NCI Clinical Trials Reporting Program Registration Site 3.1

User's Guide

Center for Biomedical Informatics
and Information Technology

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CONTENTS

About This Guide

This section introduces you to the NCI CTRP Trial Registration Site v.3.1 User's Guide. It includes the following topics:

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 and/or update 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 have worked with previous versions of NCI Clinical Trials Reporting Program Trial Registration Site, see *Additional References* on page 2.

If you are new to NCI Clinical Trials Reporting Program Trial Registration Site, read this brief overview, which explains what you will find in each chapter and appendix.

- *Chapter 1, Getting Started,* on page 5 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 27 describes how to submit, or register, trials using the CTRP Registration Site.
- *Chapter 4, Updating and Amending Registered Trials,* on page 71 describes how to update and make amendments to trials currently registered and verified in the CTRP.
- *Chapter 5, Managing Your Account,* on page 83 provides instructions for modifying your CTRP Registration Site account, resetting your password, and transferring trial ownership.
- *Appendix A, Batch Upload Data Specifications*, on page 87 describes how to prepare your trial data and documents. It also provides data specifications for the trial data.
- *Appendix B, Participating Sites Document Specifications*, on page 93 provides the specifications—rules, formats, requirements, etc.—for Participating Sites documents.
- *Appendix C, Metadata Definitions*, on page 95 defines the metadata associated with trials and provides examples of valid values for trial details.

Additional References

For more information about the NCI Clinical Trials Reporting Program Trial Registration Site, clinical trial protocols, and terminology, see the following references:

- Clinical Trials Reporting Program (http://www.cancer.gov/ncictrp)
- ClinicalTrials.gov (http://clinicaltrials.gov)
- PRS and U.S. Public Law 110-85 (http://prsinfo.clinicaltrials.gov/fdaaa.html)
- Glossary of CTRP Terms (http://www.cancer.gov/clinicaltrials/ctrp/page12)
- Dictionary of Cancer Terms (http://www.cancer.gov/dictionary/db_alpha.aspx?expand)
- CinicalTrials.gov XML File Upload Instructions (http://www.cancer.gov/clinicaltrials/ctrp/page11)

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**.

Convention	Description	Example
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 monospaced 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.

Role	Name	Affiliation
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Analyst	Nelli Shimko	ScenPro
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Tech Lead for Accruals	Hugh Reinhart	ScenPro
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Table 3.1 NCI-CTRP technical and domain experts listed by role

Role	Name	Affiliation
Developer	Kalpana Guthikonda	ScenPro
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QA Engineer	Sohal Shah	Ekagra

Table 3.1 NCI-CTRP technical and domain experts listed by role (Continued)

Application Support

If you have questions or comments regarding this document, or other CTRP topics, contact the CTRP as per the instructions below.

Email: ncictrp@mail.nih.gov (mailto:ncictrp@mail.nih.gov)	When submitting support requests via email, include the following: • 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

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

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, amend, and update 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 27. For information on registering multiple trials, see *Registering Multiple Trials in a Batch* on page 66.

Currently you can register *proprietary and non-proprietary interventional trials*. Future releases of this product 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.

Related topics:

- *Creating an Account* on page 6
- *Logging In to the CTRP Registration Site* on page 8
- *What's New in This Release* on page 6
- *Using CTRP Trial Registration Templates and Resources* on page 10

What's New in This Release

CTRP Registration Site version 3.1 has the following new features:

- User-friendly web-based interface for registering/reregistering propriety trials
- Multiple proprietary trial registration via batch upload
- Non-proprietary trial update via the user interface
- Multiple non-proprietary trial updates and amendments via batch upload
- Trial search by the principal investigator's name
- Trial search by amendment processing status
- Trial Summary Report enabled for change-tracking in MS Word
- Trial details include trial ownership and category

Related topics:

- *Creating an Account* on page 6
- *Logging In to the CTRP Registration Site* on page 8
- *Using CTRP Trial Registration Templates and Resources* on page 10

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, update, and amend multiple new trials that were conducted at a given site. Follow instructions in *Registering Multiple Trials in a Batch* on page 66

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**.

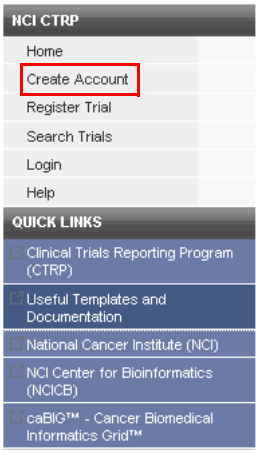


Figure 1.1 Navigation Pane

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

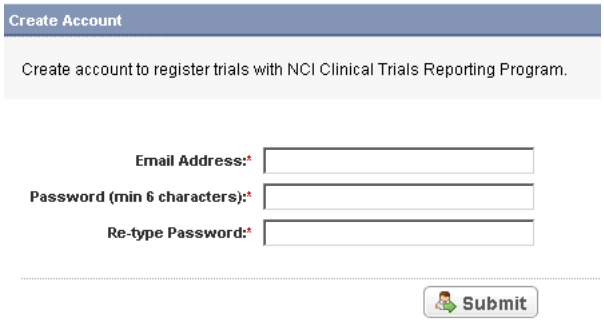


Figure 1.2 CTRP Registration Site – Create Account Page

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.

   Note: Contact information is required for internal administrative use only. Your information is not revealed to the public.

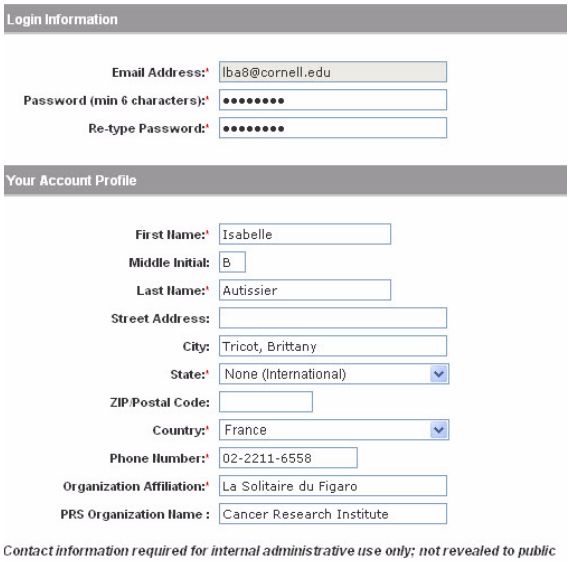


Figure 1.3 My Account Page

7. Complete the remaining personal information fields. Provide your professional information only. 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 State option **None (International).**

8. In the **Organization Affiliation** field**,** type the name of the organization you are affiliated with.
9. In the **PRS Organization Name** field, type the name of the organization as it is registered in the ClinicalTrials.gov Protocol Registration System.
10. Click **Submit**.

Related topics:

- *Logging In to the CTRP Registration Site*
- *Transferring Trial Ownership* on page 85
- *What's New in This Release*
- *Using CTRP Trial Registration Templates and Resources*
- *Managing Your User Account Profile*
- *Resetting Your Password*
- *Searching For Trials*

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**.

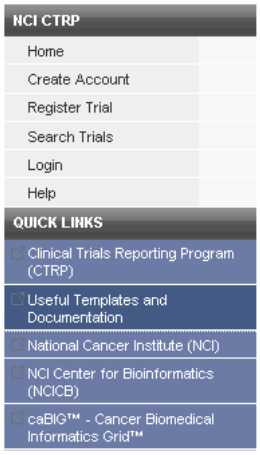


Figure 1.4 Navigation Pane

The Login page appears (*Figure 1.5*).

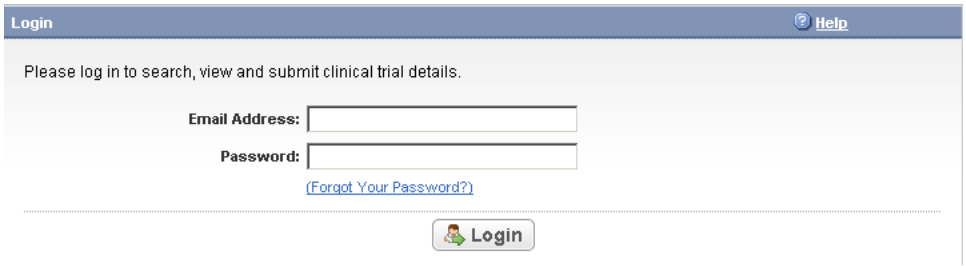


Figure 1.5 CTRP Registration Site – Login page

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 84.

4. Click **Login**.

   The notification regarding respondent burden appears.

5. After you read the public reporting burden notice, click **Accept**.

   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:

- *Resetting Your Password* on page 84
- *Searching For Trials* on page 16
- *Viewing Trial Details* on page 22
- *Registering Non-Proprietary Trials in the CTRP Registration Site* on page 27
- *About the CTRP Registration Site* on page 5

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, update, 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.

Related topics:

- *Downloading Trial Registration Templates* on page 10
- *Using the Proprietary Trial Template* on page 11
- *Using the Participating Sites Template* on page 11
- *Using the Batch Upload Template* on page 12

Downloading Trial Registration Templates

You can download the following templates (MS Excel files) from the CTRP website (http://www.cancer.gov/clinicaltrials/ctrp/page11):

- Non-proprietary trial templates:
  - **CTRP Registry non-Proprietary Batch Upload Template**. Use this template as a guide to record trial data required for registering multiple non-proprietary trials, updates, and amendments in batches.
  - **CTRP Registry non-Proprietary Participating Sites Template**. Use this template to record interventional trial 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.

Note: For information about trial updates and amendments, see *Updating and Amending Registered Trials* on page 71.

- Proprietary trial templates:
  - **CTRP Registry Proprietary Batch Upload Template**. Use this template as a guide to record trial data required for registering multiple proprietary trials.
  - **CTRP Registry Proprietary Participating Sites Template**. Use this template to record interventional proprietary trial participating site data.

How to Download CTRP Templates

1. On the navigation pane, click **Useful Templates and Documentation**.

   The NCI CTRP website Resources page appears in a new browser window.
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 mailto:ncictrp@mail.nih.gov.

Related topics:

- *Using the Proprietary Trial Template* on page 11
- *Using the Participating Sites Template* on page 11
- *Using the Batch Upload Template* on page 12

Using the Proprietary Trial Template

The proprietary trial template is designed primarily for submitting multiple industry-lead trials with contractual obligations that restrict sharing of their protocol documents.

You must email the completed trial Proprietary template to the CTRO staff, who will then register your trials using the data you provided.

Tip: You can use the same template to add participating site information to a proprietary trial that a different participating site has already registered.

Related topics:

- *Downloading Trial Registration Templates* on page 10
- *Using the Participating Sites Template* on page 11
- *Using the Batch Upload Template* on page 12

Using the Participating Sites Template

The participating sites template is designed for recording participating site data for interventional non-proprietary trials, 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 93.

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 or central contact information

  Note: Generic contact information is accepted
- 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, or if the central contact information is provided
- If the contact person is the investigator, the participating site data and study site investigator's information are mandatory

Related topics:

- *Downloading Trial Registration Templates* on page 10
- *Using the Proprietary Trial Template* on page 11
- *Using the Batch Upload Template* on page 12

Using the Batch Upload Template

The Batch Upload Template contains the trial elements required for registering, updating, and amending trials, 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. For further details, see *Batch Upload Data Specifications* on page 87.

Related topics:

- *Downloading Trial Registration Templates* on page 10
- *Using the Proprietary Trial Template* on page 11
- *Using the Participating Sites Template* on page 11

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

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 C, Metadata Definitions*, on page 95 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.

Related topics:

- *Searching For Trials*
- *Registering Non-Proprietary Trials in the CTRP Registration Site*
- *About the CTRP Registration Site*
- *Creating an Account*
- *Working with Search Results*
- *Viewing Trial Details*

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 6.

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 18. All registered users can search trials with the "Validated" processing status. Additionally, you can search trials that you registered which have not been 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*).

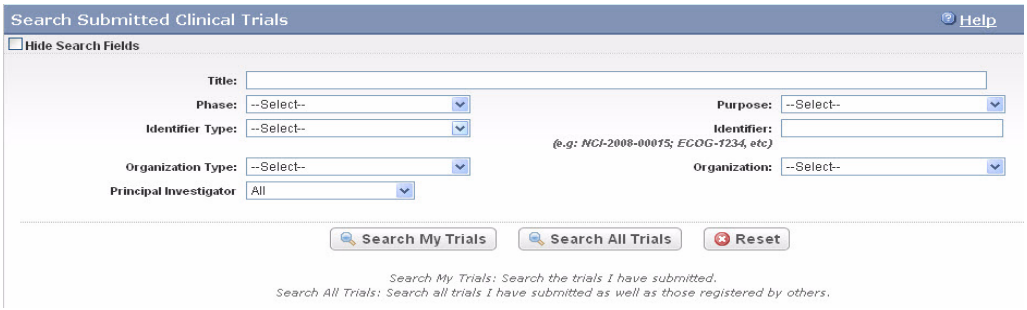


Figure 2.1 Search Trials Page

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.

Table 2.1 Trial Search Criteria

To search by this...	*Do this...*
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
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 Organization 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)

To search by this...	Do this...
Principal Investigator	Select the principal investigator's name 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*.

   Tip: You can create more space on your monitor for the search results list by hiding the search fields. To do so, select the **Hide Search Fields** check box at the top left side of the search criteria section.

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*.

Related topics:

- *About Clinical Trial Metadata*
- *Registering Non-Proprietary Trials in the CTRP Registration Site*
- *About the CTRP Registration Site*
- *Creating an Account*
- *Working with Search Results*
- *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," and the CTRO notifies you by email. Otherwise they assign the status "rejected." In the event that your submission is "rejected," the CTRO sends you an email message indicating the status and reason for the rejection.

Note: If notified about a rejected trial, 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	Original trial submitted but not validated	Submitter	Yes
Amendment Submitted	Amendment submitted but not validated	• Submitter • Other users	Yes
Accepted	Trial passed validation	• Submitter • Other users	Yes
Rejected	Trial did not pass validation	No one	No
Abstracted	Trial has been abstracted	• Submitter • Other users	Yes
Verification Pending	Trial has been abstracted, and the TSR has been sent to the trial submitter for abstraction verification	• 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

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?"
Abstraction Verified No Response	Submitter has not returned verification feedback to the CTRO within the allowed time frame	• Submitter • Other users	Yes

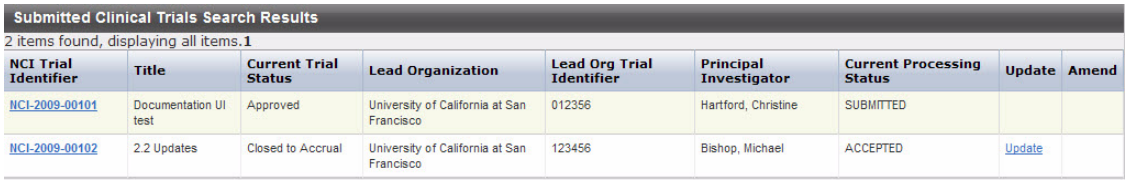
Table 2.2 Processing statuses of trials in the CTRP Registration Site (Continued)

Related topics:

- *Navigating Through the Search Results List*
- *About Clinical Trial Metadata*
- *Registering Non-Proprietary Trials in the CTRP Registration Site*
- *About the CTRP Registration Site*
- *Creating an Account*
- *Searching For Trials*
- *Viewing Trial Details*

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*).



Submitted Clinical Trials Search Results

2 items found, displaying all items.1

NCI Trial Identifier	Title	Current Trial Status	Lead Organization	Lead Org Trial Identifier	Principal Investigator	Current Processing Status	Update	Amend
NCI-2009-00101	Documentation UI test	Approved	University of California at San Francisco	012356	Hartford, Christine	SUBMITTED		
NCI-2009-00102	2.2 Updates	Closed to Accrual	University of California at San Francisco	123456	Bishop, Michael	ACCEPTED	Update	

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.
- Update – Indicates when a registered trial has been accepted or otherwise processed sufficiently to receive updates.
- Amend – Indicates when the trial has been processed sufficiently to receive amendments.

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

Related topics:

- *About Clinical Trial Metadata*
- *Registering Non-Proprietary Trials in the CTRP Registration Site*
- *About the CTRP Registration Site*

- *Creating an Account*
- *Working with Search Results*
- *Viewing 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 details provided for a given trial depend on trial ownership and trial category. Trials can be *public* or *private*, and *proprietary* or *non-proprietary*. The following table lists available trial details by ownership and category. An "**X**" in a column indicates that the given trial detail is provided.

Trial Details	***Non-Proprietary Trials***		***Proprietary Trials***	
	Private	***Public***	***Private***	***Public***
NCI Trial Identifier	**X**	**X**	**X**	**X**
NCT Number	**X**	**X**	**X**	**X**
Amendment Date	**X**			
Amendment Number	**X**			
Lead Organization Trial Identifier		**X**		**X**
Official Title	**X**	**X**	**X**	**X**
Trial Type	**X**	**X**	**X**	**X**
Primary Purpose	**X**	**X**	**X**	**X**
Phase	**X**	**X**	**X**	**X**
Sponsor/Responsible Party	**X**			
Sponsor	**X**			
Responsible Party	**X**			
Lead Organization/ Principal Investigator	**X**			
Lead Organization	**X**	**X**	**X**	**X**
Principal Investigator	**X**	**X**		
Summary 4 Information	**X**	**X**	**X**	**X**
Summary 4 Funding Category	**X**	**X**	**X**	**X**
Summary 4 Funding Source/Sponsor	**X**	**X**	**X**	**X**
NIH Grant Information	**X**	**X**		

Table 2.4 Trial details provided for public and private proprietary and non-proprietary trials

Trial Details	*Non-Proprietary Trials*		*Proprietary Trials*	
	Private	*Public*	*Private*	*Public*
Funding Mechanism	X	X		
NIH Institution Code	X	X		
Serial Number	X	X		
NCI Division/Program	X	X		
Status/Dates	X	X	X	
Current Recruitment Status			X	
Current Recruitment Status Date			X	
Opened for Accrual			X	
Closed for Accrual			X	
Current Trial Status	X	X		
Current Trial Status Date	X	X		
Trial Start Date	X	X		
Type	X	X		
Primary Completion Date	X	X		
Type	X	X		
IND/IDE Information	X			
IND/IDE Protocol?	X			
IND Type	X			
IND Number	X			
IND Grantor	X			
IND Holder Type	X			
Holder-NIH Institution/ NCI Division/Program (please specify)	X			
Has Expanded Access?*	X			
Expanded Access Status	X			
Trial Related Documents	X		X	
Protocol Document*	X		X	
IRB Approval*	X			
Participating Sites	X			
Informed Consent	X			

Table 2.4 Trial details provided for public and private proprietary and non-proprietary trials (Continued)

Trial Details	Non-Proprietary Trials		Proprietary Trials	
	Private	Public	Private	Public
Other Trial-Related Document	X			

Table 2.4 Trial details provided for public and private proprietary and non-proprietary trials (Continued)

The Trial Details page displays the metadata as entered by a trial submitter. Refer to *Appendix C, Metadata Definitions*, on page 95 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.

Related topics:

- *About Clinical Trial Metadata*
- *Registering Non-Proprietary Trials in the CTRP Registration Site*
- *About the CTRP Registration Site*
- *Creating an Account*
- *Working with Search Results*
- *Viewing Trial-Related Documents*

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.

Related topics:

- *About Clinical Trial Metadata*
- *Registering Non-Proprietary Trials in the CTRP Registration Site*
- *About the CTRP Registration Site*
- *Creating an Account*

- *Working with Search Results*
- *Viewing Trial Details*

CHAPTER

3

REGISTERING NEW TRIALS

This chapter describes how to register proprietary and non-proprietary trials using the CTRP Registration Site.

This chapter includes the following topics:

Registering Non-Proprietary Trials in the CTRP Registration Site

The CTRP Registration Site provides a user-friendly interface through which you can register new interventional non-proprietary and proprietary trials; and amend or update existing non-proprietary trials in the CTRP system.

This section provides information on registering single non-proprietary trials. For information on registering multiple trials, see *Registering Multiple Trials in a Batch* on page 66. For information on registering proprietary trials, see *Registering Proprietary Trials in the CTRP Registration Site* on page 52.

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 16. The system uses the Lead Organization ID, Lead Organization Trial ID, and the NCT number to detect duplicates. If a duplicate is detected, the system will not record your trial.

Note: You are required to provide information for all fields marked with an asterisk (*). The trial details you are asked to provide vary depending on the ownership and category of the trial you are registering. For details, see *Viewing Trial Details* on page 22.

How to Register Trials

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

   The Select Trial Type window appears (*Figure 3.1*).

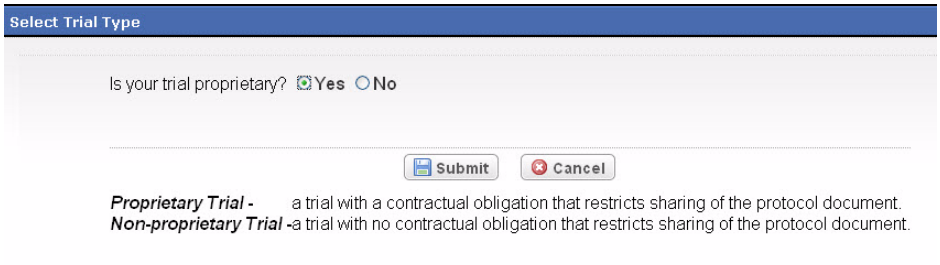


Figure 3.1 Select Trial Type Window

2. Click **No**.

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

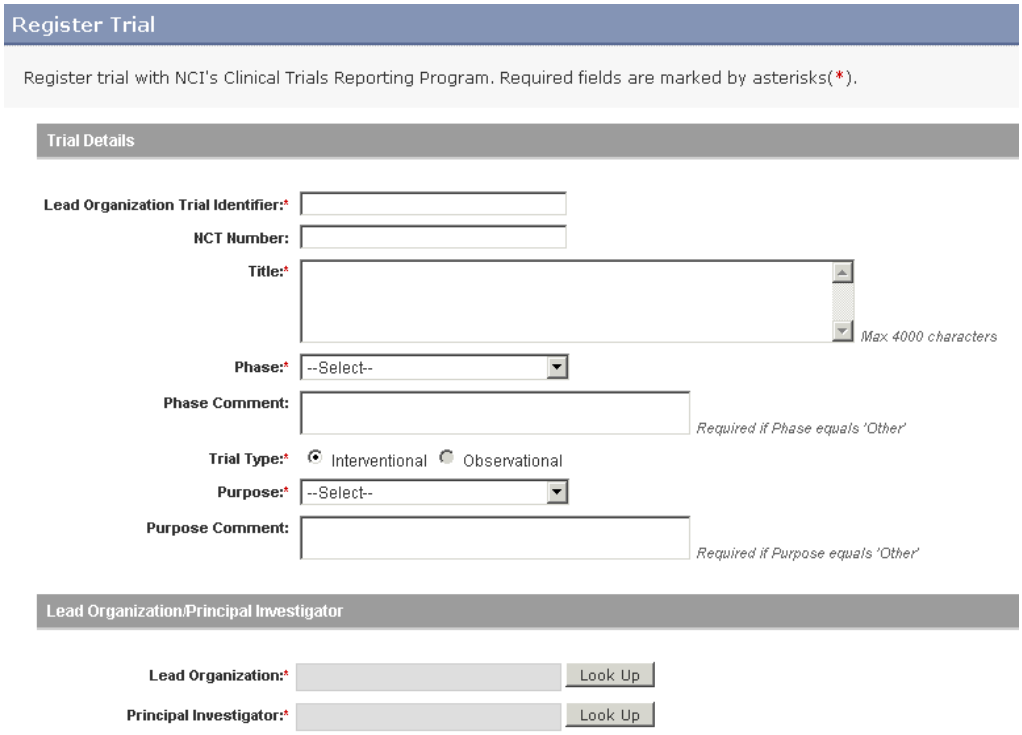


Figure 3.2 Register Trial Page – Non-Proprietary Trials, Upper Section

3. Type the appropriate information in the text fields, or select options from the drop-down lists as appropriate according to the detailed instructions provided for each of the following sections of the page:

- *Completing the Trial Details Section* on page 31
- *Completing the Lead Organization/Principal Investigator Section* on page 34
- *Completing the Sponsor/Responsible Party Section* on page 35
- *Completing the Summary 4 Information Section* on page 38
- *Completing the NIH Grant Information Section* on page 39
- *Completing the Trial Status/Dates Section* on page 44
- *Completing the IND/IDE Information Section* on page 46
- *Completing the Trial Related Documents Section* on page 51

4. 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.

5. 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 make changes to the trial data, follow the instructions in *Editing Trial Details* on page 29.

6. 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.

Related topics:

- *Editing Trial Details* on this page
- *Printing Trial Information*
- *Completing the Trial Details Section* on page 31
- *Registering Proprietary Trials in the CTRP Registration Site* on page 52
- *Registering Organizations* on page 58
- *Registering Persons* on page 62
- *Registering Multiple Trials in a Batch* on page 66

Editing Trial Details

You can edit trial details after you have reviewed them at any time before you submit the trial to the CTRP. If you want to edit a trial that you submitted previously, follow the instructions in *Updating and Amending Registered Trials* on page 71.

How to Edit Trial Details

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

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

   Caution: You must upload the trial documents again each time you click the Edit button.

2. Make changes as necessary and then click **Review Trial**.
3. After you have reviewed your edits, click **Submit**.

Related topics:

- *Amending Verified Trials* on page 76
- *Printing Trial Information* on page 30
- *Printing Amended and Updated Trial Information* on page 82
- *Completing the Trial Details Section* on page 31
- *Registering Proprietary Trials in the CTRP Registration Site* on page 52
- *Registering Organizations* on page 58
- *Registering Persons* on page 62
- *Registering Multiple Trials in a Batch* on page 66
- *Reviewing and Submitting Trial Amendments and Updates* on page 81

Printing Trial Information

You can print a copy of the trial details to facilitate the review and/or keep for your records. You must review the trial in order to access the print feature.

How to Print Trial Information

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

Related topics:

- *Editing Trial Details* on this page
- *Printing Trial Information*
- *Completing the Trial Details Section* on page 31
- *Registering Proprietary Trials in the CTRP Registration Site* on page 52
- *Registering Organizations* on page 58
- *Registering Persons* on page 62
- *Registering Multiple Trials in a Batch* on page 66

Completing the Trial Details Section

You must complete all fields in the Trial Details section (*Figure 3.21*).

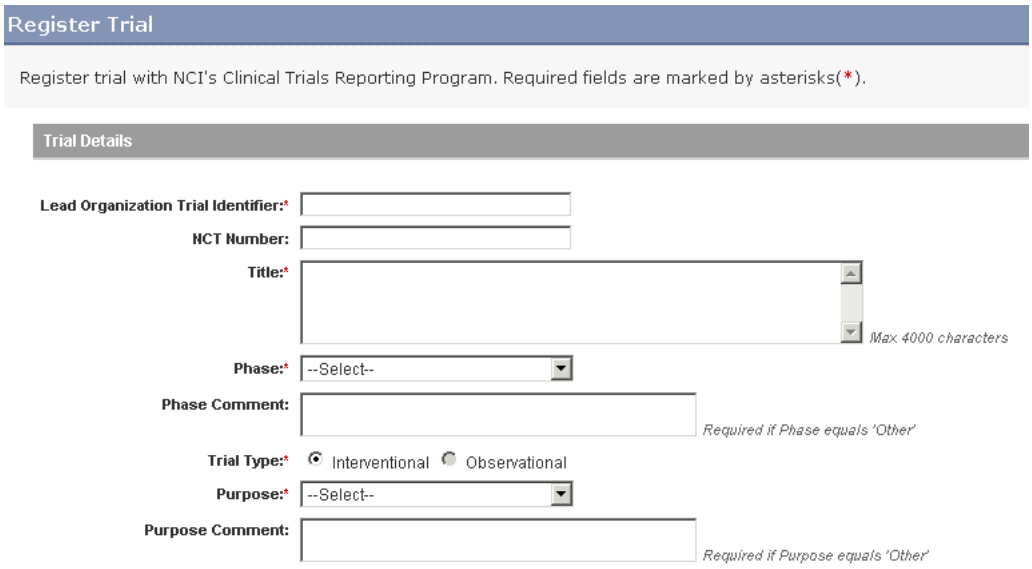


Figure 3.3 Add Trial Page – Trial Details Section, Non-Proprietary Trials

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.

Table 3.1 Trial phase definitions

Phase #	Definition
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. For non-proprietary trials, 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 product 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.

Table 3.2 Trial purpose definitions

Trial Purpose	*Definition*
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.
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

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

Related topics

- *Completing the Trial Details Section* on page 31
- *Completing the Lead Organization/Principal Investigator Section* on page 34
- *Completing the Sponsor/Responsible Party Section* on page 35
- *Completing the Summary 4 Information Section* on page 38
- *Completing the NIH Grant Information Section* on page 39
- *Completing the Trial Status/Dates Section* on page 44
- *Completing the IND/IDE Information Section* on page 46
- *Completing the Trial Related Documents Section* on page 51

Completing the Lead Organization/Principal Investigator Section

You must complete both fields in the Lead Organization/Principal Investigator section (*Figure 3.4*).

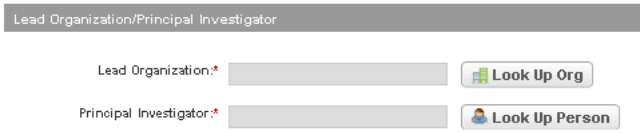


Figure 3.4 Add Trial Page – Lead Organization/Principal Investigator Section

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 59 and *Adding Organizations* on page 61.
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 63 and *Adding Principal Investigators* on page 65.

Related topics

- *Completing the Trial Details Section* on page 31
- *Completing the Trial Details Section* on page 31
- *Completing the Sponsor/Responsible Party Section* on page 35
- *Completing the Summary 4 Information Section* on page 38
- *Completing the NIH Grant Information Section* on page 39
- *Completing the Trial Status/Dates Section* on page 44

Completing the Sponsor/Responsible Party Section

The Responsible Party can be either a sponsor or a principal investigator (PI).The term “responsible party”, is either of the following:

- Sponsor of the clinical trial (as defined in 21 CFR 50.3 or successor regulation)

  - **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.

You must complete all fields in the Sponsor/Responsible Party section (*Figure 3.5*).

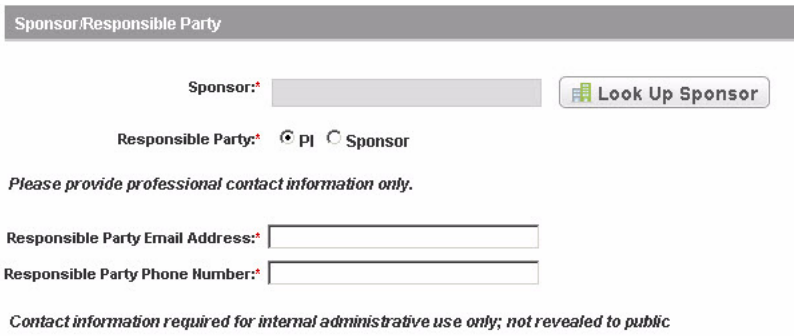


Figure 3.5 Add Trial Page – Sponsor/Responsible Party Section

How to Complete the Sponsor/Responsible Party Section

1. Click **Look up 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 59 and *Adding Organizations* on page 61.
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. For applicable clinical trials, sponsor is defined in 21 CFR 50.3. For further elaboration on the definition of Sponsor with respect to responsible party, see http://prsinfo.clinicaltrials.gov/ElaborationsOnDefinitions.pdf.

If you selected Sponsor in the previous step, the **Sponsor/Responsible Party** section (*Figure 3.6*) expands to display the **Responsible Party Contact** and **Responsible Party Generic Contact** fields.

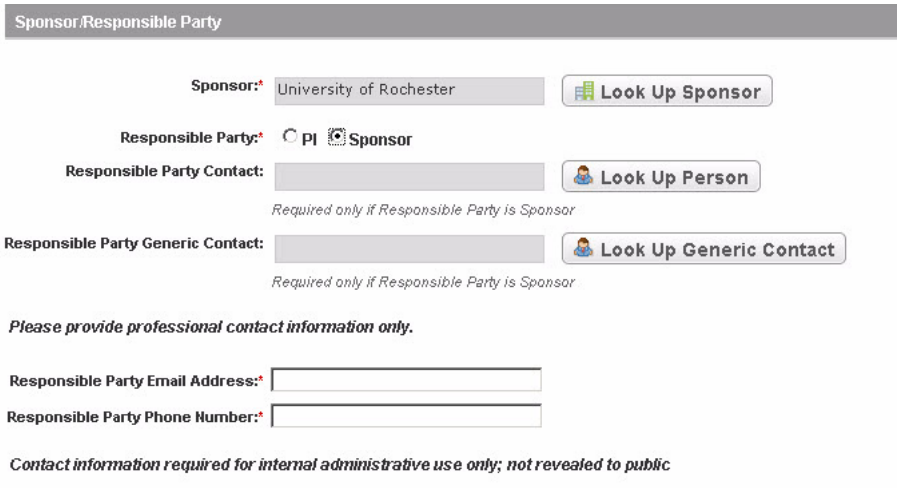


Figure 3.6 Add Trial Page – Sponsor/Responsible Party Section, Expanded

3. If the sponsor is a person rather than a generic contact, next to the **Responsible Party Contact** field, click **Look Up Person**, and follow the instructions in *Searching for Principal Investigators* on page 63 to record the responsible party's contact information.
4. If the sponsor contact is not linked to a particular person, next to the **Responsible Party Generic Contact** field, click **Look Up Generic Contact**.

   The Select Responsible Party Generic Contact window appears (*Figure 3.7*).

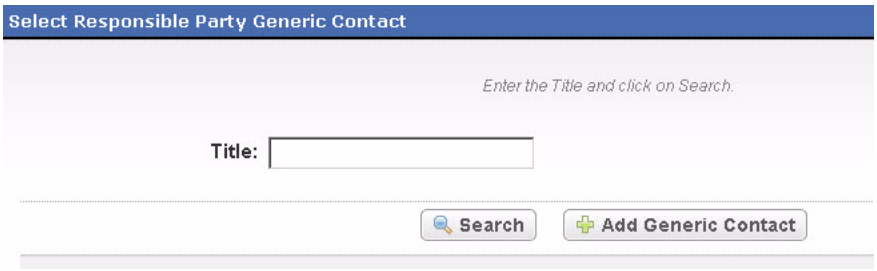


Figure 3.7 Select Responsible Party Generic Contact Window

5. In the **Title** field, type the contact's title or part of the title, and then click **Search**.
6. If no results are returned, click **Add Generic Contact**, and continue with the steps below. Otherwise, skip to Step 8.

The Add Generic Contact window appears (*Figure 3.8*).

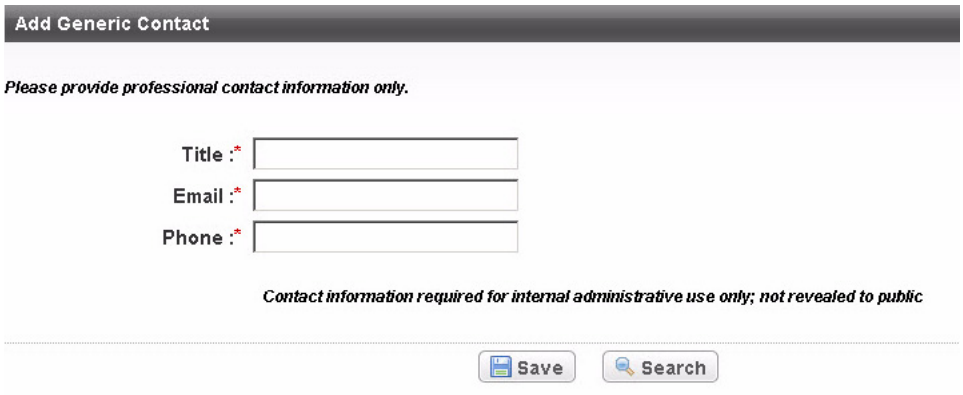


Figure 3.8 Add Generic Contact Window

7. Type the contact's title or role, and contact information in the fields provided, and then click **Save**.

   Note: Each title or role must be unique. You can not create one role with many email addresses and/or phone numbers.

   The record you created appears in the results table at the bottom of the window (*Figure 3.9*).

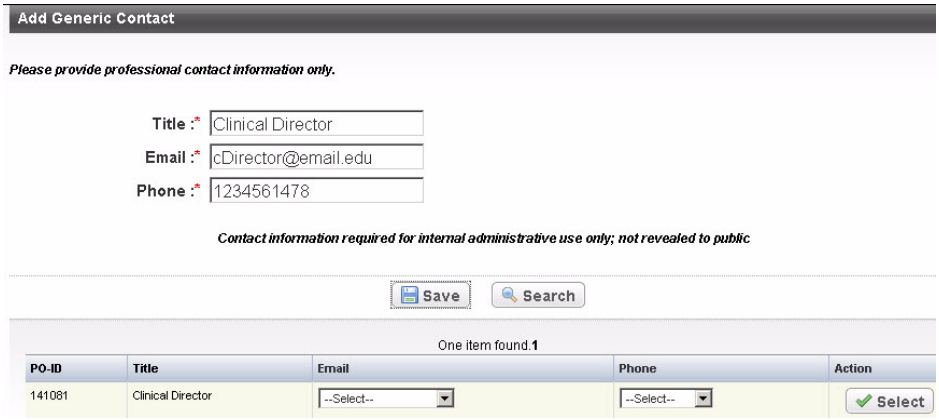


Figure 3.9 Add Generic Contact Window – Contact Record

8. In the contact record you created or searched for, select the contact's email address and phone number from the drop-down lists, and then click **Select**.

   Note: If the contact role or title you searched for contains an incorrect email address and/or phone number, do not select an address/number from the drop down list before you click **Select**. Instead, type the correct email address/phone number as per Step 10, then call the CTRO to request a change to the contact role record. (See *Application Support* on page 89.)

9. The title appears in the **Responsible Party Generic Contact** field, and the contact's email address and phone number appear in their respective fields below the title.

10. 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 as separators, or no separators at all in the **Phone Number** fields. Include phone number extensions where applicable.

Related topics

- *Completing the Trial Details Section* on page 31
- *Completing the Lead Organization/Principal Investigator Section* on page 34
- *Completing the Trial Details Section* on page 31
- *Completing the Summary 4 Information Section* on page 38
- *Completing the NIH Grant Information Section* on page 39
- *Completing the Trial Status/Dates Section* on page 44
- *Completing the IND/IDE Information Section* on page 46
- *Completing the Trial Related Documents Section* on page 51

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 3.10*).

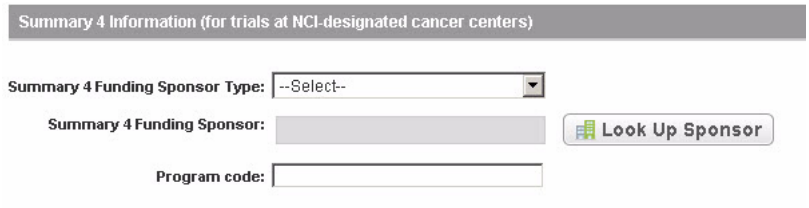


Figure 3.10 Add Trial Page – Summary 4 Information Section

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.

Table 3.3 Summary 4 funding categories definitions

Funding Category	Definition (For clinical trials involving an agent or device or other intervention)
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 59. To register an organization, follow the instructions in *Adding Organizations* on page 61.
3. In the **Program code** field, type the cancer center-specific program code.

Related topics

- *Completing the Trial Details Section* on page 31
- *Completing the Lead Organization/Principal Investigator Section* on page 34
- *Registering Non-Proprietary Trials in the CTRP Registration Site* on page 27
- *Completing the Summary 4 Information Section* on page 38
- *Completing the NIH Grant Information Section* on page 39
- *Completing the Trial Status/Dates Section* on page 44
- *Completing the IND/IDE Information Section* on page 46
- *Completing the Trial Related Documents Section* on page 51

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 3.11*). 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/

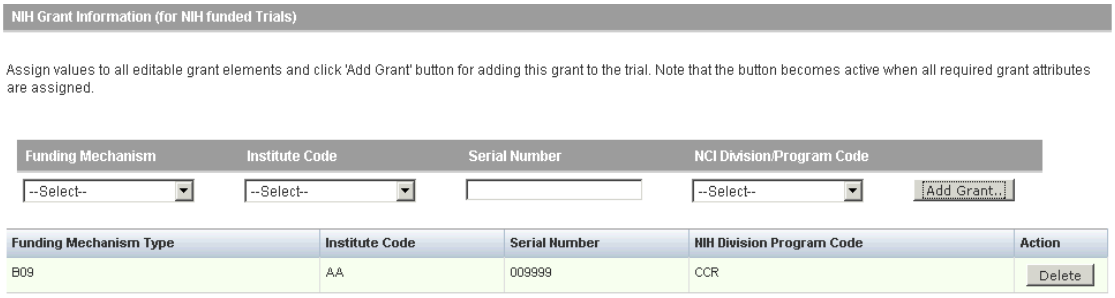


Figure 3.11 Add Trial Page – NIH Grant Information Section

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 file or 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.

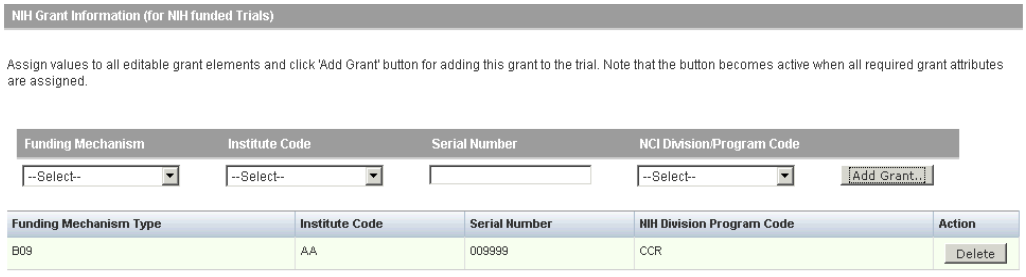


Figure 3.12 Grant Information Section – Registered Grant

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

   Another grant record appears.

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

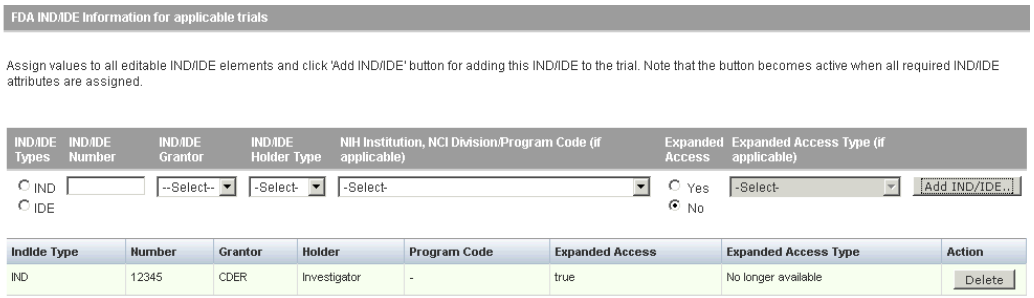


Figure 3.13 Grant Information Section – Unlink Grant

Related topics

- *Completing the Trial Details Section* on page 31
- *Completing the Lead Organization/Principal Investigator Section* on page 34
- *Completing the Sponsor/Responsible Party Section* on page 35
- *Completing the Summary 4 Information Section* on page 38
- *Completing the Trial Details Section* on page 31
- *Completing the Trial Status/Dates Section* on page 44
- *Completing the IND/IDE Information Section* on page 46
- *Completing the Trial Related Documents Section* on page 51

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***
Current Trial Status is anything *other than* "In-Review" or "Approved"	Trial Start Date must be "Actual"
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" or "In-Review"	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 "Actual" • Primary Completion Date must be the same as, or greater than, the date recorded for the Current Trial Status that preceded the "Completed" status (if one exists)
Current Trial Status is "Administratively Completed"	• Primary Completion must be "Actual" • Primary Completion Date must be the same as, or greater than, the date recorded for the Current Trial Status that preceded the "Administratively Completed" status (if one exists)
Current Trial Status is anything *other* than "Administratively Completed" or "Completed"	Primary Completion Date must be "Anticipated"
Current Trial Status is either "Withdrawn" or "Not Yet Recruiting"	Do not provide an Opened for Accrual date **Note:** Applies to non-proprietary trials only
Current Trial Status is anything *other* than "Withdrawn" or "Not Yet Recruiting"	Provide an Opened for Accrual date **Note:** Applies to non-proprietary trials only
Site Recruitment status is "Terminated" or "Completed"	Provide a Closed for Accrual date

Table 3.7 Rules for Status/Dates relationships

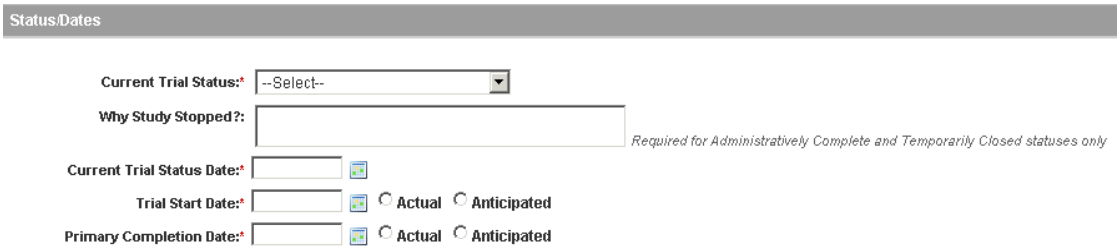


Figure 3.14 Add Trial Page – Status/Dates Section

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 values for the CTRP Registration Site.

Current Trial Status	***Definition***
In Review	Trial is currently under IRB review
Approved	Trial has been approved
Active	Trial is open for *accrual*
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.
Withdrawn	Trial has been withdrawn from development and review.
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**, **Withdrawn**, 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**.

Related topics

- *Completing the Trial Details Section* on page 31
- *Completing the Lead Organization/Principal Investigator Section* on page 34
- *Completing the Sponsor/Responsible Party Section* on page 35
- *Completing the Summary 4 Information Section* on page 38
- *Completing the NIH Grant Information Section* on page 39
- *Registering Non-Proprietary Trials in the CTRP Registration Site* on page 27
- *Completing the IND/IDE Information Section* on page 46
- *Completing the Trial Related Documents Section* on page 51

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 47.

To register IDE trials, see *Registering IDE Trials* on page 49.

Related topics

- *Completing the Trial Details Section* on page 31
- *Completing the Lead Organization/Principal Investigator Section* on page 34
- *Completing the Sponsor/Responsible Party Section* on page 35
- *Completing the Summary 4 Information Section* on page 38
- *Completing the NIH Grant Information Section* on page 39
- *Completing the Trial Status/Dates Section* on page 44
- *Registering Non-Proprietary Trials in the CTRP Registration Site* on page 27

- *Completing the Trial Related Documents Section* on page 51

Registering IND Trials

There are several dependencies between elements in the IND/IDE section (*Figure 3.15*). 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**.

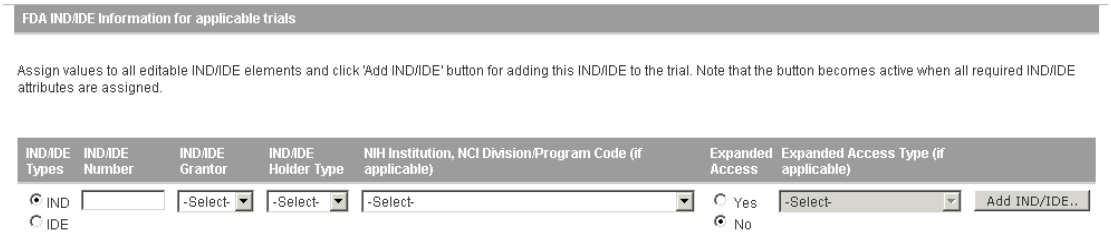


Figure 3.15 Add Trial Page – IND/IDE Section

2. In the **IND/IDE Number** field, type the trial's FDA-assigned *IND number*.

   Tip: You can enter the IND number in many formats. For example, for a biologics (BB) IND that contains the number 1234, you can type BB1234, 1234, or BB_1234.

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

5. If you select **NCI**, you must select an **NCI Division/Program** code. If you select **NIH**, you must also select an **NIH 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 statuses.

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.

Related topics

- *Registering IDE Trials* on page 49
- *Completing the Trial Details Section* on page 31
- *Completing the Lead Organization/Principal Investigator Section* on page 34
- *Completing the Sponsor/Responsible Party Section* on page 35
- *Completing the Summary 4 Information Section* on page 38

- *Completing the NIH Grant Information Section* on page 39
- *Completing the Trial Status/Dates Section* on page 44
- *Registering Non-Proprietary Trials in the CTRP Registration Site* on page 27
- *Completing the Trial Related Documents Section* on page 51

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 3.16*).

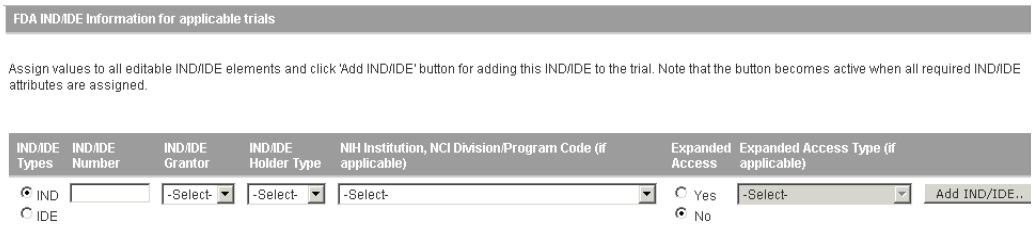


Figure 3.16 Add Trial Page – IND/IDE Section

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

5. If you select **NCI**, you must select an **NCI Division/Program** code. If you select **NIH**, you must also select an **NIH Institute Code**. See *Appendix C, Metadata Definitions*, on page 95 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 includes more than one IND/IDE, repeat the steps above, and then click **Add IND/IDE**.

   Another IND/IDE record appears (*Figure 3.17*).

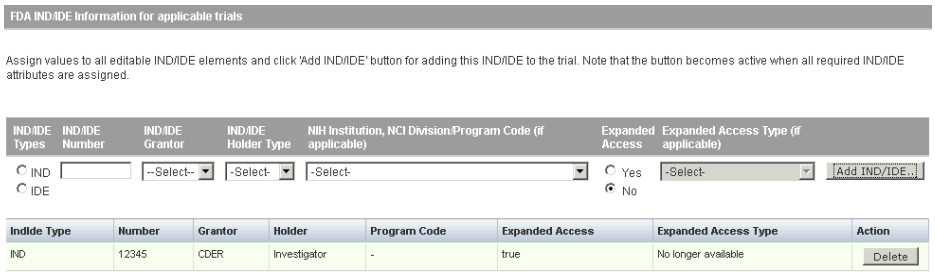


Figure 3.17 Grant Information Section – Additional Grant

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

Related topics

- *Registering IND Trials* on page 47
- *Completing the Trial Details Section* on page 31

- *Completing the Lead Organization/Principal Investigator Section* on page 34
- *Completing the Sponsor/Responsible Party Section* on page 35
- *Completing the Summary 4 Information Section* on page 38
- *Completing the NIH Grant Information Section* on page 39
- *Completing the Trial Status/Dates Section* on page 44
- *Registering Non-Proprietary Trials in the CTRP Registration Site* on page 27
- *Completing the Trial Related Documents Section* on page 51

Completing the Trial Related Documents Section

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

- For non-proprietary trials only: Complete protocol
- For proprietary trials only: Summary of the proprietary protocol or a proprietary trial template that contains disease and intervention information
- *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.

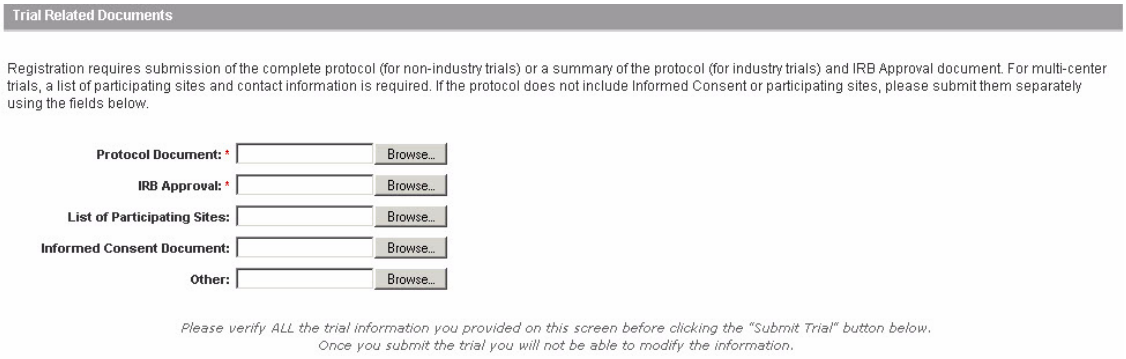


Figure 3.18 Add Trial Page – Trial Related Documents

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.

Related topics

- *Completing the Trial Details Section* on page 31
- *Completing the Lead Organization/Principal Investigator Section* on page 34
- *Completing the Sponsor/Responsible Party Section* on page 35
- *Completing the Summary 4 Information Section* on page 38
- *Completing the NIH Grant Information Section* on page 39
- *Completing the Trial Status/Dates Section* on page 44
- *Registering Non-Proprietary Trials in the CTRP Registration Site* on page 27

Registering Proprietary Trials in the CTRP Registration Site

The CTRP Registration Site provides a user-friendly interface through which you can register new non-proprietary trials.

This section provides information on registering single proprietary trials. For information on registering multiple trials, see *Registering Multiple Trials in a Batch* on page 66. For information on registering non-proprietary trials, see *Completing the Trial Details Section* on page 31.

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 16. The system uses the Lead Organization ID, Lead Organization Trial ID, and the NCT number to detect duplicates. If a duplicate is detected, the system will not record your trial.

Note: You are required to provide information for all fields marked with an asterisk (*). The trial details you are asked to provide vary depending on the ownership and category of the trial you are registering. For details, see *Viewing Trial Details* on page 22.

How to Register Proprietary Trials

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

The Select Trial Type window appears (*Figure 3.19*).

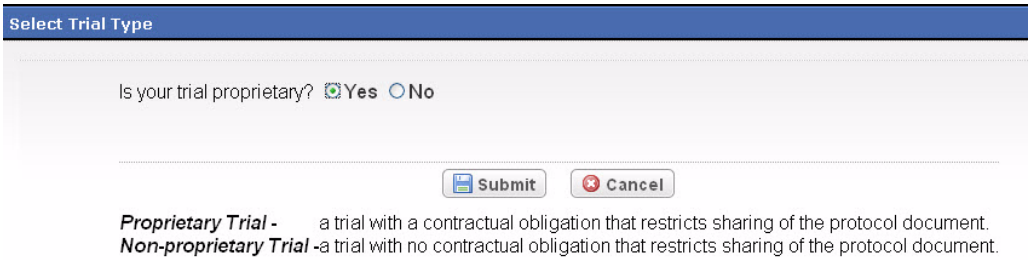


Figure 3.19 Select Trial Type Window

2. Select the **Yes** option.
3. Click **Submit**.

   The Register Trial page appears.

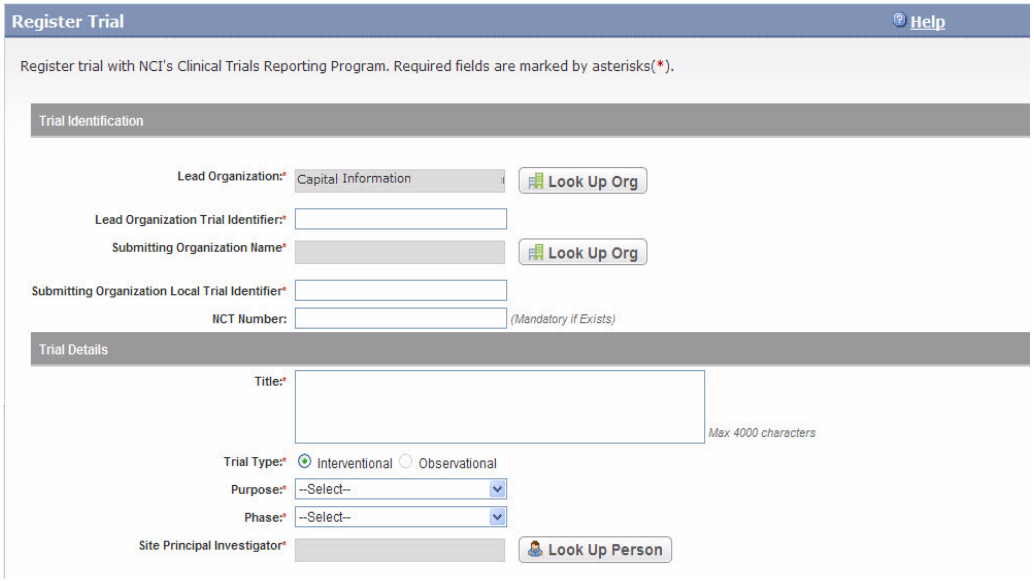


Figure 3.20 Register Trial Page – Proprietary Trials, Upper Section

4. Type the appropriate information in the text fields, or select options from the drop-down lists as appropriate, according to the detailed instructions provided for each of the following sections of the page:

   - *Completing the Trial Identification Section for Proprietary Trials* on page 54
   - *Completing the Trial Details Section for Proprietary Trials* on page 55
   - *Completing Summary 4 Information for Proprietary Trials* on page 56
   - *Completing the Trial Status/Dates Section for Proprietary Trials* on page 57
   - *Completing the Trial Related Documents Section for Proprietary Trials* on page 57

5. 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.

6. 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 make changes to the trial data, follow the instructions in *Editing Trial Details* on page 29.

7. 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.

Related topics

- *Registering Non-Proprietary Trials in the CTRP Registration Site* on page 27
- *Completing the Trial Details Section* on page 31
- *Registering Persons* on page 62
- *Registering Multiple Trials in a Batch* on page 66

Completing the Trial Identification Section for Proprietary Trials

You must complete all fields in the Trial Identification section(*Figure 3.21*).

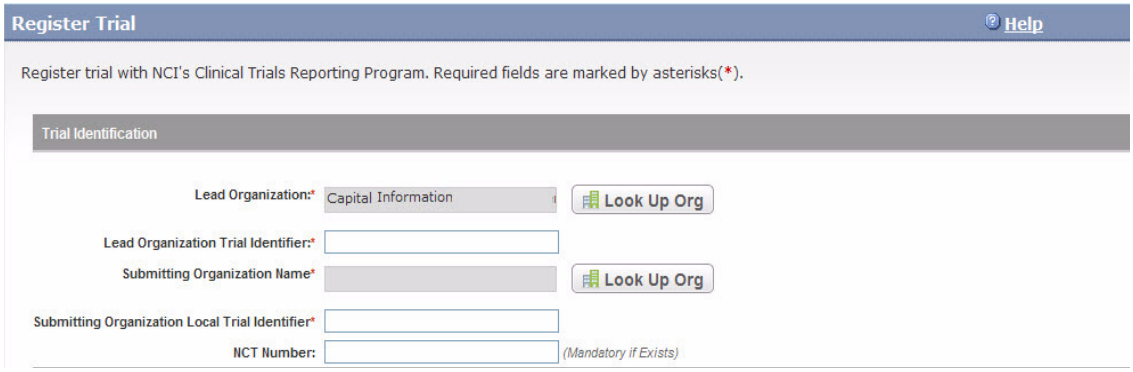


Figure 3.21 Add Trial Page – Trial Identification Section

How to Complete the Trial Identification 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 59 and *Adding Organizations* on page 61.

2. In the **Lead Organization Trial Identifier** field, type the unique identification number assigned to the protocol by the lead organization.
3. Look up the Submitting Organization and select the appropriate organization from the list of search results.
4. In the **Submitting Organization Local Trial Identifier** field, type the unique identification number assigned to the protocol by the submitting organization.

In the **NCT Number** field, type the number assigned to the trial by the National Clinical Trial program. Leave the field blank if no such number exists.

Related topics:

- *Registering Proprietary Trials in the CTRP Registration Site* on page 52
- *Completing the Trial Details Section for Proprietary Trials* on page 55
- *Completing Summary 4 Information for Proprietary Trials* on page 56
- *Completing the Trial Status/Dates Section for Proprietary Trials* on page 57
- *Completing the Trial Status/Dates Section for Proprietary Trials* on page 57
- *Completing the Trial Related Documents Section for Proprietary Trials* on page 57

Completing the Trial Details Section for Proprietary Trials

You must complete all fields in the Trial Details section (*Figure 3.21*).

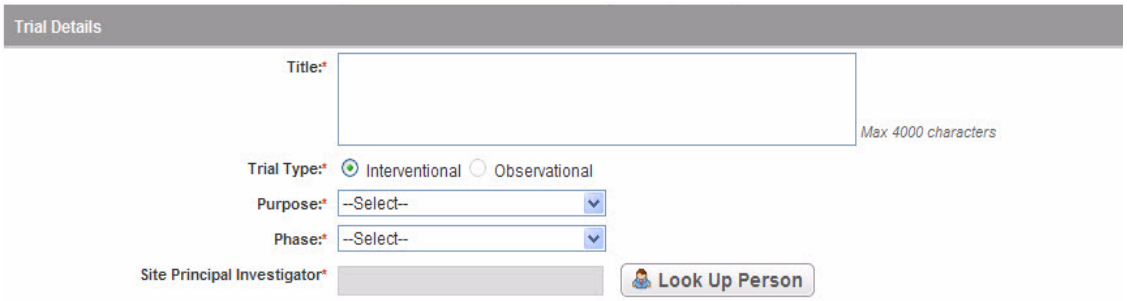


Figure 3.22 Add Trial Page – Trial Details Section, Proprietary Trials

How to Complete the Trial Details Section

1. 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"

2. 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.

3. From the **Purpose** drop-down list, select the purpose of the trial. See *Trial purpose definitions* on page 32 for valid values.

   Note: You do not have to provide a purpose if you have provided an NCT number.

4. From the **Phase** drop-down list, select the trial *phase. See Trial phase definitions* on page 31.

   Note: You do not have to provide a phase if you have provided an NCT number.

5. Look up the *Principal Investigator* and select the appropriate name from the list of search results.

   Tip: If your site's principal investigator for the trial 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 63 and *Adding Principal Investigators* on page 65.

Related topics:

- *Completing the Trial Identification Section for Proprietary Trials* on page 54
- *Registering Proprietary Trials in the CTRP Registration Site* on page 52
- *Completing Summary 4 Information for Proprietary Trials* on page 56
- *Completing the Trial Status/Dates Section for Proprietary Trials* on page 57
- *Completing the Trial Status/Dates Section for Proprietary Trials* on page 57
- *Completing the Trial Related Documents Section for Proprietary Trials* on page 57

Completing Summary 4 Information for Proprietary Trials

Instructions for completing the Summary 4 Information section are the same for both proprietary and non-proprietary trials. See *Completing the Summary 4 Information Section* on page 38.

Related topics:

- *Completing the Trial Identification Section for Proprietary Trials* on page 54
- *Completing the Trial Details Section for Proprietary Trials* on page 55
- *Registering Proprietary Trials in the CTRP Registration Site* on page 52
- *Completing the Trial Status/Dates Section for Proprietary Trials* on page 57
- *Completing the Trial Status/Dates Section for Proprietary Trials* on page 57
- *Completing the Trial Related Documents Section for Proprietary Trials* on page 57

Completing the Trial Status/Dates Section for Proprietary Trials

You must complete all fields in the Status/Dates section that are marked with an asterisk (*). If you provide a Closed for Accrual date, you must also provide an Opened for Accrual date.

Figure 3.23 Add Trial Page – Status/Dates Section

How to Complete the Status/Dates Section

1. From the **Site Current Recruitment Status** field, select the trial's current recruitment status.
2. If applicable, in the **Date Opened for Accrual** field, type the date on which accrual started, using the date format mm/dd/yyyy, or, click the calendar icon ( ) and select the date from the calendar.
3. If applicable, in the **Date Closed for Accrual** field, type the date on which accrual ended, using the date format mm/dd/yyyy, or, click the calendar icon ( ) and select the date from the calendar.

Related topics:

- *Registering Proprietary Trials in the CTRP Registration Site* on page 52
- *Completing the Trial Details Section for Proprietary Trials* on page 55
- *Completing Summary 4 Information for Proprietary Trials* on page 56
- *Completing the Trial Status/Dates Section for Proprietary Trials* on page 57
- *Completing the Trial Identification Section for Proprietary Trials* on page 54
- *Completing the Trial Related Documents Section for Proprietary Trials* on page 57

Completing the Trial Related Documents Section for Proprietary Trials

You must include a proprietary template if you did not provided an NCT number in the Trial Identification section. 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.

See *Using the Proprietary Trial Template* on page 11 for template instructions and download details.

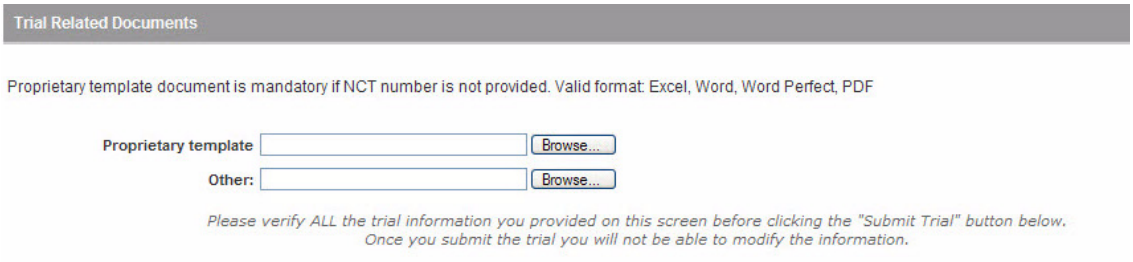


Figure 3.24 Add Trial Page – Trial Related Documents

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

How to Submit Trial Related Documents

1. Next to the **Proprietary Template** field, click **Browse**.
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 the steps above for any other document you want to submit.

Related topics:

- *Completing the Trial Identification Section for Proprietary Trials* on page 54
- *Completing the Trial Details Section for Proprietary Trials* on page 55
- *Completing Summary 4 Information for Proprietary Trials* on page 56
- *Completing the Trial Status/Dates Section for Proprietary Trials* on page 57
- *Completing the Trial Status/Dates Section for Proprietary Trials* on page 57
- *Registering Proprietary Trials in the CTRP Registration Site* on page 52

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 59.) If your search results do not contain the name of your organization, you can register a new one. (See *Adding Organizations* on page 61.)

Related topics:

- *Searching for Registered Organizations* on page 59
- *Adding Organizations* on page 61
- *Registering Persons* on page 62
- *Searching for Principal Investigators* on page 63

- *Adding Principal Investigators* on page 65

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.

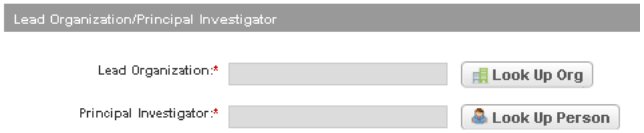


Figure 3.25 Lead Organization/Principal Investigator Section

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

   The Search Organizations window appears.

Figure 3.26 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 a series of characters in the **Name**, **City**, or **Zip** fields to narrow the search results. Because the system adds wildcards for you, do not type wildcard symbols in the search fields.

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

4. Click **Search**.

The Search Organizations window displays the results of your search.

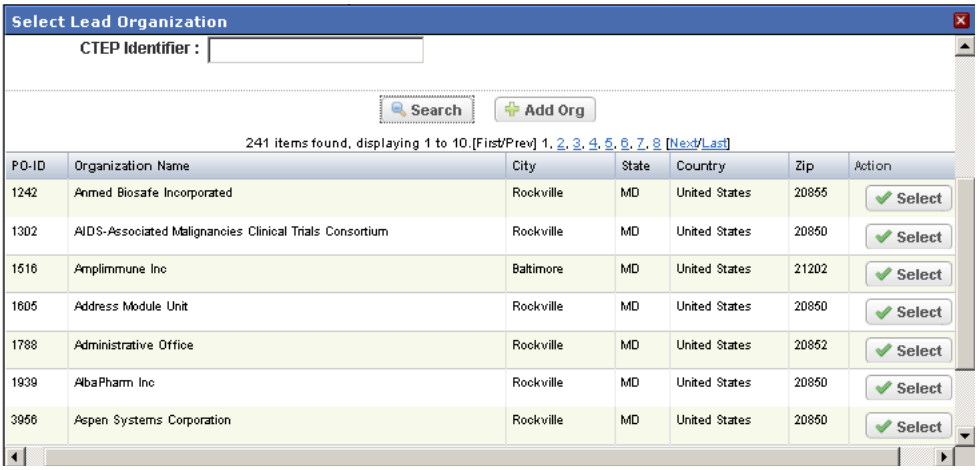


Figure 3.27 Search Organizations Window – Search Results

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 information 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 3.27, Search Organizations Window – Search Results,* on page 60.

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 61.

Related topics:

- *Registering Organizations* on page 58
- *Adding Organizations* on page 61
- *Registering Persons* on page 62
- *Searching for Principal Investigators* on page 63
- *Adding Principal Investigators* on page 65

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.

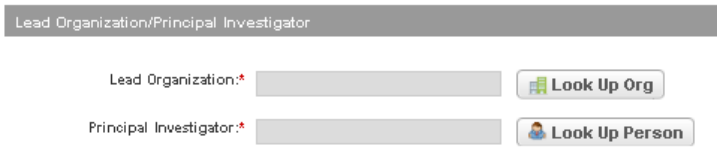


Figure 3.28 Lead Organization/Principal Investigator Section

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

   The Select Lead Organization page appears.

Figure 3.29 Select Lead Organization Page

3. Click **Add Org**.

The Add Organization window appears.

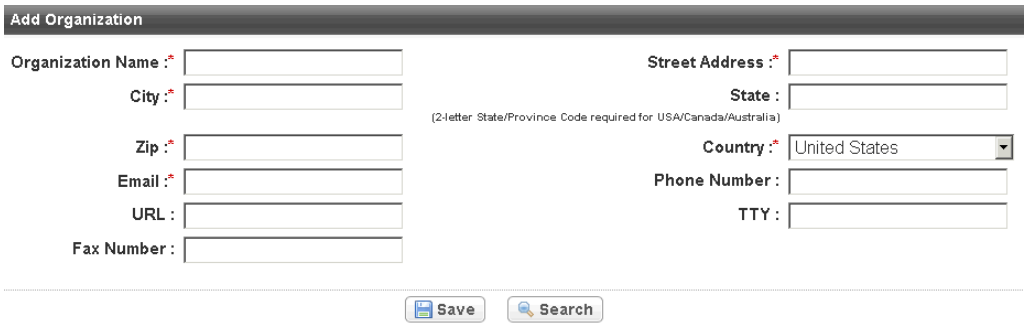


Figure 3.30 Add Organization Window

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.

Related topics:

- *Registering Organizations* on page 58
- *Searching for Registered Organizations* on page 59
- *Registering Persons* on page 62
- *Searching for Principal Investigators* on page 63
- *Adding Principal Investigators* on page 65

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 63.) If your search results do not contain the name of your investigator, you can register a new one. (See *Adding Principal Investigators* on page 65.)

Related topics:

- *Registering Organizations* on page 58
- *Adding Organizations* on page 61
- *Searching for Principal Investigators* on page 63
- *Adding Principal Investigators* on page 65

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 65.

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.

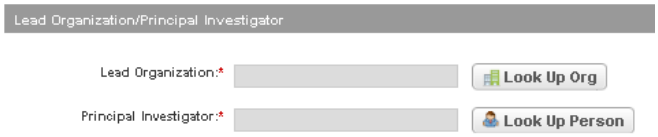


Figure 3.31 Lead Organization/Principal Investigator Section

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

   The Select Principal Investigator page appears.

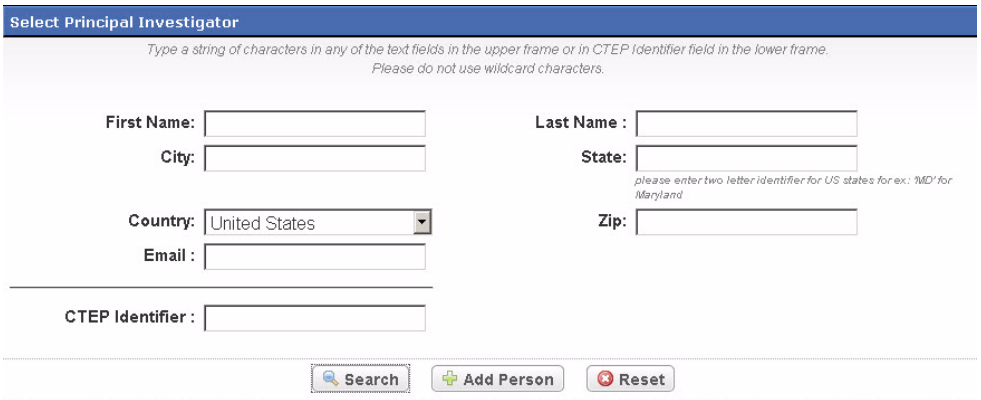


Figure 3.32 Select Principal Investigator Page – Search Persons

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

   Tip: You can type a series of characters in either of the **Name** fields to narrow the search results. Because the system adds wildcards for you, do not type wildcard symbols in the search fields.

   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.

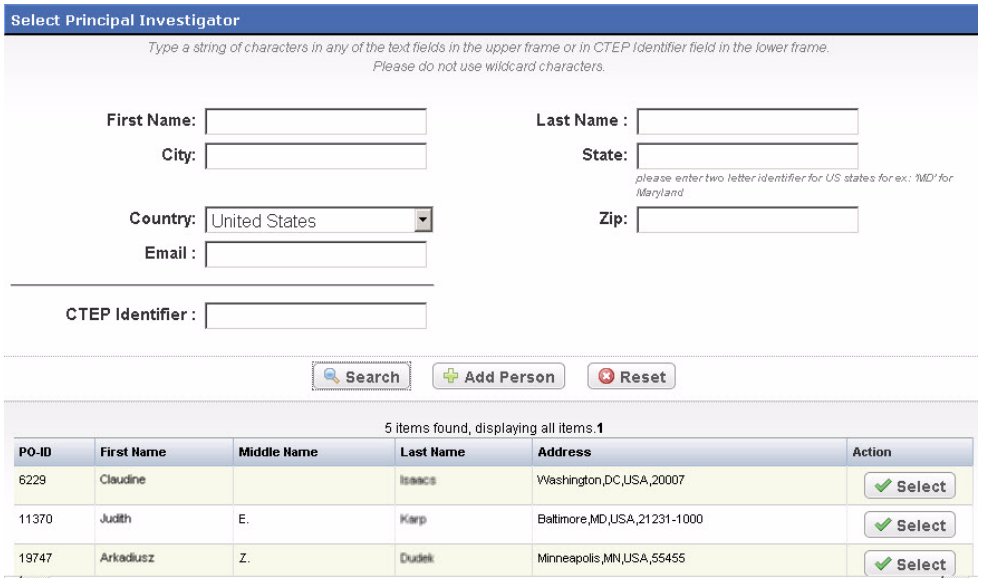


Figure 3.33 Principal Investigator Lookup Page – Search Results (partially redacted)

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.

Related topics:

- *Registering Organizations* on page 58
- *Adding Organizations* on page 61
- *Registering Persons* on page 62
- *Searching for Principal Investigators* on page 63

- *Adding Principal Investigators* on page 65

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.

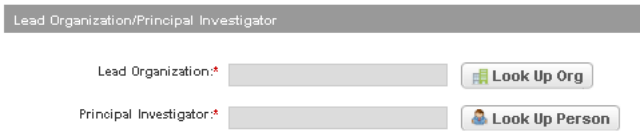


Figure 3.34 Lead Organization/Principal Investigator Section

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

   The Select Principal Investigator page appears.

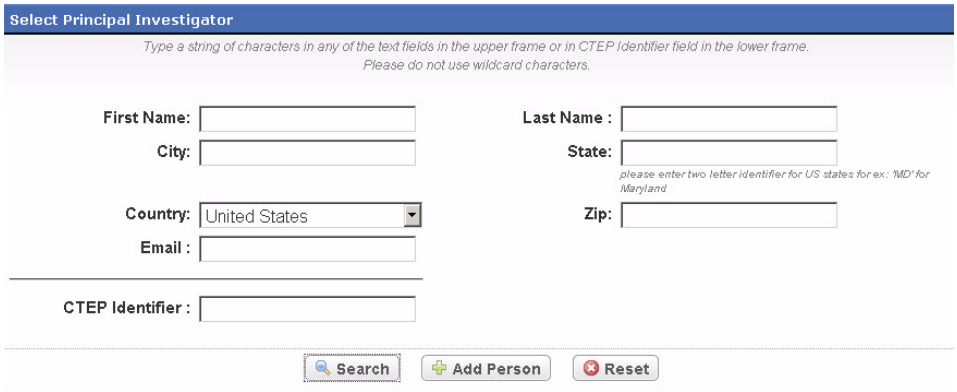


Figure 3.35 Select Principal Investigator Page – Search Persons

3. Click **Add Person**.

   The Add Person window appears.

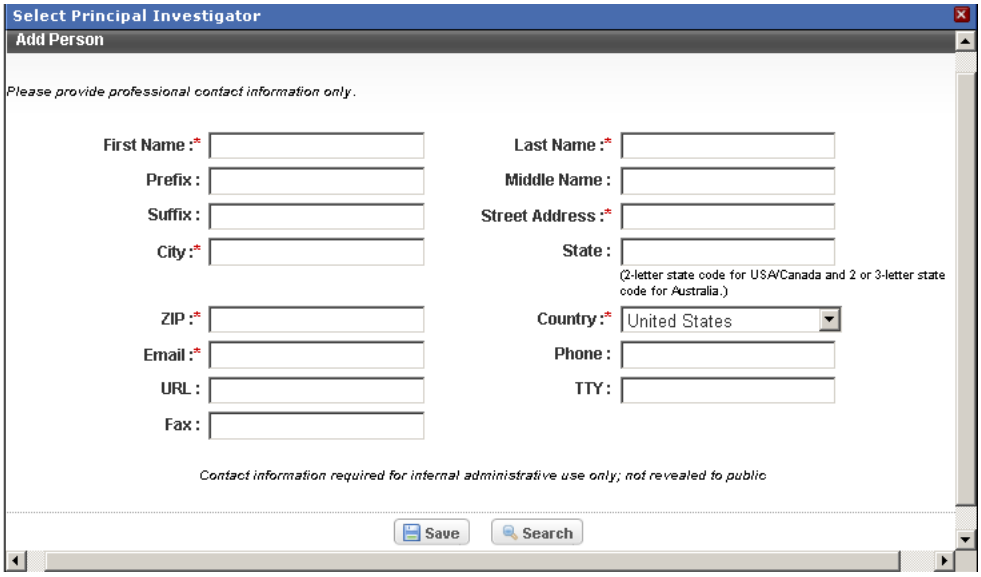


Figure 3.36 Add Person Window

4. Type or select as much information as possible in the fields provided. Use professional contact information only. You must complete all required fields, marked with an asterisk (*).

   Note: The information you provide is not revealed to the public.

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.

Related topics:

- *Registering Organizations* on page 58
- *Adding Organizations* on page 61
- *Registering Persons* on page 62
- *Searching for Principal Investigators* on page 63

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 non-proprietary trials that were conducted at a given site.

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

In the current release, you can supply 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 68 and *Appendix A, Batch Upload Data Specifications*, on page 87.
  - 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.

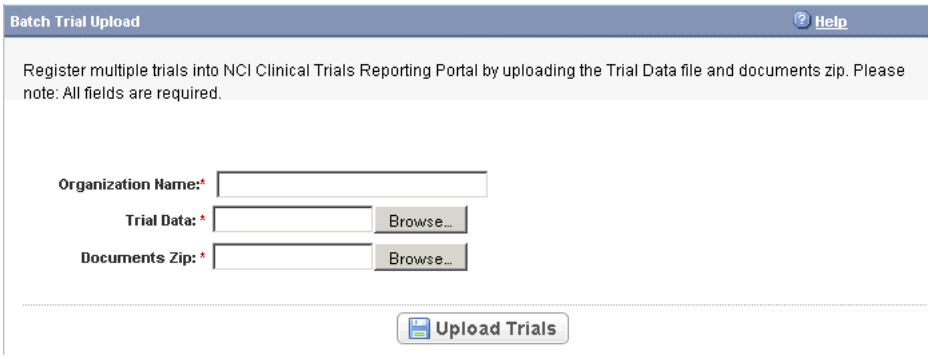


Figure 3.37 Batch Trial Upload Page

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 68.
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.

Related topics:

- *Data Requirements for Batch Uploads* on page 68
- *Using the Batch Upload Template* on page 12

- *Batch Upload Data Specifications* on page 87

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 A, Batch Upload Data Specifications*, on page 87.

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
(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

Table 3.14 Data element requirements based on selected values

If you provide this value...	*You must also provide/select this*
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” - **or** - If Current Trial Status = “In Review”	Trial Start Date type = “Anticipated”
Current Trial Status ≠ “Approved” - **or** - If Current Trial Status ≠ “In Review”	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

Related topics:

- *Using the Batch Upload Template* on page 12
- *Batch Upload Data Specifications* on page 87

CHAPTER

4

UPDATING AND AMENDING REGISTERED TRIALS

This chapter describes how to update and make amendments to non-proprietary trials currently registered and verified in the CTRP.

This chapter includes the following topics:

About Trial Updates

The CTRP Registration Site enables you, in the role of trial owner (submitter or new trial owner), to update trials that you yourself have registered with the CTRP previously. You can update only those trials that have been previously accepted (i.e., the processing status must be Accepted.)

Note: You can not update a study that has been Disapproved, Withdrawn, Completed, or Administratively Completed.

Use the Update Trial feature when changes to the trial are not a consequence of changes to the protocol document. Use the Amend Trial feature when changes to the trial involve changes to the protocol document that require IRB approval.

Note: You can update/amend non-proprietary trials only in CTRP Registration Site versions 3.0 and 3.1.

Tip: You can also update trials in batches. See *Preparing the Trial Data File for Non-Proprietary Trials* on page 87.

Related topics:

- *Updating Accepted Trials* on page 72
- *About Trial Amendments* on page 74
- *Amending Verified Trials* on page 76
- *Reviewing and Submitting Trial Amendments and Updates* on page 81

Updating Accepted Trials

You can update most information included with the original trial submission, including the following:

- Trial details
- *Responsible Party/Sponsor* personal contact and generic contact information
- Summary 4 information
- NIH Grant information
  - Update existing grant information
  - Add new unique grant (do not submit duplicates)
- IND/IDE information
  - Add new unique IND/IDE (do not submit duplicates)
- Regulatory information
- Participating sites
  - Site recruitment status and associated date and site program code for abstracted trail sites.
- Collaborator's functional role
- Regulatory information (*new* IRB approval documents)

Note: The system sends you, the trial owner, an update notification whenever you update accepted trials.

How to Update Trials

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

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

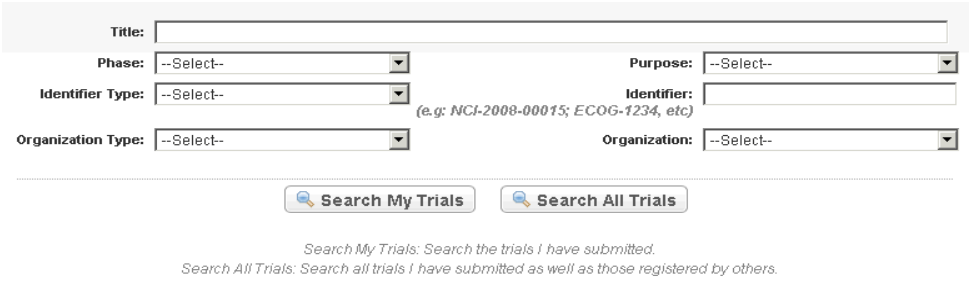


Figure 4.1 Search Trials Page

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*).

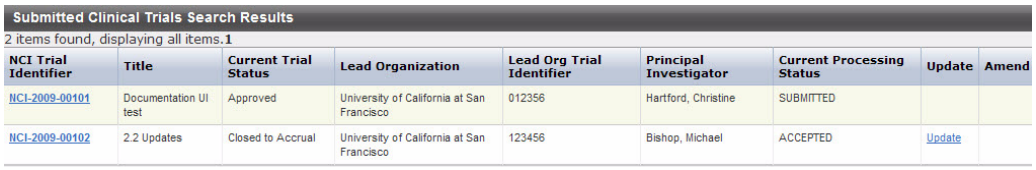


Figure 4.2 "Search My Trials" Result List

For information about navigating the search results list, see *Navigating Through the Search Results List* on page 20.

3. Locate the trial you want to update, and then click the **Update** link in the corresponding column.

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

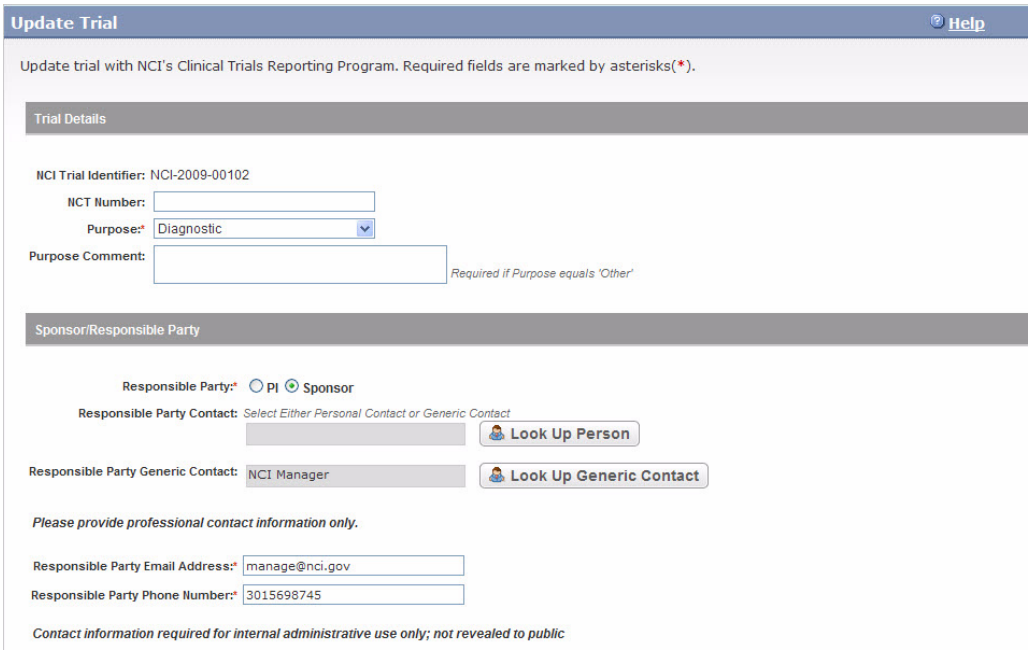


Figure 4.3 Update Trial Page – Trial Details and Sponsor/Responsible Party Sections

4. Make changes to the fields as necessary. Instructions for providing/editing trial details are provided in *Registering Non-Proprietary Trials in the CTRP Registration Site* on page 27.
5. If appropriate, upload the documents for IRB approval.
6. To review the information you provided, click **Review Trial**.

   The system checks the updated information for errors, and displays the results at the top of the Update Trial page.
7. If necessary, correct any errors, and click **Review Trial**. Repeat this cycle until your update is error-free.
8. Submit the trial update.

Related topics:

- *About Trial Updates* on page 71
- *About Trial Amendments* on page 74
- *Amending Verified Trials* on page 76
- *Reviewing and Submitting Trial Amendments and Updates* on page 81

About Trial Amendments

The CTRP Registration Site enables you, in the role of trial owner, to amend non-proprietary 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.

Note: You can also amend trials in batches. See *Preparing the Trial Data File for Non-Proprietary Trials* on page 87.

Related topics:

- *Amendment Process Life Cycle* on page 75
- *Amending Verified Trials* on page 76
- *Uploading Amendment-Specific Documents* on page 80
- *Reviewing and Submitting Trial Amendments and Updates* on page 81

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. The system sends you a submission confirmation letter.
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) and XML document that include all the newly-modified data in the CTRP.
4. You review and validate the new TSR and email your approval to the CTRO.
5. If you request a change, the CTRO makes corresponding modifications and re-send s the TSR and XML documents.
6. The amended trial appears in your Search My Trials results list upon acceptance.

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* on page 76
- *Uploading Amendment-Specific Documents* on page 80

- *Reviewing and Submitting Trial Amendments and Updates* on page 81

Amending Verified Trials

In your role as trial owner (original submitter or current owner), you can amend only non-proprietary trials. The trials you own are listed when you use the Search My Trials feature. See *Transferring Trial Ownership* on page 85 and *Searching For Trials* on page 16.

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*).

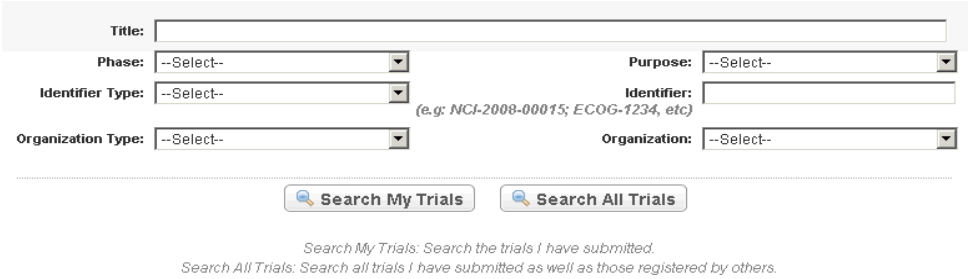


Figure 4.4 Search Trials Page

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*).

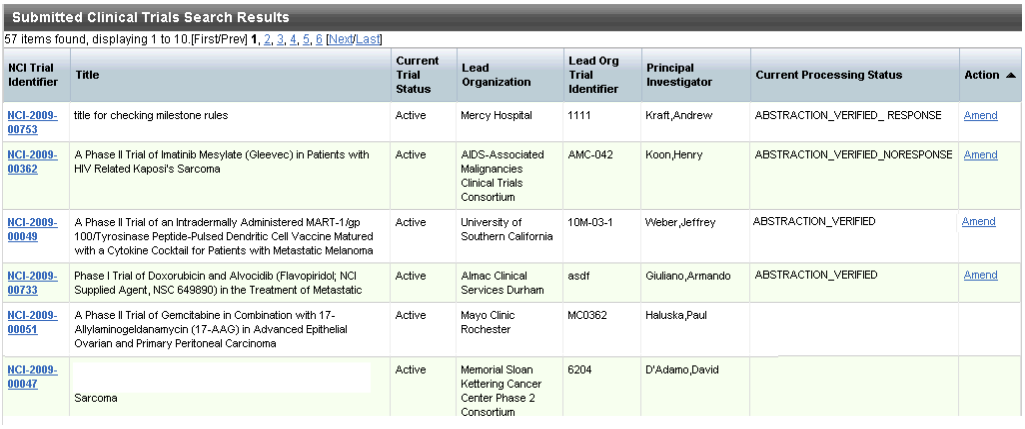


Figure 4.5 "Search My Trials" Result List

For information about navigating the search results list, see *Navigating Through the Search Results List* on page 20.

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*).

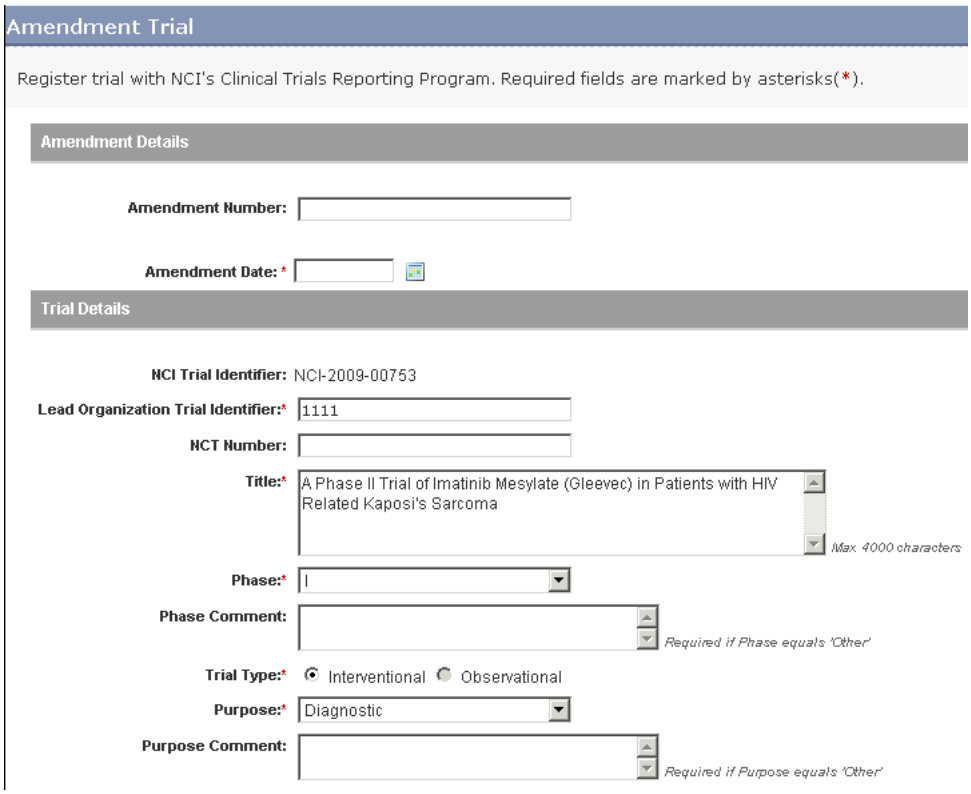


Figure 4.6 Amendment Trial Page – Amendment and Trial Details

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 Non-Proprietary Trials in the CTRP Registration Site* on page 27.

Amendment-specific rules, values, etc., are provided for each section of the Amendment Trial page as follows:

Related topics:

- *Amending Verified Trials* on page 76
- *Amending Lead Organization and Principal Investigator Details* on page 78
- *Amending Sponsor and Summary 4 Details* on page 79
- *Amending NIH Grant Details* on page 79
- *Amending Trial Status Dates* on page 79
- *Amending IND/IDE Details* on page 80
- *Uploading Amendment-Specific Documents* on page 80

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 31.

Note: You cannot change an NCI trial identifier number.

Related topics:

- *Amending Verified Trials* on page 76
- *Amending Lead Organization and Principal Investigator Details* on page 78
- *Amending Sponsor and Summary 4 Details* on page 79
- *Amending NIH Grant Details* on page 79
- *Amending Trial Status Dates* on page 79
- *Amending IND/IDE Details* on page 80
- *Uploading Amendment-Specific Documents* on page 80

Amending Lead Organization and Principal Investigator Details

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 34.

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* on page 76

- *Amending Trial Details* on page 78
- *Amending Sponsor and Summary 4 Details* on page 79

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 Summary 4 Information Section* on page 38.

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* on page 76
- *Amending Lead Organization and Principal Investigator Details* on page 78
- *Amending Verified Trials* on page 76
- *Amending Lead Organization and Principal Investigator Details* on page 78

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 39.

Note: You cannot change an existing NIH grant number.

Related topics:

- *Amending Verified Trials* on page 76
- *Amending Sponsor and Summary 4 Details* on page 79
- *Amending IND/IDE Details* on page 80

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 44.

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 44.

Related topics:

- *Amending Verified Trials* on page 76
- *Reviewing and Submitting Trial Amendments and Updates* on page 81

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 46.

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

Related topics:

- *Amending Verified Trials* on page 76
- *Amending Sponsor and Summary 4 Details* on page 79
- *Amending NIH Grant Details* on page 79

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
- Corel 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 51.

Note: You cannot update or delete existing documents.

Related topics:

- *Amending Verified Trials* on page 76
- *Amending Trial Details* on page 78
- *Amending Trial Status Dates* on page 79

Reviewing and Submitting Trial Amendments and Updates

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

How to Review and Submit Trial Amendments and Updates

1. Complete all modifications to the most recent trial submission.
2. Scroll to the bottom of the **Amendment Trial/Update 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/update is error-free.

   Note: The Review Trial Details page is read-only. To edit information that you have reviewed, see *Editing Amended and Updated Details* on page 81
4. Click **Submit**.

Related topics:

- *Amending Verified Trials* on page 76
- *Editing Amended and Updated Details* on page 81
- *Printing Amended and Updated Trial Information* on page 82

Editing Amended and Updated Details

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

How to Edit Amended and Updated Details

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

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

Caution: You must upload the amendment- or update-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 Trial Amendments and Updates* on page 81.

Related topics:

- *Amending Verified Trials* on page 76
- *Reviewing and Submitting Trial Amendments and Updates* on page 81
- *Printing Amended and Updated Trial Information* on page 82

Printing Amended and Updated Trial Information

You can print a copy of the amended/updated 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 Trial Amendments and Updates* on page 81.

How to Print Amended and Updated 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* on page 76
- *Reviewing and Submitting Trial Amendments and Updates* on page 81
- *Editing Amended and Updated Details* on page 81

CHAPTER

5

MANAGING YOUR ACCOUNT

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

This chapter includes the following topics:

Managing Your User Account Profile

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. Click **Submit Account Updates** to save changes to the account information.

Related topics:

- *Creating an Account* on page 6

- *Logging In to the CTRP Registration Site* on page 8
- *Managing Your Password* on page 84
- *Transferring Trial Ownership* on page 85

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 84 and *Resetting Your Password* on page 84.

Related topics:

- *Creating an Account* on page 6
- *Logging In to the CTRP Registration Site* on page 8
- *Changing Your Password* on page 84
- *Resetting Your Password* on page 84

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.

Related topics:

- *Creating an Account* on page 6
- *Logging In to the CTRP Registration Site* on page 8
- *Resetting Your Password* on page 84

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 in *Creating an Account* on page 6.

Related topics:

- *Creating an Account* on page 6
- *Logging In to the CTRP Registration Site* on page 8
- *Changing Your Password* on page 84

Transferring Trial Ownership

CTRP Registration Site account holders can submit new clinical trial protocol details. The trial submitter is designated trial owner upon registration. Only the trial owner can amend or update the verified trial. As a current trial owner, you can transfer ownership of your trial to a designee. Once transferred, the new owner can update and amend the trial.

How to Transfer Trial Ownership

1. Ask your prospective trial owner to register for an account in the CTRP Registration Site.
2. Submit a request for change of trial ownership to the CTRO via email at `mailto:ncictro@mail.nih.gov.` Include the following information with your request:
    - NCI ID of the trial for which you want to transfer ownership
    - Prospective trial owner's first name, last name, and email address as recorded in the account profile.

    The CTRO notifies you when they have completed the trial ownership transfer.

Related topics:

- *Creating an Account* on page 6
- *Managing Your User Account Profile* on page 83
- *Updating and Amending Registered Trials* on page 71

APPENDIX

A

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 for Non-Proprietary Trials

The CTRP website provides a batch upload template, valid data values, data definitions, examples, and rules for registering batches of trials and trial amendments/updates. This section contains a summary of the information required for the `.xls` file. See *Using the Batch Upload Template* on page 12.

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:

- Multiple grants per trial
- Multiple IND/IDEs per trial
- 100 trials per file
- Interventional trials only

- Non-proprietary 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.

Related topics:

- *Preparing Trial-Related Documents* on page 88
- *Trial Data Element Specifications For Non-Proprietary Trials* on page 89
- *Preparing the Trial Data File for Proprietary Trials* on page 90
- *Trial Specification Rules For Proprietary Trials* on page 90

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 A.1* below.

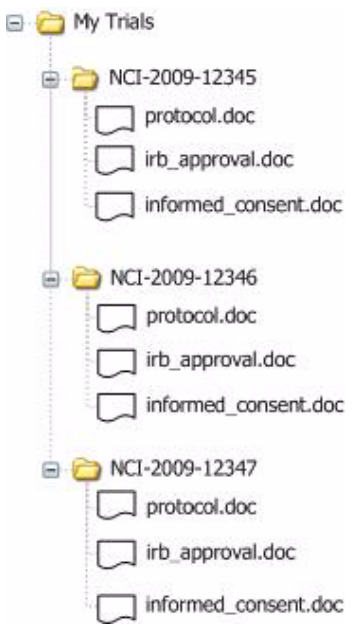


Figure A.1 Example Directory Structure for Trial-Related Documents

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.

   Note: Accepted document file types include PDF, WORD, XLS, and Word Perfect.

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.

Related topics:

- *Preparing the Trial Data File for Non-Proprietary Trials* on page 87
- *Trial Data Element Specifications For Non-Proprietary Trials* on page 89
- *Preparing the Trial Data File for Proprietary Trials* on page 90
- *Trial Specification Rules For Proprietary Trials* on page 90

Trial Data Element Specifications For Non-Proprietary Trials

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

To access the `CTRP_Registry_Batch_Upload.xls` file, see *Downloading Trial Registration Templates* on page 10.

For further details about trial data, refer to *Metadata Definitions* on page 95.

Related topics:

- *Preparing the Trial Data File for Non-Proprietary Trials* on page 87
- *Preparing Trial-Related Documents* on page 88
- *Preparing the Trial Data File for Proprietary Trials* on page 90
- *Trial Specification Rules For Proprietary Trials* on page 90

Preparing the Trial Data File for Proprietary Trials

The CTRP website provides a batch upload template, valid data values, data definitions, examples, and rules for registering batches of proprietary trials. This section contains a summary of the information required for the `.xls` document. See *Using the Proprietary Trial Template* on page 11.

How to Prepare the Trial Data File

1. In Microsoft Excel, list the trial elements required for registration in the order specified in the `Registry_Proprietary_Trial_Template.xls` file.
2. Email the file to CTRO at `mailto:ncictro@mail.nih.gov` as an attachment.

   CTRO staff process your file and register your trials.

Note: Because the CTRO staff submit your trials, they maintain trial ownership by default.

To assume ownership of the trials, send a request for trial ownership to the CTRO along with the `.xls` file. For detailed instructions, see *Transferring Trial Ownership* on page 85.

Related topics:

- *Preparing the Trial Data File for Non-Proprietary Trials* on page 87
- *Preparing Trial-Related Documents* on page 88
- *Trial Data Element Specifications For Non-Proprietary Trials* on page 89
- *Trial Specification Rules For Proprietary Trials* on page 90

Trial Specification Rules For Proprietary Trials

The `Registry_Proprietary_Trial_Template.xls` file lists all trial data required for registering multiple trials in batches.

Rules for submitting specified data include the following:

- Maintain the order in which the data appear in the `.xls` file
- Uniquely identify each trial
- If you provide an NCT trial number, you do not have to provide the following data:
    - primary purpose
    - phase
    - disease
    - intervention

If the CTRO identifies a trial as a duplicate to an existing trial, you can request that they add your organization information to the existing trial as a participating site instead of creating a duplicate.To access the `Registry_Proprietary_Trial_Template.xls`, see *Downloading Trial Registration Templates* on page 10.

Related topics:

- *Preparing the Trial Data File for Non-Proprietary Trials* on page 87
- *Preparing Trial-Related Documents* on page 88
- *Trial Data Element Specifications For Non-Proprietary Trials* on page 89
- *Preparing the Trial Data File for Proprietary Trials* on page 90
- *Transferring Trial Ownership* on page 85

APPENDIX

B

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

Participating site documents include treating site and collaborator information. They are applicable to non-proprietary trials only.

The CTRP website provides participating site document templates, valid data elements, and rules. See *Using the Participating Sites Template* on page 11.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 or study contact information
- Treating site data includes the following:
  - organization attribute

- current recruitment status
- status date
- target program code

- 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
- Study/site generic contact information includes the following:
  - generic contact's title
  - generic contact's email address and phone number
- Treating site contact information is optional if an investigator is used as contact person, or if study site contact information is provided.
- The minimal set of treating site information includes the following:
  - treating site data
  - study site investigator's information and site or study contact information
- For studies with multiple investigators, create one line per investigator/site using the treating site number as reference.

Related topics:

- *Participating Site Data Element Specifications* on page 94
- *Batch Upload Data Specifications* on page 87

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 10.

Related topics:

- *Participating Sites Document Rules* on page 93
- *Batch Upload Data Specifications* on page 87

APPENDIX C
METADATA DEFINITIONS

This appendix provides the values and definitions of the metadata associated with clinical trials.

Allocation

Assignment of participants to an intervention group.

Allocation Values	***Definitions***
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

Table C.1 Allocation definitions and valid values

Amendment Number

Number 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.

Funding Mechanism Values	***Definitions***
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 C.2 Funding Mechanism definitions and valid values

Identifier Type

Type of organization (system) that assigns the identifier to the trial (for example, Lead Organization, or NCI CTRP)

Identifier Type Values	***Definitions***
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

Table C.3 Identifier Type definitions and valid values

Intervention Model

Design of an interventional study.

Intervention Model Values	***Definitions***
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

Table C.4 Intervention Model definitions and valid values

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: Note: Inter-Group trials use the lead Groups trial number.

Masking

Hiding knowledge of intervention assignment

Masking Values	***Definitions***
Open	No masking

Table C.5 Masking definitions and valid values (Continued)

Masking Values	Definitions
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

Table C.5 Masking definitions and valid values (Continued)

Milestones

Stages in the trial processing life cycle. Record progress in trial processing and set the trial processing status. Interrelated with on-hold states.

Milestone Values	Definitions
Submission Received Date	Date the trial was successfully submitted via the NCI CTRP Registration Site
Ready for QC Date	Date the trial abstraction was completed so that Quality Control (QC) of the abstraction could be initiated
Submission Acceptance Date	Date the document specialist accepted the trial submission for validation
QC Start Date	Date of initial QC of the abstraction
Ready for PDQ Abstraction Date	Date PDQ first had access to the trial record to abstract selected subsets of trial attributes
QC Completed Date	Date that QC of the abstraction was completed
Submission Rejection Date	Date the document specialist rejected the trial submission during validation
PDQ Abstraction Completed Date	Date that PDQ completed the abstraction of the selected subset of trial attributes
Administrative Processing Start Date	Date of initial abstraction of administrative details
Trial Summary Report Sent Date	Date the Trial Summary Report was sent to the principal investigator or trial submitter
Administrative Processing Completed Date	Date the abstraction of administrative details was completed
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
Scientific Processing Start Date	Date of initial abstraction of the scientific details
Initial Abstraction Verified Date	Date the document specialist recorded that the abstracted data was verified upon receipt of the submitter's TSR feedback TSR feedback is due within 5 business days following the TSR Sent Date. The Initial Abstraction Verified Date can be later if no feedback is received

Table C.6 Milestone definitions and valid values (Continued)

Milestone Values	Definitions
Scientific Processing Completed Date	Date the abstraction of scientific details was completed
On-going Abstraction Verified Date	Date the document specialist recorded that abstracted data was verified, following a post-verified status when there has been an abstraction update or a delay in the submitter's feedback

Table C.6 Milestone definitions and valid values (Continued)

NCI Division/Program Code

Codes that represent individual NCI divisions and programs.

NCI Division/Program Code Values	Definitions
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

Table C.7 NCI Division/Program Code definitions and valid values

NCI Trial Identifier

Unique identifier assigned to the trial by the NCI Clinical Trials Reporting Program Trial Registration Site application.

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.

Example: **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

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 identifying a particular supplemental record.

NIH 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.

Institute Code Values	***Definitions***
AA	National Institute on Alcohol Abuse and Alcoholism (NIAAA)
AG	National Institute on Aging (NIA)
AI	National Institute of Allergy and Infectious Diseases Extramural Activities (NIAID)
AO	NIAID Research Support
AR	National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)
AT	National Center for Complementary and Alternative Medicine (NCCAM)
BC	Division of Basic Sciences (NCI)
CA	National Cancer Institute (NCI)
CB	Division of Cancer Biology and Diagnosis (NCI)
CL	Clinical Center (CLC)
CM	Division of Cancer Treatment (NCI)
CN	Division of Cancer Prevention and Control (NCI)
CO	Office of the Director (NCI)

Table C.8 NIH Institute Codes

Institute Code Values	***Definitions***
CP	Division of Cancer Epidemiology and Genetics (NCI)
CT	Center for Information Technology (CIT)
DA	National Institute on Drug Abuse (NIDA)
DC	National Institute on Deafness and Other Communication Disorders (NIDCD)
DE	National Institute of Dental and Craniofacial Research (NIDCR)
DK	National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)
EB	National Institute of Biomedical Imaging and Bioengineering (NIBIB)
ES	National Institute of Environmental Health Sciences (NIEHS)
EY	National Eye Institute (NEI)
GM	National Institute of General Medical Sciences (NIGMS)
GW	Genome Association Studies (GAS)
HB	Division of Blood Diseases and Resources (NHLBI)
HC	Division of Epidemiology & Clinical Applications (NHLBI)
HD	National Institute of Child Health & Human Development (NICHD)
HG	National Human Genome Research Institute (NHGRI)
HI	Division of Intramural Research (NHLBI)
HL	National Heart, Lung, and Blood Institute (NHLBI)
HO	Office of the Director (NHLBI)
HR	Division of Lung Diseases (NHLBI)
HV	Division of Heart and Vascular Diseases (NHLBI)
JT	Joint Funding
LM	National Library of Medicine (NLM)
MD	National Center on Minority Health and Health Disparities (NCMHD)
MH	National Institute of Mental Health (NIMH)
NB	Neuroscience Blueprint (NB)
NR	National Institute of Nursing Research (NINR)
NS	National Institute of Neurological Disorders and Stroke (NINDS)
OD	Office of the Director (NIH)
OF	Office of Research Facilities Development and Operations (ORFDO)
OL	Office of Logistics and Acquisition Operations (OLAO)
OR	Office of Research Services (ORS)
PC	Division of Cancer Control and Population Science (NCI)
SC	Division of Clinical Sciences (NCI)

Table C.8 NIH Institute Codes

Institute Code Values	Definitions
SF	Superfund Basic Research Program (SBRP)
WH	Women's Health Initiative (WHI, OD)
RC	Center for Cancer Research (CCR)
RG	Center for Scientific Review (CSR)
RM	NIH Roadmap Initiative, Office of the Director (RMOD)
RR	National Center for Research Resources (NCRR)
TW	Fogarty International Center (FIC)
WT	Worker Education Training Program (WETP)

Table C.8 NIH Institute Codes

Non-proprietary Trial

Trial with no contractual restrictions for sharing the protocol document.

Primary Purpose

Reason for the protocol.

Primary Purpose Values	Definitions
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

Table C.9 Primary Purpose definitions and valid values

Primary Purpose Values	Definitions
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
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

Table C.9 Primary Purpose definitions and valid values

Principal Investigator

Investigator responsible for all aspects of the conduct of the study.

Example: Moitessier, Bernard

Processing Status

Current progress of the trial with respect to the abstraction process.

Processing Status Values	Definitions
All	Any status
Abstracted	Trial has been abstracted and is available for further abstraction

Table C.10 Processing Status definitions and valid values

Processing Status Values	Definitions
Submitted	Original trial has been submitted but the abstraction process has not begun
Amendment Submitted	Amendment has been submitted but the abstraction process has not begun.
Verification Pending	TSR has been sent to the submitter, and the submitter's feedback is pending
Abstraction Verified Response	Trial has been abstracted and completed, and the trial submitter has responded to the TSR sent for verification
Accepted	Validated trial. A submitted trial that has passed validation (conforms to the CTRO rules for valid submission).
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

Table C.10 Processing Status definitions and valid values

Proprietary Trial

Trial with a contractual obligation that restricts sharing of the protocol document.

Responsible Party

As defined in US Public Law 110-85, Title VIII, Section 801, the term “responsible party”, with respect to a clinical trial, can refer to either of the following:

- 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

For further information about the definition of “responsible party”, see http://prsinfo.clinicaltrials.gov/ElaborationsOnDefinitions.pdf.

Sponsor

Name of primary organization that oversees implementation of study and is responsible for data analysis. For applicable clinical trials, sponsor is defined in 21 CFR 50.3. For further elaboration on the definition of Sponsor with respect to responsible party, see: http://prsinfo.clinicaltrials.gov/ElaborationsOnDefinitions.pdf.

Example: Bristol-Myers Squibb

Study Classification

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

Study Classification Values	***Definitions***
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 a 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

Table C.11 Study Classification definitions and valid values

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.

Summary 4 Funding Category Values	***Definitions***
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

Table C.12 Summary 4 Funding Category definitions and valid values

Summary 4 Sponsor/Source

Primary organization responsible for funding the trial. It pertains to clinical trials involving an agent or device, or other intervention only:

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.

Trial Phase Values	***Definitions***
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

Table C.13 Trial Phase definitions and valid values

Trial Status

Code that represents the status of a trial in relation to the ability to enroll participants/ patients.

Trial Status Values	***Definitions***
Approved	Trial has been approved
In Review	Trial recruitment has not started
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.l
Administratively Complete	Trial has been completed prematurely (for example, due to poor accrual, insufficient drug supply, IND closure, etc.)
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

Table C.14 Trial Status definitions and valid values

Trial Type

Nature of the investigation. It represents a clinical study by product, procedure, or method tested.

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.
approved trial	Trial status indicator for a trial that has been approved by the review board. Study activation preparation has begun.
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
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

Term	*Definition*
CTWG	Clinical Trials Working Group
compressed file	File that has been compacted to reduce file size
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.
disapproved trial	Trial status indicator for a trial that has been disapproved by the review board upon submission and will not be re-submitted
EBI	European Bioinformatics Institute
EVS	Enterprise Vocabulary Services
FDA	Food and Drug Administration
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.
IND Number	Investigational New Drug Number. Generally a 5-digit number (e.g., 66,225) for non-biologic agents and a 4-digit number beginning with "BB" for biologics (e.g., BB 1234) that the FDA assigns the investigational agent being used in a specific clinical trial. It references the drug(s) or product(s) used under a specific IND application.
IRB	Institutional Review Board
In review	Trial status indicator for a trial that has been submitted to the review board for approval. Board approval is pending.

Term	*Definition*
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
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
PRS	Protocol Registration System
private trial	Trial submitted by the user who is currently logged in to the CTRP Registration Site
principal investigator	Appointed investigator responsible for conducting clinical trial, or for multi-site trials, the study chair
public trial	Trial submitted by a registered user other than the person currently logging in to the CTRP Registration Site
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
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. For applicable clinical trials, sponsor is defined in 21 CFR 50.3. For further elaboration on the definition of Sponsor with respect to responsible party, see: http://prsinfo.clinicaltrials.gov/ElaborationsOnDefinitions.pdf.
TRP	Translational Research Program (Formerly SPORE)
trial status	The current stage or state of a clinical trial or study relative to other stages.

Term	***Definition***
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
Zip	File that contains one or more compressed files. Used as a verb when using a compression tool to compress files.

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