listed in the search results, provide more about your investigator. For example, if you searched by last name only in your original search, you may want to search by CTEP Identifier.

7. Click **Search**, and then repeat Step 5.

Adding Principal Investigators

If your trial's principal investigator's name is not currently registered in the system, you can register it at the same time you register your trial. Be sure to search the system's registered names first before you register a new one. This will ensure that you do not create a duplicate record in the system.

How to Register a Principal Investigator

1. On the navigation pane, click **Register Trial**, and then navigate to the **Lead Organization/Principal Investigator** section.

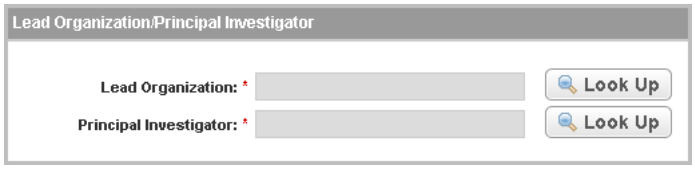


Figure 3.25 Lead Organization/Principal Investigator Section

2. Next to the **Principal Investigator** field, click **Look Up**.

   The Select Principal Investigator page appears.

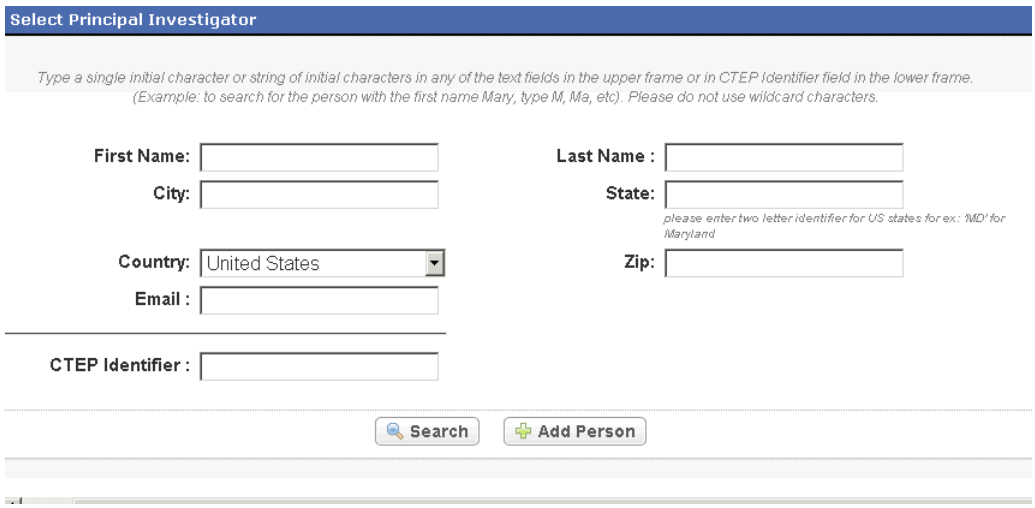


Figure 3.26 Select Principal Investigator Page – Search Persons

3. Click **Add Person**.

   The Add Person window appears.

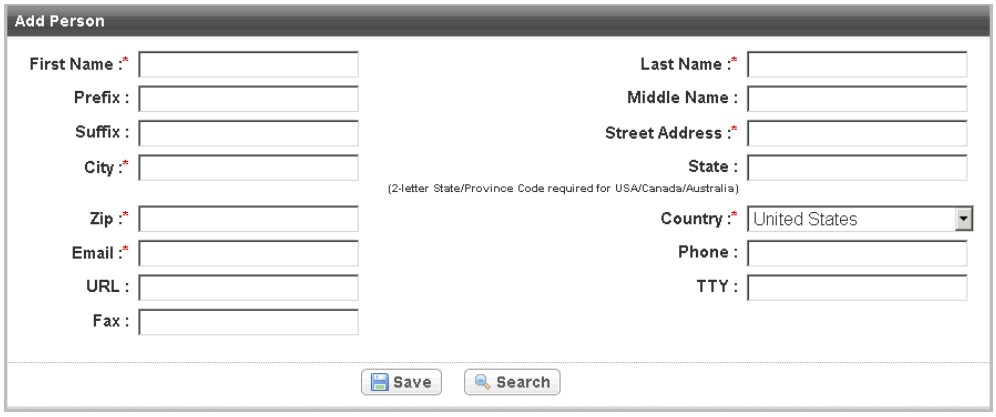


Figure 3.27 Add Person Window

4. Type or select as much information as possible in the fields provided. You must complete all required fields, marked with an asterisk (*).
5. Click **Save**.

6. Your new investigator is saved in the system and the **Principal Investigator** field on the **Register Trial** page is populated with the name you just registered.

Registering Multiple Trials in a Batch

Before you begin, you must request authorization from the CTRP to upload batches of trials. To request authorization, submit a request to the Help Desk via email addressed to: ncicb@pop.nci.nih.gov.

As an authorized CTRP submitter you can use the CTRP Registration Site's batch upload feature to register multiple new trials that were conducted at a given site.

Note: The CTRP provides you with the link to the batch upload website when it issues to authorization to upload batches.

In the current release, you can supply a single grant, a single IND/IDE, and a maximum of 5 trial documents.

You must upload each of the following types of files when you register multiple trials:

- Data documents – Documents that contain all the requisite information about the protocol. See *Data Requirements for Batch Uploads* on page 50 and *Appendix B, Batch Upload Data Specifications*, on page 75.
  - Format: Microsoft Excel file (`{filename}.xls`)
- Trial-related documents – Protocol and IRB documents, among others.
  - Format: compressed Word files (`{filename}.zip`)

  Note: Currently you are required to supply your documents as compressed Microsoft Word (`.doc`, `.docx`, or `.docm`), Adobe PDF, Microsoft Excel (`.xls`, `.xlsx`, `.xlsm`, or `.xlsb`), and/or WordPerfect files.

How to Upload a Batch of Trials

1. Navigate to the batch upload URL that you received from the CTRO.

   The Batch Upload page appears. All fields are required.

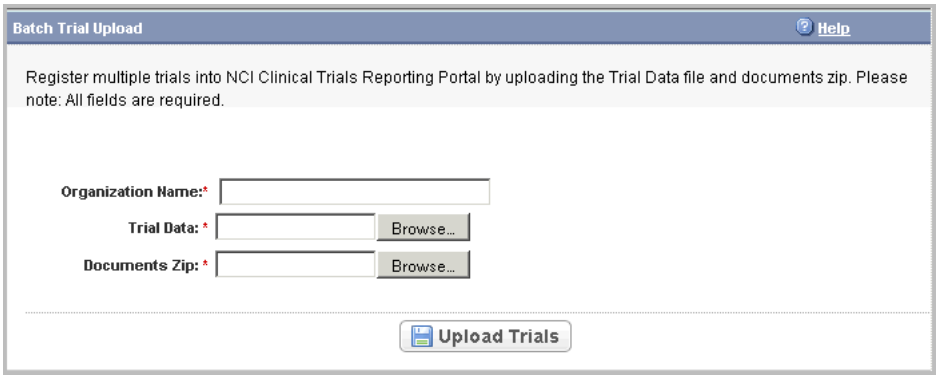


Figure 3.28 Batch Trial Upload Page

2. In the **Organization Name** field, type the name of the organization associated with the trials you want to register.

3. Beside the **Trial Data** field, click **Browse** and navigate to the `.xls` file that contains all the trial data. See *Data Requirements for Batch Uploads* on page 50.
4. Beside the **Documents Zip** field, click **Browse** and navigate to the `.zip` file that contains all the trial-related documents.
5. Click **Upload Trial**.

   The batch upload program generates a report after processing the batch data and emails it to the submitter. The report includes a brief summary and the detailed status of each trial.

Data Requirements for Batch Uploads

Elements that are required for single trial registration are also required for batch uploads, with the exception of person/organization attributes. The complete set of person/organization attributes for registering new persons/organizations is required for Principal Investigator, Lead Organization, Sponsor, and Summary 4 Sponsor/Source trial functional roles.

In addition to the data elements listed above, you must provide certain other information depending on the values you provided, as listed in*Table 3.14*

Detailed specifications are provided in *Appendix B, Batch Upload Data Specifications*, on page 75.

If you provide this value...	***You must also provide/select this***
Primary purpose of a trial = "Other"	A comment that describes the purpose of the trial.
Study type = "Interventional" - **and** - Lead organization of participating organization type = "cancer center"	Summary 4 Source Category information
If lead organization or participating organization type = "cancer center"	Summary 4 Source Category information
Any value for one of the following: • Funding Mechanism • NIH Institution Code • Serial Number • NCI Division/Program	Values for the rest of those listed as well
Any value for Grant Serial Number	A grant serial number that is 5 or 6 digits long
Any value for one of the following IND/IDE elements: • Type • Serial number • Grantor • Holder type	Values for the rest of those listed as well

Table 3.14 Data element requirements based on selected values

If you provide this value...	*You must also provide/select this*
(IND/IDE) Grantor Type = IND	CDER or CBER
(IND/IDE) Grantor Type = IDE.	CDRH
(IND/IDE) Holder Type ID = 'NIH',	NIH Institution code
(IND/IDE) Holder Type ID = 'NCI'	NCI Division/Program code
Has Expanded Access = “Yes”	Expanded Access Status code
Trial Start Date Type = “Actual”	A date that is current or past
Trial Start Date Type = “Anticipated”	A date that is in the future
Primary Completion Date Type = “Actual”	A date that is current or past
Primary Completion Date Type = “Anticipated”	A date in the future
If Current Trial Status = “Active”	Trial Start Date must be the same as, or precede, the Current Trial Status Date Trial Start Date type = “Actual”
If Current Trial Status = “Active” - **and** - Actual Trial Start Date precedes Current Trial Status Date	The actual Start Date in place of the Current Trial Status Date
If Current Trial Status = “Active”	A Trial Start Date that is the same as Current Trial Status Date, where type = “Actual”
If Current Trial Status = “Approved”	Trial Start Date type = “Anticipated”
Current Trial Status ≠ “Approved”	Trial Start Date type = “Actual”
Current Trial Status = “Completed”	A Primary Completion Date that is the same as Current Trial Status Date, where type = “Actual”
Current Trial Status = “Completed” - **or** - Current Trial Status = “Administratively Completed”	A Primary Completion Date type that is “Actual”
Current Trial Status ≠ “Completed” - **or** - Current Trial Status ≠ “Administratively Completed”	A Primary Completion Date type that is “Anticipated”
Trial Start Date	A Primary Completion Date that is the same value or greater

Table 3.14 Data element requirements based on selected values (Continued)

CHAPTER

4

AMENDING REGISTERED TRIALS

This chapter describes how to make amendments to trials currently registered and verified in the CTRP, and how to submit the amended trials using the CTRP Registration Site.

This chapter includes the following topics:

- *About Trial Amendments* on this page
- *Amending Verified Trials* on page 54
- *Reviewing and Submitting Amended Trials* on page 60

About Trial Amendments

The CTRP Registration Site enables you, in the role of trial submitter, to amend verified trials that you yourself have registered with the CTRP previously. The CTRO reviews and abstracts amended trial data just as it does with original submissions.

Most of the information, including documentation, that is required for original submissions is also required in amendments. To ensure that these requirements are met, you can review, edit, and print your amended data using the CTRP Registration Site features prior to submission.

Related topics:

- *Amendment Process Life Cycle*
- *Amending Verified Trials*
- *Uploading Amendment-Specific Documents*
- *Reviewing and Submitting Amended Trials*

Amendment Process Life Cycle

The CTRP processes submissions in much the same way as it processes original trial data. You may need to submit an amendment more than once during the course of your study, and the process is repeated each time you submit an amendment.

The progression of your trial throughout the phases of the life cycle relies on a series of communications—in the form of email messages—between you and the system at certain milestone events as follows:

1. You submit an amendment to your existing, verified trial to the CTRP.
2. The CTRO validates the new data and documents you provided, and the system sends you an acceptance (or rejection) message. If rejected, the system provides the reason for rejection and reinstates your latest verified trial.
3. If your amendment is accepted, the CTRO abstracts all the trial details and sends you a Trial Summary Report (TSR) that includes all the newly-modified data in the CTRP.
4. You review and validate the new TSR and email your approval to the CTRO.
5. The system sends you the verified TSR in MS Word and XML formats.
6. The amended trial appears in your Search My Trials results list and is again available for you to amend throughout the life of your trial.

Note: The TSR contains all the information that you submitted and all the trial data abstracted by the CTRO. The XML version of the TSR is formatted to facilitate trial registration with ClinicalTrials.gov.

Related topics:

- *Amending Verified Trials*
- *Uploading Amendment-Specific Documents*
- *Reviewing and Submitting Amended Trials*

Amending Verified Trials

In your role as submitter, you can amend only those trials that you have submitted and appear in search results when using the Search My Trials feature. See *Searching For Trials* on page 15.

Note: Only a person who is linked to a trial can submit an amendment in place of the original submitter. See *Adding Principal Investigators* on page 47.

Note: You are required to provide information for all fields marked with an asterisk (*).

How to Amend Verified Trials

1. On the navigation pane on the left side of the page, click **Search Trials**.

   The Search Trials page appears (*Figure 4.1*).

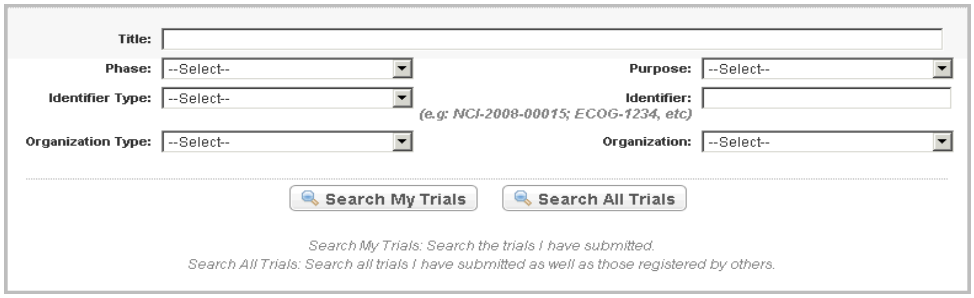
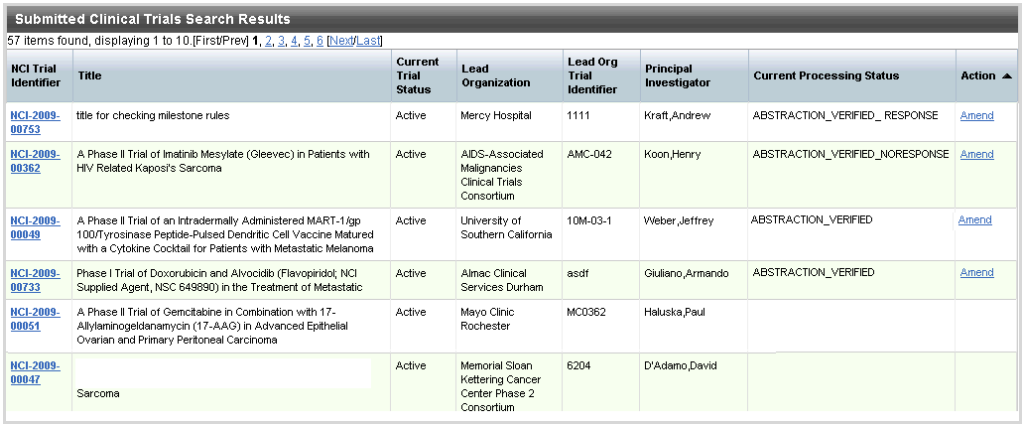


Figure 4.1 Search Trials Page

Tip: If you know the NCI trial number of your verified trial that you want to amend, in the **Identifier Type** field, select **NCI**, and then type the trial number in the **Identifier field**.

2. Click **Search My Trials**.

   The Search Trials page refreshes and displays a list of search results (*Figure 4.2*).



Submitted Clinical Trials Search Results

57 items found, displaying 1 to 10.[First/Prev] **1**, 2, 3, 4, 5, 6 [Next/Last]

NCI Trial Identifier	Title	Current Trial Status	Lead Organization	Lead Org Trial Identifier	Principal Investigator	Current Processing Status	Action
NCI-2009-00753	title for checking milestone rules	Active	Mercy Hospital	1111	Kraft,Andrew	ABSTRACTION_VERIFIED_ RESPONSE	Amend
NCI-2009-00362	A Phase II Trial of Imatinib Mesylate (Gleevec) in Patients with HIV Related Kaposi's Sarcoma	Active	AIDS-Associated Malignancies Clinical Trials Consortium	AMC-042	Koon,Henry	ABSTRACTION_VERIFIED_NORESPONSE	Amend
NCI-2009-00049	A Phase II Trial of an Intradermally Administered MART-1/gp 100/Tyrosinase Peptide-Pulsed Dendritic Cell Vaccine Matured with a Cytokine Cocktail for Patients with Metastatic Melanoma	Active	University of Southern California	10M-03-1	Weber,Jeffrey	ABSTRACTION_VERIFIED	Amend
NCI-2009-00733	Phase I Trial of Doxorubicin and Alvocidib (Flavopiridol; NCI Supplied Agent, NSC 649890) in the Treatment of Metastatic	Active	Almac Clinical Services Durham	asdf	Giuliano,Armando	ABSTRACTION_VERIFIED	Amend
NCI-2009-00051	A Phase II Trial of Gemcitabine in Combination with 17-Allylaminogeldanamycin (17-AAG) in Advanced Epithelial Ovarian and Primary Peritoneal Carcinoma	Active	Mayo Clinic Rochester	MC0362	Haluska,Paul		
NCI-2009-00047	Sarcoma	Active	Memorial Sloan Kettering Cancer Center Phase 2 Consortium	6204	D'Adamo,David		

Figure 4.2 "Search My Trials" Result List

For information about navigating the search results list, see *Navigating Through the Search Results List* on page 19.

3. Locate the trial you want to amend, and then click **Amend** in the corresponding **Action** column.

   The Amendment Trial page displays the data currently registered with the CTRP (*Figure 4.3*).

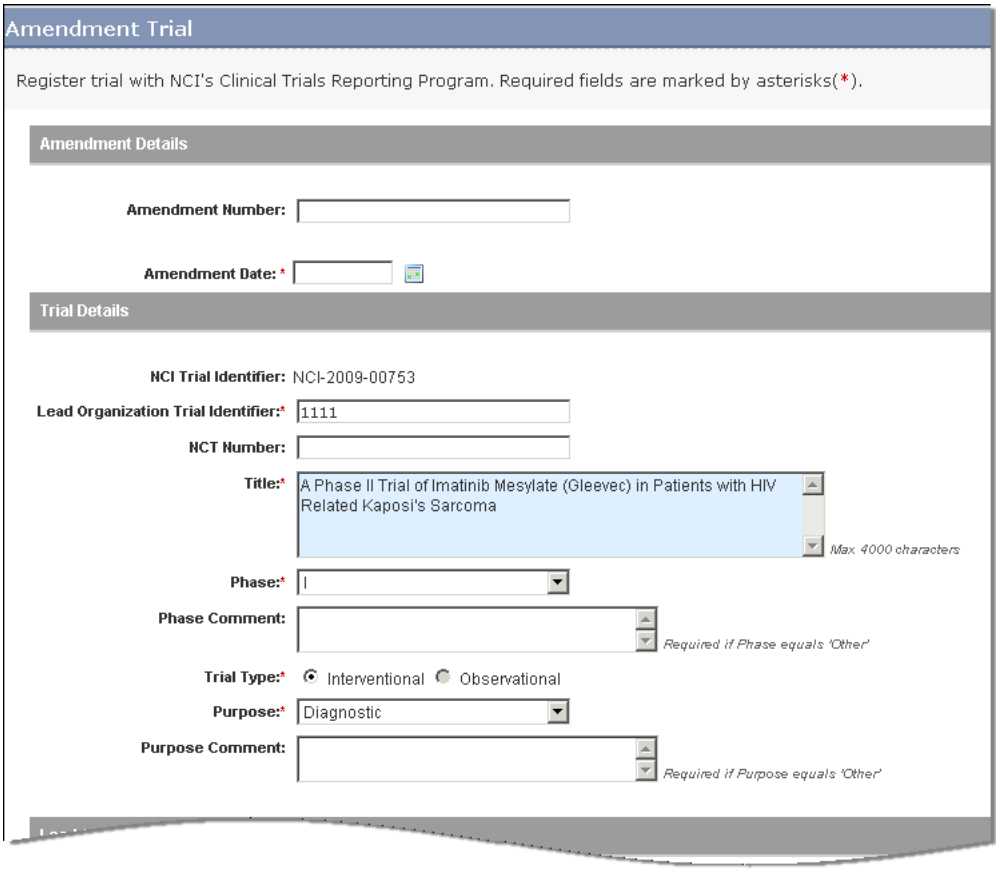


Figure 4.3 Amendment Trial Page – Amendment and Trial Details

4. In the **Amendment Number** field, type the number as recorded in the system (as designated by the leas organization) or in the amended protocol document.

   Note: Type the Amendment Number in alpha-numeric characters, dashes, and other special characters as appropriate.

5. In the **Amendment Date** field, type the date on which the trial was amended using the mm/dd/yyyy format, or, click the calendar icon ( ) and select the date from the calendar.
6. Make changes in the rest of the fields as per the amended protocol.
7. Upload the amendment-specific documents.
8. Review the amendment.
9. Submit the amended trial to the CTRP.

Instructions for providing/editing most of the trial amendment details are provided in *Registering Trials in the CTRP Registration Site* on page 23. Amendment-specific rules, values, etc., are provided for each section of the Amendment Trial page as follows:

- *Amending Trial Details* on page 57
- *Amending Lead Organization and Principal Investigator Details* on page 57

- *Amending Sponsor and Summary 4 Details* on page 58
- *Amending NIH Grant Details* on page 58
- *Amending Trial Status Dates* on page 58
- *Amending IND/IDE Details* on page 59
- *Uploading Amendment-Specific Documents* on page 59

Amending Trial Details

Instructions and values for completing the trial details section are the same for both original and amended submissions. See *Completing the Trial Details Section* on page 25.

Note: You cannot change an NCI trial identifier number.

Related topics:

- *Amending Verified Trials*
- *Amending Lead Organization and Principal Investigator Details*
- *Amending Sponsor and Summary 4 Details*
- *Amending NIH Grant Details*
- *Amending Trial Status Dates*
- *Amending IND/IDE Details*
- *Uploading Amendment-Specific Documents*

Amending Lead Organization and Principal Investigator Details

Only a person who is linked to a trial can submit an amendment in place of the original submitter or principal investigator (PI). You can amend the PI information so that a person who may be taking over the role from the current submitter/PI can submit amendments in the future.

Instructions for completing the lead organization and principal investigator section are the same for both original and amended submissions. See *Completing the Lead Organization/Principal Investigator Section* on page 28.

Tip: If the person taking on the role of PI is not registered in the CTRP system, you can "create" a new person record at this time. The record will remain pending until the CTRO curator can confirm the new person's details however. The same process applies to new lead organizations.

Related topics:

- *Amending Verified Trials*
- *Amending Trial Details*
- *Amending Sponsor and Summary 4 Details*

Amending Sponsor and Summary 4 Details

Instructions for completing the Summary 4 section are the same for both original and amended submissions. See *Completing the Lead Organization/Principal Investigator Section* on page 28.

Tip: If the person taking on the role of sponsor is not registered in the CTRP system, you can "create" a new person record at this time. The record will remain pending until the CTRO curator can confirm the new person's details however.

Related topics:

- *Amending Verified Trials*
- *Amending Lead Organization and Principal Investigator Details*
- *Amending Verified Trials*
- *Amending Lead Organization and Principal Investigator Details*

Amending NIH Grant Details

You can create a new NIH grant record only if you can provide all of the following details:

- Funding Mechanism
- NIH Institution Code
- Serial Number
- NCI Division/Program

Instructions for completing the NIH grant section are the same for both original and amended submissions. See *Completing the NIH Grant Information Section* on page 30.

Note: You cannot change an existing NIH grant number.

Related topics:

- *Amending Verified Trials*
- *Amending Sponsor and Summary 4 Details*
- *Amending IND/IDE Details*

Amending Trial Status Dates

You must complete all fields in the Status/Dates section. Valid dates for a given trial status depend on the other values you have entered, and whether those dates are actual or anticipated. Follow the rules for trial status dates provided in *Table 3.7* on page 35.

Instructions for completing the Trial Status Dates section are the same for both original and amended submissions. See *Completing the Trial Status/Dates Section* on page 35.

Related topics:

- *Amending Verified Trials*

- *Reviewing and Submitting Amended Trials*

Amending IND/IDE Details

Instructions for completing the IND/IDE section are the same for both original and amended submissions. See *Completing the IND/IDE Information Section* on page 36.

Note: You cannot change an existing IND/IDE serial number.

Related topics:

- *Amending Verified Trials*
- *Amending Sponsor and Summary 4 Details*
- *Amending NIH Grant Details*

Uploading Amendment-Specific Documents

The following amendment-specific documents are required with submission:

- Change memo document – Contains a summary of changes to the original, or last amended, trial submission
- Amended protocol (or Proprietary Protocol document)
- IRB approval for the amended protocol
- Participating sites document – Required if there have been changes to the following:
  - Participating sites/investigators
  - Contact information
  - Trial status
- Informed Consent – Required if you have a new informed Consent document that is not attached to the amendment protocol

The CTRP Registration Site accepts documents in the following formats:

- PDF
- MS Word
- MS Excel
- Correl Word Perfect

Instructions for completing the IND/IDE section are the same for both original and amended submissions. However, additional fields are provided specifically for the amendment-related documents. See *Completing the Trial Related Documents Section* on page 40.

Note: You cannot update or delete existing documents.

Related topics:

- *Amending Verified Trials*

- *Amending Trial Details*
- *Amending Trial Status Dates*

Reviewing and Submitting Amended Trials

After you have completed amending the trial information, review the amendment for errors and edit any details that do not match the changes in your change memo or amended protocol document. You can print a copy of the Amendment Trial page to facilitate the review and/or keep for your records.

How to Review and Submit Amended Trials

1. Complete all modifications to the most recent trial submission.
2. Scroll to the bottom of the **Amendment Trial** page, and click **Review Trial**.

   The system checks for errors and missing information and displays the results in a message at the top of the Review Trial Details page. Indicators mark specific fields that you must complete or correct in order to submit the trial.
3. Correct any errors if indicated, and repeat the previous step as many times as necessary until the amendment is error-free.

   Note: The Review Trial Details page is read-only. To edit information that you have reviewed, see *Editing Amendment Details* on page 60
4. Click **Submit**.

Related topics:

- *Amending Verified Trials*
- *Editing Amendment Details*
- *Printing Amended Trial Information*

Editing Amendment Details

You can edit your amended trial details after you have reviewed them at any time before you submit the trial to the CTRP.

How to Edit Amendment Details

1. Scroll to the bottom of the **Review Trial Details** page, and click **Edit**.

   The **Amendment Trial** page displays all information you have provided in editable form.

   Caution: You must upload the amendment-related trial documents again each time you click the Edit button.
2. Make changes as necessary and then follow the instructions in *Reviewing and Submitting Amended Trials* on page 60.

Related topics:

- *Amending Verified Trials*

- *Reviewing and Submitting Amended Trials*
- *Printing Amended Trial Information*

Printing Amended Trial Information

You can print a copy of the amended trial to facilitate the review and/or keep for your records. You must review the amendment in order to access the print feature. For instructions on reviewing the trial, see *Reviewing and Submitting Amended Trials* on page 60.

How to Print Amended Trial Information

1. Review the amended trial.
2. Scroll to the bottom of the **Review Trial Details** page, and click **Print**.

Related topics:

- *Amending Verified Trials*
- *Reviewing and Submitting Amended Trials*
- *Editing Amendment Details*

CHAPTER

5

MANAGING YOUR ACCOUNT

This chapter provides instructions for modifying your CTRP Registration Site account, and for resetting your password.

This chapter includes the following topics:

- *Editing User Information* on this page
- *Managing Your Password* on page 64

Editing User Information

You can update account information after you register as a user.

How to Edit Your Account Information

1. Do one of the following to access the **My Account** page:

   - On the right side of the title bar at the top of the page, click your ***Username*** link

   - **or** -

   - On the navigation pane on the left side of the page, click **My Account**.

   The My Account page appears, populated with the information you previously supplied for your account.

2. In the **Your Account Profile** section, complete the remainder of the fields requesting personal information. Fields with an asterisk (*) are required.
3. Specify the organization with which you are affiliated.
4. Click **Submit Account Updates** to save changes to the account information.

Managing Your Password

You can change your CTRP Registration Site password at any time when logged in. And, should you forget your password, you can reset it. For instructions, see *Changing Your Password* on page 64 and *Resetting Your Password* on page 64.

Changing Your Password

You can change your CTRP Registration Site password only once you have logged in to the application.

How to Change Your Password

1. Do one of the following to access the **User Account** page:
   - On the right side of the title bar at the top of the page, click your ***Username*** link

   - **or** -

   - On the navigation pane on the left side of the page, click **My Account**.

   The My Account page appears, populated with the information you previously supplied for your account.
2. In the **Login Information** section, type a new password in the **Password** field.
3. In the **Re-type Password** field, retype the password to confirm it.
4. Click **Submit Account Updates** to save your changes.

Resetting Your Password

In the event that you can not remember your password, you can request a password reset.

How to Reset Your Password

1. On the navigation pane on the left side of the page, click **Log In**.
2. On the Login page, click the **Forgot Your Password** link, and continue with step 3 on page 8.

APPENDIX A

METADATA DEFINITIONS

The NCI Clinical Trials Reporting Program Trial Registration Site captures trial details, or metadata, as entered by a trial submitter. *Table A.1* describes the metadata associated with clinical trials.

ALLOCATION	
Participant assignment to an intervention group.	
N/A – Single arm study.	Randomized Controlled Trial – Participants are assigned to intervention groups by chance.
Non-randomized Trial – Participants are expressly assigned to intervention groups through a non-random method, such as physician choice.	
Amendment Number	
Number that is assigned to the amended protocol by the lead organization. Can be the part of the amended protocol document.	
CURRENT TRIAL STATUS DATE	
Date the trial status was assigned to the trial, using the format mm/dd/yyyy.	
Example: 10/28/2008	
FUNDING MECHANISM	
NCI code used to identify areas of extramural research activity applied to various funding mechanisms.	
B09 – Mental Health Services Block Grant	**D43** – International Training Grants in Epidemiology
C06 – Research Facilities Construction Grant	**D71** – International Training Program Planning Grant
DP1 – NIH Director's Pioneer Award (NDPA)	**X02** – Pre-application
DP2 – NIH Director's New Innovator Awards	

Table A.1 Descriptions of trial metadata

IDENTIFIER TYPE	
Type of organization (system) that assigns the identifier to the trial (for example, Lead Organization, or NCI CTRP)	
NCI – National Cancer Institute	**Lead Organization** – Organization responsible for the overall scientific and administrative coordination, study monitoring, and data management activities of a particular clinical trial.
***INSTITUTE CODE** (NIH GRANT CODE)*	
NIH code used to identify the first major-level subdivision—the NIH organization that supports a grant. The support may be financial or administrative.	
AA – National Institute on Alcohol Abuse and Alcoholism	**HD** – National Institute of Child Health and Human Development (NICHD)
AG – National Institute on Aging	**HG** – National Human Genome Research Institute (NHGRI) - formerly NCHGR
AI – National Institute of Allergy and Infectious Diseases	**HL** – National Heart, Lung and Blood Institute (NHLBI)
AO – NIAID Research Support	**HS** – Agency for Healthcare Research and Quality (AHRQ) - not a part of NIH
AR – National Institute of Arthritis and Musculoskeletal and Skin Disease	**LM** – National Library of Medicine (NLM)
AT – National Center for Complementary and Alternative Medicine	**MD** – National Center on Minority Health and Health Disparities (NCMHD)
CA – National Cancer Institute (NCI)	**MH** – National Institute of Mental Health (NIMH)
CC – NIH Clinical Center	**NCCAM** – National Center for Complementary and Alternative Medicine
DA – National Institute on Drug Abuse (NIDA)	**NCMHD** – National Center on Minority Health and Health Disparities
DC – National Institute on Deafness and Other Communication Disorders (NIDCD)	**NR** – National Institute of Nursing Research (NINR)
DE – National Institute of Dental and Craniofacial DK National Institute of Diabetes and Digestive and Kidney Diseases	**NS** – National Institute of Neurological Disorders and Stroke (NINDS)
EB – National Institute of Biomedical Imaging and Bioengineering (NIBIB)	**OD** – Office of the Director
ES – National Institute of Environmental Health Sciences (NIEHS)	**RR** – National Center for Research Resources (NCRR)
EY – National Eye Institute (NEI)	**TW** – Fogarty International Center (FIC)
GM – National Institute of General Medical Sciences (NIGMS)	
INTERVENTION MODEL	
Design of an interventional study.	

Table A.1 Descriptions of trial metadata (Continued)

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.
LEAD ORGANIZATION	
Organization responsible for the overall scientific and administrative coordination, study monitoring, and data management activities of a particular clinical trial.	
Example: NSABP-B-40	
LEAD ORGANIZATION TRIAL IDENTIFIER (ID)	
Unique identification assigned to the protocol by the lead 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.	
Example: Merck-023 Note: Inter-Group trials use the lead Groups trial number.	
MASKING	
Knowledge of intervention assignment	
Open – No masking	**Double Blind** – Two or more parties are unaware of the intervention assignment.
Single Blind – One party, either the investigator or participant, is unaware of the intervention assignment; also called single-masked study.	
MILESTONES	
Record progress in trial processing and set the trial processing status. Interrelated with on-hold states	
Submission Received Date – Date the trial was successfully submitted via the NCI CTRP Registration Site	**QC Completed Date** – Date that Quality Control (QC) of the abstraction was completed
Submission Acceptance Date – Date the trial submission was accepted by a document specialist who validated it	**PDQ Abstraction Completed Date** – Date that PDQ completed the abstraction of the selected subset of trial attributes
Ready for PDQ Abstraction Date – Initial date the trial record can be accessed by PDQ to abstract selected subsets of trial attributes	**Trial Summary Report Sent Date** – Date the Trial Summary Report was sent to the principal investigator or trial submitter
Submission Rejection Date – Date the trial submission was rejected by a document specialist who validated trial submission	**Submitter Trial Summary Report Feedback Date** – Date input was received by a document specialist from a principal investigator or trial submitter regarding data contained on the Trial Summary Report

Table A.1 Descriptions of trial metadata (Continued)

Ready for QC Date – Date the trial abstraction was completed so that QC of the abstraction can be initiated	**Initial Abstraction Verified Date** – Date the verification of abstracted data is recorded by a document specialist who received principal investigator's or trial submitter's approval on abstraction
QC Start Date – Date that QC of the abstraction was initiated	**On-going Abstraction Verified Date** – Recordation date for the update on verified abstraction by the principal investigator/trial submitter who reviewed the abstraction and confirmed that trial related data are correct. OR the date of the verified abstraction update triggered by specified events and automatically recorded by the system
NCI DIVISION/PROGRAM CODE	
Codes that represent individual NCI divisions and program codes.	
CCR – Center for Cancer Research	**OD** – Office of the Director, NCI, NIH
CTEP – Cancer Therapy Evaluation Program	**OSB/SPOREs** – Organ Systems Branch (OSB)/Specialized Programs of Research Excellence (SPOREs)
DCB – Division of Cancer Biology	**CIP** – Cancer Imaging Program
DCCPS – Division of Cancer Control and Population Sciences	**CDP** – Cancer Diagnosis Program
DCEG – Division of Cancer Epidemiology and Genetics	**TRP** – Translational Research
DTP – Developmental Therapeutics Program	**RRP** – Radiation Research Program
DCP – Division of Cancer Prevention	**N/A** – Not applicable
DEA – Division of Extramural Activities	
NCI TRIAL IDENTIFIER	
Unique identifier assigned to the trial by the NCI Clinical Trials Reporting Program Trial Registration Site.	
Example: NCI-2010-ABCD	
NIH GRANT INFORMATION	
NIH grant code. A concatenation of a number of elements. Note: The Grant Identification Number is also commonly referred to as Assignment Number, Application Number, or the Award Identification Number, depending upon its processing status.	
`1 R01 CA 009999 - 08 A1 S2` Note: There are no spaces in the grant code; they have been inserted in this example for clarification purposes only. where, **`1`** is the single-digit code identifying the type of application received and processed **`R01`** is the three-digit code identifying a specific category of extramural activity	

Table A.1 Descriptions of trial metadata (Continued)

CA is the two-letter code identifying the assignment or funding NIH Institute or Center

009999 is the six-digit number generally assigned sequentially to a series within an Institute, Center, or Division

- separates the serial number from the grant year

08 is the two-digit number indicating the actual segment or budget period of a project The grant year is preceded by a dash to separate it from the serial number.

A1 is the letter code for a resubmitted application, (commonly referred to as an Amendment) and related number that identifies a particular amendment record

S2 is the letter code for Revision (for Supplemental funding) and related number identifing a particular supplemental record.

PRIMARY PURPOSE	
Reason for the protocol.	
Epidemiologic – Studies among cancer patients and healthy populations that involve no intervention or alteration in the status of the participants, e.g., surveillance, risk assessment, outcome, environmental, and behavioral studies.	**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
Treatment – Protocol designed to evaluate one or more interventions for treating a disease, syndrome or condition.	**Outcome** – Studies among cancer patients and healthy populations that involve no intervention or alteration in the status of the participants, e.g., surveillance, risk assessment, outcome, environmental, and behavioral studies.
Prevention – Protocol designed to assess one or more interventions aimed at preventing the development of a specific disease or health condition.	**Ancillary** – Auxiliary studies that are stimulated by, but are not a required part of, a main clinical trial/study, and that utilize patient or other resources of the main trial/ study to generate information relevant to it. Ancillary studies included must be linked to an active trial or epidemiologic or other study and should include only patients accrued to that trial or study. Only studies that can be linked to individual patient or participant data should be reported.
Early Detection – Clinical trials directly testing the efficacy of devices, techniques, procedures; or tests for earlier detection or diagnosis of efficacy of devices, techniques, procedures; or tests for earlier or more accurate detection or diagnosis of disease.	**Correlative** – Laboratory based studies using specimens to assess cancer risk, clinical outcomes, response to therapies, etc. Only studies that can be linked to individual patient or participant data should be reported.
Diagnostic – Protocol designed to evaluate one or more interventions aimed at identifying a disease or health condition.	**Health Services Research** – Protocol designed to evaluate the delivery, processes, management, organization or financing of health care.

Table A.1 Descriptions of trial metadata (Continued)

Basic Science – Protocol designed to examine the basic mechanism of action (e.g., physiology, biomechanics) of an intervention.	**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).
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.	**Other** – Any trial type not defined here.

PRINCIPAL INVESTIGATOR
Investigator responsible for all aspects of the conduct of the study.
Example: Moitessier, Bernard

PROCESSING STATUS	
Position of the trial with respect to the abstraction process.	
All – Any status.	**Abstracted** – Trial has been abstracted and is available for further abstraction.
Submitted – Trial has been submitted but the abstraction process has not begun.	**Abstraction Verified Response** – Trial has been abstracted and completed, and the trial submitter has responded to the TSR sent for verification.
Rejected – Trial has been found invalid and is no longer available for abstraction.	**Abstraction Verified No Response** – Trial has been abstracted and completed, but the trial submitter has not responded to the TSR sent for verification.

RESPONSIBLE PARTY
Either of the following parties: • Sponsor of the clinical trial - or - • 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.
Example: Moitessier, Bernard

SPONSOR
Name of primary organization that oversees implementation of study and is responsible for data analysis.
Example: Bristol-Myers Squibb

STUDY CLASSIFICATION
Type of primary outcome or endpoint that the protocol is designed to evaluate

Table A.1 Descriptions of trial metadata (Continued)

Safety – Indication that an intervention is safe under conditions of proposed use.	**Bio-availability** – Rate and extent to which a drug is absorbed or otherwise available to the treatment site in the body.
Efficacy – The maximum ability of a drug or treatment to produce a result regardless of dosage. A drug passes efficacy trials if it is effective at the dose tested and against the illness for which it is prescribed. In the procedure mandated by the FDA, Phase II clinical trials gauge efficacy, and Phase III trials confirm it.	**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.
Safety/Efficacy – Combined study of safety and efficacy.	**Pharmacodynamics** – Action of drugs in living systems.
Bio-equivalence – Scientific basis for comparing generic and brand name drugs.	**Pharmacokinetics/dynamics**– Combined study of pharmacokinetics and pharmicodynamics.
SUMMARY 4 FUNDING CATEGORY	
Type of external sponsor or funding source based on the role/responsibility/participation in the study. Based on authorship, drug supplement, trial monitoring design, and implementation.	
National – National Cooperative Group trials	**Institutional** – In-house, internally reviewed trials, including those collaborative studies conducted with industry sponsorship in which the center is a primary contributor to the design, implementation, and monitoring of the trial, or participation in a multi-site trial initiated by an investigator at another center.
Externally Peer-Reviewed – R01s and P01s or other trial mechanisms funded by NIH or supported by other peer-reviewed funding organizations.	**Industrial** – Design and implementation of the study is controlled by the pharmaceutical company
SUMMARY 4 SPONSOR/SOURCE	
For clinical trials involving an agent or device or other intervention only: Primary organization responsible for funding the trial.	
Example: CTEP	
TITLE	
Official name of the protocol provided by the study principal investigator or sponsor.	
Example: A Pilot Study of Chemotherapy Plus Radiotherapy for Selected Stage IIIB (No Malignant Effusion) Non-Small Cell Lung Cancer	
TRIAL PHASE	
Code for a clinical trial that represents a distinguishable part or stage in a series of events or in a process of development. Clinical trials are broken into three or four phases. The different phases are as follows:	

Table A.1 Descriptions of trial metadata (Continued)

Phase 0 – Tests a new treatment that is available only in very limited quantities and which has never previously given to humans or for which there is extremely limited human experience to enable researchers to understand the path of the drug in the body and its efficacy.	**Phase III** – A study to compare the results of people taking a new treatment with the results of people taking the standard treatment (for example, which group has better survival rates or fewer side effects). In most cases, studies move into phase III only after a treatment seems to work in phases I and II. Phase III trials may include hundreds of people.
Phase I – The first step in testing a new treatment in humans. These studies test the best way to administer a new treatment (e.g., by mouth, intravenous infusion, or injection) and the best dose. The dose is usually increased a little at a time in order to find the highest dose that does not cause harmful side effects. Because little is known about the possible risks and benefits of the treatments being tested, phase I trials usually include only a small number of patients who have not been helped by other treatments	**Phase IV** – Evaluates the long-term safety and efficacy of a treatment for a given indication and studies side effects that may have become apparent after the phase III study was completed
Phase I/II – A clinical research protocol designed to study the safety, dosage levels and response to new treatment. Phase I/II trials combine a Phase I and a Phase II trial of the same treatment into a single protocol.	**Pilot** – Initial study examining a new method or treatment.
Phase II – A study to test whether a new treatment has an anticancer effect (for example, whether it shrinks a tumor or improves blood test results) and whether it works against a certain type of cancer.	**N/A** – Not applicable
Phase II/III – A trial to study response to a new treatment and the effectiveness of the treatment compared with the standard treatment regimen.	**Other** – Any phase not listed
TRIAL STATUS	
Code that represents the status of a trial in relation to the ability to enroll participants/patients.	
Approved – Trial has been approved	**Temporarily Closed to Accrual and Intervention** – Trial is temporarily not accruing. Participants are not receiving intervention.
Active – Trial is open for accrual	**Temporarily Closed to Accrual** – Trial is temporarily not accruing.
Closed to Accrual – Trial has been closed to participant accrual. Participants are still receiving treatment/intervention.	**Administratively Complete** – Trial has been completed prematurely (for example, due to poor accrual, insufficient drug supply, IND closure, etc.)

Table A.1 Descriptions of trial metadata (Continued)

Closed to Accrual and Intervention – Trial has been closed to participant accrual. No participants are receiving treatment/ intervention, but participants are still being followed according to the primary objectives of the study.	**Complete** – The trial has been closed to accrual; participants have completed treatment/intervention, and the study has met its primary objectives.
TRIAL TYPE	
Nature of the investigation; represents a clinical study by product, procedure, or method tested.	
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.

Table A.1 Descriptions of trial metadata (Continued)

APPENDIX

B

BATCH UPLOAD DATA SPECIFICATIONS

This chapter describes how to prepare trial data and trial documents when registering multiple trials in a batch. It also provides data specifications for the trial data.

This chapter includes the following topics:

- *Preparing the Trial Data File* on this page
- *Preparing Trial-Related Documents* on page 76
- *Trial Data Element Specifications* on page 77

Preparing the Trial Data File

The CTRP website provides a batch upload template, valid data values, data definitions, examples, and rules for registering batches of trials. This section contains a summary of the information required for the .xls document. See *Using the Batch Upload Template* on page 13.

The `.xls` file that contains the trial data you want to register via the CTRP Registration Site's batch upload feature, and the trial-related documents associated with it, must meet certain specifications for successful registration.

You must provide trial data in the Microsoft Excel format, `.xls`. This version of the batch upload feature supports the following data elements:

- One grant per trial
- One IND/IDE per trial
- 100 trials per file
- Interventional trials only

How to Prepare the Trial Data File

- In Microsoft Excel, list the trial elements required for registration in the order specified in the `CTRP_Registry_Batch_Upload.xls` file.

Preparing Trial-Related Documents

You must ensure that all trial-related document file names are unique. Depending on your own method of storing documents, you may have to rename your files.

For example:

Your directory structure is set up so that each trial has its own folder, and you name each document file by its topic, as illustrated in *Figure B.1* below.

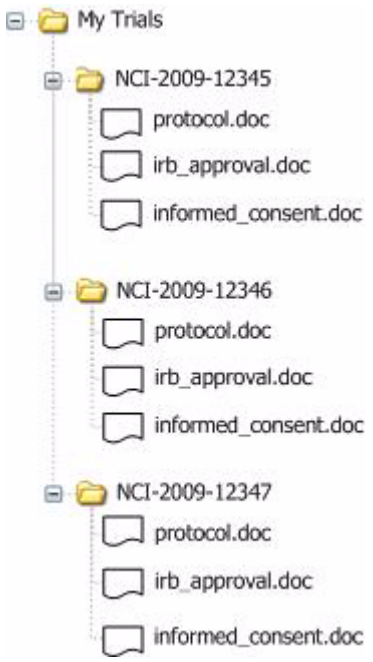


Figure B.1 Example Directory Structure for Trial-Related Documents

Without the directory structure, there is no way to tell which trial a document belongs to. Because there is no indication of directory structure in the batch upload file, you need to rename each file to associate it with a given trial and to prevent one file from overwriting another document that shares the same file name.

The best way to rename the files is to add the unique trial identifier as a prefix to each of the file names, as follows:

- `NCI-2009-12345_protocol.doc`
- `NCI-2009-12345_irb_approval.doc`
- `NCI-2009-12345_informed_consent.doc`
- `NCI-2009-12346_protocol.doc`
- `NCI-2009-12346_irb_approval.doc`

- NCI-2009-12346_informed_consent.doc
- NCI-2009-12347_protocol.doc
- NCI-2009-12347_irb_approval.doc
- NCI-2009-12347_informed_consent.doc

How to Prepare the Trial-Related Documents

1. If appropriate, identify each of the documents associated with a given trial by adding the trial's unique trial identifier as a prefix to the beginning of their file names.
2. Ensure that no two documents for the same trial share the same file name.
3. List the trial-related document file names for each trial in the trial data file (`.xls` file). You can list up to 5 files per trial record.
4. Zip all the trial documents. Do not include path names in the `.zip` file.

Trial Data Element Specifications

The `CTRP_Registry_Batch_Upload.xls` file lists all trial data required for registering multiple trials in batches. Trial data specifications include the following:

- Order in which the data must appear in an `.xls` file
- Trial data elements for which you provide the trial protocol details
- Designation of data element as being required or not
- Valid data values
- Comments
- Specifications for proprietary trials

To access the `CTRP_Registry_Batch_Upload.xls` file, see *Downloading Trial Registration Templates* on page 11.

For further details about trial data, refer to *Metadata Definitions* on page 65.

APPENDIX C

PARTICIPATING SITES DOCUMENT SPECIFICATIONS

This chapter provides the specifications—rules, formats, requirements, etc.—for Participating Sites documents.

This chapter includes the following topics:

- *Participating Sites Document Rules* on this page
- *Participating Site Data Element Specifications* on page 80

Participating Sites Document Rules

Participating site documents include treating site and collaborator information.

The CTRP website provides paricipating site document templates, valid data elements, and rules. See *Using the Participating Sites Template* on page 12.This section contains a summary of the participating sites document rules.

Note: Collaborator information is optional.

The following rules apply to participating site documents:

- Treating site information must include the following:
  - study treating site data
  - at least one study site investigator's information
  - treating site contact information
- Treating site data includes the following:
  - organization attribute
  - current recruitment status
  - status date
  - target accrual.
- Target accrual information for a study at a treating site is optional if the following are true:
  - the site is not a cancer center (as defined by the CTRP)
  - the lead organization is not a cancer center.

- Study site investigator information includes the following:
  - study site investigator data with person's attributes
  - investigator's role at the study at site
- Treating site contact information is optional if an investigator is used as contact person.
- The minimal set of treating site information includes the following:
  - treating site data
  - for single investigator studies: study site investigator's information if the investigator information is used as the site contact information
- For studies with multiple investigators, create one line per investigator/site using the treating site number as reference.

Participating Site Data Element Specifications

The `CTRP_Participating_Sites_Template.xls` file lists all trial data required for for participating site documents, including collaborating site information. To access the template, see *Downloading Trial Registration Templates* on page 11

GLOSSARY

Acronyms, objects, tools and other terms referred to throughout this CTRP Registration Site user's guide are described in this glossary.

Term	***Definition***
accepted trial	Validated trial. A submitted trial that has passed validation (conforms to the CTRO rules for valid submission).
accrual	The process of obtaining subjects for a study.
arm	Treatment group.
basic science	Protocol designed to examine the basic mechanism of action (e.g., physiology, biomechanics) of an intervention.
caBIG	Cancer Biomedical Informatics Grid
caDSR	Cancer Data Standards Repository
CBER	Center for Biologics Evaluation and Research
CBIIT	Center for Biomedical Informatics and Information Technology (formerly known as the National Cancer Institute Center for Bioinformatics or NCICB)
CCB	Cancer Centers Branch
CCCT	Coordinating Center for Clinical Trials
CCR	Center for Cancer Research
CDE	Common Data Element
CDER	Center for Drug Evaluation and Research
CDP	Cancer Diagnosis Program
CDRH	Center for Devices and Radiological Health
CGH	Comparative Genomic Hybridization
CIP	Cancer Imaging Program
CTAC	Clinical Trials Advisory Committee
CTEP	Cancer Therapy Evaluation Program
CTRO	Clinical Trials Reporting Office
CTRP	Clinical Trials Reporting Program
CTWG	Clinical Trials Working Group

Term	*Definition*
DCB	Division of Cancer Biology
DCCPS	Division of Cancer Control and Population Sciences
DCEG	Division of Cancer Epidemiology and Genetics
DCP	Division of Cancer Prevention
DCTD	Division of Cancer Treatment and Diagnosis
DEA	Division of Extramural Activities
DTP	Developmental Therapeutics Program
data monitoring committee	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 harm, or for futility.
delayed posting	Release of trial information on ClinicalTrials.gov is delayed until after an interventional device has been approved or cleared.
EBI	European Bioinformatics Institute
EVS	Enterprise Vocabulary Services
FDA	Food and Drug Administration
FDAAA	Food and Drug Administration Amendment Act (2007)
IDE	Investigational Device Exemption. Allows the investigational device to be used in a clinical study in order to collect safety and effectiveness data required to support a Premarket Approval (PMA) application or a Premarket Notification [510(k)] submission to FDA.
inclusion/exclusion criteria	Medical or social standards determining whether a person may or may not be allowed to enter a clinical trial. These criteria are based on such factors as age, gender, the type and stage of a disease, previous treatment history, and other medical conditions.
IND	Investigational New Drug. Authorization from the Food and Drug Administration (FDA) to administer an investigational drug or biological product to humans. Such authorization must be secured prior to interstate shipment and administration of any new drug or biological product that is not the subject of an approved New Drug Application or Biologics/Product License Application.
IRB	Institutional Review Board
lead organization	Organization responsible for the overall scientific and administrative coordination, study monitoring, and data management activities of a given clinical trial.
MedDRA	Medical Dictionary for Regulatory Activities
N/A	Not applicable
NCI	National Cancer Institute
NCICB	National Cancer Institute Center for Bioinformatics (now known as the Center for Biomedical Informatics and Information Technology or CBIIT)
NCT	National Clinical Trial

Term	*Definition*
NCTID	National Clinical Trial Identifier (ClinicalTrials.gov identifier)
OCE	Office of Communications and Education
OD	Office of the Director, NCI, NIH
OSB/SPOREs	Organ Systems Branch (OSB)/Specialized Programs of Research Excellence (SPOREs)
P01	NIH grant activity code for Research Program Project
PDQ	Physician Data Query
PI	Principal Investigator
PIO	Protocol Information Office
principal investigator	Appointed investigator responsible for conducting clinical trial, or for multi-site trials, the study chair
QC	Quality control
rejected trial	Trial did not pass validation (does not conform to the CTRO rules for valid submissions.)
R01	NIH grant activity code for Research Project
RRP	Radiation Research Program
section 801 trial	FDA-regulated interventional trial as defined in US Public Law 110-85, Title VIII, Section 801.
SPORE	Specialized Program of Research Excellence (Now TRP: Translational Research Program)
sponsor	Name of primary organization that oversees implementation of study and is responsible for data analysis.
TRP	Translational Research Program (Formerly SPORE)
trial status	The current stage or state of a clinical trial or study relative to other stages.
trial type	Nature of the trial. Identifies a clinical study by product, procedure, or method tested. The type of clinical trial performed, for example. efficacy, safety.
TRP	Translational Research
TSR	Trial Summary Report
URI	Uniform Resource Identifier
URL	Uniform Resource Locators
validated trial	Trial who’s details—as entered by a submitter—have been confirmed by a curator.
XML	Extensible Markup Language

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