
NCI CLINICAL TRIALS REPORTING PROGRAM

User's Guide v. 1.0



**NATIONAL[®]
CANCER
INSTITUTE**

Center for Biomedical Informatics
and Information Technology

TABLE OF CONTENTS

About This Guide	1
Purpose	1
Audience	1
Topics Covered	1
Text Conventions Used	2
Credits and Resources	3
Application Support	4
Chapter 1	
Getting Started	5
About the NCI Clinical Trials Reporting Program	5
Registering as a New User	5
Logging In to the NCI Clinical Trials Reporting Program	7
Chapter 2	
Searching For Trials	9
About Clinical Trial Metadata	9
Searching For Trials	9
Working with Search Results	12
Navigating Through the Search Results List	13
Viewing Trial Details	14
Viewing Trial-Related Documents	14
Chapter 3	
Registering New Trials	15
Registering Trials in the NCI Clinical Trials Reporting Program	15
Completing the Trial Details Section	16
Completing the Lead Organization/Principal Investigator Section	19
Completing the Sponsor/Responsible Party Section	20
Completing the Summary 4 Information Section	21
Completing the NIH Grant Information Section	22

Completing the Trial Status/Dates Section	25
Completing the IND/IDE Information Section	26
<i>Registering IND Trials</i>	27
<i>Registering IDE Trials</i>	28
Completing the Trial Related Documents Section	30
Registering Organizations	31
Searching for Registered Organizations	32
Adding Organizations	33
Registering Persons	35
Searching for Principal Investigators	35
Adding Principal Investigators	37
Registering Multiple Trials Concurrently	38
Data Requirements for Batch Uploads	40
Chapter 4	
Managing Your Account	43
Editing User Information	43
Managing Your Password	44
Changing Your Password	44
Resetting Your Password	44
Appendix A	
Metadata Definitions	45
Appendix B	
Batch Upload Data Specifications	53
Preparing the Trial Data File	53
Preparing Trial-Related Documents	54
Trial Data Specifications	54
Glossary	63
Index	67

ABOUT THIS GUIDE

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

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

Purpose

This guide provides an overview of the NCI Clinical Trials Reporting Program (CTRP) 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 trial details.

Audience

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

Topics Covered

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

- *Chapter 1, Getting Started*, on page 5 introduces you to the NCI Clinical Trials Reporting Program and provides instructions for registering for an account and for logging in to the system.
- *Chapter 2, Searching For Trials*, on page 9 describes how to search for, submit, and view trials in the NCI Clinical Trials Reporting Program.
- *Chapter 3, Registering New Trials*, on page 15 describes how to submit, or register, trials using the NCI Clinical Trials Reporting Program.

- [Chapter 4, Managing Your Account](#), on page 43 provides instructions for modifying your NCI Clinical Trials Reporting Program account.
- [Appendix A, Metadata Definitions](#), on page 45 defines the metadata associated with trials and provides examples of valid values for trial details.
- [Appendix B, Batch Upload Data Specifications](#), on page 53 describes how to prepare your trial data and documents. It also provides data specifications for the trial data.
- [Glossary](#) provides definitions of acronyms, abbreviations, and terminology used in this guide.

Text Conventions Used

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

Convention	Description	Example
Bold	Highlights names of option buttons, check boxes, drop-down menus, menu commands, command buttons, or icons.	Click Search .
<u>URL</u>	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.
<i>Italics</i>	Highlights references to other documents, sections, figures, and tables.	See <i>Figure 4.5</i> .
<i>Italic boldface monospace type</i>	Represents text that you type.	In the New Subset text box, enter <i>Proprietary Proteins</i> .
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.

NCI Clinical Trials Reporting Program Development and Management Teams		
Development	Documentation	Project and Product Management
Smita Hastak ⁵	Lauren Anthon ²	John Speakman ¹
Nellie Shimko ⁵	Jill Hadfield ¹	Christo Andonyadis ¹
Lisa Schick ⁵	Quality Assurance	Charlie Mead ⁶
Wendy Ver Hoef ⁵	Paula Brown ⁸	Nancy Roche ⁷
Todd Parnell ⁴	Sohal Shah ⁸	Edmond Mulaire ³
Paul Boyes ⁶	Jyothsna Chilukuri ⁷	Kevin Stern ⁶
John Koisch ⁶	Kavitha Thulasiraman ⁷	Rebecca Teague ⁶
Naveen Amiruddin ⁵	Ujala Kapoor	
Scott Miller ⁴		
Bala Nair ⁵		
Hugh Reinhart ⁵		
Harsha Jayanna ⁵		
Kalpana Guthikonda ⁵		
Steve Matyas ⁴		
Leslie Power ⁴		
Gax Ayalew ⁴		
Hong-Qiang Gao ⁵		
¹ National Cancer Institute Center for Biomedical Informatics and Information Technology (NCI-CBIIT)	² Lockheed Martin ³ SemanticBits ⁴ 5AM Solutions ⁵ ScenPro, Inc.	⁶ Booz Allen Hamilton ⁷ Science Application International Corporation (SAIC) ⁸ Ekagra

Key Contributors	
Troy Budd ³	Jeff Shilling ⁴
Steve Friedman ⁵	John Speakman ¹
Lakshmi Grama ²	Pat Winkler ⁶
Beverly Meadows ³	Jo Anne Zujewski ⁵
Elizabeth Ness ⁴	Kumar Chandran ⁷
¹ National Cancer Institute Center for Biomedical Informatics and Information Technology (NCI-CBIIT) ² Office of Communications and Education (OCE) ³ Division of Cancer Prevention (DCP) ⁴ Center for Cancer Research (CCR) ⁵ Cancer Therapy Evaluation Program (CTEP) ⁶ Cancer Centers Branch (CCB) ⁷ Capital Technology Information Services, Inc.(CTIS)	

References	
Protocol definitions	<ul style="list-style-type: none"> • http://clinicaltrials.gov • http://www.cancer.gov/dictionary/db_alpha.aspx?expand • http://prsinfo.clinicaltrials.gov/fdaaa.html • http://www.cancer.gov/ncictrp

Application Support

For technical assistance when registering your trials with CTRP, or for any general information about the application, application support, or to report a bug, contact NCICB Application Support.

Email: ncicb@pop.nci.nih.gov (mailto:ncicb@pop.nci.nih.gov)	When submitting support requests via email, please include: <ul style="list-style-type: none"> • Your contact information, including your telephone number. • The name of the application/tool you are using • The URL if it is a Web-based application • A description of the problem and steps to recreate it. • The text of any error messages you have received
Application Support URL	http://ncicb.nci.nih.gov/NCICB/support
Telephone: 301-451-4384 Toll free: 888-478-4423	Telephone support is available: Monday to Friday, 8 am – 8 pm Eastern Time, excluding government holidays.

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

GETTING STARTED

This chapter introduces you to the NCI Clinical Trials Reporting Program and provides instructions for registering for an account and for logging in to the system. This section includes the following topics:

- [About the NCI Clinical Trials Reporting Program](#) on this page
- [Registering as a New User](#) on page 5
- [Logging In to the NCI Clinical Trials Reporting Program](#) on page 7

About the NCI Clinical Trials Reporting Program

The NCI Clinical Trials Reporting Program (CTRP) 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, registered users can submit new clinical trial protocol details.

The CTRP enables users to register trials one-at-a-time, or in batches consisting of multiple trials. For information on registering single trials, see [Chapter 3, Registering New Trials](#), on page 15. For information on registering multiple trials, see [Registering Multiple Trials Concurrently](#) on page 38.

Currently you can register [interventional trials](#). Future releases of this produce will enable you to register [observational](#) trials as well.

Registering as a New User

Registering as a NCI Clinical Trial Portal user enables you to search for and submit individual clinical trial protocol details. Additionally, you can request authorization from the CTRP to use the CTRP's batch upload feature to register multiple new trials that were conducted at a given site. Follow instructions in [Registering Multiple Trials Concurrently](#) on page 38

Note: You must provide, and have access to, a valid e-mail address to register for an account.

How to Register as a New User

1. Navigate to the NCI Clinical Trials Reporting Program 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.

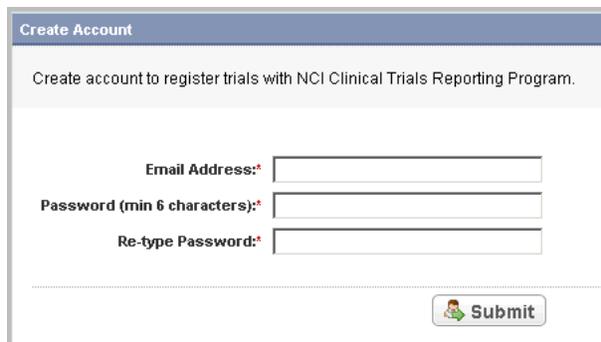
The image shows the 'Create Account' page. At the top is a blue header with the text 'Create Account'. Below the header is a sub-header: 'Create account to register trials with NCI Clinical Trials Reporting Program.' The main content area contains three input fields, each with a label and an asterisk: 'Email Address:*', 'Password (min 6 characters):*', and 'Re-type Password:*'. At the bottom right of the form is a 'Submit' button with a small icon of a person.

Figure 1.2 NCI Clinical Trials Reporting Program – Create Account Page

3. Type a valid e-mail 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 **Continue**.

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

- Open the confirmation e-mail and click the embedded link to confirm your registration.

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

Figure 1.3 My Account page

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

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

- In the **Affiliate Organization** field, type the name of the organization you are affiliated with.
- Click **Submit**.

Logging In to the NCI Clinical Trials Reporting Program

Once you have registered for an NCI Clinical Trials Reporting Program account, you can log in to search for and submit clinical trial details.

Note: 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 two hours.

How to Log In to the NCI Clinical Trials Reporting Program

1. Navigate to the NCI Clinical Trials Reporting Program home page at: <http://trials.nci.nih.gov/registration>
2. On the navigation pane on the left side of the page (*Figure 1.4*), click **Login**.



Figure 1.4 Navigation Pane

The Login page appears.

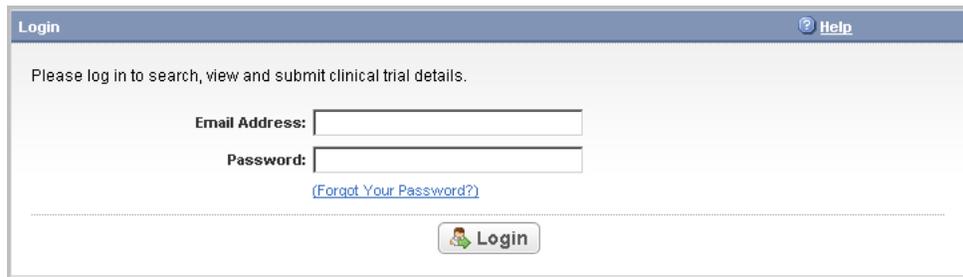


Figure 1.5 NCI Clinical Trials Reporting Program – Login page

3. Type the e-mail address and password you registered earlier. See [Registering as a New User](#) for more information on creating a user account.

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

4. Click **Login**.

The **Search Trials** page appears.

After you have logged in to NCI Clinical Trials Reporting Program, you can proceed to search for and/or add clinical trials in the system.

CHAPTER 2

SEARCHING FOR TRIALS

This chapter describes how to search for existing trials in the NCI Clinical Trials Reporting Program.

This chapter includes the following topics:

- [About Clinical Trial Metadata](#) on this page
- [Searching For Trials](#) on page 9
- [Working with Search Results](#) on page 12
- [Viewing Trial Details](#) on page 14

About Clinical Trial Metadata

The NCI Clinical Trials Reporting Program captures trial details, or metadata, as entered by a trial protocol submitter. This metadata enables the research community to share common elements. [Appendix A, Metadata Definitions](#), on page 45 describes the metadata associated with trials and provides examples of valid values.

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

Searching For Trials

You can retrieve existing trials through the NCI Clinical Trials Reporting Program once you have registered for an account. See [Registering as a New User](#) on page 5.

Note: You can search the registration information for all trials registered with NCI 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 11. All registered users can search trials with the “Validated” processing status. Additionally,

you can search trials that you registered, but not validated. These trials are indicated by the “Submitted” status.

How to Search For Existing Trials

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

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

Figure 2.1 Search Trials Page

2. Provide one or more search criteria for the trials you want to retrieve.

Tip: To display a list of all trials, leave all fields blank and select **Any** from the drop-down menus.

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.
Trial Phase	Select the <i>trial phase</i> from the drop-down menu. <ul style="list-style-type: none"> • Phase 0 • Phase I • Phase I/II • Phase II • Phase II/III • Phase III • Phase IV • Pilot • N/A • Other

Table 2.1 Trial Search Criteria

<i>To search by this...</i>	<i>Do this...</i>
Trial Type	Select the <i>type of clinical trial</i> from the drop-down menu. <ul style="list-style-type: none"> • <i>Treatment</i> • <i>Prevention</i> • <i>Diagnostic</i> • <i>Supportive Care</i> • <i>Screening</i> • <i>Health Services Research</i> • <i>Basic Science</i> • <i>Expanded Access</i> • <i>Early Detection</i> • <i>Observational</i> • <i>Outcome</i> • <i>Ancillary</i> • <i>Correlative</i> • <i>Interventional</i> • <i>Screening</i> • Other – Any other type of trial not included in this list
Identifier Type	Select the <i>type of trial identifier</i> from the drop-down list. NCI – National Cancer Institute Lead Organization – An NCI Clinical Trials Reporting Office (CTRO) organization responsible for the overall scientific and administrative coordination, study monitoring, and data management activities of a particular clinical trial.
Trial Identifier	Type the unique identifier assigned to the trial by the NCI Clinical Trials Reporting Program system or the identifier assigned to it by the lead organization. For Inter-Group trials, type the Lead Groups trial number.
Organization Type	Select either Lead or All from the drop-down list.
Organization	Type the initial letter(s) of your organization and then select the name of your organization from the drop-down list.

Table 2.1 Trial Search Criteria (Continued)

3. Do one of the following to submit your search criteria:
 - 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**.

The Search Trials page refreshes and displays a list of search results. For more information on navigating and working with search results, see [Working with Search Results](#).
4. To view the trial, click the link corresponding to the [NCI Trial Identifier](#).

The Trial Details page appears. For more information on viewing trial details, see [Viewing Trial Details](#).

Working with Search Results

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

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

The search returns results and displays them accordingly 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 NCI Clinical Trials Reporting Program.
- Public trials – Trials submitted by other registered users.

[Table 2.2](#) table 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.

Status	Definition	Which roles can see this trial in the list?	Listed in “My Trials?”
Submitted	Trial submitted but not validated	Submitter	Yes
Rejected	Trial did not pass validation	No one	No
Accepted	Trial passed validation	<ul style="list-style-type: none"> • Submitter • Other users 	Yes

Table 2.2 Processing statuses of trials in the NCI Clinical Trials Reporting Program

Status	Definition	Which roles can see this trial in the list?	Listed in "My Trials?"
Abstracted	Trial has been abstracted	<ul style="list-style-type: none"> • Submitter • Other users 	Yes
Abstraction Verified	Abstraction has been verified by the submitter	<ul style="list-style-type: none"> • Submitter • Other users 	Yes

Table 2.2 Processing statuses of trials in the NCI Clinical Trials Reporting Program

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. You can navigate through the search results in several ways, as detailed in [Table 2.3](#).

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

Table 2.3 Methods for viewing search results and trial details

Viewing Trial Details

To view details for a given clinical trial listed on a search results page, click its associated [NCI Trial Identifier](#) hypertext link.

The Trial Details page displays the metadata as entered by a trial submitter. Refer to [Appendix A, Metadata Definitions](#), on page 45 for a description of the metadata.

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

Viewing Trial-Related Documents

Only submitters can view/download trial-related documents.

How to Download Trial-Related Documents

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

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

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

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

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

CHAPTER 3

REGISTERING NEW TRIALS

This chapter describes how to register trials using the NCI Clinical Trials Reporting Program.

This chapter includes the following topics:

- *Registering Trials in the NCI Clinical Trials Reporting Program* on this page
- *Registering Organizations* on page 31
- *Registering Persons* on page 35
- *Registering Multiple Trials Concurrently* on page 38

Registering Trials in the NCI Clinical Trials Reporting Program

NCI Clinical Trials Reporting Program provides a user-friendly interface through which you can register new trials.

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 9.

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

See the following topics for more detailed instructions and definitions:

- *Completing the Trial Details Section* on page 16
- *Completing the Lead Organization/Principal Investigator Section* on page 19
- *Completing the Sponsor/Responsible Party Section* on page 20
- *Completing the Summary 4 Information Section* on page 21
- *Completing the NIH Grant Information Section* on page 22

- [Completing the Trial Status/Dates Section](#) on page 25
- [Completing the IND/IDE Information Section](#) on page 26
- [Completing the Trial Related Documents Section](#) on page 30

How to Submit a Trial

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

Figure 3.1 Register Trial Page – Upper Section

2. Type the appropriate information in the text fields, or select options from the drop-down lists as appropriate.
3. Click **Submit Trial**.

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

Completing the Trial Details Section

You must complete all fields in the Trial Details section.

Figure 3.2 Add Trial Page – Trial Details Section

How to Complete the Trial Details Section

1. Type the *Lead Organization Trial Identifier* in the field provided, or for Inter-Group trials, type the Lead Groups 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 assigned per the first submission.

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. The following table *Table 3.1* lists valid trial phases:

Phase #	Definition
0	Tests a new treatment that is available only in very limited quantities and which has never previously given to humans or for which there is extremely limited human experience to enable researchers to understand the path of the drug in the body and its efficacy.
I	The first step in testing a new treatment in humans. These studies test the best way to administer a new treatment (e.g., by mouth, intravenous infusion, or injection) and the best dose. The dose is usually increased a little at a time in order to find the highest dose that does not cause harmful side effects. Because little is known about the possible risks and benefits of the treatments being tested, phase I trials usually include only a small number of patients who have not been helped by other treatments

Table 3.1 Trial phase definitions

Phase #	Definition
I/II	A clinical research protocol designed to study the safety, dosage levels and response to new treatment. Phase I/II trials combine a Phase I and a Phase II trial of the same treatment into a single protocol.
II	A study to test whether a new treatment has an anticancer effect (for example, whether it shrinks a tumor or improves blood test results) and whether it works against a certain type of cancer.
II/III	A trial to study response to a new treatment and the effectiveness of the treatment compared with the standard treatment regimen.
III	A study to compare the results of people taking a new treatment with the results of people taking the standard treatment (for example, which group has better survival rates or fewer side effects). In most cases, studies move into phase III only after a treatment seems to work in phases I and II. Phase III trials may include hundreds of people.
IV	Evaluates the long-term safety and efficacy of a treatment for a given indication and studies side effects that may have become apparent after the phase III study was completed
Pilot	Initial study examining a new method or treatment.
N/A	Not applicable
Other	Any phase not listed above

Table 3.1 Trial phase definitions

4. If you selected Other in Step 3, in the **Phase Comment** field, type a description about the phase of the trial.
5. The *Interventional Trial Type* is pre-selected.
Note: Currently you can register *interventional* trials only. Future releases of this produce will enable you to register *observational* trials as well.
6. From the **Purpose** drop-down list, select the purpose of the trial.

The following table *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.
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.
Diagnostic	Protocol designed to evaluate one or more interventions aimed at identifying a disease or health condition.

Table 3.2 Trial type definitions

Trial Purpose	Definition
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 type definitions (Continued)

Completing the Lead Organization/Principal Investigator Section

You must complete both fields in the Lead Organization/Principal Investigator section.

Lead Organization:Principal Investigator

Lead Organization: *

Principal Investigator: *

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

How to Complete the Lead Organization/Principal Investigator Section

1. Look up the [Lead Organization](#) and select the appropriate organization from the list of search results. If your trial's lead organization is not listed, you can register it in the system at this point. To search for and register an organization, follow the instructions in [Searching for Registered Organizations](#) on page 32 and [Adding Organizations](#) on page 33.
2. Look up the [Principle 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 35 and [Adding Principal Investigators](#) on page 37.

Completing the Sponsor/Responsible Party Section

You must complete all fields in the Sponsor/Responsible Party section.

Figure 3.4 Add Trial Page – Sponsor/Responsible Party Section

How to Complete the Sponsor Section

1. Look up the [Sponsor](#) and select the appropriate sponsor organization from the list of search results. If your trial's sponsor is not listed, you can register it in the system at this point. To search for and register a sponsor, follow the instructions in [Searching for Registered Organizations](#) on page 32 and [Adding Organizations](#) on page 33.
2. Indicate the party who is responsible for the trial. Select one of the following options:
 - [PI](#) (principal investigator) – Primary medical researcher in charge of carrying out a clinical trial's protocol.
 - or -
 - [Sponsor](#) – Name of primary organization that oversees implementation of study and is responsible for data analysis.
3. If you selected Sponsor in the previous step, the **Sponsor/Responsible Party** section expands to display the **Responsible Party Contact**. Follow the instructions in [Looking Up Registered Persons](#) on page 65 to record the responsible party contact person information.

Figure 3.5 Add Trial Page – Sponsor Section, Expanded

4. In the **E-mail Address** and **Phone Number** fields, type the responsible party's contact e-mail address and phone number.

Caution: Do not add spaces in the phone number.

Completing the Summary 4 Information Section

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

Figure 3.6 Add Trial Page – Summary 4 Information Section

How to Complete the Summary 4 Information Section

1. Select the [Summary 4 Funding Category](#) from the drop-down list. [Table 3.3](#) lists valid categories:

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

Table 3.3 Summary 4 funding categories definitions

2. Look up the [Summary 4 Funding Sponsor/Source](#) and select the appropriate organization from the list of search results. If your trial's lead organization is not listed, you can register it in the system at this point. To search for an

organization, follow the instructions in [Searching for Registered Organizations](#) on page 32. To register an organization, follow the instructions in [Adding Organizations](#) on page 33.

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. 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 identifying 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/>

NIH Grant Information (for NIH funded Trials)

Assign values to all editable grant elements and click 'Add Grant' button for adding this grant to the trial. Note that the button becomes active when all required grant attributes are assigned.

Funding Mechanism	Institute Code	Serial Number	NCI Division/Program Code	
--Select--	--Select--		--Select--	[Add Grant...]

Funding Mechanism Type	Institute Code	Serial Number	NIH Division Program Code	Action
B09	AA	009999	CCR	[Delete]

Figure 3.7 Add Trial Page – NIH Grant Information Section

How to Complete the NIH Grant Information Section

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

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

The following table [Table 3.5](#) lists examples of valid codes:

<i>Funding Mechanism</i>	<i>Definition</i>
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.

The following table *Table 3.5* lists examples of valid codes:

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

Table 3.5 NIH institute code definitions

3. Type the six-digit number generally assigned sequentially to a series within an Institute, Center, or Division, for example, 009999, in the **Serial Number** field.
4. Type the initial letter(s) of the division or program code in the **NCI Division/Program Code** field and then select the code from the drop-down list.

The following table *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.

NIH Grant Information (for NIH funded Trials)

Assign values to all editable grant elements and click 'Add Grant' button for adding this grant to the trial. Note that the button becomes active when all required grant attributes are assigned.

Funding Mechanism: --Select--
 Institute Code: --Select--
 Serial Number:
 NCI Division/Program Code: --Select--

[Add Grant...]

Funding Mechanism Type	Institute Code	Serial Number	NIH Division Program Code	Action
B09	AA	009999	CCR	Delete

Figure 3.8 Grant Information Section – Registered Grant

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

Another grant record appears.

Funding Mechanism: --Select--
 Institute Code: --Select--
 Serial Number:
 NCI Division/Program Code: --Select--

[Add Grant...]

Funding Mechanism Type	Institute Code	Serial Number	NIH Division Program Code	Action
B09	AA	009999	CCR	Delete
DP1	CO	004444	DCP	Delete

Figure 3.9 Grant Information Section – Additional Grant

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

Completing the Trial Status/Dates Section

You must complete all fields in the Status/Dates section.

Trial Status/Dates

Current Trial Status: * - Select a Status -

Current Trial Status Date: *

Trial Start Date: * Actual Anticipated

Primary Completion date: * Actual Anticipated

Figure 3.10 Add Trial Page – Status/Dates Section

How to Complete the Status/Dates Section

- Select the trial's current **status** from the **Current Trial Status** drop-down list. [Table 3.7](#) lists valid categories.

Status	Definition
Approved	Trial has been approved

Table 3.7 Current trial status definitions

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

Table 3.7 Current trial status definitions

2. 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.
3. 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.
4. 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**.
5. 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.
6. Indicate whether the completion date is the one on which you expect the trial to end, or the date on which the trial actually ended by selecting either **Anticipated** or **Actual**.

Completing the IND/IDE Information Section

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

To register IND trials, see [Registering IND Trials](#) on page 27.

To register IDE trials, see [Registering IDE Trials](#) on page 28.

Registering IND Trials

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

How to Register IND Trials

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

Figure 3.11 Add Trial Page – IND/IDE Section

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

The following table lists valid grantors.

Valid Grantors
<i>CDER</i> – Center for Drug Evaluation and Research
<i>CDER</i> – Center for Biologics Evaluation and Research

Table 3.8 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.

The following table lists valid holder types.

Valid Holder Types
Investigator
Organization
Industry
NIH
NCI

Table 3.9 Valid holder types

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

5. If you selected either NIH or NCI, from the **NIH Institution, NCI Division/Program Code** drop-down list, select the appropriate *institute code*.
6. 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**.

The following table 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
Approved for marketing	This treatment has been approved for sale to the public

Table 3.10 Valid values for expanded access status

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

Registering IDE Trials

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

How to Register IDE Trials

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

Figure 3.12 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.

The following table lists valid holder types.

Valid Holder Types
Investigator
Organization
Industry
NIH
NCI

Table 3.11 Valid holder types

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

5. If you selected either NIH or NCI, from the **NIH Institution, NCI Division/Program Code** drop-down list, select the appropriate Institute code. See [Appendix A, Metadata Definitions](#), on page 45 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**.

The following table 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
Approved for marketing	This treatment has been approved for sale to the public

Table 3.12 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.

Funding Mechanism	Institute Code	Serial Number	NCI Division/Program Code	
--Select--	--Select--		--Select--	[Add Grant.]
Funding Mechanism Type	Institute Code	Serial Number	NIH Division Program Code	Action
B09	AA	009999	CCR	[Delete]
DP1	CO	004444	DCP	[Delete]

Figure 3.13 Grant Information Section – Additional Grant

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

Completing the Trial Related Documents Section

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

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

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

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

Trial Related Documents

Registration requires submission of the complete protocol (for non-industry trials) or a summary of the protocol (for industry trials) and IRB Approval document. For multi-center trials, a list of participating sites and contact information is required. If the protocol does not include Informed Consent or participating sites, please submit them separately using the fields below.

Protocol Document: *

IRB Approval: *

List of Participating Sites:

Informed Consent Document:

Other:

Please verify ALL the trial information you provided on this screen before clicking the "Submit Trial" button below.
Once you submit the trial you will not be able to modify the information.

Figure 3.14 Add Trial Page – Trial Related Documents

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

How to Submit Trial Related Documents

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

Note: Depending on your operating system, you may see a different command name for “Open.”

3. Repeat these steps above for each type of document.
4. When you have completed all fields, click **Submit Trial**.

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

Summary 4 Funding Sponsor Type: National
Summary 4 Funding Sponsor/Source: Bluewater Research

Status / Dates

Current Trial Status: Active
Current Trial Status Date: Jan 2, 2009
Trial Start Date: Jan 2, 2009 Actual
Primary Completion Date: Jan 15, 2010 Anticipated

FDA IND/IDE Information for applicable trials

IND/IDE Type	IND/IDE Number	IND Grantor	IND/IDE Holder Type	NIH Institution, NCI Division/Program Code	Has Expanded Access	Expanded Access Type
IDE	163567	CDRH	Investigator		No	
IND	123456	CBER	Investigator		No	

NIH Grant Information (for NIH funded Trials)

Funding Mechanism	NIH Institute Code	Serial Number	NCI Division/Program Code
B09	AI	12345	CCR

Trial Related Documents

Document Types	File Name
PROTOCOL DOCUMENT	CTRP Acronyms 121608v6.doc
IRB APPROVAL DOCUMENT	CTRP Glossary 102208v4.doc

[Back](#)

Figure 3.15 Trial Details Page After Successful Submission – Lower Sections

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

Registering Organizations

You can register an organization if you are unable to find your organization listed in the system. Before you register an organization, be sure to search the system’s registered organizations to ensure that you do not create a duplicate record. (See [Searching for Registered Organizations](#) on page 32.) If your search results do not contain the name of your organization, you can register a new one. (See [Adding Organizations](#) on page 33.)

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/Principle Investigator** section.

Figure 3.16 Lead Organization/Principle Investigator Section

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

The Search Organizations window appears.

Figure 3.17 Search Organizations Window

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

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

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

4. Click **Search**.

The Search Organizations window displays the results of your search.

The screenshot shows a web interface for searching organizations. At the top, there are input fields for Name, City, Country (set to United States), and Zip. Below these is a CTEP Identifier field. A Search button and an Add Org button are present. The results section shows 5 items found, displaying all items. The results are as follows:

Organization Name	PO-ID	City	State	Country	Zip	Action
NIH	400	Rockville	MD	United States	20852	Select
Adult and Pediatric Urology	455	Milburn	NJ	United States	07041	Select
Doctors Regional Cancer Treatment Center	623	Laredo	TX	United States	78045	Select
El Paso Ear Nose Throat Association	744	El Paso	TX	United States	79925	Select

Figure 3.18 Search Organizations Window – Search Results

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

5. If your organization was not listed, do one of the following to modify your search:
 - To broaden your search so that more organizations are listed in the search results, delete one or more of your criteria. For example, if you searched by part of the organization's name, city, state, and zip code in your original search, you may want to search by state alone.
- or -
- To narrow your search so that fewer organizations are listed in the search results, provide more about your organization. For example, if you searched by organization name only in your original search, you may want to search by city in addition to the name.

6. Click **Search**.

The Search Organizations window displays the results of your new search. See [Figure 3.18, Search Organizations Window – Search Results](#), on page 33.

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/Principle 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 33.

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/Principle Investigator** section.

Figure 3.19 Lead Organization/Principle Investigator Section

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

The Organization Lookup page appears.

Figure 3.20 Organization Lookup Page – Search for an Organization

3. Click **Add Org**.

The Add Organization window appears.

Figure 3.21 Add Organization Window

4. In the **Organization Name** field, type the full name of your organization.

5. Provide information in all required fields—those marked with an asterisk (*), and then click **Save**.

Your new organization is saved in the system and appears below the information you provided.

6. Click **Select**.

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

Registering Persons

You can register an investigator if you are unable to find the person listed in the system. Before you register an investigator, be sure to search the system's registered investigators to ensure that you do not create a duplicate record. (See [Searching for Principal Investigators](#) on page 35.) If your search results do not contain the name of your investigator, you can register a new one. (See [Adding Principal Investigators](#) on page 37.)

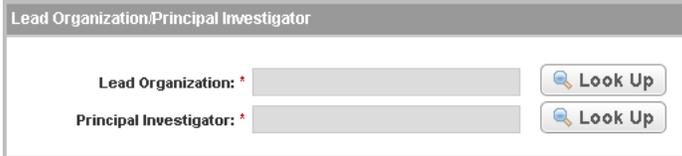
Searching for Principal Investigators

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 37.

How to Search For Principal Investigators

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



The screenshot shows a web interface titled "Lead Organization/Principle Investigator". It contains two rows of input fields. The first row is labeled "Lead Organization: *" and the second row is labeled "Principal Investigator: *". Each input field is followed by a "Look Up" button with a magnifying glass icon.

Figure 3.22 Lead Organization/Principle Investigator Section

2. Next to the **Principle Investigator** field, click **Look Up**.
The Select Principal Investigator page appears.

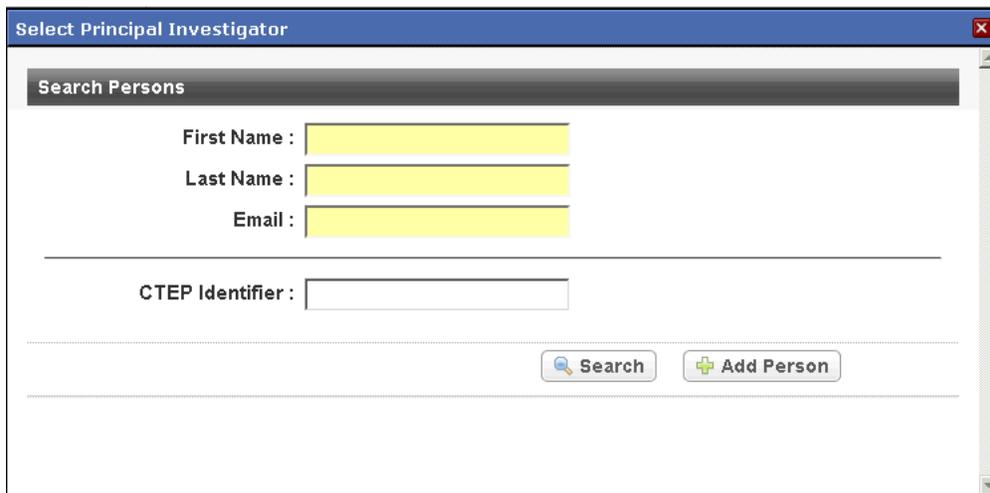


Figure 3.23 Select Principal Investigator Page – Search Persons

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

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

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

4. Click **Search**.

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

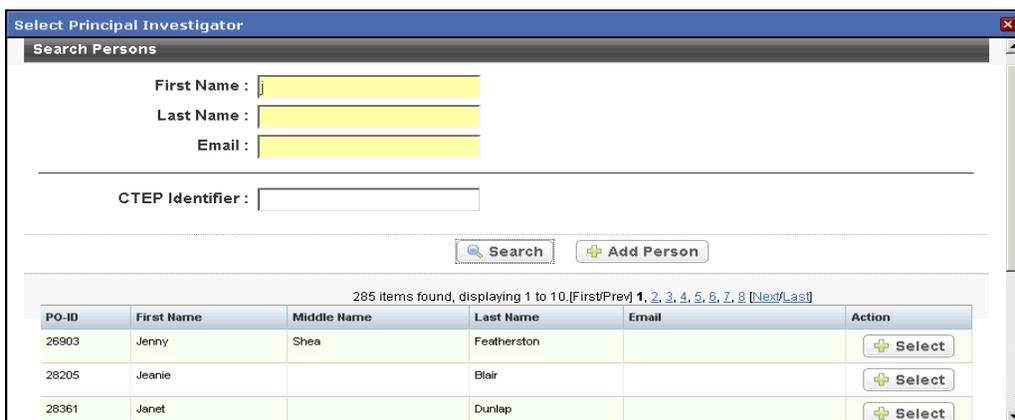


Figure 3.24 Principal Investigator Lookup Page – Search Results (partially redacted)

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

5. Scroll through the results list until you locate your principal investigator, and then click **Select**. The investigator's name you selected appears in the

Principal Investigator field in the **Lead Organization/Principle 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, e-mail address, and CTEP Identifier in your original search, you may want to search by last name alone.
 - or -
 - To narrow your search so that fewer names are listed in the search results, provide more about your investigator. For example, if you searched by last name only in your original search, you may want to search by CTEP Identifier.
7. Click **Search**, and then repeat Step 5.

Adding Principal Investigators

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

How to Register a Principal Investigator

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



The screenshot shows a web form titled "Lead Organization/Principle Investigator". It contains two rows of input fields. The first row is labeled "Lead Organization: *" and the second row is labeled "Principal Investigator: *". Each input field is followed by a "Look Up" button with a magnifying glass icon.

Figure 3.25 Lead Organization/Principle Investigator Section

2. Next to the **Principle Investigator** field, click **Look Up**.
The Select Principal Investigator page appears.

The screenshot shows a window titled "Select Principal Investigator" with a sub-header "Search Persons". Below the sub-header are three input fields: "First Name :", "Last Name :", and "Email :". Below these is a "CTEP Identifier :" field. At the bottom right, there are two buttons: "Search" and "Add Person".

Figure 3.26 Select Principal Investigator Page – Search Persons

3. Click **Add Person**.

The Add Person window appears.

The screenshot shows a window titled "Select Principal Investigator" with a sub-header "Add Person". It contains a grid of input fields: "First Name :*", "Prefix :", "Suffix :", "City :*", "Zip :*", "Email :*", "URL :", "Fax :", "Last Name :*", "Middle Name :", "Street Address :*", "State :", "Country :* --Select--", "Phone :", and "TTY :". At the bottom, there are "Save" and "Search" buttons.

Figure 3.27 Add Person Window

4. Type or select as much information as possible in the fields provided. You must complete all required fields, marked with an asterisk (*).
5. Click **Save**.
6. Your new investigator is saved in the system and the **Principal Investigator** field on the **Register Trial** page is populated with the name you just registered.

Registering Multiple Trials Concurrently

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

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

Note: Before you begin, you must obtain authorization from the CTRP and the link to the upload website.

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

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

- Data documents – Documents that contain all the requisite information about the protocol. See [Data Requirements for Batch Uploads](#) on page 40 and [Appendix B, Batch Upload Data Specifications](#), on page 53.
 - 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 CTEP.

The Batch Upload page appears. All fields are required.

Figure 3.28 Batch Trial Upload Page

2. In the **Organization Name** field, type the name of the organization associated with the trials you want to register.
3. Beside the **Trial Data** field, click **Browse** and navigate to the `.xls` file that contains all the trial data. See [Data Requirements for Batch Uploads](#) on page 40.
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 e-mails it to the submitter. The report includes a brief summary and the detailed status of each trial.

Data Requirements for Batch Uploads

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

In addition to the data elements listed above, you must provide certain other information depending on the values you provided, as listed in [Table 3.13](#)

Detailed specifications are provided in [Appendix B, Batch Upload Data Specifications](#), on page 53.

<i>If you provide this value...</i>	<i>You must also provide/select this</i>
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: <ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> • 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
Primary Completion Date Type = "Actual"	A date that is current or past
Primary Completion Date Type = "Anticipated"	A date in the future

Table 3.13 Data element requirements based on selected values

<i>If you provide this value...</i>	<i>You must also provide/select this</i>
If Current Trial Status = "Active"	A Trial Start Date that is the same as Current Trial Status Date, where type = "Actual"
If Current Trial Status = "Approved"	Trial Start Date type = "Anticipated"
Current Trial Status \neq "Approved"	Trial Start Date type = "Actual"
Current Trial Status = "Completed"	A Primary Completion Date that is the same as Current Trial Status Date, where type = "Actual"
Current Trial Status = "Completed" - or - Current Trial Status = "Administratively Completed"	A Primary Completion Date type that is "Actual"
Current Trial Status \neq "Completed" - or - Current Trial Status \neq "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 3.13 Data element requirements based on selected values (Continued)

CHAPTER 4

MANAGING YOUR ACCOUNT

This chapter provides instructions for modifying your NCI Clinical Trials Reporting Program account, and for resetting your password.

This chapter includes the following topics:

- *Editing User Information* on this page
- *Managing Your Password* on page 44

Editing User Information

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

How to Edit Your Account Information

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

- or -

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

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

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

Managing Your Password

You can change your NCI Clinical Trials Reporting Program 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 44 and [Resetting Your Password](#) on page 44.

Changing Your Password

You can change your NCI Clinical Trials Reporting Program password only once you have logged in to the Portal.

How to Change Your Password

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

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

Resetting Your Password

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

How to Reset Your Password

1. On the navigation pane on the left side of the page, click **Log In**.
2. On the Login page, click the **Forgot Your Password** link, and continue with [step 3](#) on page 6.

APPENDIX

A

METADATA DEFINITIONS

The NCI Clinical Trials Reporting Program captures trial details, or metadata, as entered by a trial submitter. *Table A.1* describes the metadata associated with clinical trials. See *Batch Upload Data Specifications* on page 53 for further data details.

Definitions/Valid Values and/or Examples	
Current Trial Status Date	
Date the trial status was assigned to the trial, using the format mm/dd/yyyy.	
Example: 10/28/2008	
Funding Mechanism	
NCI code used to identify areas of extramural research activity applied to various funding mechanisms.	
B09 – Mental Health Services Block Grant	D43 – International Training Grants in Epidemiology
C06 – Research Facilities Construction Grant	D71 – International Training Program Planning Grant
DP1 – NIH Director’s Pioneer Award (NDPA)	X02 – Pre-application
DP2 – NIH Director’s New Innovator Awards	
Identifier Type	
Type of organization (system) that assigns the identifier to the trial (for example, Lead Organization, or NCI CTRP)	
NCI – National Cancer Institute	Lead Organization – Organization responsible for the overall scientific and administrative coordination, study monitoring, and data management activities of a particular clinical trial.
Institute Code	

Table A.1 Descriptions of trial metadata

Definitions/Valid Values and/or Examples	
NIH code used to identify the first major-level subdivision—the NIH organization that supports a grant, contract, or inter-agency agreement. The support may be financial or administrative.	
AA – National Institute on Alcohol Abuse and Alcoholism	HD – National Institute of Child Health and Human Development (NICHD)
AG – National Institute on Aging	HG – National Human Genome Research Institute (NHGRI) - formerly NCHGR
AI – National Institute of Allergy and Infectious Diseases	HL – National Heart, Lung and Blood Institute (NHLBI)
AO – NIAID Research Support	HS – Agency for Healthcare Research and Quality (AHRQ) - not a part of NIH
AR – National Institute of Arthritis and Musculoskeletal and Skin Disease	LM – National Library of Medicine (NLM)
AT – National Center for Complementary and Alternative Medicine	MD – National Center on Minority Health and Health Disparities (NCMHD)
CA – National Cancer Institute (NCI)	MH – National Institute of Mental Health (NIMH)
CC – NIH Clinical Center	NCCAM – National Center for Complementary and Alternative Medicine
DA – National Institute on Drug Abuse (NIDA)	NCMHD – National Center on Minority Health and Health Disparities
DC – National Institute on Deafness and Other Communication Disorders (NIDCD)	NR – National Institute of Nursing Research (NINR)
DE – National Institute of Dental and Craniofacial DK National Institute of Diabetes and Digestive and Kidney Diseases	NS – National Institute of Neurological Disorders and Stroke (NINDS)
EB – National Institute of Biomedical Imaging and Bioengineering (NIBIB)	OD – Office of the Director
ES – National Institute of Environmental Health Sciences (NIEHS)	RR – National Center for Research Resources (NCRR)
EY – National Eye Institute (NEI)	TW – Fogarty International Center (FIC)
GM – National Institute of General Medical Sciences (NIGMS)	
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)	

Table A.1 Descriptions of trial metadata (Continued)

Definitions/Valid Values and/or Examples	
Unique identification assigned to the protocol by the lead organization, usually an accession number or a variation of a grant number. Multiple studies conducted under the same grant must each have a unique number.	Example: Merck-023 Note: Inter-Group trials use the lead Groups trial number.
NCI Division/Program Code	
Codes that represent individual NCI divisions and program codes.	
CCR – Center for Cancer Research	OD – Office of the Director, NCI, NIH
CTEP – Cancer Therapy Evaluation Program	OSB/SPOREs – Organ Systems Branch (OSB)/Specialized Programs of Research Excellence (SPOREs)
DCB – Division of Cancer Biology	CIP – Cancer Imaging Program
DCCPS – Division of Cancer Control and Population Sciences	CDP – Cancer Diagnosis Program
DCEG – Division of Cancer Epidemiology and Genetics	TRP – Translational Research
DTP – Developmental Therapeutics Program	RRP – Radiation Research Program
DCP – Division of Cancer Prevention	N/A – Not applicable
DEA – Division of Extramural Activities	
NCI Trial Identifier	
Unique identifier assigned to the trial by the NCI Clinical Trials Reporting Program.	
Example: NCI-2010-ABCD	
NIH Grant Information	
NIH grant code. A concatenation of a number of elements. Note: The Grant Identification Number is also commonly referred to as Assignment Number, Application Number, or the Award Identification Number, depending upon its processing status.	
1 R01 CA 009999 - 08 A1 S2 Note: There are no spaces in the grant code; they have been inserted in this example for clarification purposes only. where, 1 is the single-digit code identifying the type of application received and processed R01 is the three-digit code identifying a specific category of extramural activity 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	

Table A.1 Descriptions of trial metadata (Continued)

Definitions/Valid Values and/or Examples	
<p>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.</p> <p>A1 is the letter code for a resubmitted application, (commonly referred to as an Amendment) and related number that identifies a particular amendment record</p> <p>s2 is the letter code for Revision (for Supplemental funding) and related number identifying a particular supplemental record.</p>	
Primary Purpose	
Reason for the protocol.	
<p>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.</p>	<p>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</p>
<p>Treatment – Protocol designed to evaluate one or more interventions for treating a disease, syndrome or condition.</p>	<p>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.</p>
<p>Prevention – Protocol designed to assess one or more interventions aimed at preventing the development of a specific disease or health condition.</p>	<p>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.</p>
<p>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.</p>	<p>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.</p>
<p>Diagnostic – Protocol designed to evaluate one or more interventions aimed at identifying a disease or health condition.</p>	<p>Health Services Research – Protocol designed to evaluate the delivery, processes, management, organization or financing of health care.</p>

Table A.1 Descriptions of trial metadata (Continued)

Definitions/Valid Values and/or Examples	
Basic Science – Protocol designed to examine the basic mechanism of action (e.g., physiology, biomechanics) of an intervention.	Screening – Protocol designed to assess or examine methods of identifying a condition (or risk factors for a condition) in people who are not yet known to have the condition (or risk factor).
Supportive Care – Protocol designed to evaluate one or more interventions where the primary intent is to maximize comfort, minimize side effects or mitigate against a decline in the subject's health or function. In general, supportive care interventions are not intended to cure a disease.	Other – Any trial type not defined here.
Principal Investigator	
Investigator responsible for all aspects of the conduct of the study.	
Example: Moitessier, Bernard	
Responsible Party	
Either of the following parties:	
<ul style="list-style-type: none"> • Sponsor of the clinical trial - or - • Principal investigator of such clinical trial if so designated by a sponsor, grantee, contractor, or awardee, so long as the principal investigator is responsible for conducting the trial, has access to and control over the data from the clinical trial, has the right to publish the results of the trial, and has the ability to meet all of the requirements for the submission of clinical trial information. 	
Example: Moitessier, Bernard	
Sponsor	
Name of primary organization that oversees implementation of study and is responsible for data analysis.	
Example: Bristol-Myers Squibb	
Summary 4 Funding Category	
Type of external sponsor or funding source based on the role/responsibility/participation in the study. Based on authorship, drug supplement, trial monitoring design, and implementation.	
National – National Cooperative Group trials	Institutional – In-house, internally reviewed trials, including those collaborative studies conducted with industry sponsorship in which the center is a primary contributor to the design, implementation, and monitoring of the trial, or participation in a multi-site trial initiated by an investigator at another center.
Externally Peer-Reviewed – R01s and P01s or other trial mechanisms funded by NIH or supported by other peer-reviewed funding organizations.	Industrial – Design and implementation of the study is controlled by the pharmaceutical company

Table A.1 Descriptions of trial metadata (Continued)

Definitions/Valid Values and/or Examples	
Summary 4 Sponsor/Source	
For clinical trials involving an agent or device or other intervention only: Primary organization responsible for funding the trial.	
Example: CTEP	
Title	
Official name of the protocol provided by the study principal investigator or sponsor.	
A Pilot Study of Chemotherapy Plus Radiotherapy for Selected Stage IIIB (No Malignant Effusion) Non-Small Cell Lung Cancer	
Trial Phase	
Code for a clinical trial that represents a distinguishable part or stage in a series of events or in a process of development. Clinical trials are broken into three or four phases. The different phases are as follows:	
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

Table A.1 Descriptions of trial metadata (Continued)

Definitions/Valid Values and/or Examples	
Phase II/III – A trial to study response to a new treatment and the effectiveness of the treatment compared with the standard treatment regimen.	Other – Any phase not listed
Trial Status	
Code that represents the status of a trial in relation to the ability to enroll participants/patients.	
Approved – Trial has been approved	Temporarily Closed to Accrual and Intervention – Trial is temporarily not accruing. Participants are not receiving intervention.
Active – Trial is open for accrual	Temporarily Closed to Accrual – Trial is temporarily not accruing.
Closed to Accrual – Trial has been closed to participant accrual. Participants are still receiving treatment/intervention.	Administratively Complete – Trial has been completed prematurely (for example, due to poor accrual, insufficient drug supply, IND closure, etc.)
Closed to Accrual and Intervention – Trial has been closed to participant accrual. No participants are receiving treatment/intervention, but participants are still being followed according to the primary objectives of the study.	Complete – The trial has been closed to accrual; participants have completed treatment/intervention, and the study has met its primary objectives.
Trial Type	
Nature of the investigation; represents a clinical study by product, procedure, or method tested.	
Interventional – Studies in human beings in which individuals are assigned by an investigator based on a protocol to receive specific interventions. Subjects may receive diagnostic, therapeutic or other types of interventions. The assignment of the intervention may or may not be random. The individuals are then followed and biomedical and/or health outcomes are assessed.	Observational – Studies in human beings in which biomedical and/or health outcomes are assessed in pre-defined groups of individuals. Subjects in the study may receive diagnostic, therapeutic, or other interventions, but the investigator does not assign specific interventions to the subjects of the study.

Table A.1 Descriptions of trial metadata (Continued)

APPENDIX B

BATCH UPLOAD DATA SPECIFICATIONS

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

This chapter describes how to prepare your trial documents. It also provides data specifications for the trial data.

This chapter includes the following topics:

- *Preparing the Trial Data File* on this page
- *Preparing Trial-Related Documents* on page 54
- *Trial Data Specifications* on page 54

Preparing the Trial Data File

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

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

How to Prepare the Trial Data File

1. In Microsoft Excel, list the trial elements required for registration in the order specified in *Table B.1* on page 54.

2. Rename each file. Add the unique trial identifier (for example, your cancer center unique trial identifier) to the beginning of the file name.
3. List the trial-related document file names for each trial.

Preparing Trial-Related Documents

You must provide trial-related documents as `.zip` files.

How to Prepare the Trial-Related Documents

1. Rename each file. Add the unique trial identifier (for example, your cancer center unique trial identifier) to the beginning of the file name.
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 name.

Trial Data Specifications

Table B.1 provides the following specifications:

- Order in which the data must appear in an `.xml` file
- Trial data elements for which you provide the trial protocol details
- Designation of data element as required
- Valid data values
- Comments

Order	Trial Data	Required?	Valid Values	Comments
1	Unique Trial Identifier	Yes		
2	Lead Organization Trial Identifier	Yes		AS IS in the protocol document
3	Title	Yes	Max 4000 characters	
4	Trial Type	Yes	<ul style="list-style-type: none"> • Interventional • Observational 	

Table B.1 Specifications for the batch upload .xls file

Order	Trial Data	Required?	Valid Values	Comments
5	Primary Purpose	Yes	<ul style="list-style-type: none"> • Treatment • Prevention • Supportive Care • Screening • Early Detection • Diagnostic • Epidemiologic • Outcome • Observational • Ancillary • Correlative • Health Service Research • Other • Basic Science 	
6	Primary Purpose 'Other' value specification	Yes if Primary Purpose = 'Other'		
7	Phase	Yes	0, I, I/II, II/III, III, IV, Pilot, N/A, Other	If "Other" selected, specify phase
8	Phase 'Other' value specification	Yes if Phase = "Other"		
9	[Sponsor] Organization Name	Yes		
10	[Sponsor] CTEP Organization Number			
11	[Sponsor] Street Address	Yes		
12	[Sponsor] City	Yes		
13	[Sponsor] State/Province (US/Canada)	Yes	two-digit state code required for US/Canada	
14	[Sponsor] Zip/Postal code (US/Canada)	Yes		
15	[Sponsor] Country	Yes	three-digit country code required	
16	[Sponsor] Email Address	Yes		
17	[Sponsor] Phone			Include phone extension if any

Table B.1 Specifications for the batch upload .xls file (Continued)

Order	Trial Data	Required?	Valid Values	Comments
18	[Sponsor] TTY			
19	[Sponsor] FAX			
20	[Sponsor] URL			
21	Responsible Party	Yes	<ul style="list-style-type: none"> • PI • Sponsor 	
22	[Sponsor Contact] First Name	Yes: if Responsible Party = Sponsor		
23	[Sponsor Contact] Middle Name			
24	[Sponsor Contact] Last Name	Yes: if Responsible Party = Sponsor		
25	[Sponsor Contact] CTEP Person Number			
26	[Sponsor Contact] Street Address	Yes: if Responsible Party = Sponsor		
27	[Sponsor Contact] City	Yes: if Responsible Party = Sponsor		
28	[Sponsor Contact] State/Province (US/Canada)		Two-digit State/Province code required for US/Canada	
29	[Sponsor Contact] Zip/Postal code (US/Canada)	Yes: if Responsible Party = Sponsor		
30	[Sponsor Contact] Country		Three-digit Country code required	
31	[Sponsor Contact] Email Address	Yes: if Responsible Party = Sponsor		
32	[Sponsor Contact] Phone	Yes: if Responsible Party = Sponsor		Include phone extension if any

Table B.1 Specifications for the batch upload .xls file (Continued)

Order	Trial Data	Required?	Valid Values	Comments
33	[Sponsor Contact] TTY			
34	[Sponsor Contact] FAX			
35	[Sponsor Contact] URL			
36	[Lead Organization] Name	Yes		
37	[Lead Organization] CTEP Organization Number			
38	[Lead Organization] Street Address	Yes		
39	[Lead Organization] City	Yes		
40	[Lead Organization] State/Province (US/Canada)	Yes	Two-digit State/Province code required for US/Canada	
41	[Lead Organization] Zip/Postal code (US/Canada)	Yes		
42	[Lead Organization] Country	Yes	Three-digit Country code required	
43	[Lead Organization] Email Address	Yes		
44	[Lead Organization] Phone			
45	[Lead Organization] TTY			
46	[Lead Organization] FAX			
47	[Lead Organization] URL			

Table B.1 Specifications for the batch upload .xls file (Continued)

Order	Trial Data	Required?	Valid Values	Comments
48	[Lead Organization] Organization Type	Yes	<ul style="list-style-type: none"> • Institution • ordering group • repository • research based • cooperative group • cancer center • consortium • drug company • network 	
49	[Principal Investigator] First Name	Yes		
50	[Principal Investigator] Middle Name			
51	[Principal Investigator] Last Name	Yes		
52	[Principal Investigator] CTEP Person Number			
53	[Principal Investigator] Street Address	Yes		
54	[Principal Investigator] City	Yes		
55	[Principal Investigator] State/Province (US/Canada)		2 digit State/Province code required for US/Canada	
56	[Principal Investigator] Zip/Postal code (US/Canada)	Yes		
57	[Principal Investigator] Country		3 digit Country code required	
58	[Principal Investigator] Email Address	Yes		
59	[Principal Investigator] Phone	Yes		Include phone extension if any

Table B.1 Specifications for the batch upload .xls file (Continued)

Order	Trial Data	Required?	Valid Values	Comments
60	[Principal Investigator] TTY			
61	[Principal Investigator] FAX			
62	[Principal Investigator] URL			
63	Summary 4 Funding Category	For interventional trial only and if Lead Org or any Participating Org = NCI-designated Cancer Center	<ul style="list-style-type: none"> • National • Externally Peer-Reviewed • Institutional • Industrial 	Applicable if Lead Org or Participating Org is NCI-designated Cancer Center
64	[Summary 4 Funding Sponsor/Source] Organization Name	Yes		Applicable if Lead Org or Participating Org is NCI-designated Cancer Center
65	[Summary 4 Funding Sponsor/Source] CTEP Organization Number			Applicable if Lead Org or Participating Org is NCI-designated Cancer Center
66	[Summary 4 Funding Sponsor/Source] Street Address	Yes		Applicable if Lead Org or Participating Org is NCI-designated Cancer Center
67	[Summary 4 Funding Sponsor/Source] City	Yes		Applicable if Lead Org or Participating Org is NCI-designated Cancer Center
68	[Summary 4 Funding Sponsor/Source] State/Province (US/Canada)	Yes	Two- digit State/Province code required for US/Canada	Applicable if Lead Org or Participating Org is NCI-designated Cancer Center
69	[Summary 4 Funding Sponsor/Source] Zip/Postal code (US/Canada)	Yes		Applicable if Lead Org or Participating Org is NCI-designated Cancer Center
70	[Summary 4 Funding Sponsor/Source] Country	Yes	Three-digit Country code required	Applicable if Lead Org or Participating Org is NCI-designated Cancer Center

Table B.1 Specifications for the batch upload .xls file (Continued)

Order	Trial Data	Required?	Valid Values	Comments
71	[Summary 4 Funding Sponsor/ Source] Email Address	Yes		Applicable if Lead Org or Participating Org is NCI-designated Cancer Center
72	[Summary 4 Funding Sponsor/ Source] Phone			Include phone extension if any
73	[Summary 4 Funding Sponsor/ Source] TTY			
74	[Summary 4 Funding Sponsor/ Source] FAX			
75	[Summary 4 Funding Sponsor/ Source] URL			
76	[NIH Grant] Funding Mechanism	Yes, if NIH grant exists	Refer Funding Mechanism in Valid Values worksheet	
77	[NIH Grant] Institute Code	Yes, if NIH grant exists	Refer Institute Code in Valid Values worksheet	
78	[NIH Grant] Serial Number	Yes, if NIH grant exists	format: five or six digits	
79	[NIH Grant] NCI Division/Program Code	Yes, if NIH grant exists	Refer NCI Division/ Program Code in Valid Values worksheet. Specify only the code.	Defaults to N/A if not specified
80	Current Trial Status	Yes	<ul style="list-style-type: none"> • Approved • Active • Closed to Accrual • Closed to Accrual and Intervention • Temporary Closed to Accrual • Temporary Closed to Accrual and Intervention • Complete • Administratively Complete 	
81	Current Trial Status Date	Yes		Date when the status changed

Table B.1 Specifications for the batch upload .xls file (Continued)

Order	Trial Data	Required?	Valid Values	Comments
82	Study Start Date	Yes		Date that enrollment to the protocol begins
83	Study Start Date Type	Yes	Actual, Anticipated	Only current/past date (in respect to batch upload date) is accepted for actual type and only future date is accepted for anticipated type.
84	Primary Completion Date	Yes		Date that the final subject was examined or received an intervention for the purposes of final collection of data for the primary outcome, whether the clinical trial concluded according to the pre-specified protocol or was terminated
85	Primary Completion Date Type	Yes	Actual, Anticipated	Only current/past date (in respect to batch upload date) is accepted for actual type and only future date is accepted for anticipated type.
86	IND/IDE Type	Yes, if IND/IDE trial	IND, IDE	
87	IND/IDE Number	Yes: if IND/IDE trial		
88	IND/IDE Grantor	Yes, if IND/IDE trial	CDER, CBER, CDRH	
89	IND/IDE Holder Type	Yes, if IND/IDE trial	<ul style="list-style-type: none"> • Investigator • Organization • Industry • NIH • NCI 	
90	[IND/IDE] NIH Institution	If (IND/IDE Holder Type) = NIH	Refer NIH Institution in Valid Values worksheet.	For IND/IDE trials
91	[IND/IDE] NCI Division /Program	If (IND/IDE Holder Type) = NCI	Refer NCI Division/ Program Code in Valid Values worksheet.	For IND/IDE trials

Table B.1 Specifications for the batch upload .xls file (Continued)

Order	Trial Data	Required?	Valid Values	Comments
92	[IND/IDE] Has Expanded Access?	Yes	Yes, No	For IND/IDE trials
93	[IND/IDE] Expanded Access Status	If (Has Expanded Access?) = Yes	<ul style="list-style-type: none"> • Available • No longer available • Temporarily not available • Approved for marketing 	For IND/IDE trials
94	Protocol Document File Name	Yes		Rename each document using the unique trial identifier as a prefix
95	IRB Approval Document File Name	Yes		Rename each document using the unique trial identifier as a prefix Dummy file if IRB approval is not required with the statement 'IRB approval is not required'. One IRB Approval is only needed
96	Participating Sites Document File Name			Rename each document using the unique trial identifier as a prefix
97	Informed Consent Document File Name			Rename each document using the unique trial identifier as a prefix
98	Other Trial Related Document File Name			Rename each document using the unique trial identifier as a prefix

Table B.1 Specifications for the batch upload .xls file (Continued)

For further details about trial data, refer to [Metadata Definitions](#) on page 45.

GLOSSARY

Acronyms, objects, tools and other terms referred to throughout this NCI Clinical Trials Reporting Program user's guide are described in this glossary.

Term	Definition
accepted trial	Trial that has been validated by an abstractor.
accrual	The process of obtaining subjects for a study.
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
CTWG	Clinical Trials Working Group
DCB	Division of Cancer Biology
DCCPS	Division of Cancer Control and Population Sciences

Term	Definition
DCEG	Division of Cancer Epidemiology and Genetics
DCP	Division of Cancer Prevention
DCTD	Division of Cancer Treatment and Diagnosis
DEA	Division of Extramural Activities
DTP	Developmental Therapeutics Program
data monitoring committee	Group of independent scientists who are appointed to monitor the safety and scientific integrity of a human research intervention, and to make recommendations to the sponsor regarding the stopping of the trial for efficacy, for harm, or for futility.
delayed posting	Release of trial information on ClinicalTrials.gov is delayed until after an interventional device has been approved or cleared.
EBI	European Bioinformatics Institute
EVS	Enterprise Vocabulary Services
FDA	Food and Drug Administration
FDAAA	Food and Drug Administration Amendment Act (2007)
IDE	Investigational Device Exemption. Allows the investigational device to be used in a clinical study in order to collect safety and effectiveness data required to support a Premarket Approval (PMA) application or a Premarket Notification [510(k)] submission to FDA.
IND	Investigational New Drug. Authorization from the Food and Drug Administration (FDA) to administer an investigational drug or biological product to humans. Such authorization must be secured prior to interstate shipment and administration of any new drug or biological product that is not the subject of an approved New Drug Application or Biologics/Product License Application.
IRB	Institutional Review Board
lead organization	Organization responsible for the overall scientific and administrative coordination, study monitoring, and data management activities of a given clinical trial.
MedDRA	Medical Dictionary for Regulatory Activities
N/A	Not applicable
NCI	National Cancer Institute
NCICB	National Cancer Institute Center for Bioinformatics (now known as the Center for Biomedical Informatics and Information Technology or CBIIT)
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

Term	Definition
PI	Principal Investigator
PIO	Protocol Information Office
principal investigator	Appointed investigator responsible for conducting clinical trial, or for multi-site trials, the study chair
R01	NIH grant activity code for Research Project
RRP	Radiation Research Program
section 801 trial	FDA-regulated interventional trial as defined in US Public Law 110-85, Title VIII, Section 801. See also Section 801 in <i>Appendix A, Metadata Definitions</i> , on page 69.
SPORE	Specialized Program of Research Excellence (Now TRP: Translational Research Program)
sponsor	Name of primary organization that oversees implementation of study and is responsible for data analysis.
TRP	Translational Research Program (Formerly SPORE)
trial status	The current status of a clinical study in relation to the ability to enroll participants/patients.
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
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

INDEX

A

accepted trial, defined 63
accrual, defined 63
ancillary trial, defined 11, 48
application support 4

B

basic science, defined 49, 63

C

caDSR, defined 63
CBER, defined 63
CBIIT, defined 63
CCB, defined 63
CCCT, defined 63
CCR, defined 63
CDE, defined 63
CDER, defined 63
CDP, defined 63
CGH, defined 63
CIP, defined 63
correlative trial, defined 11, 48
credits and resources 3
CTAC, defined 63
CTEP, defined 63
CTRO, defined 63
CTRP, defined 63
CTWG, defined 63

D

data monitoring committee 64
DCB, defined 63
DCCPS, defined 63
DCEG, defined 64
DCP, defined 64
DCTD, defined 64
DEA, defined 64
diagnostic trial, defined 48

DTP, defined 64

E

early detection trial, defined 11, 48
EBI, defined 64
epidemiologic trial, defined 48
EVS, defined 64
expanded access trial, defined 11
externally peer-reviewed funding, defined 49

F

FDA, defined 64
FDAAA, defined 64

H

health services research trial, defined 48

I

IDE, defined 64
IND, defined 64
industrial funding category, defined 49
institute code, defined 45
institutional funding category, defined 49
interventional trial, defined 51
IRB, defined 64

L

lead organization, defined 64
login 7
 editing user information 43

M

MedDRA, defined 64

N

N/A, defined 64
national funding category, defined 49
NCI, defined 64

NCICB

application support 4
defined 64

NCTID, defined 64

new user, register 5

O

observational trial, defined 11, 48, 51

OCE, defined 64

OD, defined 64

OSB/SPOREs, defined 64

outcome trial, defined 11, 48

P

P01, defined 64

PDQ, defined 64

phase, defined 50

PI, defined 65

PIO, defined 65

prevention trial, defined 48

primary purpose

ancillary, defined 48

basic science 49

epidemiologic, defined 48

health services research, defined 48

observational, defined 48

outcome, defined 48

prevention, defined 48

screening, defined 49

supportive care, defined 49

treatment, defined 48

primary purpose, defined 48

principal investigator 49

defined 65

protocols, submitting 15

purpose, defined 48

R

R01, defined 65

registration 5

RRP, defined 65

S

screening trial, defined 49

sponsor, defined 65

SPORE, defined 65

status

see also trial status 51

user view criteria 12

summary 4 funding category

externally peer-reviewed, defined 49

industrial defined 49

institutional, defined 49

national, defined 49

Summary 4 Funding Category, defined 49

Summary 4 Sponsor/Source, defined 50

supportive care trial, defined 49

T

treatment trial, defined 11, 48

trial phase, defined 50

trials

searching for 9

viewing details 14

trial status

approved, defined 51

closed to accrual, defined 51

closed to accrual and invention, defined 51

complete, defined 51

defined 65

temporarily closed to accrual, defined 51

temporarily closed to accrual and invention,
defined 51

trial type

ancillary, defined 11

basic science, defined 11

correlative, defined 11, 48

defined 65

diagnostic, defined 11, 48

early detection, defined 11, 48

expanded access, defined 11

health services research 11

interventional, defined 51

observational, defined 11, 51

outcome, defined 11

prevention, defined 11

screening, defined 11

supportive care, defined 11

treatment, defined 11

trial type, defined 51

TRP, defined 65

U

URI, defined 65

URL, defined 65

user information, editing 43

User's Guide, organization of 1

V

validated trial, defined 65

X

XML, defined 65