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NCI CTRP Registration User Guide

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 **You can print and export wiki pages**

You can send this page to a printer or convert it to a PDF, HTML, or Word document. See [Printing and Exporting Wiki Pages](#).

Application Support

If you have problems with the program or have suggestions for any of the CTRP User's Guides, contact the NCI Clinical Trials Reporting Office using the information and guidelines provided in [Application Support](#).

About this Guide

This guide provides an overview of NCI Clinical Trials Reporting Program (CTRP) Registration and instructions for using its tools and resources to submit new clinical trials and amend and/or update those currently registered and verified in the CTRP. Additionally it contains instructions for searching for and viewing details of existing registered clinical trials.


In the following panel, you can search within or browse the page tree for this guide:

Audience

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

CTRP Registration Tasks

This page tree provides instructions on performing tasks in CTRP Registration. In the following panel, you can search within or browse the page tree:

 **Opening Linked Pages**

- To open the topic in this tab, click the relevant topic link.
-
- To open the topic in a new tab, right-click the topic link and then click **Open Link in New Tab**.

Getting Started with Registration

This page tree introduces you to NCI Clinical Trials Reporting Program (CTRP) Registration, and provides instructions for registering for an account.

For browser information, refer to [Browser Support](#).

Application Support

If you are experiencing technical issues with the CTRP web application, or if you have questions, contact us at ctrp_support@nih.gov. When submitting support requests, include:

- Your contact information, including your telephone number
- The name of the application/tool you are using
- The relevant URL
- A description of the problem and steps to recreate it
- The text of any error messages you have received

For other CTRP topics, contact the Clinical Trials Reporting Office (CTRO) at ncictro@mail.nih.gov.

About Registration and Clinical Trial Details

Registration provides cancer clinical trial access to researchers who have CTRP accounts. It enables these users to register, amend, and update trials one at a time, and to view details of existing trials submitted by members of the cancer research community. You can register *Complete* and *Abbreviated* interventional and non-interventional trials. (For the definition of *Complete* and *Abbreviated*, refer to [CTRP Trial Categories](#), [Study Sources](#).)

Registration captures clinical trial details, a sanctioned set of key data elements. This set of recorded data enables the research community to share and analyze standardized clinical trial details.



The glossary on the CTRP web site at <http://www.cancer.gov/aboutnci/organization/ccct/ctrp/glossary> provides definitions, attributes, and examples of metadata associated with trials. You can access other CTRP resources from the same page.

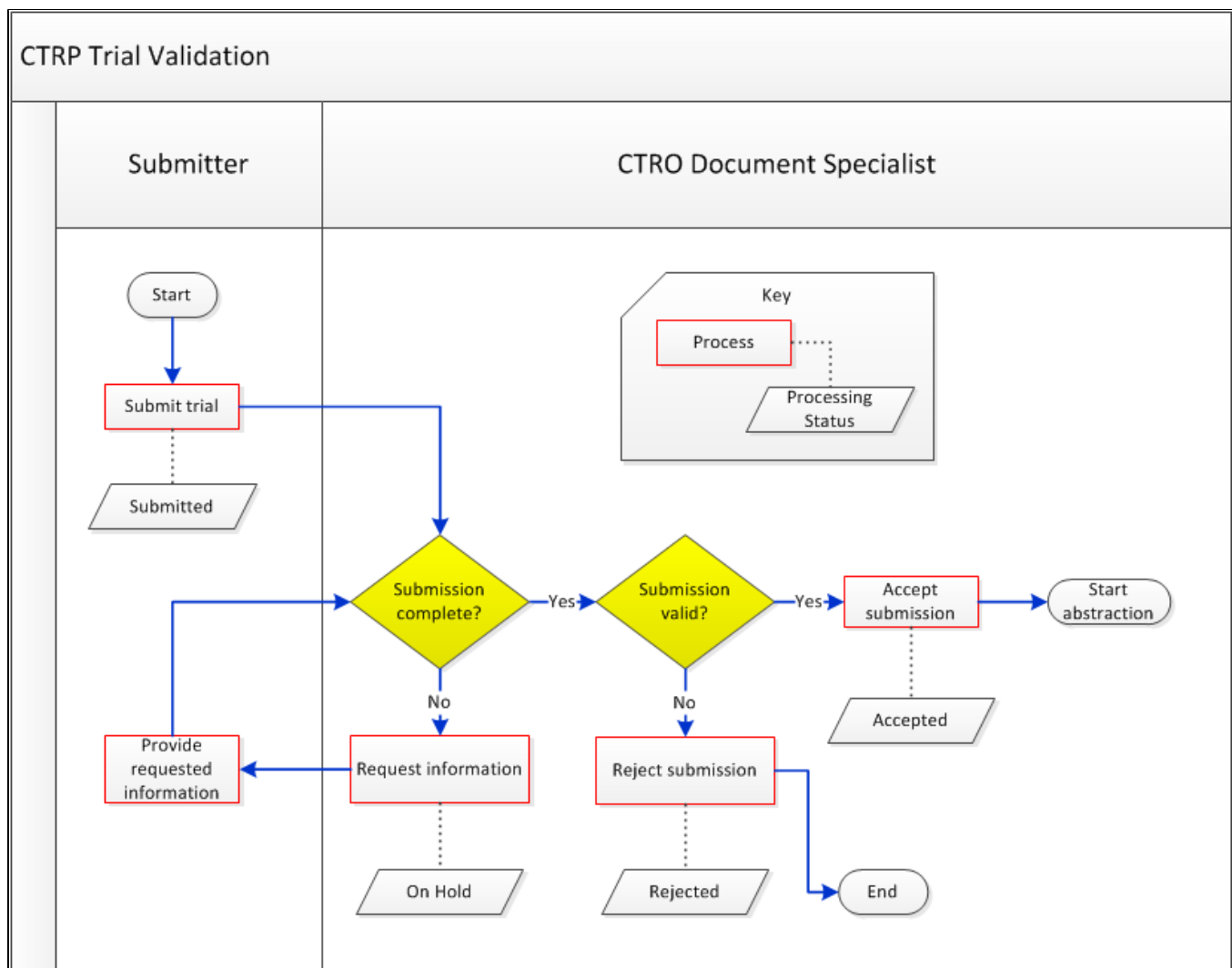
As a CTRP account holder, you can search for and review a subset of registered data that has been submitted to CTRP and validated by the Clinical Trials Reporting Office (CTRO).

Typical Life Cycle of a Trial

This section describes, in words and visually, the typical life cycle of a trial:

1. The submitter submits the trial. The trial has a processing status of **Submitted**.
2. The CTRO Document Specialist performs validation on the Submitted trial:
 - a. If the trial is not complete, the specialist sends a request to the submitter for information. The trial has a processing status of **On Hold**. When the CTRO receives the requested information, a Document Specialist takes the trial off hold. The trial's processing status returns to the previous status, which in this case would be **Submitted**.
 - b. If the trial is not valid, the specialist rejects the submission. The trial has a processing status of **Rejected**.
 - c. If the trial is complete and valid, the specialist accepts the submission. The trial has a processing status of **Accepted**.
3. One or more CTRO Document Specialists perform abstraction on the Accepted trial, including administrative processing, scientific processing, and quality control. The trial has a processing status of **Abstracted**.
4. The system sends the Trial Summary Report (TSR) of the Abstracted trial to the submitter. The trial has a processing status of **Verification Pending**.
5. The submitter verifies the abstraction as per the TSR, and returns feedback to the CTRO within five business days after receiving the TSR. (A business day is any weekday that is not a Federal holiday. For a list of Federal holidays, refer to the U.S. Office of Personnel Management's list of [Federal Holidays](#).) The trial has a processing status of **Abstraction Verified Response**.
6. The CTRO Document Specialist decides, based on the feedback received, whether to restart administrative processing, scientific processing, or both for the trial (step 3).
7. The CTRO Document Specialist completes the verification.

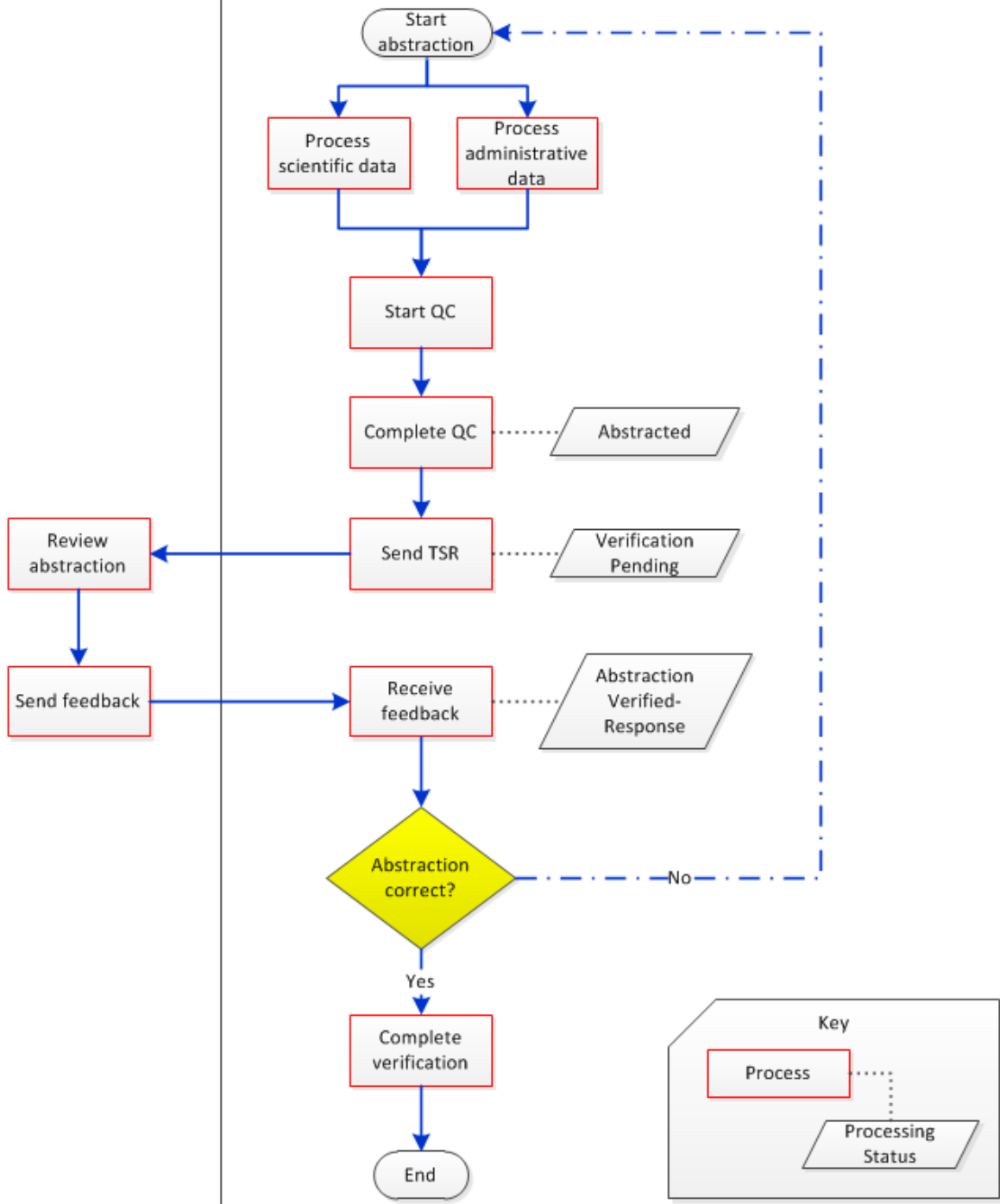
The following diagrams illustrate the typical life cycle of a trial and the relationship between actions and processing statuses:



CTRP Trial Abstraction

Submitter

CTRO Document Specialist



For more information, refer to [Trial Processing Statuses](#) and [Amendment Process Life Cycle](#).

Role-Based Tasks in Registration

Each person who registers for a CTRP account is associated with a role. One registered user from an organization can request an Administrator role from the CTRO. That Administrator can grant administrative privileges to other users in the Administrator's organization.


CTRP account holders can perform only those tasks that are associated with their assigned roles.

The following table is a matrix of roles and tasks. A *Yes* or *No* in each table cell indicates whether someone with a given role can perform the task.

Tasks	User	Site Administrator
Manage Accrual Access	No	Yes <ul style="list-style-type: none"> • A registered user logged in as the Lead Organization's Site Administrator for any trial other than DCP or CTEP trials • Super Abstractor for DCP and CTEP trials
View Accrual Assignment History	No	Yes For trials associated with Administrator's organization or family member organization.
Display Trial Ownership	No	Yes For any trial associated with the Administrator's site for which the organization is the lead organization.
Manage Trial Ownership	No	Yes
Manage Participating Site Record Ownership	No	Yes For registered users who are affiliated with the Administrator's organization.
Grant Administrative Authority	No	Yes For registered users who are affiliated with the Administrator's organization.
Manage Program Codes	No	Yes For details, refer to Managing Program Codes .
Request Administrative Authority	Yes	Yes
Manage System-Generated Emails	Yes Globally, for user's own account (receive all messages or none)	Yes The system sends emails (including TSRs) to Site Administrators automatically only if the site Administrator's affiliated organization is the trial's lead organization, or if the Site Administrator is the trial submitter and/or trial owner. Site Administrators can manage their own email notification globally, and other users' notifications on a trial-by-trial basis.
Register Trials	Yes	Yes
Update/Amend Trials	Yes	Yes
Add/Update Participating Site Information	Yes	Yes

Creating a CTRP Account

Even if you already have an NIH (or NCI) account, you must register for an associated CTRP account. You can create an account using Registration's account creation feature.

 New users must have access to a valid email address to create an account.



A CTRP account identifies your organization affiliation, whether or not you own a particular trial record, and other such details.

How to Create a New CTRP Account

1. Navigate to the CTRP Registration home page at <https://trials.nci.nih.gov/registration>. For browser information, refer to [Browser Support](#).
2. Click the **Sign Up** tab.
3. In the **Email Address** field, enter the email address you will use for registering trials (this should be your business email address), and then click **Next**. The Sign Up tab displays the new account form, pre-populated with the email address you provided.
4. Select or enter the appropriate information in the text fields and drop-down lists. The following table describes the fields. An asterisk (*) indicates a required field.

 **Privacy concerns**

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

Field Label	Description/Instructions
Contact information*	Enter your contact information in the fields provided. Provide your professional information only. For countries other than the United States, select None (International) in the State field, and enter <i>None</i> in the Zip Code field.
Organization Affiliation*	Click Look Up and select the appropriate organization from the list of search results. To search for an organization, follow the instructions in Looking up Registered Organizations . (If your trial's affiliated organization is not listed, you can ask the CTRO to create the organization record. To do so, follow the instructions in Requesting Creation of an Organization Record .) <div style="border: 1px solid #ccc; padding: 5px; margin-top: 10px;"> <p> Once organization affiliation is established, the system displays one of the following:</p> <ul style="list-style-type: none"> • If no one in your organization has site administrative (Admin) access, the My Account page displays a check box that enables you to request Admin privileges. • If at least one other person in your organization currently has a Site Admin role, the system displays the View Admins link, which enables you to display the name(s) of the current Admin(s). </div>
Request for Admin Access	This check box is displayed if no one in your organization has site administrative (admin) access. Optionally, to request administrative rights for your organization, select the check box. You will receive an email message from the CTRO once your request has been approved or rejected.
PRS Organization Name	Type the full name of the organization as it appears in the ClinicalTrials.gov Protocol Registration System account list at http://prinfo.clinicaltrials.gov/prs_organizations.html . <div style="border: 1px solid #ffc107; padding: 5px; margin-top: 10px;"> <p> Keep your account up to date</p> <p>The PRS organization name is required for uploading trial records to ClinicalTrials.gov via a system-generated file. The PRS organization name you include in your profile is included in that file. This precludes having to update the PRS name in the file. Therefore it is very important for you to update your account whenever there is a change in PRS.</p> </div>
Receive Email Notifications	The CTRP system can automatically send you an email message whenever some aspect of a trial you have submitted or own has changed. For example, the system would notify you when the CTRO has accepted a trial that you submitted. It would send another message when the Trial Summary Report (TSR) is available for review. You can choose to receive all messages or none of them: <ul style="list-style-type: none"> • To receive all system messages, set Receive Email Notifications to Yes. • To opt out, set Receive Email Notifications to No.

5. Click the **Sign Up** button. The system sends you a message stating that you will receive an email notification with instructions for activating your account.



Allow two business days for your account to be processed

It may take up to two business days to create your account. If you have any questions in the interim, contact us by sending an email to ctrp_support@nih.gov.

(A business day is any weekday that is not a Federal holiday. For a list of Federal holidays, refer to the U.S. Office of Personnel Management's list of [Federal Holidays](#).)

6. When the account information email message arrives, open it and click the embedded link to the **My Account** page.

Browser Support

We test on Firefox the CTRP web applications (*Registration, Accrual, Protocol Abstraction, and Person and Organization Curation*). For most modern browsers (Internet Explorer, Chrome, Safari), CTRP should also work without issue. However, please note that it has been officially tested only on Firefox.

If you discover a browser-related issue, please contact us at ctrp_support@nih.gov. Please include the following information:

- Your browser name and version
- Your operating system version
- When possible, a screen shot illustrating the difficulty

Using the Toolbar in Registration

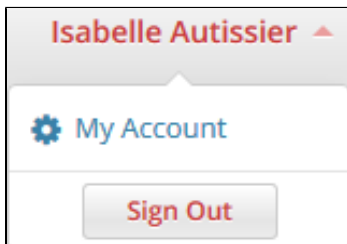
1. Visit the CTRP Registration home page at <https://trials.nci.nih.gov/registration>.
2. Log in.

The toolbar runs across the top of each page and remains in place even if you scroll down the page. Menus on the toolbar provide access to sub-menus whenever an arrow appears next to a menu name. Otherwise, clicking a menu item launches another web page.



Your name appears on the upper right corner of the page and the associated arrow provides access to the My Account page.

You can also sign out of the application from this sub-menu.



Requesting Organization Admin Rights

You can request Admin rights for your affiliated organization to take advantage of the following features:

- **Site administration** - Accept or reject requests for Admin rights from other users within your organization
- **Trial ownership management** - Assign and unassign ownership of trials associated with your organization to other registered users within your organization
- **Accrual access** - Assign and unassign access to Accrual to registered users within your organization
- **Program code management** - Manage the set of program codes and program code assignments for your organization family. For details, refer to [Managing Program Codes](#).



Condition for Admin Requests

The **Request for Admin Access** check-box on the **My Account** page is displayed only if no one else in your organization is an administrator.

How to Request Admin Rights

1. Visit the CTRP Registration home page at <https://trials.nci.nih.gov/registration>.
2. Log in.
3. On the top right corner of any page, click **Your Username > My Account**. The My Account page displays all of your Registration account information.
4. Verify that you have indicated your current organization affiliation.
5. If you need to update your affiliated organization, click **Look Up** and select the appropriate organization from the list of search results. To search for an organization, follow the instructions in [Looking up Registered Organizations](#). (If your trial's affiliated organization is not listed, you can ask the CTRO to create the organization record. To do so, follow the instructions in [Requesting Creation of an Organization Record](#).)



Once organization affiliation is established, the system displays one of the following:

- If no one in your organization has site administrative (Admin) access, the My Account page displays a check box that enables you to request Admin privileges.
- If at least one other person in your organization currently has a Site Admin role, the system displays the View Admins link, which enables you to display the name(s) of the current Admin(s).

6. Request Admin privileges as follows:
 - If the **Request for Admin Access** check box is available, select it. The system sends you an email message from the CTRO once your request has been approved or rejected.
 - If the **View Admins** link is available, select it and examine the resulting information. Request administration authority from a current site administrator.

Managing Registration Email Notifications


The CTRP system can automatically send you an email message whenever some aspect of a trial you have submitted or own has changed. For example, the system would notify you when the CTRO has accepted a trial that you submitted. It would send another message when the Trial Summary Report (TSR) is available for review. You can choose to receive all messages or none of them.

How to Manage Registration Email Messages


1. Visit the CTRP Registration home page at <https://trials.nci.nih.gov/registration>.
2. Log in.
3. On the top right corner of any page, click **Your Username > My Account**. The My Account page displays all of your Registration account information.
4. You have the following choices:
 - To receive all system messages, set **Receive Email Notifications** to **Yes**.
 - To opt out, set **Receive Email Notifications** to **No**.
5. Click **Save**.

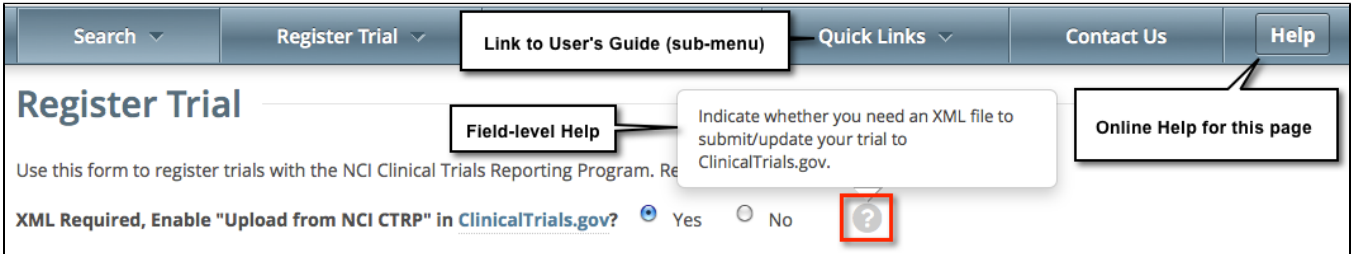
Getting Help in Registration

Help is available on both a field and page level. More comprehensive information is available in this User's Guide.

A Help icon  is available beside most fields in which you enter trial data.

How to Display Instructions/Information for a Field

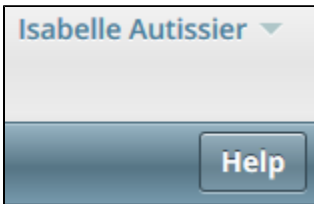
1. Visit the CTRP Registration home page at <https://trials.nci.nih.gov/registration>.
2. Log in.
3. Hover your cursor over the Help icon  next to it.



Online Help provides instruction/information for the topic you are working on.

How to Launch Online Help

1. Visit the CTRP Registration home page at <https://trials.nci.nih.gov/registration>.
2. Log in.
3. Below your name on the toolbar, click **Help**.



How to Return to this User's Guide

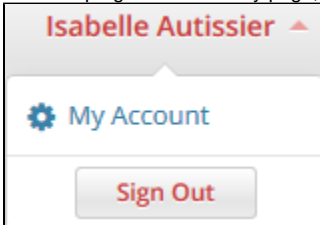
1. Visit the CTRP Registration home page at <https://trials.nci.nih.gov/registration>.
2. Log in.
3. On the toolbar, click **Quick Links > Registration User's Guide**.

Changing the Color Scheme in Registration

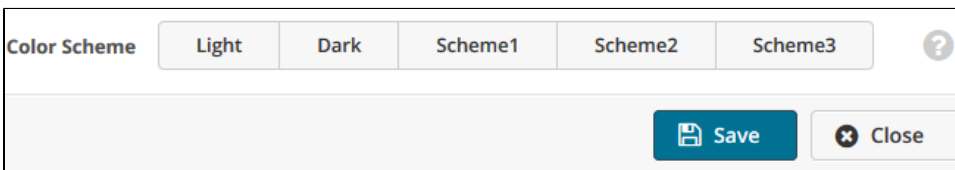
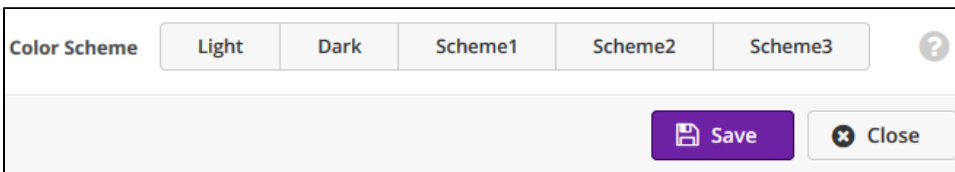
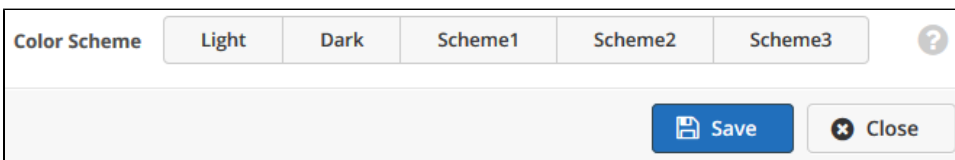
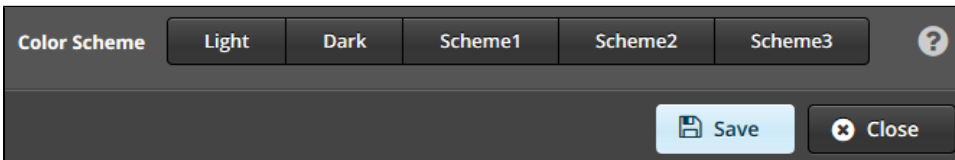
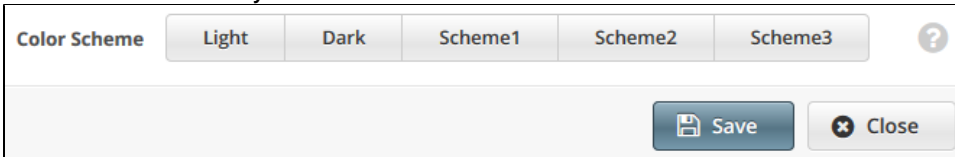
You can choose a site-wide color scheme to suit your preferences.

How to Change the Color Scheme

1. Visit the CTRP Registration home page at <https://trials.nci.nih.gov/registration>.
2. Log in.
3. On the top right corner of any page, click **(User Name) > My Account**.



4. Scroll to the bottom of the **My Account** window and select one of the five color schemes.



5. Click **Save**.

Searching for Trial, Organization, and Person Records

This page tree provides instructions for searching for trials, organizations, and persons currently registered with the CTRP. In each case you are presented with a predefined set of search criteria that is appropriate for the type of search you are conducting.


Searching for Trial Records


You can retrieve existing trial records once you have registered for an account. For instructions, refer to [Creating a CTRP Account](#).

After you have selected your search criteria, you can further limit or expand your search for trials as follows:

- Use the **Search All Trials** feature to search for all trials registered with the CTRP from all organizations/accounts, whether or not you are the submitter or owner.
- Use the **Search My Trials** feature to search for trials that you own, whether or not your organization is listed as the lead organization or participating site.
- Use the **Search Saved Drafts** feature to search for trials that you have saved as drafts but have not submitted.

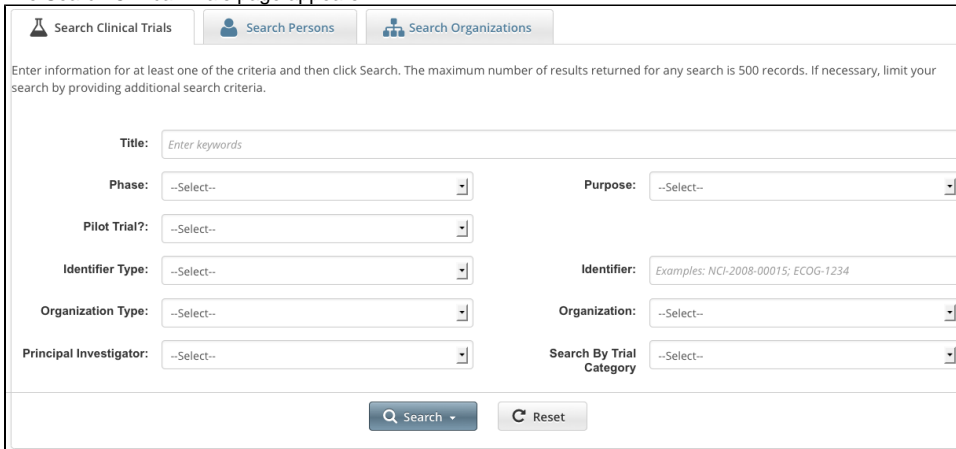
The search feature you choose determines which categories of trials will be returned, and the actions you can perform with those results, as shown in the table below. For rules that determine which trial details are displayed, refer to [Types of Trials Included in Trial Search Results](#).

Search Option	Search All Trials	Search My Trials	Search Saved Drafts
Types of Trials Returned	All trials	<ul style="list-style-type: none"> • Trials you own that are on hold • Trials you own, including those conducted at an affiliated site. 	Partial Submissions
Actions Permitted	<ul style="list-style-type: none"> • View Trial Details • Add/Update My Site (Abbreviated trials only) • Verify Trials (for trials you submitted but may not own) <div style="border: 1px solid #ccc; padding: 5px; margin-top: 10px;">  The results of this search may include a subset of trials that you own or submitted. </div>	<ul style="list-style-type: none"> • View Trial Details • Update Trials • Amend Trials • Request TSR/XML • Change Status • Add/Update My Site (Abbreviated trials only) • Verify Trials 	<ul style="list-style-type: none"> • View Trial Details • Complete Submissions • Add/Update My Site (Abbreviated trials only)

 All registered users can search trials with the "Accepted" and subsequent processing status. Additionally, you can search for trials that you own that have not been validated. These trials are indicated by the "Submitted" status. See [Trial Processing Statuses](#) for information about statuses that occur during the course of the trial processing workflow.

How to Search for Existing Trials

1. Click the **Search Clinical Trials** tab. Or, on the toolbar, click **Search > Clinical Trials**. The Search Clinical Trials page appears.



2. Select or enter the appropriate information in the drop-down lists and text fields. (You do not have to select or enter any search criteria if you use the **Search My Trials** feature. When searching **All Trials**, you must select or enter at least one search criterion.) The following table describes the fields.




 **Tip**

If you are searching for a saved draft, you can search by the following criteria only:

- Title
- Phase
- Purpose
- Identifier Type (NCT Exact Match, Lead Organization, or Other Identifier only)
- Organization Type (Lead Organization only)
- Organization
- Principal Investigator

Because the system adds wildcards for you, do not enter wildcard symbols in the search fields.

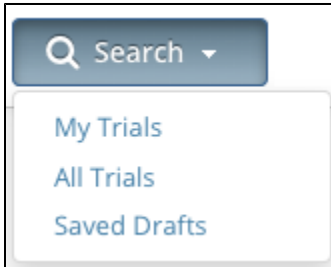
Trial Search Criteria

Field	Instructions/Description
Title	<p>To narrow the search by this trial attribute, specify one or more words from the official name of the protocol provided by the study principal investigator or sponsor (as it appears in the protocol document).</p> <div style="border: 1px solid green; padding: 5px; margin-top: 10px;"> <p> Avoid specifying the entire title in the search field</p> <p>Use keywords rather than phrases or the entire title. Doing so minimizes the potential for excluding from the search results any titles with misspellings or slightly different phrasing.</p> </div>
Phase	To narrow the search by this trial attribute, specify the phase of investigation, as defined by the US FDA for trials involving investigational new drugs. For valid values, refer to Trial Phase Value Definitions .
Pilot Trial?	<p>To narrow the search by this trial attribute, specify whether the trial is a pilot trial.</p> <ul style="list-style-type: none"> • To find trials identified as pilot trials, select Yes. • To find trials identified as not pilot trials, select No. • To find trial records on which no pilot value has been specified, select None.
Purpose	To narrow the search by this trial attribute, specify the main reason for conducting the trial. For valid values, refer to Primary Purpose Value Definitions .
Identifier Type	<p>To narrow the search by both identifier and the type of trial identifier, specify both. Valid identifier types are as follows:</p> <ul style="list-style-type: none"> • NCI - The unique identifier assigned to the trial by the NIH National Cancer Institute. • NCT (Exact Match) - The unique identifier assigned to the trial by the ClinicalTrials.gov Protocol Registration System (PRS). Provide the <i>exact</i> number, including the NCT prefix. Example: NCT00012345 • Lead Organization - The unique identifier assigned to the trial by the lead organization. • Other identifier - Additional trial identifier such as unique identifier from other registries, NIH grant numbers, or protocol numbers assigned by the Review Board. <p>The Identifier Type field is optional, even when specifying an identifier.</p>
Identifier	To narrow the search by this trial attribute, specify the numeric or alphanumeric identifier assigned to the trial. For Inter-Group trials, specify the Lead Group's trial number.
Organization Type	<p>To narrow the search by both organization and organization type, specify both. Valid organization types are as follows:</p> <ul style="list-style-type: none"> • Lead Organization - Returns all trials on which the selected organization is the Lead Organization • Participating Site - Returns all trials on which the selected organization is a Participating Site • Both - Returns all trials on which the selected organization is either the Lead Organization or Participating Site <div style="border: 1px solid green; padding: 5px; margin-top: 10px;"> <p> You can change the Organization Type without affecting any other search criteria you may have selected previously.</p> </div>
Organization	<p>To narrow the search by this trial attribute, specify the initial letter(s) of the organization. The system suggests organizations as you type. Select the organization from the list of suggestions.</p> <div style="border: 1px solid green; padding: 5px; margin-top: 10px;"> <p> To search for trials by organization without having to specify what role the organization plays in the trial, select Both from the Organization Type list, and then select the name of the organization of interest.</p> </div>

Principal Investigator	To narrow the search by this trial attribute, specify the <input type="text" value="Unable to render {include}"/> The included page could not be found. Enter the initial letter(s) of the principal investigator's last name. The system suggests names as you type. Select the investigator name from the list of suggestions.
Search by Trial Category	To narrow the search by this trial attribute, specify the category of the trial, as determined by the submission of a full protocol (Complete) or a ClinicalTrials.gov import (Abbreviated). For information about these categories, refer to CTRP Trial Categories , Study Sources . Otherwise, select Both .

3. Click **Search**.

The Search menu options are displayed.



4. Do one of the following:

- To search all registered trials in the system, click **All Trials**.
- or-
- To search only the trials that you submitted or own, click **My Trials**. This feature enables access to all the trials that you have submitted, including those that are currently on hold. (The Clinical Trials Reporting Office staff places trials on hold when they are unable to process a trial without further information, usually from the submitter.)
- or-
- To search only the trials that you have saved for later completion, click **Saved Drafts**.
- or-
- To clear all search criteria and begin a new search, click **Reset**.

Allow sufficient time for the system to conduct your search before you run your search again

The search is complete only when the system displays search results or alerts you that it could not find a trial to match your search criteria.

The trials that meet your search criteria are listed on the **Search Results** page. For more information on navigating and working with search results, see [Working with Tables and Search Results](#).

Search Clinical Trials	Search Persons	Search Organizations	Search Results
------------------------	----------------	----------------------	----------------

Clinical Trials Search Results			
Show 10	Search: thyr	Choose columns	<< < 1 > >>
NCI Trial Identifier	Title	Current Trial Status	Lead Organization
NCI-2013-01471	(*) A Phase I/II Trial of Crolibulin (EPC2407) plus Cisplatin in Adults with Solid Tumors with a Focus on Anaplastic Thyroid Cancer (ATC)	Active	NCI - Center for Cancer Research
NCI-2013-01438	Phase I/II Trial of Vandetanib (ZD6474, ZACTIMA) in Children and Adolescents with Hereditary Medullary Thyroid Carcinoma	Closed to Accrual	NCI - Center for Cancer Research
NCI-2011-02530	Phase I/II Trial of Cediranib Alone or Cediranib and Lenalidomide in Iodine 131-Refractory Differentiated Thyroid Cancer	Active	University of Chicago Comprehensive Cancer Center
NCI-2009-01166	A Targeted Phase I/II Trial of ZD6474 (Vandetanib; CAPRELSA) plus the Proteasome Inhibitor, Bortezomib (Velcade), in Adults with Solid Tumors with a Focus on Hereditary or Sporadic, Locally Advanced or Metastatic Medullary Thyroid Cancer (MTC)	Closed to Accrual	NCI - Center for Cancer Research

Showing 1 to 4 of 4 (filtered from 761 total entries) << < 1 > >>

Export options: CSV | Excel

Clinical Trials Search Results

Show 10 | Search: | Choose columns | << < 1 > >>

NCI Trial Identifier	Title	Current Trial Status	Lead Organization	Lead Org Trial Ide
NCI-2013-02396	(*) Phase II Study of Above-Label Octreotide-LAR in Patients with Insufficiently Controlled Carcinoid Syndrome	Active	H. Lee Moffitt Cancer Center and Research Institute	MCC 17410

Showing 1 to 1 of 1
Export options: CSV | Excel

(*) Trial has alternate titles. Click to view.

Trials may have more than one title. For example, the CTRO staffs may add an alternate title if they find a misspelling in the registered title. Any trial identified by more than one title is identified in the search results table by an asterisk (*) in the Title column.

- To see the alternate titles associated with a trial, click the asterisk (*) link. The list of alternate titles is displayed in the Trial Alternate Titles window.

Clinical Trials Search Results

Show 10 | Search: | Choose columns | << < 1 > >>

NCI Trial Identifier	Title	Current Trial Status	Lead Organization	Lead Org Trial Ide
NCI-2013-02396	(*) Phase II Study of Above-Label Octreotide-LAR in Patients with Insufficiently Controlled Carcinoid Syndrome	Active	H. Lee Moffitt Cancer Center and Research Institute	MCC 17410

Showing 1 to 1 of 1
Export options: CSV | Excel

(*) Trial has alternate titles. Click to view.

Trial Alternate Titles

2 items found, displaying all items. 1

- Phase II Study of Above-Label Octreotide-LAR in Patients with Insufficiently Controlled Carcinoid Syndrome
- Phase II Study of Above-Label Octreotide-LAR in Patients with Insufficiently Controlled Carcinoid Syndrome

You can change Accrual Disease terminologies for individual trials

If you searched for "My Trials", the search results table displays an additional column, **Accrual Disease Terminology**. You can select a new terminology from the drop-down list only if the trial has *not* accrued patients.

Additionally, you can change accrual disease terminology at any time for trials currently recording accruals at the summary level only.

Clinical Trials Search Results

Current Trial Status	Current Processing Status	Available Actions	Accrual Disease Terminology	Sites
Used to Accrual and Intervention	Accepted	Select Action	SDC	View
Active	Abstraction Verified No Response	Select Action	--Select-- SDC ICD10 ICD9 ICD-O-3	View
Approved	Accepted	Select Action		View


- To view a trial, click its **NCI Trial Identifier** link. The Trial Details page appears. For information about this page, refer to [Viewing Trial Details](#).

For more information, refer to the following pages:

Types of Trials Included in Trial Search Results

The search results table lists the trials that match your search criteria, as well as additional criteria, including a trial processing status. This status reflects the work of the Clinical Trials Reporting Office (CTRO). The CTRO reviews each trial submitted to the system in order to validate submitted information. During the validation process, the reviewers check for duplicate records and ensure that the submitter has provided all required information. CTRO does one of the following as part of the validation process, before abstraction:


- If all data is complete and accurate, the reviewers assign the trial the status "Accepted," and the system notifies the submitter by email.
- If information is missing, or there are discrepancies in the information provided, the reviewers can place a trial on hold. The CTRO contacts the submitter for clarification and/or to request missing documents, and resumes processing once the trial is validated.
- If the trial is a duplicate (i.e., another user has submitted the same trial), the reviewers assign the trial the status "Rejected," and the system sends the submitter an email message indicating the status and reason for the rejection. Reviewers may also reject a trial if CTEP/DCP/CCR has approved the trial. NCI transfers these trials internally.

 If you have questions about a rejected trial, contact the CTRO at ncictro@mail.nih.gov. For more information about this process, refer to [Typical Life Cycle of a Trial](#) and [Amendment Process Life Cycle](#).

The search results table lists the trials that match your search criteria, as well as the following criteria:

- Processing status of the trial at the time of the search. For a definition of each status, refer to [Trial Processing Statuses](#).
 - **Submitted** - Submitter has registered original trial but CTRO has not validated it yet.
 - **Amendment Submitted** - Submitter has submitted amendment but CTRO has not validated it yet.
 - **Accepted** - Trial has passed validation.
 - **Rejected** - Trial did not pass validation. The search results table does not list these trials.
 - **Abstracted** - CTRO has abstracted the trial.
 - **Verification Pending** - CTRO has abstracted the trial and has sent the Trial Summary Report (TSR) to the trial submitter for abstraction verification.
 - **Abstraction Verified Response** - Submitter has verified the abstraction as per the TSR, and has returned feedback to the CTRO within five business days after receiving the TSR.
 - **Abstraction Verified No Response** - Submitter has not responded or returned verification feedback to the CTRO within five business days after receiving the TSR.
- User's role with respect to the trial. User roles include the following:
 - **Site Administrator** - Has full access to the trials led by the organization (plays lead organization role).
 - **Trial Submitter/Owner** - Has full access to the trials they own or submitted.
 - **Other user** - Any user other than the trial submitter, owner, or trial's lead organization system administrator.
- **Trial ownership.** Trial ownership types are as follows:
 - **Private trials** - Trials submitted or owned by the user who is currently logged in to Registration.
 - **Public trials** - Trials submitted by other registered users.

(A business day is any weekday that is not a Federal holiday. For a list of Federal holidays, refer to the U.S. Office of Personnel Management's list of [Federal Holidays](#).)

 The search results table does not list Private trials with a processing status of Rejected nor Public trials with a processing status of Submitted or Rejected.

Clinical Trials Search Results

Show **10**
 Search:
 Choose columns

 << < 1 > >>

NCI Trial Identifier	Title	Current Trial Status	Lead Organization	Lead Org Trial Identifier	Principal Investigator
NCI-2014-00260	A Phase II Open-Label, Parallel Group Study of Abiraterone Acetate Plus Prednisone in African American and Caucasian Men With Metastatic Castrate-Resistant Prostate Cancer	Active	Duke University Medical Center	Pro00046383	George
NCI-2012-02535	Parallel Phase II Trials of ZD1839 (Iressa®) Alone or Weekly Carboplatin and Paclitaxel followed by ZD1839 (Iressa®) (Oncologists Must Choose) for Metastatic Non-Small Cell Lung Cancer in Patients ≥65 Years of Age	Complete	North Central Cancer Treatment Group	N0222	Jatoi, Ar
NCI-2012-01641	Parallel (Randomized) Phase II Evaluation of ARQ 197 and ARQ 197 in Combination with Erlotinib in Papillary Renal Cell Carcinoma	Temporarily Closed to Accrual	Southwest Oncology Group	S1107	Twardo
NCI-2011-02670	A Phase III Randomized Trial for Patients with de novo AML Using Bortezomib and Sorafenib (IND#114480; NSC# 681239, NSC# 724772) for Patients with High Allelic Ratio FLT3/ITD	Active	Children's Oncology Group	AAML1031	Applenc
NCI-2009-01104	Genome-Wide Association Study (GWAS) for Modifiers of Breast Cancer Risk in BRCA2 Mutation Carriers: Breast Cancer Protective Alleles by Whole Genome Association and Copy Number Analysis	Active	Gynecologic Oncology Group	GOG-8010	Greene

Showing 1 to 5 of 5 (filtered from 7,711 total entries)

 << < 1 > >>

Export options: [CSV](#) | [Excel](#)


To navigate the search results table, see [Working with Tables and Search Results](#).

Columns in Registered Trial Search Results

Trial records returned from "Search My Trials" and "Search All Trials" options display the following details and actions you can take for each trial when applicable. The columns available for these details and actions depend on trial ownership types, as follows:

- **Private trials** - Trials submitted or owned by the user who is currently logged in to Registration
- **Public trials** - Trials submitted by other registered users

The following table describes the columns in the search results table:

Column	Displayed for Public trials?	Description
NCI Trial Identifier	Yes	The unique ID assigned to the trial by the CTRP.
Title	Yes	The official name of the protocol provided by the study principal investigator or sponsor (as it appears in the protocol document).
Lead Organization	Yes	The name of the organization responsible for the trial's research protocol, and responsible for the overall scientific and administrative coordination, study monitoring, and data management activities of the trial.
Lead Org (Organization) Trial Identifier	Yes	The unique ID assigned to the trial by the sponsoring organization, usually an accession number or a variation of a grant number. Multiple studies conducted under the same grant must each have a unique number.
Principal Investigator	Yes	The <div style="border: 1px solid orange; padding: 2px; display: inline-block;">Unable to render {include}</div> The included page could not be found.
ClinicalTrials.gov Identifier	Yes	The unique ID assigned to the trial by the National Clinical Trial program (ClinicalTrials.gov) for trials that have been submitted to ClinicalTrials.gov Protocol Registration System (PRS) previously. This ClinicalTrials.gov ID appears as "NCT" followed by 8 numeric characters (such as NCT12345678).
Other Identifiers	Yes	Identifiers other than Lead Organization Trial Identifier or ClinicalTrials.gov Identifier.
Current Trial Status	Yes	The current stage or state of a clinical trial or study relative to its ability to enroll participants/patients. For valid ClinicalTrials.gov recruitment values, refer to Trial Status Values in the CTRP and ClinicalTrials.gov and Expanded Access Statuses .
Current (Trial) Processing Status	No	The current status of the trial in the CTRP trial processing work flow. For information, refer to Trial Processing Statuses .
Available Actions	Yes	<p>Actions that are applicable to the trial according to the processing rules:</p> <ul style="list-style-type: none"> • Update - Link used to initiate trial updates. For instructions, refer to Updating Trials. • Amend - Link used to initiate trial amendments. Available for trials with processing statuses abstraction verified (response/no response). For instructions, refer to Amending Complete Trials. • Change Status - Link used to initiate a change to the trial status and status dates. For instructions, refer to Updating Trial Statuses. • Add My Site - Link used to initiate adding an organization as a participating site. For instructions, refer to Adding Your Site to Abbreviated Trials. • Update My Site - Link available to Participating Site Record owners to initiate participating site information changes. For instructions, refer to Updating Participating Site Organization Records. • Request TSR and XML documents (for Complete trials) - Documents are sent via email to all trial owners. For instructions, refer to Viewing Trial Summary Reports and XML Documents. • Verify Trial Data - Link used to verify open trial records twice per year to ensure that information is accurate and up-to-date. For instructions, refer to Verifying Trial Data. <div style="border: 1px solid orange; padding: 10px; margin-top: 10px;">  The actions available for a trial depend on its processing status and participating site record ownership. </div>

Accrual Disease Terminology	No	The disease terminology for reporting accruals. Keep in mind: <ul style="list-style-type: none"> For a trial recording accruals at the patient level, you can specify a new terminology only if the trial has not accrued patients. For a trial recording accruals at the summary level, you can change accrual disease terminology at any time. For information, refer to About Accrual and Recording Trial Details .
(Participating) Sites	Yes	One or more organizations participating in the trial. Click View in the Sites column to view participating site details.
Phase	No	The phase of investigation, as defined by the US FDA for trials involving investigational new drugs. For information, refer to Trial Phase Value Definitions .
Primary Purpose	No	The main reason for conducting the trial. For information, refer to Primary Purpose Value Definitions .
Category	No	The category of the trial, as determined by the submission of a full protocol (Complete) or a ClinicalTrials.gov import (Abbreviated). For information, refer to CTRP Trial Categories, Study Sources .
Trial Start Date	No	The date on which the enrollment of participants for a clinical study began (or will begin).
Responsible Party	No	The party who is responsible for submitting information about a clinical study and updating that information, as defined by FDAAA. The responsible party can be the sponsor, sponsor-investigator, or sponsor-designated principal investigator.
Sponsor	No	The name of the primary organization that oversees the implementation of the study and is responsible for data analysis, as defined in 21 CFR 50.3.
Data Table 4 Funding Sponsor Type	No	The type of Data Table 4 funding sponsorship (National, Externally Peer-Reviewed, Institutional, or Industrial). For information, refer to CTRP Trial Categories, Study Sources .
Record Verification Date	No	The date on which the abstracted data for the trial was last verified. ClinicalTrials.gov displays the verification date along with an organization name to indicate to the public whether the information is being kept current, particularly recruiting status and contact information. In CTRP, the last verified date is the most recent date on which the CTRO confirmed all of a clinical study's information in CTRP as accurate and current.
Submitter	No	The name of CTRP user who submitted the trial.
Primary Completion Date	No	The date that the final subject was (or will be) examined or received (or will receive) an intervention for the purposes of final collection of data for the primary outcome, whether the clinical trial concluded according to the prespecified protocol or was terminated (as specified in US Public Law 110-85, Title VIII, Section 801, with respect to an applicable clinical trial).
Last Update Submitted	No	The date on which the trial was last updated.
Last Updater Name	No	The name of the person who last updated the trial.
Last Amendment Submitted	No	The date on which the trial was last amended.
Last Amender Name	No	The name of person who amended the trial.
On-Hold Reason	No	The reason why the abstractor put the trial on hold, if applicable.




Trial ownership and current processing status determine which of the trial details and actions listed above are displayed in the Search Results table. Refer to [Trial Processing Statuses](#).

Columns in Draft Trial Search Results

Trial records returned from "Search Saved Drafts" display the following details and actions you can take for each trial when applicable:

Column	Description
Temporary Trial Identifier	The unique identifier that the system assigned to the saved draft
Title	The official name of the protocol provided by the study principal investigator or sponsor (as it appears in the protocol document).
Lead Organization	The name of the organization responsible for the trial's research protocol, and responsible for the overall scientific and administrative coordination, study monitoring, and data management activities of the trial.
Lead Organization Trial Identifier	The unique ID assigned to the trial by the sponsoring 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.
Action	Actions that are applicable to the draft trial: <ul style="list-style-type: none">• Complete - Link to initiate trial record completion• Delete - Link to initiate trial deletion

 Trial ownership and current processing status determine which of the trial details and actions listed above are displayed in the Search Results table. Refer to [Trial Processing Statuses](#).

Viewing Trial Details

The Submitted Clinical Trials Search Results table lists the trials that match your search criteria, as well as additional criteria. For information on that additional criteria, refer to [Types of Trials Included in Trial Search Results](#).

Search Clinical Trials
 Search Persons
 Search Organizations
 Search Results

Clinical Trials Search Results

Show **10** ▾
Search:
Choose columns
<< < 1 > >>

NCI Trial Identifier ▾	Title	Current Trial Status	Lead Organization
NCI-2013-01471	(*) A Phase I/II Trial of Crolibulin (EPC2407) plus Cisplatin in Adults with Solid Tumors with a Focus on Anaplastic Thyroid Cancer (ATC)	Active	NCI - Center for Cancer Research
NCI-2013-01438	Phase I/II Trial of Vandetanib (ZD6474, ZACTIMA) in Children and Adolescents with Hereditary Medullary Thyroid Carcinoma	Closed to Accrual	NCI - Center for Cancer Research
NCI-2011-02530	Phase I/II Trial of Cediranib Alone or Cediranib and Lenalidomide in Iodine 131-Refractory Differentiated Thyroid Cancer	Active	University of Chicago Comprehensive Cancer Center
NCI-2009-01166	A Targeted Phase I/II Trial of ZD6474 (Vandetanib; CAPRELSA) plus the Proteasome Inhibitor, Bortezomib (Velcade), in Adults with Solid Tumors with a Focus on Hereditary or Sporadic, Locally Advanced or Metastatic Medullary Thyroid Cancer (MTC)	Closed to Accrual	NCI - Center for Cancer Research

Showing 1 to 4 of 4 (filtered from 761 total entries)
<< < 1 > >>

Export options: [CSV](#) | [Excel](#)

To view details for a given clinical trial listed on a search results page, click its associated **NCI Trial Identifier** hypertext link. The details provided for a given trial depend on the following criteria:

- Trial ownership types, as follows:
 - **Private trials** - Trials submitted or owned by the user who is currently logged in to Registration
 - **Public trials** - Trials submitted by other registered users
- Data Table 4 Category (*Complete* or *Abbreviated*), as described in [CTRP Trial Categories](#), [Study Sources](#).

The Trial Details page displays the metadata as entered by a trial submitter. The following image shows the upper part of the Trial Details page.

Trial Details

Trial Identifiers

NCI Trial Identifier: NCI-2014-00298

**Lead Organization
Trial Identifier:** M10-338

Trial Details

Title: A Phase 1 Safety and Pharmacokinetic Study of ABT-263 in Combination With Taxotere® (Docetaxel) in the Treatment of Subjects With Solid Tumors

Phase: I

Trial Type: Interventional

Primary Purpose: Treatment

Secondary Purpose:

Lead Organization:

Lead Organization: Abbott Laboratories

Summary 4 Information

**Trial Submission
Category:** Industrial

**Summary 4 Funding
Sponsor/Source:** Abbott Laboratories

Industrial? Yes

[← Back to Search Results](#)



The system displays responsible party, IND/IDE, NIH grant information and trial-related documents for Private trials only.

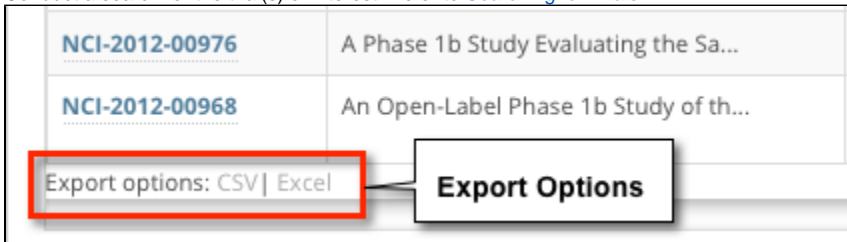
To return to the **Search Trials** page, scroll to the bottom of the **Trial Details** page, and click **Back to Search Results**.

Exporting Search Results

You can export the results from any search you conduct. You can export them in a format suitable for Microsoft Excel or other spreadsheet application.

How to Export Search Results

1. Conduct a search for the trial(s) of interest. Refer to [Searching for Trials](#).



2. At the bottom left corner of the **Search Results** page, next to **Export Options**, click one of the following links:
 - **CSV** - Exports comma-separated values to a **resultsTrialSearch.csv** file
 - **Excel** - Exports Excel-formatted data to a **resultsTrialSearch.xls** fileA download pop-up dialog box appears.
3. Follow your browser/operating system instructions to view or save the document.

Searching for Organization Records

You can search for organizations that are currently registered in CTRP by any of the following criteria:

- Organization Identifying Information
 - **PO ID** - Enter the exact PO ID only
 - **CTEP ID** - Enter all or part of the CTEP ID
 - **Name** - Enter all or part of the Organization's name
 - **Family Name**. Enter all or part of the Organization Family's name
- Organization Address
 - **Country** - Select the country from the drop-down list
 - **City** - Enter all or part of the organization's primary location
 - **State** - Select the state from the drop-down list
 - **Zip Code** - Enter all or part of the Zip code
- Organization Type. Select one of the following:
 - **Lead Organization** - Returns organizations that are Lead Organizations
 - **Participating Site** - Returns organizations that are Participating Sites
 - **Both** - Returns organizations that are *either* Lead Organizations *or* Participating Sites

How to Search for Registered Organizations

1. Click the **Search Organizations** tab. Or, on the toolbar, click **Search > Organizations**.

Search Clinical Trials | Search Persons | **Search Organizations**

Enter information for at least one of the criteria and then click Search. The maximum number of results returned for any search is 500 records. If necessary, limit your search by providing additional search criteria.

Organization Identifying Information | Organization Address

PO ID (Exact Match): Country:


CTEP ID: City:

Name: State:


Family Name: Zip Code:

Organization Type:

2. Provide as much information as you can about the organization you are looking for, or, enter the Person/Organization (PO) ID or Cancer Therapy Evaluation Program (CTEP) Identifier. You must enter search criteria in at least one field.

 **Searching by PO ID**

The PO ID you enter for your search criterion must be exact and complete. That is, do not use partial IDs or wildcards.

 **Using wildcard characters (%)**

You can enter a series of characters in any of the search fields (except the PO ID, which must be an exact match) to narrow the search results. The system adds wildcards on both sides of the search string (the series of letters you type) for you implicitly. You can type wildcard symbols (% or *) between characters of the string as necessary.

3. Click **Search**.

The organizations that meet your search criteria are listed in the Search Results table. To navigate the search results table, see [Working with Tables and Search Results](#).

The screenshot shows a search results interface with four tabs: Search Clinical Trials, Search Persons, Search Organizations, and Search Results. The Search Results tab is active. Below the tabs, there is a section titled "Organization(s):" with a table of results. The table has columns for PO-ID, CTEP ID, Name, Family Name, City, State, Country, and Zip. The first three rows of data are visible.

PO-ID	CTEP ID	Name	Family Name	City	State	Country	Zip
24827	AK001	Anchorage Medical and Surgical Clinic		Anchorage	AK	United States	99501
24856	AK002	Providence Alaska Medical Center		Anchorage	AK	United States	99508
24885	AK003	Anchorage Radiation Therapy Center		Anchorage	AK	United States	99504

Tip
 If the organization you are searching for 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 the one you are searching for, you can narrow your search by providing more information.

- If the organization does not appear in the results table, 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 state in your original search, you may want to search by city in addition to the state.

5. To view the details of any organization in the search results list, click its **PO-ID**.

The Organization Details window displays current information about the organization, including a live web and/or email link that you can use to contact the organization.

The screenshot shows a window titled "Organization Details" with a close button (X) in the top right corner. The window displays the following information:

Name	MD Anderson Cancer Center- Bay Area	PO ID	29888347
Family Name	M.D. Anderson Cancer Center	CTEP ID	TX403
Address	18100 Saint John Drive	Type	Participating Site
City	Nassau Bay		
State	TX		
Postal Code	77058		
Country	United States		
Phone	713-745-9940		
Fax	N/A		
Email	N/A		
Website	http://www.mdanderson.org/patient-and-cancer-information/care-centers-and-clinics/regional-care/bay-area/contact-us/index.html		

Searching for Person Records

You can search for persons that are currently registered in CTRP.

How to Search for Registered Persons

1. Click the **Search Persons** tab. Or, on the toolbar, click **Search > Persons**.

Enter information for at least one of the criteria and then click Search. The maximum number of results returned for any search is 500 records. If necessary, limit your search by providing additional search criteria.

PO ID (Exact Match) Person Role

CTEP ID Organization Affiliation

First Name Last Name

2. Provide as much information as you can about the person you are looking for, or, enter the Person/Organization (PO) ID or Cancer Therapy Evaluation Program (CTEP) Identifier. To search by person role, select a role from the **Person Role** drop-down list. You must enter search criteria in at least one field.

Searching by PO ID

The PO ID you enter for your search criterion must be exact and complete. That is, do not use partial IDs or wildcards.

Using wildcard characters (%)

You can enter a series of characters in any of the search fields (except the PO ID, which must be an exact match) to narrow the search results.

3. Click **Search**.
The persons that meet your search criteria are listed in the Search Results table. To navigate the search results table, see [Working with Tables and Search Results](#).

PO-ID	CTEP ID	First Name	Last Name	Email	Organization Affiliation	Role	City
302582	10192	[REDACTED]	[REDACTED]	[REDACTED]@mdanderson.org	M D Anderson Cancer Center Cancer Therapy Evaluation Program	Clinical Research Staff Healthcare Provider	Houston
317786	13610	[REDACTED]	[REDACTED]	[REDACTED]@dhs.lacounty.gov	Olive View-University of California Los Angeles Medical Center Cancer Therapy Evaluation Program	Clinical Research Staff Healthcare Provider	Sylmar

Tip

If the person you are searching for is not listed, you may have searched too narrowly (that is, you may have provided too much information about the person). If the list of results is very long and contains many persons that are similar to the one you are searching for, you can narrow your search by providing more information.

4. If the person does not appear in the results table, do one of the following to modify your search:

- To broaden your search so that more persons are listed in the search results, delete one or more of your criteria. For example, if you searched by part of the person'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 persons are listed in the search results, provide more about your person. For example, if you searched by state in your original search, you may want to search by city in addition to the state.
5. To view the details of any person in the search results list, click its **PO-ID** link.
The Person Details window displays current information about the person.

Person Details ✕

Prefix	N/A	PO ID	25976099
First Name	Test	CTEP ID	N/A
Middle Name	N/A		
Last Name	Test	Role	Clinical Research Staff Healthcare Provider Organizational Contact
Address	100 Main Street		
City	Rockville		
Postal Code	20111		
Country	USA		

Organization Affiliation

3 items found, displaying all items.1

PO ID	Name
154376	National Cancer Institute
9559134	CTEP_PROD_TEST
18222446	Test Organization

6. To view the details of the organization with which the person is affiliated, click its **PO-ID** link.

Submitting Clinical Trial Data


This page tree describes how to use CTRP to register, amend, and update clinical trials. The following table describes the circumstances in which you should use each submission type:

Submission Type	Description
Registration	Use the Register Trial feature for a trial that has not been registered with CTRP previously. For more information and instructions, refer to Registering New Trials .
Amendment	<p>Use the Amend Trial feature (for <i>Complete</i> trials only) when changes to the trial involve changes to the protocol document that require Investigational Review Board (IRB) approval. Amendments include changes that substantively alter any of the following elements:</p> <ul style="list-style-type: none">• The treatment administered.• The study design.• The sites in which patients are being enrolled on the trial. <p>Amendments include all changes (and updates) since the last amendment to the protocol was submitted. For more information and instructions, refer to Amending Complete Trials, including Examples of Amendments.</p>
Update	Use the Update Trial feature when changes to the trial <i>do not</i> substantively affect the scientific conduct of the study, the study design, and/or the sites in which patients are enrolled on the trial. Update Trial also accommodates certain protocol document changes. For more information and instructions, refer to Updating Trials , including Examples of Protocol Document Updates .


For more information and instructions, refer to the following pages:

Registering New Trials

This page tree describes how to register new *National*, *Externally Peer-Reviewed*, and *Institutional* trials (collectively referred to as *Complete* trials) in the CTRP system. (For the definition of *Complete*, refer to [CTRP Trial Categories](#), [Study Sources](#).) This page tree also describes how to import Industrial trials from ClinicalTrials.gov for registration in the CTRP. It applies to both interventional and non-interventional trials.

 **Gather all the protocol data you need before you begin**

The system logs you off if it detects that you have not used the application for 90 minutes.

 The system locks you out after three unsuccessful attempts to log in within 24 hours. In the event that you have been locked out of your account, contact us at ctrp_support@nih.gov. If you have forgotten your password, or if you want to reset it for any reason, refer to [Resetting Your Password](#).

For instructions, refer to the following pages:



About Trial Registration

The way in which you register trials in the CTRP depends on a combination of the trial's Data Table 4 Categorization as either *Complete* or *Abbreviated*, your affiliated organization and its role in the trial, and whether the trial currently is registered in ClinicalTrials.gov with an NCT ID. (For the definition of *Complete* and *Abbreviated*, refer to [CTRP Trial Categories](#), [Study Sources](#).)

Keep in mind the following points about the entities in CTRP that represent NCI-designated Cancer Centers:

- A CTRP organization family represents an NCI-designated Cancer Center family of organizations. For brevity, this guide refers to this entity as a *Cancer Center family*, a *Cancer Center*, or an *organization family*.
- A CTRP organization that is a member of a Cancer Center family is considered a Cancer Center organization. For brevity, this guide refers to this entity as a *Cancer Center organization*.



The following table lists the guidelines:

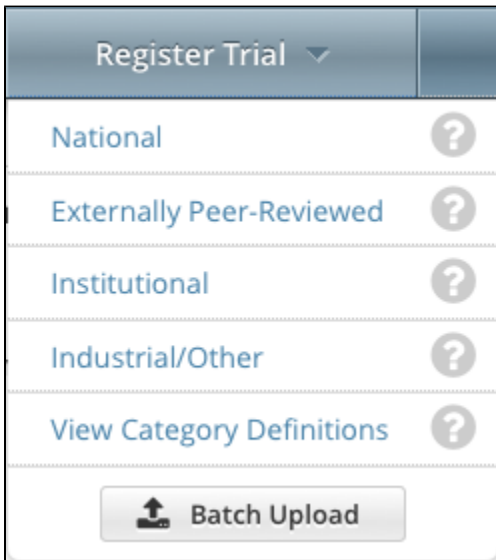
<p>Guidelines for Complete Trials</p>	<p>If your trial is <i>Complete</i>, follow the instructions in Registering New Complete Trials.</p> <ul style="list-style-type: none"> • Cancer Center trials must meet the following criteria to be eligible for registration: <ul style="list-style-type: none"> • Trials must have been active as of January 1, 2009 or any time thereafter. • Submitting organization is the Lead Organization or the Coordinating Center. • CTEP or DCP PIO-managed trials must meet the following criteria to be eligible for registration: <ul style="list-style-type: none"> • If NCI-managed, trials must have been active as of January 1, 2009 or any time thereafter. • If NCI-sponsored, trials must have been still open (not yet <i>Completed</i>) as of December 26, 2007 or opened anytime thereafter. <div style="border: 1px solid #f0e68c; padding: 10px; margin-top: 10px;">  Cancer Centers do not register PIO-managed trials or NCI-CCR trials. PIO-managed trials are submitted to CTRP directly by CTEP and DCP. NCI-CCR trials are managed in ClinicalTrials.gov by CCR. </div>
<p>Guidelines for Abbreviated Trials</p>	<p>If your trial is <i>Abbreviated</i>, registration differs according to a combination of the following trial attributes:</p> <ul style="list-style-type: none"> • NCT ID (which indicates that the trial has been registered with ClinicalTrials.gov) • Cancer Center type (NCI-designated Cancer Centers or other centers) • NCI grant • Lead organization <p>Guidelines for Trials with NCT IDs</p> <p>If the trial is an Industry funded trial, and has an NCT ID, then it can be imported into CTRP from ClinicalTrials.gov in most cases. In some special cases, however, the trial cannot be imported directly and instead you must contact the CTRO for assistance.</p> <ul style="list-style-type: none"> • If your organization is not an NCI-designated Cancer Center organization, NIH institute, or pharmaceutical company, you will need to import the trial directly from ClinicalTrials.gov. For instructions on this process, refer to Registering Abbreviated (Industrial and Other) Trials. <div style="border: 1px solid #d9e1f2; padding: 10px; margin-top: 10px;">  The system assigns the trial you import from ClinicalTrials.gov the Data Table 4 Category (funding source) <i>Industrial/Other</i>. (For information, refer to CTRP Trial Categories, Study Sources.) To specify whether the trial is <i>Industrial</i>, or to specify if an <i>Other</i> trial is <i>National</i> or <i>Externally Peer-Reviewed</i>, contact the CTRO for assistance at ncictro@mail.nih.gov. For funding source definitions, refer to https://cancercenters.cancer.gov/GrantsFunding/eData#dt4. </div> <ul style="list-style-type: none"> • If your organization is the Lead Organization on a trial, and your organization is an NCI-designated Cancer Center organization, do not import the trial from ClinicalTrials.gov. Instead, submit the trial to CTRP as a Complete trial. For instructions, refer to Registering New Complete Trials. • If your organization is the Lead Organization for any trial on anything other than an NCI-designated Cancer Center organization, NIH institute, or pharmaceutical company trial, the CTRO contacts the Center and further categorizes the trial as <i>Other/National</i> or <i>Other/Externally Peer-Reviewed</i> based on whether your trial is conducted under an NIH grant, as follows: <ul style="list-style-type: none"> • If your trial is conducted under an NCI grant, the CTRO categorizes it as a <i>Consortia</i> trial. • If your trial is not conducted under an NCI grant, the CTRO categorizes it as follows: <ul style="list-style-type: none"> • <i>Other/National</i>, for trials sponsored by an NIH institute • <i>Other/Externally Peer-Reviewed</i>, for trials managed by a hospital or a center other than one designated by the NCI
<p>Guideline for Trials without NCT IDs</p>	<p>If your trial is <i>Abbreviated</i> but does not have an NCT ID, please contact the CTRO for assistance at ncictro@mail.nih.gov. CTRO registers these trials manually.</p>

Registering New Complete Trials


How to Register New Complete Trials

1. Perform a search for the trial. For instructions, refer to [Searching for Trial Records](#). If the trial does not already exist, proceed to the next step. (The system uses the Lead Organization ID, Lead Organization Trial ID, and the ClinicalTrials.gov Identifier to detect duplicates. If the system detects a duplicate, the system does not record your trial.)
2. On the toolbar, click **Register Trial**, and select your trial's Submission Category (funding source) from the drop-down list, either **National**, **Externally Peer-Reviewed**, or **Institutional**. (For information, refer to [CTRP Trial Categories](#), [Study Sources](#).)

 To read a definition of each of the trial submission categories (study sources), click **View Trial Category Definitions**, click the Help icon () next to each category, or refer to <https://cancercenters.cancer.gov/GrantsFunding/eData#dt4>.



The Register Trial page appears.


 **You can expand and collapse sections of the registration page**

By default, all sections of the registration form are displayed.

To collapse or expand each section individually, click the **Collapse** or **Expand** icon on the right side of the section title as shown in the figures below.


To collapse all sections, click **Collapse All**.

3. In the various fields, specify the appropriate information. The following table describes the fields.


 **Tip**

Be sure to provide information for all fields marked with an asterisk (*). If you cannot complete the registration of a trial in one Registration session, you can save a draft of the trial details you have completed. (Refer to "Save as Draft" below.) Later you can return to complete the registration in another session.

Field Label	Description/Instructions
Various	<p>In the various fields, specify information as appropriate according to the detailed instructions provided for each of the following sections:</p> <ol style="list-style-type: none"> Recording Trial Identification Information Recording Trial Details Recording Lead Organizations and Principal Investigators

	<ul style="list-style-type: none"> d. Recording Sponsors and Responsible Parties e. Recording Data Table 4 Information f. Recording NIH Grants g. Recording Trial Statuses h. Recording Trial Dates i. Recording INDs and IDEs j. Recording Regulatory Information k. Uploading Trial-Related Documents
Save as Draft	<p>Click to save a draft of the record so that you can complete the registration at another time. You must have provided, at the minimum, both the Lead Organization and Lead Organization Trial Identifier to save a draft.</p> <p>The system saves your draft, assigns it a unique ID (for tracking purposes), and sends you an email message confirming that the information has been saved. You can end your Registration session and retrieve your draft later to complete the registration.</p>
Review Trial	<p>Click to initiate the system check for errors and missing information. The system displays the results in a message at the top of the Review Trial Details page. Indicators mark specific fields that you must complete or correct in order to submit the trial.</p> <p>The Review Trial Details page is read-only. To make changes to the trial data, follow the instructions in Editing Trial Details.</p>
Cancel	<p>Click to cancel the registration. A pop-up message prompts you to confirm cancellation.</p> <div style="border: 1px solid #ccc; padding: 10px; margin-top: 10px;">  If you choose to cancel the registration, you will lose all data that you may have entered. </div>

4. To continue with the trial registration, scroll to the bottom of the **Review Trial Details** page, and then click **Submit**. To prevent creating a duplicate record, do not click **Submit** more than once. If you have to make changes after you click **Submit**, contact the CTRO at ncictro@mail.nih.gov rather than using your browser's Back button to make changes.
- The registration notification message system sends you an email message to acknowledge that the trial has been submitted. Later it sends another email message to notify you when your trial has been accepted or rejected.

 After submission, most users other than the trial submitter can not see the trial information you provided until the information has been validated. However, an organization administrator (if one exists) and an assigned owner can access the information prior to validation.

Recording Trial Identification Information

You must provide a Lead Organization trial identifier for each trial you register. Optionally, provide a ClinicalTrials.gov Identifier.

Trial Identifiers* ▼

Lead Organization Trial Identifier:* ?

30 characters left

ClinicalTrials.gov Identifier: ?

Other Identifiers ▼

Other Trial Identifier **+** Add Other Identifier ?

How to Complete the Trial Identifiers Section

Select or enter the appropriate information in the text fields and drop-down lists. The following table describes the fields. An asterisk (*) indicates a required field.


Instructions for recording Trial Identifiers for Complete trials

Field Label	Description/Instructions
Lead Organization Trial Identifier*	Enter the unique identification assigned to the protocol by the sponsoring organization, exactly as it appears in the protocol document. For Inter-Group trials, type the Lead Group's trial number. For multi-site trials that have no assigned single center, use the protocol ID, for example, NSAGP-B-40.
ClinicalTrials.gov Identifier	<p>If the trial has been submitted to ClinicalTrials.gov previously, enter the number assigned to the trial by PRS (ClinicalTrials.gov).</p> <div style="border: 1px solid #ffc107; padding: 5px; margin-bottom: 5px;"> ! The CTRP renamed the previous identifiers "NCT Number" and "NCT ID" to "ClinicalTrials.gov Identifier". </div> <div style="border: 1px solid #ffc107; padding: 5px; margin-bottom: 5px;"> ! You cannot change the ClinicalTrials.gov Identifier once you have added it. If you need to make changes thereafter, contact the CTRO at NCICTRO@mail.nih.gov. </div> <div style="border: 1px solid #17a2b8; padding: 5px;"> i When you submit the trial, the system checks the ClinicalTrials.gov identifier you entered to ensure that no other registered trial has the same one. The system displays an error message if it finds another trial with the same ClinicalTrials.gov identifier. If this occurs, check the number you entered and try again. If you are certain that the number you entered is correct, contact the CTRO at NCICTRO@mail.nih.gov. </div>
Other Trial Identifier	<p>Enter an additional trial identifier such as unique identifier from other registries, NIH grant numbers, or protocol numbers assigned by the Review Board, and then click Add Other Identifier. Repeat this step for each additional identifier. The ID you added is displayed in the <i>Other Identifier</i> list. To delete an identifier you have added, in the Action Column, click Delete.</p>


Recording Trial Details

How to Complete the Trial Details Section

- In the various fields, specify the appropriate information. The following table describes the fields. An asterisk (*) indicates a required field.




Field Label	Description/Instructions
Title*	Enter the official name of the protocol provided by the study principal investigator or sponsor. (Limit 4000 characters) For example: "Study of Recombinant Vaccinia Virus That Expresses Prostate Specific Antigen in Metastatic Adenocarcinoma of the Prostate"
Phase*	Select the phase or stage of the clinical trial as defined by the US FDA, from the drop-down list. For valid values, refer to Trial Phase Value Definitions . <div style="border: 1px solid #ccc; padding: 5px; margin-top: 10px;">  Select N/A for observational and ancillary-correlative trials. </div>
Is this a Pilot?	Select Yes or No from the drop-down list to indicate whether the trial you are registering is a pilot trial.
Trial Type*	Select the trial type indicated in the protocol.

- If you selected interventional as the trial type, select or enter the appropriate information in the following fields. The following table describes the fields. An asterisk (*) indicates a required field.

Field Label	Description/Instructions
Primary Purpose*	a. Select the primary reason for conducting the trial. For valid values, refer to Primary Purpose Value Definitions . b. Optionally, if the primary purpose is Other , type a detailed description of the trial's purpose in the text field provided. <div style="border: 1px solid #ccc; padding: 5px; margin-top: 10px;">  The text field is displayed only after you have selected Other. The limit is 200 characters; the system counts down the character numbers as you type. </div>
Secondary Purpose	a. Select one of the following reasons for conducting the trial. <ul style="list-style-type: none"> • Ancillary-Correlative. A trial that is secondary to another trial, or a type of trial that tests for a relationship between a condition and a potential causal factor of the condition. <ul style="list-style-type: none"> • Ancillary. 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 must be linked to an active clinical research study and should include only patients accrued to that clinical research study. Report only those studies that can be linked to individual patient or participant data. • Correlative. Laboratory-based studies using specimens to assess cancer risk, clinical outcomes, response to therapies, etc. Report only those studies that can be linked to individual patient or participant data. • Other. Any purpose other than Ancillary-Correlative.
Accrual Disease Terminology*	Click to select the disease terminology used to report subject accruals for this trial.

- If you selected non-interventional as the trial type, select or enter the appropriate information in the following fields. The following table describes the fields. An asterisk (*) indicates a required field.

Field Label	Description/Instructions
Non-Interventional Trial Type*	Select one of the following trial types: <ul style="list-style-type: none"> • Observational. Studies among cancer patients and healthy populations that involve no interventions or alteration of the participants. Biomedical and/or health outcome(s) are assessed in pre-defined groups of participants. The participants in the study may receive diagnostic, therapeutic, or other interventions but the investigator of the observational study is not responsible for assigning specific interventions to the participants of the study. • Ancillary-Correlative. A trial that is secondary to another trial, or a type of trial that tests for a relationship between a condition and a potential causal factor of the condition.

	<ul style="list-style-type: none"> • Ancillary. 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 must be linked to an active clinical research study and should include only patients accrued to that clinical research study. Report only those studies that can be linked to individual patient or participant data. • Correlative. Laboratory-based studies using specimens to assess cancer risk, clinical outcomes, response to therapies, etc. Report only those studies that can be linked to individual patient or participant data.
Primary Purpose*	<p>a. Select the primary reason for conducting the trial. For valid values, refer to Primary Purpose Value Definitions.</p> <p>b. If none of the values is appropriate, select Other, and then enter the same Non-Interventional Study Type you selected earlier, either <i>Observational</i> or <i>Ancillary -Correlative</i> , in the text field.</p> <div style="border: 1px solid #ccc; padding: 5px; margin-top: 10px;"> <p> The text field is displayed only after you have selected Other. The limit is 200 characters; the system counts down the character numbers as you type.</p> </div>
Study Model Code*	<p>a. Select the primary strategy for subject identification and follow-up. The following list provides valid values.</p> <ul style="list-style-type: none"> • Cohort. Group of individuals, initially defined and composed, with common characteristics (e.g., condition, birth year), who are examined or traced over a given time period • Case-control. Group of individuals with specific characteristics (e.g., conditions or exposures) compared to group(s) with different characteristics, but otherwise similar • Case-only. Single group of individuals with specific characteristics • Case-crossover. Characteristics of case immediately prior to disease onset (sometimes called the hazard period) compared to characteristics of same case at a prior time (i.e., control period) • Ecologic or community studies. Geographically defined populations, such as countries or regions within a country, compared on a variety of environmental (e.g., air pollution intensity, hours of sunlight) and/or global measures not reducible to individual level characteristics (e.g., health care system, laws or policies median income, average fat intake, disease rate) • Family-based. Studies conducted among family members, such as genetic studies within families or twin studies and studies of family environment • Other. Any model not described above <p>b. If the study model is Other, type a detailed description of the trial's study model in the text field provided.</p> <div style="border: 1px solid #ccc; padding: 5px; margin-top: 10px;"> <p> The text field is displayed only after you have selected Other.</p> </div>
Time Perspective Code*	<p>a. Select the temporal relationship of observation period to time of subject enrollment. The following list provides valid values.</p> <ul style="list-style-type: none"> • Prospective - Look forward using periodic observations collected predominantly following subject enrollment • Retrospective - Look back using observations collected predominantly prior to subject selection and enrollment • Cross-sectional - Observations or measurements made at a single point in time, usually at subject enrollment • Other - Any time perspective not described above <p>b. If the time perspective is Other, type a detailed description of the trial's time perspective in the text field provided.</p> <div style="border: 1px solid #ccc; padding: 5px; margin-top: 10px;"> <p> The text field is displayed only after you have selected Other. The limit is 200 characters; the system counts down the character numbers as you type.</p> </div>
Site Principal Investigator*	Click Look Up Person and search for the principal investigator. For instructions, refer to Looking Up Registered Persons .

Recording Lead Organizations and Principal Investigators

The Lead Organization is the institution that is the principal administrative organization responsible for the study. Each trial can have one Lead Organization only.

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

 **Tip**

The Principal Investigator is the individual who is responsible and accountable for conducting the clinical trial. The PI assumes full responsibility for the treatment and evaluation of human subjects, and for the integrity of the research data and results.

Lead Organization/Principal Investigator*

Lead Organization:* [Please Select the Lead Organization. ▾](#)

Principal Investigator:* Look Up Person ?

Sponsor/Responsible Party*

Sponsor* [Please Select the Sponsor Organization. ▾](#)

Responsible Party:*

How to Complete the Lead Organization/Principal Investigator Section

- Next to the **Lead Organization** field, click **Please Select the Lead Organization**.

The system displays your affiliated organization first, followed by affiliated organization family members. Organizational roles are displayed when applicable.

Lead Organization/Principal Investigator*

Lead Organization:* [Please Select the Lead Organization. ▾](#)

PO ID	CTEP ID	Name
129345	244600	M D Anderson Cancer Center (Your Affiliation)
129374	74097525	MD Anderson Phase 2 Consortium
9200000	544612	M D Anderson Cancer Center (IND Holder)
18478	79966622	M D Anderson International Spain
227400	244689	M D Anderson Cancer Center
129345	244600	M D Anderson Cancer Center
29888347	119380965	MD Anderson Cancer Center- Bay Area
70797	74253034	UF Cancer Center at Orlando Health
-16984721	74353788	U.T.M.D. Anderson Cancer Center
227050	74191123	MD Anderson Cancer Network
213790	423638	M D Anderson Cancer Center (MDACC) Research Base
Search...		

Sponsor/Responsible Party*

Sponsor* [Please Select the Sponsor Organization. ▾](#)

Responsible Party:*

[Click to search for other organizations](#)

Summary 4 Information*

- Select the appropriate organization from the list. If the organization is not listed, click **Search**, and search for the organization as per the instructions in [Looking up Registered Organizations](#). (If the search does not return your trial's lead organization, you can ask the CTRO to create the organization record. To do so, follow the instructions in [Requesting Creation of an Organization Record](#).)
- Next to **Principal Investigator** click **Look Up Person**, and search for the principal investigator as per the instructions in [Looking Up Registered Persons](#). (If your trial's principal investigator's name is not listed, you can ask the CTRO to create the person record. To do so, follow the instructions in [Requesting Creation of a Person Record](#).)

Recording Sponsors and Responsible Parties

Complete this section only if you require an XML document to register your trial with ClinicalTrials.gov.

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

1. **Sponsor.** Name of the primary organization that oversees the implementation of the study and is responsible for data analysis. For applicable clinical trials, sponsor is defined in 21 CFR 50.3.
- or -
2. **Principal Investigator.** The individual who serves as the principal investigator and is designated as responsible party, consistent with the conditions described in the statute.
- or -
3. **Sponsor-Investigator:** The individual who both initiates and conducts the study.



For further elaboration on the definition of these roles with respect to responsible party, refer to <http://prsinfo.clinicaltrials.gov/ElaborationsOnDefinitions.pdf>.

The fields displayed in the Sponsor/Responsible Party section depend on your selection of the Responsible Party role:

- If you select **Sponsor**, you do not submit any further information about the Responsible Party.
- If you select **Principal Investigator**, this section expands to display the investigator's title and organization affiliation. The system populates the Investigator's Name field with the name you selected as Principal Investigator in the Lead Organization/Principal Investigator section.
- If you select **Sponsor-Investigator**, this section expands to display the investigator's title and organization affiliation. Although the system populates the Investigator's name field with the name you selected as Principal Investigator in the Lead Organization/Principal Investigator section, you can select another person for this role.

How to Complete the Sponsor/Responsible Party Section

1. Complete the Lead Organization/Principal Investigator section, as described in [Recording Lead Organizations and Principal Investigators](#). Doing so will ensure that the Sponsor/Responsible Party section is pre-populated when applicable.
2. In the Sponsor/Responsible Party section, select or enter the appropriate information in the text fields and drop-down lists. The following table describes the fields. An asterisk (*) indicates a required field.

Field Label	Description/Instructions
Sponsor	Click Look Up Sponsor and search for the organization as per the instructions in Looking Up Registered Organizations .
Responsible Party	Indicate the party who is responsible for the trial. Select one of the following options: <ul style="list-style-type: none"> • Sponsor. Name of primary organization that oversees implementation of study and is responsible for data analysis. If you select this role, you do not submit any further information about the Responsible Party. • Principal Investigator. Primary medical researcher in charge of carrying out a clinical trial's protocol. If you select this role, this section expands to display the investigator's title and organization affiliation. The system populates the Investigator's Name field with the name you selected as Principal Investigator in the Lead Organization/Principal Investigator section. • Sponsor-Investigator. The individual who both initiates and conducts the study. If you select this role, this section expands to display the investigator's title and organization affiliation. The system populates the Investigator's Name field with the name you selected as Principal Investigator in the Lead Organization/Principal Investigator section.
Investigator*	If the Responsible Party is the Principal Investigator, you can not change the person's name. If the Responsible Party is the Sponsor-Investigator, you can change the person's name. To do so, click Look Up Sponsor , and follow the instructions in Looking Up Registered Persons .
Investigator Title*	The system populates this field. Enter a new title in the field provided if other than Principal Investigator.
Investigator Affiliation*	If the Responsible Party is the Principal Investigator, you can change the affiliated organization. To do so, click Look Up Organization , and follow the instructions in Looking Up Registered Organizations . If the Responsible Party is the Sponsor-Investigator, you can not change the affiliated organization.

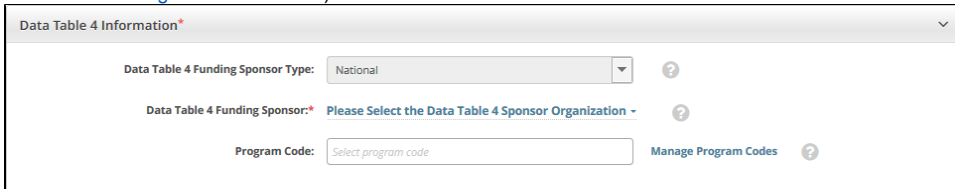
Recording Data Table 4 Information

Complete all fields in the Data Table 4 Information section. The Trial Submission Category (study source) or Data Table 4 Funding Sponsor Type fields are pre-populated with the sponsor type.

 The lead organization or at least one participating site must be a Cancer Center organization.

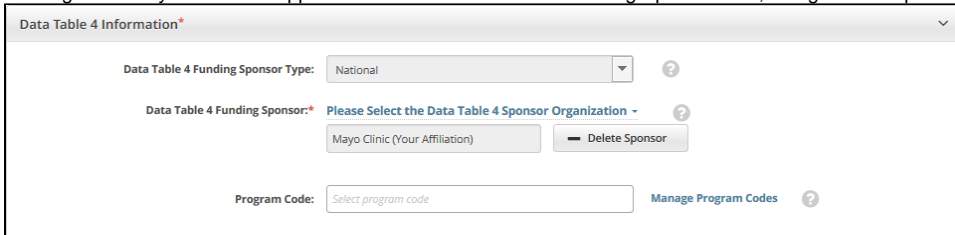
How to Complete the Data Table 4 Information Section

1. Hover your mouse over **Please Select the Data Table 4 Sponsor Organization**. A list of organizations appears.
2. Select the name of the external sponsor or funding source as defined by the Data Table 4 report. Refer to [Looking Up Registered Organizations](#). (If your trial's funding sponsor is not listed, you can ask the CTRO to create the organization record. To do so, follow the instructions in [Requesting Creation of an Organization Record](#).)




The screenshot shows the 'Data Table 4 Information' form. The 'Data Table 4 Funding Sponsor Type' is set to 'National'. The 'Data Table 4 Funding Sponsor' field is currently empty and displays the prompt 'Please Select the Data Table 4 Sponsor Organization'. Below this field is the 'Program Code' field, which is also empty and displays 'Select program code'. There is a 'Manage Program Codes' link next to the program code field.

The organization you selected appears under the Data Table 4 Funding Sponsor field, along with an option to delete the sponsor.




The screenshot shows the 'Data Table 4 Information' form after a sponsor has been selected. The 'Data Table 4 Funding Sponsor' field now displays 'Mayo Clinic (Your Affiliation)'. A 'Delete Sponsor' button is visible next to the selected sponsor name. The 'Program Code' field remains empty with the prompt 'Select program code'.

 A trial can have multiple sponsors. Repeat the steps above to add other sponsors. The system ensures that you don't duplicate an existing sponsor.

3. To delete an existing sponsor, click **Delete Sponsor**. You can not "undo" the deletion but you can add the sponsor back if necessary. If you have selected a lead organization for the trial and if that lead organization belongs to an organization family, the Program Code field is available. The Program Code field lists all program codes available for that organization family. If you are a site administrator, an option to manage program codes is also available.
4. If you want to specify a program code for the trial, select one or more codes in the **Program Code** field.
5. If you want to manage program codes, save a draft of the trial details you have completed. (Refer to "Save as Draft" in [Registering New Complete Trials](#).) Then you can do one of the following:
 - a. Retrieve that draft trial for completion (as described in [Completing and Deleting Saved Drafts](#)), return to this Data Table 4 Information section, and click **Manage Program Codes**.
 - b. On the toolbar, click **Administration > Program Codes > Manage Master List**.

Recording NIH Grants


This section pertains to *Complete* trials. You must record NIH grant information for your trial, including the funding mechanism, institute code, serial number, and NCI division/program. You can add up to five NIH grants.

 If the Lead Organization for the trial is a Cancer Center organization, you must record a valid P30 grant.


For a complete guide to NIH grant information, refer to the Grants and Funding page at http://grants.nih.gov/grants/funding/funding_program.htm.

How to Complete the NIH Grant Information Section

1. Select or enter the appropriate information in the text fields and drop-down lists. The following table describes the fields. All fields in this section are required if your study is funded by NIH.
Instructions for recording NIH Grant Information

Field Label	Description/Instructions
Is this trial funded by an NCI grant?	If the trial is funded in part or whole by an NCI Grant or Contract, select Yes . Otherwise, select No .
Funding Mechanism	<p>Enter the initial letter(s) and or number(s) in the Funding Mechanism field and then select the NIH unique identifier from the drop-down list. The funding mechanism is a 3-character code used to identify areas of extramural research activity applied to funding mechanisms.</p> <div style="border: 1px solid green; padding: 5px; margin: 10px 0;"> <p> Tip</p> <p>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.</p> </div> <p>For a list of valid codes, refer to Funding Mechanism Code Values.</p>
Institute Code	<p>Select the two-letter code identifying the first major-level subdivision, the organization that supports an NIH grant, contract, or inter-agency agreement. The support may be financial or administrative.</p> <p>For a list of valid codes, refer to NIH Grant Institute Code Values.</p>
Serial Number	<p>Enter the five- or six-digit number generally assigned sequentially to a series within an Institute, Center, or Division, for example, 123660. If you selected CA in the Institute Code field, the system displays the top ten grants that match the sequence of serial numbers as you type them one-by-one. By selecting a grant from the list, you ensure that you record a valid serial number.</p>
NCI Division /Program	<p>Enter the initial letter(s) of the division or program, and then select the organizational unit that provides funding for the study, from the drop-down list.</p> <p>For a list of Divisions and Programs, refer to NCI Division and Program Values.</p>

2. Click **Add Grant**.

 The **Add** 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.
3. If your trial is funded by more than one grant, repeat the steps above, and then click **Add Grant**.
4. To delete a grant record from a trial, in the **Action** column, click **Delete**.

Recording Trial Statuses

Trial status refers to the current stage or state of a clinical trial or study relative to other stages and its ability to enroll participants/patients.

Valid trial statuses used in CTRP are mapped to ClinicalTrials.gov-defined recruitment values. For valid [ClinicalTrials.gov](#) recruitment values, refer to [Trial Status Values in the CTRP and ClinicalTrials.gov](#) and [Expanded Access Statuses](#).

If you register a trial after it has reached any *Closed to Accrual* related trial status or a *Complete* trial status, you must create a complete Trial Status History by adding all previous statuses in order, as per the rules provided in [Status Transition Rules](#).

How to Complete the Trial Status Section

Trial Status*

Status Date ?	Status ?	Why Study Stopped? ?	
mm/dd/yyyy	--Select--	 1000 characters left <i>Administratively Complete, Withdrawn and Temporarily Closed statuses only</i>	+ Add Status

Please refer to the [Trial Status Transition Rules](#).

1. Select or enter the appropriate information in the text fields and drop-down lists. The following table describes the fields. All fields in this section are required.

Field Label	Description/Instructions
Trial Status Date*	Enter the date on which the current trial status became effective.
Trial Status	Select the trial's accrual status from the drop-down list. For valid values, refer to Trial Status Values in the CTRP and ClinicalTrials.gov and Expanded Access Statuses .
Why Study Stopped	If you selected the Administratively Complete, Withdrawn, or Temporarily Closed to Accrual status, type the reason why the study has ended or is not currently accruing, using up to 160 characters. As you type, the number of characters remaining is displayed below the text field.

2. Click **Add Status**.
The new status record is displayed.

Trial Status*

Status Date ?	Status ?	Why Study Stopped? ?	
mm/dd/yyyy	--Select-- <i>Participants are being (or will be) selected from a predetermined population.</i>	 1000 characters left <i>Administratively Complete, Withdrawn and Temporarily Closed statuses only</i>	+ Add Status

Please refer to the [Trial Status Transition Rules](#).

Trial Status History
Show **10** entries

Status Date	Status	Comments	Validation Messages	Actions
12/01/2014	Enrolling by Invitation		WARNING: Interim status [IN REVIEW] is missing WARNING: Interim status [APPROVED] is missing	

3. If the system indicates that the status you added is invalid, do one of the following.

- To edit the status, in the **Actions** column, click the **Edit** icon and make changes as indicated in the Error and/or Warning message.

Edit Trial Status [X]

Status Date:* 02/03/2015 [Calendar Icon]

Status:* Enrolling by Invitation [Dropdown Arrow]

Why Study Stopped:* [Text Area]


1000 characters left
Administratively Complete, Withdrawn and Temporarily Closed statuses only

Comment:* [Text Area]

1000 characters left

[Save] [Cancel]

- To delete the status, in the **Actions** column, click the **Delete** icon. Enter a comment indicating the reason why you deleted the record, and then add the correct status information.

 The system does not change the status of participating sites when you close a trial.

Recording Trial Dates

The Trial Dates section captures start, primary completion, and completion dates.

How to Complete the Trial Dates Section

1. In the various date fields, specify dates as they occur according to the rules specified in [Status Rules for Trial Dates](#). The following table describes the fields. In this table, an asterisk (*) indicates a required field and an asterisk within square brackets ([*]) indicates a conditionally required field.

Field Label	Description/Instructions
Trial Start Date*	Enter the date on which the trial started, or is expected to start.
Primary Completion Date [*]	Enter the date on which the final subject was examined or received an intervention, or the date on which that is expected to happen. Primary Completion Dates are optional in the following cases: <ul style="list-style-type: none">• For non-interventional trials.• For DCP trials, if you select N/A as the type. In both cases, the system excludes such trials when submitting XML documents to ClinicalTrials.gov. Otherwise, Primary Completion Dates are required.
Completion Date	Enter the final date on which data was (or is expected to be) collected for the trial.

- In the Primary Completion Date field, the N/A option is available only for Non-Interventional trials and for Interventional DCP trials.
2. Indicate whether each date you entered is **Actual** or **Anticipated**, according to the rules specified in [Status Rules for Trial Dates](#).
 3. To clear the selection of Actual or Anticipated for the Primary Completion Date of a non-interventional trial, clear the Primary Completion Date and click **Review Trial**. (If the page indicates any errors, resolve them and click **Review Trial** again.)

Recording INDs and IDEs


Enter 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.

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

How to Register IND/IDE Trials

1. Select or enter the appropriate information in the text fields and drop-down lists. Fields are described in the following table.

Instructions for recording IND/IDE Information

Field Label	Description/Instructions
IND/IDE Types*	If the trial involves an Investigational New Drug Application, select IND . If the trial involves an Investigational Device Exemption, select IDE .
IND/IDE Number*	Enter the number assigned to an Investigational New Drug Application (IND) or Investigational Device Exemption (IDE) <div style="border: 1px solid green; padding: 10px; margin-top: 10px;"> <p> IND number formats</p> <p>You can enter the IND number in many formats. For example, for a biologics (BB) IND that contains the number 1234, you can type BB1234, 1234, or BB_1234. For IDE trials, type the IDE number associated with the grant.</p> </div>
IND/IDE Grantor*	Select one of the following organizations that holds the IND/IDE approval: <ol style="list-style-type: none"> a. For IND trials: <ol style="list-style-type: none"> i. Center for Drug Evaluation and Research ii. Center for Biologics Evaluation and Research b. For IDE trials: <ol style="list-style-type: none"> i. Center for Devices and Radiological Health ii. Center for Biologics Evaluation and Research
IND/IDE Holder Type*	Select one of the following holder types: <ol style="list-style-type: none"> a. Investigator b. Organization c. Industry d. NIH e. NCI
NIH Institution, NCI Division /Program Code* (required if the holder type is NIH or NCI)	Select a code from the drop-down list. <ul style="list-style-type: none"> • If you selected NIH from the IND/IDE Holder Type list, refer to NIH Institution Code Values for valid values. • If you selected NCI from the IND/IDE Holder Type list, refer to NCI Division and Program Values for valid values.
Availability of Expanded Access	If the drug, biologic, or device product is known to be available outside any clinical trial protocol, select Yes . If it is known to be <i>unavailable</i> outside any clinical trial protocol, select No . Otherwise, select Unknown . If you select Yes in this field, the Expanded Access Record field becomes available.
Expanded Access Record	Specify the ClinicalTrials.gov identifier (NCT ID) for the associated Expanded Access record. Also, consider specifying each of these trials as an Associated Trial for the other. For instructions, refer to Associating Trials .

2. Click **Add IND/IDE**.
3. To delete an IND/IDE record from a trial, in the **Action** column, click **Delete**.
4. Optionally, to add another IND/IDE record, repeat the steps above.


Recording Regulatory Information

Complete this section only if you require an XML document to register your trial with ClinicalTrials.gov.

How to Complete the Regulatory Information Section

Select or enter the appropriate information in the text fields and drop-down lists. The following table describes the fields. An asterisk (*) indicates a required field. For a definition of each field, refer to <http://prsinfo.clinicaltrials.gov/definitions.html>.

Instructions for recording regulatory information

Field Label	Description/Instructions
Studies a U.S. FDA-regulated Drug Product	If the trial studies one or more U.S. FDA-regulated drug or biologic products (a drug subject to section 505 of the Federal Food, Drug, and Cosmetic Act or a biological product subject to section 351 of the Public Health Service Act), select Yes . Otherwise, select No .
Studies a U.S. FDA-regulated Device Product	If the trial studies one or more U.S. FDA-regulated device products (a device subject to section 510(k), 515, 520(m), or 522 of the Federal Food, Drug, and Cosmetic Act), select Yes . Otherwise, select No . If you select Yes in this field, the Unapproved/Uncleared Device field and Pediatric Post-market Surveillance field become available.
Unapproved /Uncleared Device	This field is read-only. The default value is No, which indicates the release of trial information on Cancer.gov is not being delayed until after an interventional device has been approved or cleared. You may request a change in the value for this field by submitting a request to the CTRO at ncictro@mail.nih.gov .
Pediatric Post-market Surveillance	If the U.S. FDA has ordered a pediatric post-market surveillance of the device product, select Yes . Otherwise, select No .
Product Exported from the U.S.	If the product is manufactured in the U.S. or one of its territories and exported for study in a clinical trial in another country, select Yes . Otherwise, select No .
FDA Regulated Intervention Indicator	If the trial is regulated by the FDA, select Yes . (If the trial includes an IND or IDE, you must select Yes .) Otherwise, select No . If you select Yes in this field, the Section 801 Indicator field becomes available.
Section 801 Indicator	If the FDA-regulated interventional trial is an applicable trial as defined in US Public Law 110-85, Title VIII, Section 801, select Yes . Otherwise, select No .
Data Monitoring Committee Appointed Indicator	Optionally, if a data monitoring committee has been appointed for this trial, select Yes . Otherwise, select No . <div style="border: 1px solid #ccc; padding: 10px; margin-top: 10px;">  This information is required for compliance with the Public Law 110-85 of the Food and Drug Administration Amendment Act of 2007. If you are unsure about how to classify a trial, or what information to provide, contact the FDA's regulatory affairs office. </div>

Uploading Trial-Related Documents

When registering *Complete* trials, you must upload the following types of documents:

- *Complete* clean Protocol document.
- IRB Approval.
- List of Participating Sites (if not included in the protocol document). Multi-site trials require a list of participating sites and contact information.
- Informed Consent (if not included in the protocol document).

Currently, the system requires you to supply each of your documents as one of the following formats:

- Microsoft Word (.doc, .docx, or .docm).
- Adobe PDF. Adobe PDF files require special processing. For information about creating PDFs, refer to [Converting Files to PDFs](#).
- Microsoft Excel (.xls, .xlsx, .xlsm, or .xlsb).
- WordPerfect.

Trial Related Documents *

To ensure successful registration, upload a Protocol document and an IRB Approval document. If the Protocol document does not include the Informed Consent and/or participating sites, upload the Informed Consent document and a list of participating sites separately.
To ensure successful registration of multi-center trials, upload a list of participating sites that includes contact information in addition to the files described above.
You can use the [Participating Sites template](#) to submit your list of participating sites.

Tips for creating CTRP compatible PDF documents

Protocol Document: *	<input type="button" value="Browse..."/>	No file selected.	<input type="button" value="?"/>
IRB Approval: *	<input type="button" value="Browse..."/>	No file selected.	<input type="button" value="?"/>
List of Participating Sites:	<input type="button" value="Browse..."/>	No file selected.	<input type="button" value="?"/>
Informed Consent Document:	<input type="button" value="Browse..."/>	No file selected.	<input type="button" value="?"/>
Other:	<input type="button" value="Browse..."/>	No file selected.	<input type="button" value="?"/>

How to Submit Trial Related Documents

1. Next to the document-type field, (such as **Protocol Document**), click **Browse**.
2. Follow your browser/operating system instructions to navigate to, select, and open the appropriate document.
3. Repeat the steps above for each type of document.



Adding Multiple "Other" Documents

You can upload more than one (1) "Other" document. After you have uploaded the first of your "Other" documents, click the **Add More** link. The system displays a new **Other** document field.

Converting Files to PDFs

Abstractors use the information provided in the documents you upload in Registration to validate and complete trial data in Protocol Abstraction (PA). To facilitate data entry, the abstractors may copy and paste information from your documents into fields in the PA interface.

Trial-related documents uploaded as Microsoft Word (.doc), Microsoft Excel (.xls, .xlsx, .xlsm, or .xlsb), and WordPerfect files contain text that abstractors can copy and paste directly. PDFs (portable document format) contain text that abstractors can copy *only if* the content was created from other text-based applications such as Word or Excel.



Abstractors can not copy and paste text from scanned documents

Avoid uploading PDFs of scanned documents. They can not be edited, copied, or read with OCR (optical character recognition) applications.

Adobe provides a plug-in for most text-based word processing applications that enables you to convert your files to PDFs. Once you have converted the files, you can read the documents in Adobe Reader. Others can read the content as well but are not able to make changes to your file. You can download the Adobe PDF Reader for free from the [Adobe website](#).

Microsoft provides instructions for converting files to PDFs both on their [website](#) and in the Help documentation in each of its applications.



When searching for help, use "save file as pdf" as the search term.


You do not need a document converter in Mac OSX. Instead, *print* your documents to a PDF file.

How to Convert Text-Based Files to PDFs in Mac OSX

1. Open your text file in its original format (such as .doc or .xls).
2. Click **File > Print**.
3. In the **Print** window, click the **PDF** button at the bottom-left and select the **Save as PDF** option.
4. Choose the file location, rename your PDF file, and then click **Save**.

Registering Abbreviated (Industrial and Other) Trials



You can register Industrial/Other trials in the CTRP by importing them directly from ClinicalTrials.gov. You must enter a ClinicalTrials.gov Identifier (NCT ID) for each trial you register. If the trial you want to register does not have an NCI ID, or if you do not know it, contact the CTRO for assistance at ncictro@mail.nih.gov.

 The system registers the trials you import from ClinicalTrials.gov as *Abbreviated* trials. To classify a trial as "Other", contact the Clinical Trials Reporting Office staff at ncictro@mail.nih.gov after importing/registering the trial in the CTRP system.

For more information about Data Table 4 categorization, see [Guidelines for Abbreviated Trials](#).


How to Register Industrial Trials

1. On the toolbar, click **Register Trial**, and select **Industrial/Other**.

 To read a definition of each of the trial submission categories (study sources), click **View Trial Category Definitions**, or, click the Help icon () next to each category.

The Import ClinicalTrials.gov Trials page appears.

2. Enter the ClinicalTrials.gov Identifier, and then click **Search Studies**. The system searches for the ID you entered. If it finds a match in the CTRP, you can not import the trial.
3. If the system does not find a match in the CTRP, the trial record from ClinicalTrials.gov appears.
4. Click **Import Trial From ClinicalTrials.gov**.

 While it is possible for two users to attempt to import a trial at the exact same time, the system cannot process simultaneous imports. If you receive an error message the first time you attempt to import a trial, wait a short while, and then try again.

The trial is registered in the CTRP and assigned a unique NCI identifier with the processing status Submitted. The system synchronizes the imported record in the CTRP with the one in ClinicalTrials.gov.

5. To add your site as a participant in the trial, click **Add My Site**. The Add Participating Site page appears. The Participating Site list contains all organizations in the Organization Family associated with your CTRP account.
6. From the **Participating Site** list, select the organization that you want to add to this trial. Click **Next**. Another Add Participating Site page appears.
7. Complete the fields as per the instructions in [Adding Your Site to Abbreviated Trials](#), and then click **Save**. The system sends you an email message when the CTRO has accepted the trial for registration in the CTRP. If your trial is not *Industrial*, contact the CTRO at ncictro@mail.nih.gov to request categorization of the trial as either *National* or *Externally Peer-Reviewed*.

The system synchronizes *Industrial* and *Other* trials currently registered in the CTRP with ClinicalTrials.gov trials every night by comparing their ClinicalTrials.gov Identifiers. The system updates CTRP trial records with the data imported from ClinicalTrials.gov if it finds matching records.

 The CTRP system does not import Person information from ClinicalTrials.gov.

Printing Trial Information

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

How to Print Trial Information

1. Scroll to the bottom of the **Register Trial** page, and then click **Review Trial**. If necessary, provide any missing information.
2. Scroll to the bottom of the **Review Trial Details** page, and then click **Print**.

Editing Trial Details

You can edit the details of the trial that you are registering *before* you submit the trial to the CTRP. If you want to edit a *registered* trial that you own, follow the instructions in [Updating Trials](#).

How to Edit Trial Details

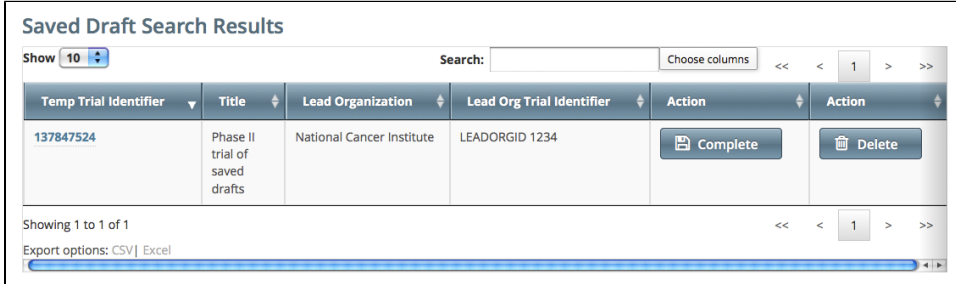
1. Scroll to the bottom of the **Register Trial** page, and then click **Review Trial**.
2. Scroll to the bottom of the **Review Trial Details** page, and then click **Edit**.
The Register Trial page displays all information you have provided in editable form.
3. Make changes as necessary, and then click **Review Trial**.
4. After you have reviewed your edits, click **Submit**.

Completing and Deleting Saved Drafts

During the course of registering a trial, you can save the information you have already provided as a draft, and return to it later. Once you retrieve your draft, you can complete the registration or delete the draft altogether.

How to Complete or Delete Saved Drafts

1. Retrieve the draft by searching for it using the **Search Saved Drafts** option. (For details, refer to [Searching for Trials.](#)) Saved draft records are listed on the Search Results page.



Temp Trial Identifier	Title	Lead Organization	Lead Org Trial Identifier	Action	Action
137847524	Phase II trial of saved drafts	National Cancer Institute	LEADORGID 1234	Complete	Delete

2. Do one of the following in the appropriate **Action** column on the right side of the table:
 - a. To delete the record, click **Delete**. The draft record is deleted from the system permanently.
- Or -
 - b. To complete the record, click **Complete**.

The Register Trial page displays all the information you provided previously. You can complete the rest of the information by following the steps in [Registering New Complete Trials.](#)

Amending Complete Trials

This page tree describes how to use CTRP to amend clinical trials. The ability to amend a trial depends on multiple factors, as described in the following table:

Factor	Description
Who can amend a trial?	Only the <i>trial owner</i> . A trial may have more than one owner. To request ownership of a trial, contact your Site Administrator. (If you are a Site Administrator, refer to Managing Trial Ownership .)
What types of trials can be amended?	Only <i>National</i> , <i>Externally Peer-Reviewed</i> , and <i>Institutional</i> trials that have been registered with the CTRP previously. For information, refer to CTRP Trial Categories , Study Sources .
At which trial processing statuses can a trial be amended?	Only trials that have reached the <i>Abstraction Verified Response</i> or <i>Abstraction Verified No Response</i> processing status. For information, refer to Trial Processing Statuses . The CTRO reviews and abstracts amended trial data just as it does with original submissions.
At which trial statuses can a trial be amended?	Only trials that have reached the <i>In Review</i> or <i>Approved</i> trial status. You can not amend trials in the <i>Complete</i> , <i>Administratively Complete (Terminated)</i> , or <i>Withdrawn</i> status. For valid ClinicalTrials.gov recruitment values, refer to Trial Status Values in the CTRP and ClinicalTrials.gov and Expanded Access Statuses .
Which parts of a trial record can be amended?	Any part <i>except</i> <ul style="list-style-type: none"> • NCI trial identifier number • NIH grant number • IND/IDE serial number

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

Amendment Process Life Cycle

The CTRP processes submissions in much the same way as it processes original trial data. (For information, refer to [Typical Life Cycle of a Trial](#).) You may need to submit an amendment more than once during the course of your study, and the process is repeated each time you submit an amendment.

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

1. The system sends you a submission confirmation letter.
2. The CTRO validates the new data and documents you provided, and the system sends you an acceptance (or rejection) message.
 - a. If the amendment is rejected, the system provides the reason for rejection and reinstates your latest verified trial submission.
 - b. If your amendment is accepted, the CTRO abstracts all the trial details.
3. When abstraction is complete, the CTRO sends you a Trial Summary Report (TSR) that includes all the newly-modified data in the CTRP.
4. You review and validate the new TSR and email your approval to the CTRO.
5. If you request a change, the CTRO makes corresponding modifications and re-sends the TSR.

The amended trial appears in your Search My Trials results list upon acceptance.



The TSR contains all the information that you submitted and all the trial data abstracted by the CTRO.

Amendment Rules

In your role as trial owner (original submitter or current owner), you can amend only *Complete* trials. The trials you own are listed when you use the Search My Trials feature. Refer to [Searching for Trials](#). In addition to rules provided in [Registering New Trials](#), the following rules apply to amendments:

- You can create a new NIH grant record only if you can provide all of the following details:
 - Funding Mechanism
 - NIH Institution Code
 - Serial Number
 - NCI Division/Program
- You can not change the following existing information:
 - NCI trial identifier number
 - NIH grant number
 - IND/IDE serial number
- The following list is the minimum set of required documents that must be submitted with each amendment:
 - Protocol document.
 - IRB approval document.
 - A change memo document or protocol highlighted document:
 - A change memo is a document that contains a summary of changes as compared to the original, or last amended, trial submission.
 - A protocol highlighted document is a document that has been marked up, with or without using a Track Changes feature.
 - List of participating sites and contact information (for multi-site trials, if not included in the protocol document).
 - Informed consent (if not included in the protocol document) and only when there are documented changes to the consent.

When you are submitting an amendment, we recommended that you provide any additional documents that you think will be useful to the CTRO for reviewing and processing the amendment document.



A trial may have more than one owner. Review the recorded information carefully to see if another owner has modified the trial.

Examples of Amendments

The following are examples of amendments that the Amend Trial feature accommodates.

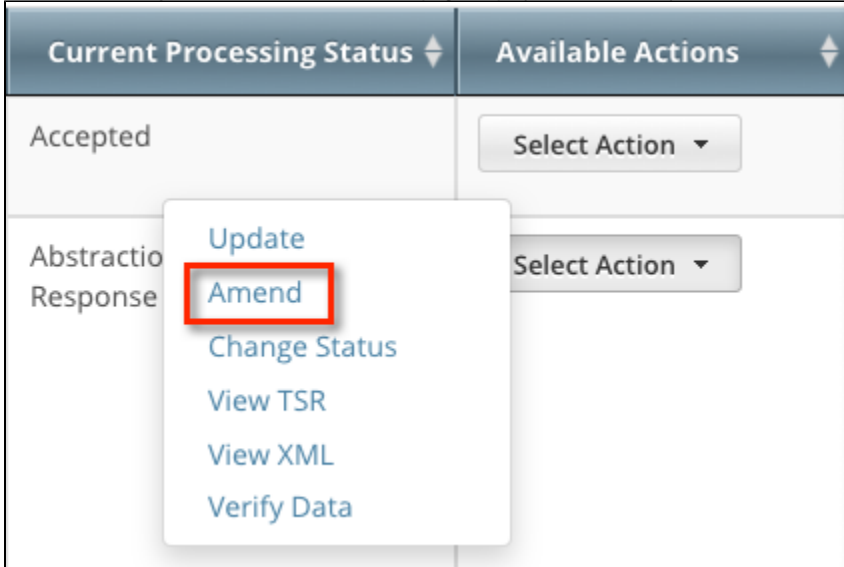
- **Dose Escalation Amendment** (change in the number of patients treated at a given dose level)
- **Change in Sites Open to Patient Accrual**
- **Change in Principal Investigators**
- **Change in Risk to Participants** (new risk identified [new CAEPR], changes made as a result of an updated Severe Adverse Event)
- **Scientific Change** (opening an arm, adding a new arm, closing an arm, changing objectives, changing statistical analysis, adding correlative studies, increase or decrease in the accrual goal, changing from Phase I to Phase II, additional data points)
- **Correction of Typographical Errors which Change Scientific Meaning** (mg vs. mcg)
- **Eligibility Change** (change to the inclusion or exclusion criteria)
- **Therapy Change** (change in dose, adding another agent, change in administration, change in route)

To open the trial record for amending, refer to [Amending Trials](#).

Amending Trials

How to Amend Trials

1. On the toolbar, click **Search > Clinical Trials**. The Search Trials page appears.
2. Click **Search > My Trials**. The Search Results page displays the results of your search and actions available (if any) for each record.



3. In the **Available Actions** column, click **Select Action > Amend**. The Amendment Trial page displays the data currently registered with the CTRP.
4. Make changes to the fields as necessary. The system requires you to provide information for all fields marked with an asterisk (*). The instructions are the same for trial registration and trial amendment, with some exceptions:

- In the Amendment Details section, specify the appropriate information in the various fields. The following table describes the fields.

Field Label	Description/Instructions
Amendment Number	Enter an appropriate number.
Amendment Date*	Select or enter an appropriate date.

- You can select a different disease code only if the trial has not accrued any subjects to date.
 - A trial can accumulate program codes from different organization families. For example, a participating site might belong to a different organization family than the lead organization. When you amend a trial, the Program Code field displays all codes from the master list for the organization family of the lead organization.
 - Primary Completion Dates are optional for non-interventional trials and for DCP trials. In both cases, the system excludes such trials when submitting XML documents to ClinicalTrials.gov. Otherwise, Primary Completion Dates are required.
 - The system does not change the status of participating sites when you close a trial.
 - For instructions on recording each field otherwise, refer to [Registering New Trials](#).
5. Review the amendment. Refer to [Reviewing and Submitting Trial Amendments](#).
 6. Submit the amended trial to the CTRP. The system sends you an email notification — with the details of what has changed — whenever you amend accepted trials.

Reviewing and Submitting Trial Amendments

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

How to Review and Submit Trial Amendments

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



The Review Trial Details page is read-only. To edit information that you have reviewed, see [Editing Amended Trials](#).

4. Click **Submit**.

Printing Amended Trial Information

You can print a copy of the amended trial to facilitate the review and/or keep for your records. You must review the amendment in order to access the print feature. For instructions on reviewing the trial, see [Reviewing and Submitting Trial Amendments](#).

How to Print Amended Trial Information

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

Editing Amended Trials

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

How to Edit Amended Details

1. Scroll to the bottom of the **Review Trial Details** page, and click **Edit**.
The **Amendment Trial** page displays all information you have provided in editable form.
2. Make changes as necessary and then follow the instructions in [Reviewing and Submitting Trial Amendments](#).



Editing Trial-Related Documents

The Edit Trial page lists all documents that were submitted with previous trial submissions. You can view, but not delete these documents. However, you can remove/replace the documents associated with the amendment you are submitting.

Updating Trials

This page tree describes how to use CTRP to update clinical trials that are currently registered and verified in CTRP. The ability to update a trial depends on multiple factors, as described in the following table:

Factor	Description
Who can update a trial?	Only the <i>trial owner</i> . A trial may have more than one owner. To request ownership of a trial, contact your Site Administrator. (If you are a Site Administrator, refer to Managing Trial Ownership .)
What types of trials can be updated?	Only trials that have been registered with the CTRP previously.
At which trial processing statuses can a trial be updated?	Only trials that have been previously accepted. (That is, the processing status must be Accepted or a subsequent processing status.) For information, refer to Trial Processing Statuses .
Which parts of a trial record can be updated?	Only a subset of the information included with the original trial submission. For details, refer to Trial Attributes You Can Update .
What types of changes can be made as a trial update?	Only changes that do <i>not</i> require Investigational Review Board (IRB) approval. For examples, refer to Examples of Protocol Document Updates .

You can also update the trial status and trial status start/completion dates without having to update other trial details. For instructions, refer to [Updating Trial Statuses](#).

For instructions, refer to the following pages:

Trial Attributes You Can Update

As trial owner, you can update a subset of the information included with the original trial submission, including the following:

- **ClinicalTrials.gov Identifier** (other than Industrial/Other trials)
- **Other Identifier**
- **Local Trial Identifier** (Industrial/Other trials)
- **Title** (other than Industrial/Other trials)
- **Accrual Disease Terminology** (other than Industrial/Other trials)
- **NIH grant information** (for NIH-funded trials).



You can add grants but you can not update existing grant information.

- **Participating site**
 - Site recruitment status and associated date for abstracted trial sites. Refer to [Recording Trial Statuses](#).
- **Status dates**



Changing the overall trial status must reflect changes to the trial status at the site. For example, if you change the overall status from Approved to Active, you must change the recruitment status from Not Yet Recruiting to Recruiting.

- **Trial documents**



Documents you upload when using the Update Trial feature do not overwrite existing documents.

You can change the trial status information directly from the Search Results table without having to open the trial record. To use this method, in the Search Results table's **Action** column, select **Change Status** and make your changes as per the instructions in [Recording Trial Statuses](#).

To open the trial record for editing, refer to [Updating Trial Information](#).

Examples of Protocol Document Updates

The Update Trial feature accommodates the following type of protocol document changes.

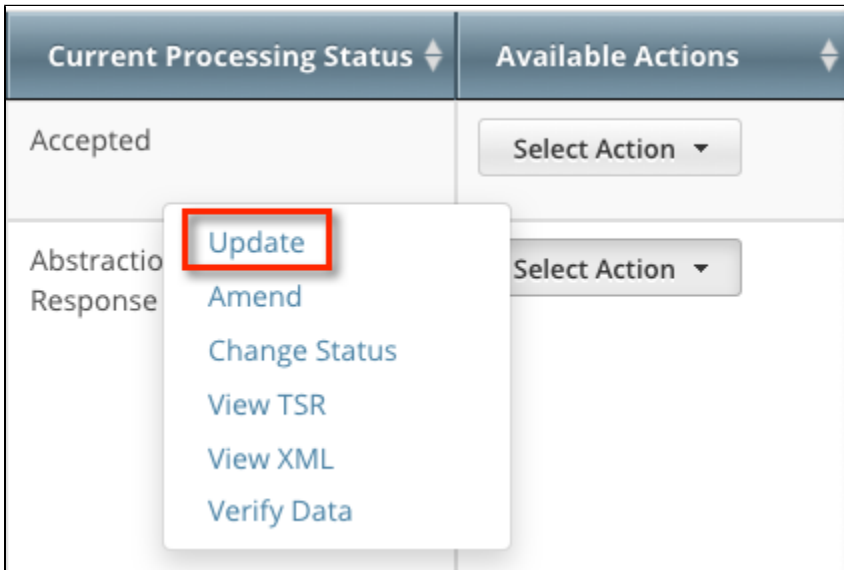
- **Editorial, Administrative Changes** (correction of minor typographical errors; clarifications made to previously approved descriptions of research)
- **Data, Data Collection, and Data Collection Materials** (revised study diaries; revised questionnaires or QOL surveys given to participants)
- **Recruitment of Subjects** (changes in the way subjects are recruited; a new or revised advertisement)
- **Principal Investigator Contact Information**

To open the trial record for editing, refer to [Updating Trial Information](#).

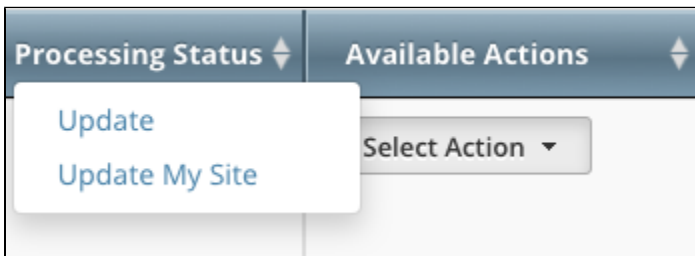
Updating Trial Information

How to Update Trials

1. Click **Search > Clinical Trials**. The Search Trials page appears.
2. Click **Search > My Trials**. The Search Results table displays the results of your search and actions available (if any) for each record. For information about navigating the search results list, refer to [Viewing Trial Details](#).



Available Actions column - Select Action list for Complete trials



Available Actions column - Select Action list for Industrial trials

3. In the **Available Actions** column, click **Select Action > Update**. The Update Trial page displays the data currently registered with CTRP.

The 'Update Trial' page features a header with the title 'Update Trial' and a sub-header 'Use this form to update trial information. You can not change the information in certain fields, including the trial title.' Below this is an 'Expand All' button. The form is organized into three main sections, each with a dropdown arrow on the right: 'Trial Identifiers*', 'Other Identifiers*', and 'Trial Details*'. The 'Trial Identifiers*' section contains: 'Lead Organization Trial Identifier:*' with the value '05-12-3', a text input for 'ClinicalTrials.gov Identifier:' with an 'Add ClinicalTrials.gov Identifier' button, and 'NCI Trial Identifier:' with the value 'NCI-2014-00314'. The 'Other Identifiers*' section contains a text input for 'Other Trial Identifier' and an 'Add Other Identifier' button. The 'Trial Details*' section contains a text input for 'Title:*' with the value '18F-FMAU for Imaging in Cancer Patients'.

Update Trial page for Complete trials

Participating Sites*

Organization/Investigator	Local Trial Identifier*	Current Site Recruitment Status*	Current Site Recruitment Status Date* (mm/dd/yyyy)	Date Opened for Accrual (mm/dd/yyyy)	Date Closed for Accrual (mm/dd/yyyy)
Case Co	THKO1Z15	Approved	09/01/2015	mm/dd/yyyy	mm/dd/yyyy

Existing Trial Related Documents*

Document Type	File Name
Other	NCT02524847.xml

Trial Related Documents*

Please submit documents as Word (.doc) or Acrobat (.pdf) files.

Tips for creating CTRP compatible PDF documents

IRB Approval: No file selected. ?

Informed Consent Document: No file selected. ?

Other: NCT02524847.xml

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

Update Trial page for Industrial trials

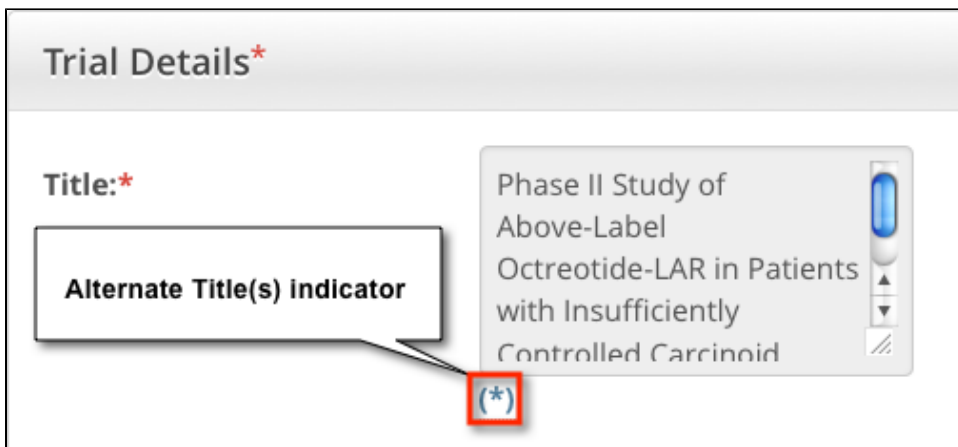
4. Make changes to the fields as necessary. The system requires you to provide information for all fields marked with an asterisk (*). The instructions are the same for trial registration and trial update, with some exceptions:

- If applicable, enter a ClinicalTrials.gov ID, and then click **Add ClinicalTrials.gov Identifier**.

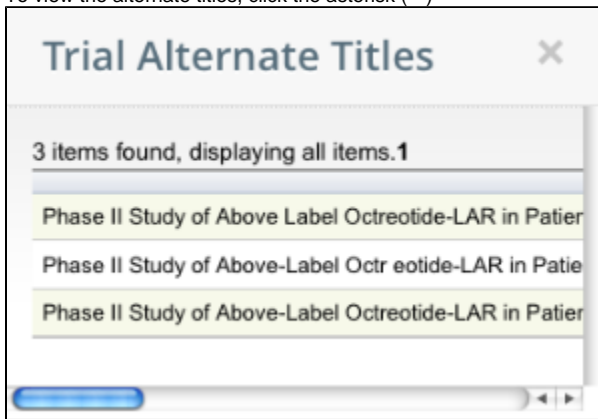
You cannot change the ClinicalTrials.gov ID once you have added it. Also, if the trial record already has a ClinicalTrials.gov ID, you cannot change it. If the ClinicalTrials.gov ID specified for a trial is incorrect, contact the CTRO at NCICTRO@mail.nih.gov.

When you submit the trial, the system checks the NCT number you entered to ensure that no other registered trial has the same one. The system displays an error message if it finds another trial with the same NCT number. If this occurs, check the number you entered and try again. If you are certain that the number you entered is correct, contact the CTRO at NCICTRO@mail.nih.gov.

- An asterisk (*) at the end of a trial title indicates that the trial has alternate titles.



To view the alternate titles, click the asterisk (*)



- A trial can accumulate program codes from different organization families. For example, a participating site might belong to a different organization family than the lead organization. When you update a trial, the Program Code field displays all codes from the master list for the organization family of the lead organization.
 - Primary Completion Dates are optional for non-interventional trials and for DCP trials. In both cases, the system excludes such trials when submitting XML documents to ClinicalTrials.gov. Otherwise, Primary Completion Dates are required.
 - If appropriate, upload any new or updated documents. For instructions, refer to [Uploading Trial-Related Documents](#). If you upload an IRB document, the CTRO reviews the updated record you submit and makes changes to the record as necessary. For example, if you upload an IRB document for a trial currently in the In Review state, the CTRO updates the IRB information section of the trial record (e.g., IRB status and approval number).
 - For instructions on recording each field otherwise, refer to [Registering New Trials](#).
5. To review the information you provided, click **Review Trial**. The system checks the updated information for errors, and displays the results at the top of the Update Trial page.
 6. If necessary, correct any errors, and click **Review Trial**. Repeat this cycle until your update is error-free.
 7. Submit the trial update. The system sends you an update notification — with the details of what has changed — whenever you update accepted trials.

Updating Trial Statuses

You can update trial statuses for the trials you own without having to update other trial details.

Updating trial statuses from the Search Results table

After your trial has been accepted, you can change the trial status information directly from the Search Results table without having to open the trial record. To use this method, search for the trial, and then, in the Search Results table's **Action** column, select **Change Status**.

Errors and Warnings

The system validates each new status as you add/update it. The system also validates each new status when you review the trial information (as described in [Reviewing and Submitting Trial Updates](#)) before submitting the update.

If you add a status that does not conform to the rules provided in [Status Transition Rules](#), the system displays errors and/or warnings. For example, if you add the status Closed to Accrual the system warns you that both the status In Review and Approved are missing. Because Warnings indicate that fixing the record is optional, you do not have to add the indicated statuses. However, Errors indicate that you must record the missing status (in this case, Active) in order to submit the trial for registration

How to Update Trial Status Information

1. Search for the trial whose status information you want to update. For instructions, refer to [Searching for Trial Records](#). The Search Results table displays the results of your search and actions available (if any) for each record.

Available Actions	Participating Sites
Select Action ▾	View
Select Action ▾	View
Update Amend Change Status View TSR View XML Verify Data	W W W

- In the **Available Actions** column, click **Select Action > Change Status**, or if you want to update other aspects of the trial coincidentally, click **Update**.

The Update Trial Status window displays Trial Status fields and lists the previously-recorded trial statuses in the Trial Status History section.

Trial Status*

Status Date ?	Status ?	Why Study Stopped? ?	
mm/dd/yyyy	--Select--	<div style="border: 1px solid #ccc; height: 20px;"></div>	+ Add Status
<p><small>Trial has been closed to accrual and follow-up. Participant treatment/intervention has been completed and participants are no longer monitored for trial endpoints (i.e., last patient's visit has occurred). The trial has met its objectives.</small></p>		<p><small>970 characters left</small></p> <p><small>Administratively Complete, Withdrawn and Temporarily Closed statuses only</small></p>	

Please refer to the [Trial Status Transition Rules](#).

Trial Status History

Show **10** entries

Status Date	Status	Comments	Validation Messages	Actions
05/16/2012	Approved	Invalid transition		
10/07/2014	Enrolling by Invitation	Incorrect status date		
12/29/2014	Temporarily Closed to Accrual			
01/05/2015	Temporarily Closed to Accrual and Intervention	Invalid transition		

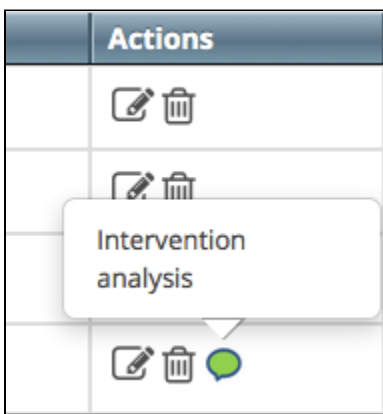
Showing 1 to 4 of 4 entries Previous **1** Next

- Edit or add a new status as necessary. (For instructions, refer to [Recording Trial Statuses](#).) If you changed the status to *Administratively Complete*, *Withdrawn*, or *Temporarily Closed*, enter the reason for the status change.

The system does not change the status of participating sites when you close a trial.

- To display comments about previous changes to trial status records, hover your cursor over the **Comment** icon.

Comments appear in a pop-up message.



Errors and Warnings

The system validates each new status as you add/update it. The system also validates each new status when you review the trial information (as described in [Reviewing and Submitting Trial Updates](#)) before submitting the update.

If you update or add a status that does not conform to the rules provided in [Status Transition Rules](#), the system displays errors and/or warnings. *Warnings* indicate that fixing the record is optional, you do not have to add/update the indicated statuses. However, *Errors* indicate that you must record the missing status in order to update the trial.

If you update a trial registered prior to the CTRP v4.2 release, the Trial Status History records may contain errors and warning as shown below. You must correct each of the errors before you can update the trial.

Status Date ?	Status ?	Why Study Stopped? ?		
mm/dd/yyyy	--Select-- <i>Participants are being (or will be) selected from a predetermined population.</i>	<input type="text"/> <i>Administratively Complete, Withdrawn and Temporarily Closed statuses only</i>	Add Status	
<small>1000 characters left</small>				
<small>Please refer to the Trial Status Transition Rules.</small>				
Trial Status History				
Show <input type="text" value="10"/> entries				
Status Date	Status	Comments	Validation Messages	Actions
12/01/2014	Enrolling by Invitation		WARNING: Interim status [IN REVIEW] is missing WARNING: Interim status [APPROVED] is missing	

The system refreshes the Trial Status History records as shown below. After you correct the errors, you can add/update a new status record.

5. Click **Review Trial**.

If the system detects errors and/or warnings, it prompts you to correct them. You cannot update the trial until you have corrected all errors.

Status Date	Status	Comments	Validation Messages	Actions
Status Transition Errors and Warnings were found. This trial cannot be submitted until all Status Transition Errors have been resolved. Please use the action icons below to make corrections.				
Show <input type="text" value="10"/> entries				
Status Date	Status	Comments	Validation Messages	Actions
10/16/2014	Approved			
12/16/2014	Enrolling by Invitation			
12/17/2014	Complete	Invalid transition	ERROR: Interim status [CLOSED TO ACCRUAL] is missing WARNING: Interim status [CLOSED TO ACCRUAL AND INTERVENTION] is missing	

6. Fix any errors as necessary. (For instructions, refer to [Recording Trial Statuses](#).) Then click **Review**.

7. Click **Submit**.

Updating Trial Dates







The trial status dates section captures start, primary completion, and completion dates as they occur according to the rules specified in [Status Rules for Trial Dates](#).

You can update trial start/completion dates for trials you own without having to update other trial details.

Updating trial statuses from the Search Results table

After your trial has been accepted, you can change the trial status information directly from the Search Results table without having to open the trial record. To use this method, search for the trial, and then, in the Search Results table's **Action** column, select **Change Status**.

Trial Dates*

Trial Start Date:*	<input type="text" value="10/01/2014"/>		<input checked="" type="radio"/> Actual	<input type="radio"/> Anticipated	
Primary Completion Date: *	<input type="text" value="09/01/2016"/>		<input type="radio"/> Actual	<input checked="" type="radio"/> Anticipated	
Completion Date:	<input type="text" value="mm/dd/yyyy"/>		<input type="radio"/> Actual	<input type="radio"/> Anticipated	

Please refer to [Trial Status Rules for Start and Completion dates](#).

How to Update Trial Dates Section

1. Select or enter the appropriate information in the text fields and drop-down lists. The following table describes the fields. An asterisk (*) indicates a required field.
2. Indicate whether the dates you entered are **Actual** or **Anticipated**.

Updating Participating Site Statuses in Complete Trials

The Update Participating Sites section captures site statuses and dates. When updating sites, you must follow the the rules specified in [Status Transition Rules](#).

For Abbreviated trials, refer to [Updating Participating Site Organization Records](#).



Errors and Warnings

The system validates the trial and site status transition(s) you make to each participating site when you review the trial information (as described in [Reviewing and Submitting Trial Updates](#)) before submitting the update.

If you add a status that does not conform to the rules provided in [Status Transition Rules](#), the system displays errors and/or warnings. Warnings indicate that fixing the record is optional. However, Errors indicate that you must correct the site status and/or status date.

How to Update Participating Site Status Information

1. Search for the trial whose participating site status information you want to update. For instructions, refer to [Searching for Trial Records](#). The Search Results table displays the results of your search and actions available (if any) for each record.

Current Processing Status	Available Actions
Accepted	Select Action
Abstraction Response	Select Action

2. In the **Available Actions** column, click **Select Action > Update**. The Update Trial window lists the previously-recorded participating site statuses in the Participating Sites section.

Site	Recruitment Status	Date
M D Anderson Cancer Center (MDACC) Research Base	In Review	12/22/2014
University of North Carolina at Chapel Hill	In Review	12/22/2014
Mayo Clinic	In Review	12/22/2014

3. Select new statuses and enter dates as necessary.

4. Click **Review Trial**.

If you entered invalid values, error messages display instructions for correcting the statuses and/or dates.

Participating Sites*

Site	Recruitment Status	Date
M D Anderson Cancer Center (MDACC) Research Base	Approved <ul style="list-style-type: none">You are attempting to change this status from: Old Status: In Review Old Status Date: 12/22/2014 Error: New status date must be greater or equal to the most recent status date	12/22/2013
University of North Carolina at Chapel Hill	In Review	12/22/2014

5. Fix any errors as necessary, and then click **Submit**.



The system does not change the status of participating sites when you close a trial.

Reviewing and Submitting Trial Updates

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

How to Review and Submit Trial Updates

1. Complete all modifications to the most recent trial submission.
2. Scroll to the bottom of the Update Trial page, and click **Review Trial**. The system checks for errors and missing information and displays the results in a message at the top of the Review Trial Details page. Indicators mark specific fields that you must complete or correct in order to submit the trial.
3. Correct any errors if indicated, and repeat the previous step as many times as necessary until the update is error-free.



The Review Trial Details page is read-only. To edit information that you have reviewed, refer to [Editing Updated Details](#).

4. Consider printing a copy of the updated trial to facilitate the review and/or keep for your records. Scroll to the bottom of the Review Trial Details page, and click **Print**.
5. Click **Submit**.

Printing Updated Trial Information

You can print a copy of the updated trial to facilitate the review and/or keep for your records. You must review the trial update in order to access the print feature. For instructions on reviewing the trial, refer to [Reviewing and Submitting Trial Updates](#).

How to Print Updated Trial Information

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

Editing Updated Details

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

How to Edit Updated Details

1. Scroll to the bottom of the **Review Trial** Details page, and click **Edit**. The Update Trial page displays all information you have provided, in editable form.
2. Make changes as necessary and then review the trial again. For instructions, refer to [Reviewing and Submitting Trial Updates](#).

Adding Your Site to Abbreviated Trials

This section provides instructions for adding your affiliated organization and its family members as participating sites in *Abbreviated* trials.

You can use the Add My Site feature to add your site to eligible trials one at a time. Site Administrators can use the [Add Sites](#) feature when adding their sites or family member organizations to multiple trials, or add multiple participating sites to the same trial.



Before you begin, review your CTRP user account information and verify that you have indicated your current organization affiliation. For instructions, refer to [Requesting Organization Admin Rights](#).

For instructions, refer to the following pages:

Using the Add My Site Feature

You can add your organization as a participating site to any *Abbreviated trial that meets the following criteria:*

(To add your organization as a participating site to a Complete trial, contact the lead organization.)

Trial Attribute	Requirement
Lead Organization	Not an organization in RSS
Your Organization	Not currently participating in the trial
Trial Processing Status	Accepted or beyond


Once added, you can update your site's record at any time.

Trial information that you can update after adding your site includes the following:

- Organization's local trial identifier
- Site principal investigator
- Organization family's program codes
- Site recruitment status and dates

How to Add Your Organization as a Participating Site

1. Select the trial that your site is participating in. The **Available Actions** column in the search results table displays actions currently available for the trial.
2. In the **Available Actions** column, click the **Select Action** button and click **Add My Site**. The Add Participating Site page appears. The Participating Site list contains all organizations in the Organization Family associated with your CTRP account.
3. From the **Participating Site** list, select the organization that you want to add to this trial. Click **Next**. Another Add Participating Site page appears.
4. In the **Local Trial Identifier** field, enter the identifier used at the participating site.
5. Next to the **Site Principal Investigator** field, click **Look Up** to search for and select the site principal investigator.
6. (Optional) Specify a contact for the trial at this participating site. You can do so in one of the following ways:
 - Next to the **Site Primary Contact** field, click **Look Up** to search for and select the site primary contact.
 - Next to the **Generic Contact** field, click **Look Up Generic Contact** to search for and select a CTRP person record.
7. (Optional) Consider whether the default contact information for the selected person record is appropriate for the trial at this participating site. The system accepts either the contact's primary telephone number or the contact's primary email address. You can provide both if available. Enter the phone number in the format 123-456-7890. You can provide an extension if available.
8. (Optional) In the **Program Code** field, select one or more program codes for the trial. The Program code field lists all program codes available for the organization family.
9. Add site recruitment status information:
 - a. Select or enter the appropriate information in the text fields and drop-down lists. The following table describes the fields. An asterisk (*) indicates a required field.

Field	Description/Instructions
Site Recruitment Status Date*	Enter the date on which the current trial status became effective. To ensure that you record valid status dates, review the information provided in Status Rules for Trial Dates .
Site Recruitment Status*	Select the current stage or state of the trial or study.  The system validates all status transitions when you save a status record. If you add or update a status transition that does not conform to the rules provided in Status Transition Rules , the system displays errors and/or warnings. <i>Warnings</i> indicate that fixing the status record is optional; you do not have to resolve the transitions. However, <i>Errors</i> indicate that you must resolve the transitions by correcting trial status records.

- b. Click **Add Status**. The Site Recruitment Status History section appears, displaying the site recruitment information you entered.
 - c. Repeat the process of entering a status date, entering a status, and clicking **Add Status** until you have entered all statuses for the site.
10. If the system displays Errors or Warnings indicating that the status you added is invalid, do one of the following.
 - a. To edit the status, in the **Actions** column, click the **Edit** icon. Then, in the **Edit Trial Status** dialog box, make changes as indicated in the Error and/or Warning message.
 - b. To delete the status, in the **Actions** column, click the **Delete** icon. Enter a comment indicating the reason why you deleted the record. Then add the correct status information.
 12. Click **Save**. Your information is added to the trial details.

Viewing Participating Sites

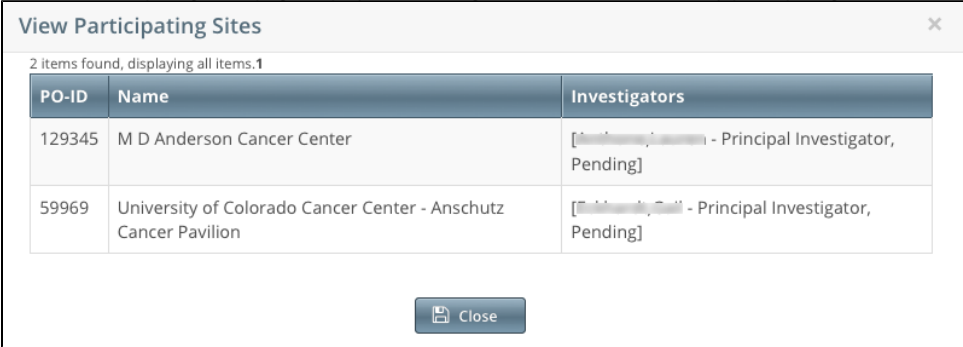
You can view a list of organizations that are participating in a trial whether or not you are the trial owner or submitter.

How to View Participating Sites

1. Search for the trial of interest.



2. In the trial record's **Participating Sites** column, click **View**.
The View Participating Sites page displays a list of organizations that are currently participating in the trial.



View Participating Sites ×

2 items found, displaying all items.1

PO-ID	Name	Investigators
129345	M D Anderson Cancer Center	[Redacted] - Principal Investigator, Pending]
59969	University of Colorado Cancer Center - Anschutz Cancer Pavilion	[Redacted] - Principal Investigator, Pending]

Close

Updating Participating Site Organization Records

Keep in mind the following about the representation of NCI-designated Cancer Centers in CTRP:

- A CTRP organization family represents an NCI-designated Cancer Center family of organizations. For brevity, this guide refers to this entity as a Cancer Center family.
- A CTRP organization that is a member of a Cancer Center family is considered a Cancer Center organization. For brevity, this guide refers to this entity as a Cancer Center organization.

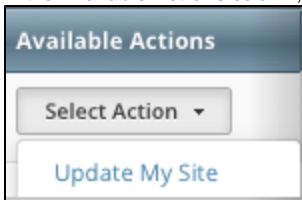
If you are affiliated with a Cancer Center organization that has been added to a trial as a participating site, the following points indicate whether you can update that participating site:

- If you added an organization as a participating site to a trial, you will be the participating site record owner and can update information about that organization in the same trial record.
- If you are affiliated with an organization and that organization is a participating site on a trial, you can update information about that organization in the same trial record.
- If you are a Site Administrator and your affiliated organization is in a Cancer Center family, you can update your organization's sibling sites on a trial (that is, other participating sites in the Cancer Center family).
- If you are not a Site Administrator and are affiliated with a Cancer Center family, you must request Site Administrator privileges from your Site Administrator before you can update any organization that is a participating site in the family. For directions on how to grant or revoke Site Administrator privileges click [here](#).

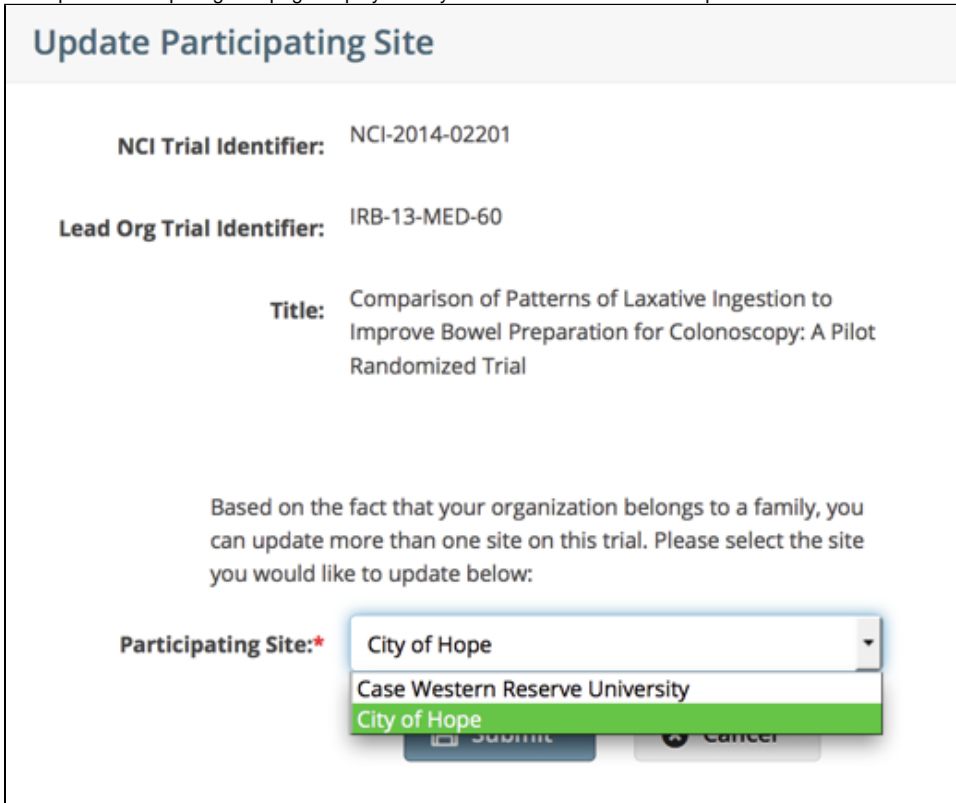
For information about appointed participating site records, see [Managing Trial Ownership](#).

How to Update Participating Site Organization Records

1. Search for the trial that you are participating in by following the instructions in [Searching for Trials](#).
2. In the **Available Actions** column, click **Select Action > Update My Site**.



The Update Participating Site page displays family member sites available for update.



3. From the **Participating Site** drop-down list, select the site you want to update.

- Click **Submit**. The Update Participating Site page appears. The Organization Name field is pre-populated with the organization you selected on the previous page.

Organization Name:* Mayo Clinic
Local Trial Identifier:* RSF-12345
Site Principal Investigator:* Doe, Jane
Program Code: [Manage Program Codes](#) Note: Program Codes will be assigned to all family member organizations participating on this trial

Site Recruitment Status Date:*
Site Recruitment Status:* --Select--

Please refer to the [Site Status Transition Rules](#). Note: Site Recruitment Status of Active or Enrolling by Invitation indicates that the Site is Open for Patient Accruals. Closed to Accrual Site Status indicates that the Site is Closed to Patient Accruals.

Site Recruitment Status History

Show **10** entries

Status Date	Status	Comments	Validation Messages	Actions
11/03/2014	Closed to Accrual		ERROR: Interim status [ACTIVE] is missing WARNING: Interim status [IN REVIEW] is missing WARNING: Interim status [APPROVED] is missing	<input type="button" value="Edit"/> <input type="button" value="Delete"/>
11/04/2014	Enrolling by Invitation		ERROR: Invalid status transition from [CLOSED TO ACCRUAL] to [ENROLLING BY INVITATION]	<input type="button" value="Edit"/> <input type="button" value="Delete"/>

Showing 1 to 2 of 2 entries Previous **1** Next

- Enter the new information in the fields as appropriate.
- If the system displays Errors or Warnings, follow the instructions in Using the Add My Site Feature to edit or delete the records.
- Click **Save**. Your information is updated.

Registration Site Administration

This page tree provides instructions for Site Administrators. A Site Administrator is a user with administrative privileges who is responsible for:

- Assigning Site Administrator status to other users in the organization
- Reviewing and updating user access to trials associated with the organization
- Authorizing users to submit subject accrual data for trials that have been fully abstracted and verified
- Adding participating sites to Abbreviated trials
- Managing the set of program codes and program code assignments for the organization family
- Managing targeted accrual, the total number of participants expected to accrue at all of the sites within your organization family participating on a study.

This page tree introduces you to site administration management and provides instructions for these tasks.

Each organization registered in the CTRP system can have more than one site administrator. You can request primary site administration authority from the CTRO. For instructions, refer to [Requesting Organization Admin Rights](#).

Granting and Revoking Administrative Rights

The Site Administrator for a site is the CTRP user with the following qualities:

- The CTRO or another Site Administrator has granted the user profile the administrative rights.
- The user profile is affiliated with that site (an organization family or a single organization that does not belong to an organization family).

The relationships between Site Administrators and trials in a single site are as follows:

- An organization:
 - Can have one original Site Administrator.
 - Can have many Site Administrators appointed by the original Site Administrator.
 - Can be the lead organization for many trials.
 - Can be the affiliated organization for many users who can submit and own trials.
- A trial:
 - Can have one submitter.
 - Can have one organization affiliation, defined by the lead organization.
 - Can have many trial owners.
- Trial ownership:
 - Can be implicit. By default, if a Site Administrator's affiliated organization is the lead organization for a trial, that Site Administrator is an implicit owner of that trial.
 - Can be explicit. By default, the trial submitter is the only explicit trial owner. A Site Administrator can grant ownership of a trial to more users and can remove trial ownership from the original submitter and other users. (Refer to [Managing Trial Ownership](#).) If you add a Site Administrator as an owner of a trial, that Site Administrator has explicit ownership of that trial, rather than just implicit ownership.
- A Site Administrator can do the following:
 - Display trial ownership
 - Manage trial ownership
 - Manage site record ownership
 - Manage accrual access
 - Manage the administrative rights of other users in the organization
 - Revoke own administrative rights



Site administrators do not receive system-generated emails automatically

The system sends generated emails (including TSRs) to a Site Administrator only if the Site Administrator's affiliated organization is the trial's lead organization, or if the Site Administrator is the trial submitter and/or trial owner. The Site Administrator can also manage email notification globally. For instructions, refer to [Managing Registration Email Notifications](#).

As a Site Administrator, you can grant and revoke administrative rights to other users in your organization. (You can grant/revoke administrative rights to users who have a CTRP account and whose organizational affiliation is the same as your own.) Site Administrators are the only Registration users who can access the Site Administration menu.

How to Grant and Revoke Site Administrative Rights

1. On the toolbar, click **Administration > Site Administration**. The Site Administration page appears, listing Registration users and indicating which ones have previously been granted administrative rights.

The screenshot shows the 'Site Administration' interface. It features a search section with three input fields for 'First Name', 'Last Name', and 'E-Mail'. Below these fields are 'Search' and 'Reset' buttons. A 'Hide Search Criteria' checkbox is located to the right of the search fields. Below the search section is a 'Search Results' table with the following data:

First Name	Last Name	E-Mail	Allow as Site Admin?
Isabelle	Autissier	anthonel@mail.nih.gov	<input checked="" type="checkbox"/>
Laura	Stackhouse	example@example.com	<input type="checkbox"/>
Teresa	Melton	example@example.com	<input type="checkbox"/>
Valerie	Kordowski	example@example.com	<input type="checkbox"/>

At the bottom of the table is a 'Save' button.

2. Search for the Registration user for whom you want to adjust administrative rights: Specify the user by first name, last name, or email address, and then click **Search**. The user's name appears in the **Search Results** list.
 - a. To promote the user to Site Administrator, select the check box in the **Allow as Site Admin?** column.




As a Site Administrator, you can revoke your own administrative rights. Use caution if you do so because you can not promote yourself thereafter.

- b. To revoke administrative access, clear the check box in the **Allow as Site Admin?** column.
3. Click **Save**.

Assigning and Unassigning Accrual Access

Site Administrators can authorize users to submit subject accrual data for trials that have been fully abstracted and verified. Once assigned, users can submit accrual data for all trials associated with their affiliated organization or organization family members. For Complete trials (National, Externally Peer-Reviewed, or Institutional), the organization must be a lead; for Abbreviated trials (Industrial or Other), the organization must be a participating site.

Assignment at the organization level pertains to trials that the organization has registered in CTRP and extends to those that it will register in the future. Similarly, assignment at the organization family level pertains to trials that any member organization has registered in CTRP and extends to those that it will register in the future.

 Only the CTRO has access to CTEP and DCP trial accruals.

The table below outlines the access and trial assignment rules for Complete and Abbreviated trials.

Access/Assignment	Complete Trial	Abbreviated Trial
Who can assign access?	<ul style="list-style-type: none"> A registered user logged in as the lead organization's Site Administrator for any trial other than DCP or CTEP trials Super Abstractor for DCP and CTEP trials 	<ul style="list-style-type: none"> A registered user logged in as Site Administrator for any trial other than DCP or CTEP trials Super Abstractor for DCP and CTEP trials
To whom can you assign access?	Any registered user affiliated with the Site Administrator's organization, or family member organization (including the Site Administrator)	Any registered user affiliated with the assigner's organization (including the Site Administrator)
What types of trials can you assign?	Complete trials for which the assigner's organization is the lead organization	Abbreviated trials for which the assigner's organization is the lead organization or participating site
How can you assign access?	<ul style="list-style-type: none"> By trial By organization By organization family member <p>The system automatically assigns the organization family Accrual Submitter access to any trial registered by new organizations added to an organization family in the future. It withdraws access if anyone removes the organization family Accrual Submitter's organization from the organization family in the future.</p>	<ul style="list-style-type: none"> By trial By participating site
Who can submit accrual data?	Any assigned user affiliated with the lead organization, or with a lead organization that is a member of the user's affiliated organization family	Any assigned user affiliated with the participating site
To which trials can the organization family Accrual Submitter submit accrual data?	<ul style="list-style-type: none"> All Complete trials registered by the submitter's organization or family member organization Trials currently registered in CTRP Trials that the organization registers in CTRP in the future, once abstracted 	<ul style="list-style-type: none"> All Abbreviated trials registered by the submitter's participating site <i>only</i> Trials currently registered in CTRP Trials that the organization registers in CTRP in the future, once abstracted

For instructions, refer to the following pages:

Assigning and Unassigning Accrual Access by Trial

As a Site Administrator, you can assign a user accrual access to any trial that the user submitted to the CTRP or currently owns. You can assign specific trials to specific users.

1. On the toolbar, click **Administration > Accrual Access > Manage**. The Manage Accrual Access page appears.

Accrual Access Assignment By Trial

EXTERNALLY PEER-REVIEWED

Show 10 Search: Choose columns << < 1 2 3 4 5 > >>

NCI Trial Identifier	Title	Accrual Submitter
NCI-2014-00281	Vaccination of Patients With Ovarian Cancer With Dendritic Cell/Tumor Fusions With GM-CSF and Imiquimod	CTRP QATester1 Edmond Malowe Isabelle Autissier Rachel Severt Suzelha Pavesoni Yael Rubinsztein
NCI-2014-00248	Global Proteomic and Phosphoproteomic Profiling of Normal B Cells Isolated From	CTRP QATester1

INSTITUTIONAL

Show 10 Search: Choose columns << < 1 2 3 4 5 ... 32 > >>

NCI Trial Identifier	Title	Accrual Submitter
NCI-2014-00508	Papillary Carcinoma Trial	CTRP QATester1 Edmond Malowe Isabelle Autissier Rachel Severt Suzelha Pavesoni Yael Rubinsztein

INDUSTRIAL

Show 10 Search: Choose columns << < 1 2 3 4 5 ... 70 > >>

NCI Trial Identifier	Title	Accrual Submitter
NCI-2014-00109	A Phase Ib/II Open-label, Multi-center Study of the Combination of MEK162 Plus AMG 479 (Ganitumab) in Adult Patients With Selected Advanced Solid Tumors	CTRP QATester1 Camille Lannon Edmond Malowe Isabelle Autissier Lindsay Syed Rachel Severt Suzelha Pavesoni Yael Rubinsztein

Showing 1 to 10 of 691 << < 1 2 3 4 5 ... 70 > >>

Export options: CSV | Excel

2. Select **Assign user access to individual trials**.
3. From the **Select a user** list, select the user to whom you want to assign or unassign accrual submission privileges. The list of trials available for accrual submission for the user you selected appears in the Not Assigned list on the left side of the page, and trials to which access had previously been granted (if any) appear on the right.

To view the entire text of a trial's title, hover your cursor over the part of the title displayed.

Manage Accrual Access

Affiliated Site: **Children's Hospital Boston**
 Member of Family(s): **Dana-Farber/Harvard Cancer Center**

Assign/Unassign Accrual submission privilege to users affiliated with this site:

Select Assignment Type Assign user access to individual trials Make user a Site Submitter Make user an Org Family Submitter

Select a user: Autissier, Isabelle (site submitter) (org family submitter)

Select a trial category: All

Not Assigned

INDUSTRIAL	
NCI-2010-00037	Randomized, Double-Blind, Placebo-Controlled Study of Ef...
NCI-2009-01134	A Phase 1/Phase 2 Study Of CP-751,871 In Patients With Re...
INSTITUTIONAL	
NCI-2014-00508	Papillary Carcinoma Trial

Assign

>

>>

Unassign

<

<<

Assigned

INDUSTRIAL	
NCI-2014-00106	A Phase I, Multi-center, Open-label Study of LEED11 in Pa...
NCI-2013-00631	Phase IIIa, 2-Part, Multi-Center, Single-Arm, Open-Label...
NCI-2012-01726	A Phase 1, Open Label, Multi-center Study to Assess the S...
NCI-2012-01052	A Phase 2 Multi-Center, Historically-controlled Study of ...
NCI-2011-03684	A Phase III, Randomized, Double-Blind, Active Comparator...
NCI-2011-01171	A Phase I/II Open Label Individual Dose Titration Trial o...
NCI-2011-01144	A Phase II Study of Dasatinib in Children and Adolescents...
NCI-2011-00404	A Phase I/II Study of LDE225 in Pediatric Patients With R...
NCI-2009-01770	A Multicenter, Open-Label Single-Arm Study of YONDELIS (T...
NCI-2009-01762	A Randomized, Double-blind, Placebo-controlled Study of E...
NCI-2009-01755	A Phase 2 Study of ARQ 197 in Patients With Microphthalmi...
NCI-2009-01704	A Phase 1/2 Dose-Escalation Study of Clofarabine in Combi...

i Trials in the Not Assigned list that have not been validated appear in grey text and are unavailable for selection.

- In the **Select a trial category** list, consider narrowing the list of trials to a category.
- From the **Not Assigned** trial list, select the trial to which the user should be able to submit accrual data, and then click the single arrow (>) under **Assign**. Or, to assign all eligible trials, click the double arrow (>>).

✓ You can select multiple trials

To select multiple trials, click one trial, then press and hold the CTRL (or CMD) key and click one or more additional trials. Then click the single arrow (>) under **Assign**.

A Comments box appears.

Comments

Please provide an optional comment for this action and then click either Save to execute or Cancel to abort:

- Optionally, in the Comments box, enter a comment about this assignment, and then click **Save**.

i Comments are optional. You can leave the comment field blank and still save the accrual assignment. To abort the assignment, click **C**ancel instead.

- A message confirms your assignment. The assigned trial(s) appear in the **Assigned** list.
- To unassign access, from the **Assigned** trial list, select the trial you want to unassign, and then click the single arrow (<) under **Unassign**. Or, to unassign all trials, click the double arrow (<<).
 - Optionally, enter a comment in the comment box, and then click **Save**. The system moves the trial(s) you selected to the **Not Assigned** list, and the user no longer has access to them.

Assigning and Unassigning Accrual Access by Site

As a Site Administrator, you can assign a user accrual access globally by site. You can grant users rights to submit accruals for all trials in CTRP that have been submitted or will be submitted by the affiliated site.

1. On the toolbar, click **Administration > Accrual Access > Manage**. The Manage Accrual Access page appears.
2. Select **Make user a Site Submitter**.

Manage Accrual Access

Affiliated Site: **Children's Hospital Boston**
Member of Family(s): **Dana-Farber/Harvard Cancer Center**

Assign/Unassign Accrual submission privilege to users affiliated with this site:

Select Assignment Type

Assign user access to individual trials ? Make user a Site Submitter ? Make user an Org Family Submitter ?

Select a user ?

Assign/Unassign

3. Select the user from the **Select a user** drop-down list.
4. To assign access, click **Assign**.
5. To unassign access, click **Unassign**.

Assigning and Unassigning Accrual Access by Organization Family

As a Site Administrator, you can assign a user accrual access globally by organization family. You can grant users rights to submit accruals for all trials in CTRP that have been submitted or will be submitted by any site that is a member of the organization family.

1. On the toolbar, click **Administration > Accrual Access > Manage**. The Manage Accrual Access page appears.
2. Select **Make user an Org Family Submitter**.

Manage Accrual Access

Affiliated Site: **Children's Hospital Boston**
Member of Family(s): **Dana-Farber/Harvard Cancer Center**

Assign/Unassign Accrual submission privilege to users affiliated with this site:

Select Assignment Type

Assign user access to individual trials ? Make user a Site Submitter ? Make user an Org Family Submitter ?

Select a user ?

Assign/Unassign

3. Select the user from the **Select a user** drop-down list.
4. To assign access, click **Assign**.
5. To unassign access, click **Unassign**.

Viewing Accrual Assignment History

As a Site Administrator, you can view a history of the trials associated with your organization, to which users have been assigned/unassigned user access.

1. On the toolbar, click **Administration > Accrual Access > Assignment History**. The Accrual Assignment History page lists all access assignments.

Accrual Access Assignment History

Show: 10 Search: Choose columns << < 1 2 3 4 5 ... 500 > >>

Date	Assignee	Trial ID	Assignment Action	Comments	Assigner
06/16/2014	Edward Mulaine	NCI-2009-00127	Assigned		Edward Mulaine
06/16/2014	Edward Mulaine	NCI-2009-00130	Assigned		Edward Mulaine
06/16/2014	Edward Mulaine	NCI-2009-00148	Assigned		Edward Mulaine
06/16/2014	Edward Mulaine	NCI-2009-00241	Assigned		Edward Mulaine
06/16/2014	Edward Mulaine	NCI-2009-00254	Assigned		Edward Mulaine
06/16/2014	Edward Mulaine	NCI-2009-00267	Assigned		Edward Mulaine
06/16/2014	Edward Mulaine	NCI-2009-00292	Assigned		Edward Mulaine
06/16/2014	Edward Mulaine	NCI-2009-00635	Assigned		Edward Mulaine
06/17/2014	Charles Mulanese	NCI-2009-00909	Unassigned	unassign all	Charles Mulanese
06/17/2014	Charles Mulanese	NCI-2009-00909	Assigned		Charles Mulanese

Showing 1 to 10 of 5,000 << < 1 2 3 4 5 ... 500 > >>

Export options: CSV | Excel

2. To navigate the table, refer to [Working with Tables and Search Results](#).
3. To export the assignment history to a file, click **CSV** (comma-separated values) or **Excel** in the bottom left corner. Your browser prompts you to open or save the file.

Viewing Accrual Assignment History by Trial

As a Site Administrator, you can view a history of your organization's accrual access assignment on a per-trial basis.

1. On the toolbar, click **Administration > Accrual Access > View**. The Accrual Access Assignment by Trial page lists all current access assignments by trial, grouped by trial category.

Accrual Access Assignment By Trial

EXTERNALLY PEER-REVIEWED

Show 10 Search: Choose columns << < 1 2 3 4 5 > >>

NCI Trial Identifier	Title	Accrual Submitter
NCI-2014-00281	Vaccination of Patients With Ovarian Cancer With Dendritic Cell/Tumor Fusions With GM-CSF and Imiquimod	CTRP QATester1 Edmund Wolowic Isabelle Autissier Rachel Severt Suzanne Rowland Yael Rubinsztein
NCI-2014-00248	Global Proteomic and Phosphoproteomic Profiling of Normal B Cells Isolated From	CTRP QATester1

INSTITUTIONAL

Show 10 Search: Choose columns << < 1 2 3 4 5 ... 32 > >>

NCI Trial Identifier	Title	Accrual Submitter
NCI-2014-00508	Papillary Carcinoma Trial	CTRP QATester1 Edmund Wolowic Isabelle Autissier Rachel Severt Suzanne Rowland Yael Rubinsztein

INDUSTRIAL

Show 10 Search: Choose columns << < 1 2 3 4 5 ... 70 > >>

NCI Trial Identifier	Title	Accrual Submitter
NCI-2014-00109	A Phase Ib/II Open-label, Multi-center Study of the Combination of MEK162 Plus AMG 479 (Ganitumab) in Adult Patients With Selected Advanced Solid Tumors	CTRP QATester1 Camille Lannon Edmund Wolowic Isabelle Autissier Lindsay Eynd Rachel Severt Suzanne Rowland Yael Rubinsztein

Showing 1 to 10 of 691 << < 1 2 3 4 5 ... 70 > >>

Export options: CSV | Excel

2. To navigate the table, refer to [Working with Tables and Search Results](#).
3. To export the assignment history to a file, click **CSV** (comma-separated values) or **Excel** in the bottom left corner. Your browser prompts you to open or save the file.

Managing Trial Ownership

You can review and update user access to trials associated with the organization. For instructions, refer to the following pages:

About Trial Ownership

As a Site Administrator, you can assign and unassign trial ownership rights to multiple users in your affiliated organization and its family member organizations, and multiple trials at the same time. (Trials displayed on the Manage Trial Ownership page are those that you have submitted or those submitted by users if the trial's lead organization is the same as your affiliated organization or its family member organizations.)

For example, you can grant ownership of one trial to three CTRP users within your organization. Or, you can grant one user ownership of three trials.

Additionally, you can tell the system to send notifications about the trial(s) via email to the owners you assign.

i Users must have a CTRP account, complete with organizational affiliation, in order for you to grant them trial ownership.

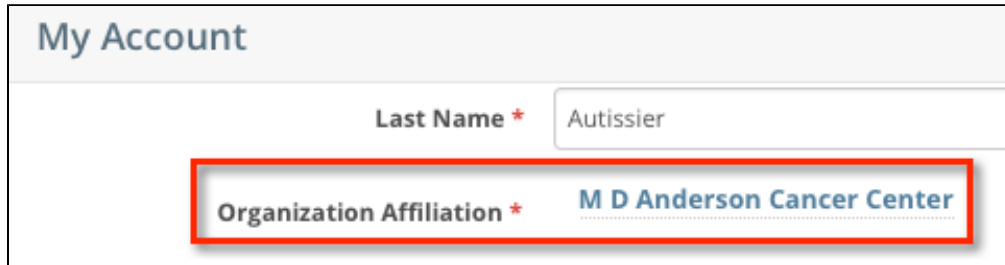
For Abbreviated trials, owners are responsible for updating their affiliated organization's information on trials in which their site is a participant, using the Update My Site action. Owners can update the following information:

- Organization family's program code
- Organization's local trial identifier
- Site principal investigator
- Site recruitment status and dates

i Trial ownership requirements

In certain circumstances, you may not be able to change trial ownership using the Manage Trial Ownership functionality. For example, you may not be able to change trial ownership if the trial status is Complete rather than Active, and the lead organization is not the trial submitter's affiliated organization. (Refer to [Recording Trial Statuses](#).) However, you can request trial ownership changes by contacting the CTRO at NCICTRO@mail.nih.gov. When requesting trial ownership changes, include the new owner's first name, last name, and email address. Ensure that the user has a valid CTRP account. For instructions, refer the user to [Creating a CTRP Account](#).

The system stores your affiliated organization with your account information on the My Account page. Your affiliation determines which trials and which users you can assign.



The screenshot shows the 'My Account' page with two input fields. The first field is labeled 'Last Name *' and contains the text 'Autissier'. The second field is labeled 'Organization Affiliation *' and contains the text 'M D Anderson Cancer Center'. This second field is highlighted with a red rectangular border.

You can assign any trial submitted by your affiliated organization or its family member organizations. For example, if you are affiliated with the M D Anderson Cancer Center, you can manage trial assignments for trials associated with the M D Anderson International and UF Cancer Center at Orlando Health organizations. The following image lists the organizations in the M.D. Anderson Cancer Center organization family.

i The organization must be a lead organization for Complete trials, or a participating site for Abbreviated trials.

Organization(s):

Show **10** entries

PO-ID	CTEP ID	Name	Family Name
18478	65024	M D Anderson International Spain	M.D. Anderson Cancer Center
70797	FL020	UF Cancer Center at Orlando Health	M.D. Anderson Cancer Center
129345	MDA	M D Anderson Cancer Center	M.D. Anderson Cancer Center
129374	MDAC	MD Anderson Phase 2 Consortium	M.D. Anderson Cancer Center
213790	RSB001	M D Anderson Cancer Center (MDACC) Research Base	M.D. Anderson Cancer Center
227050	TX022	MD Anderson Cancer Network	M.D. Anderson Cancer Center
227400	TX035	M D Anderson Cancer Center	M.D. Anderson Cancer Center
9200000		M D Anderson Cancer Center (IND Holder)	M.D. Anderson Cancer Center
16984721		U.T.M.D. Anderson Cancer Center	M.D. Anderson Cancer Center
29888347	TX403	MD Anderson Cancer Center- Bay Area	M.D. Anderson Cancer Center

Trial Ownership Example

The system associates trials with the user who last submitted the trial, and with the last submitter's affiliated organization.

For example, in the figure below, Isabelle Autissier (username = CTRPDOC1) submitted the trial while affiliated with M D Anderson. She is the last submitter and trial owner. M D Anderson is the last submitter organization and associated with the trial.

The screenshot shows a 'My Account' form. The 'Last Name *' field contains 'Autissier'. The 'Organization Affiliation *' field contains 'M D Anderson Cancer Center'. Both fields are highlighted with a red border.

The CTRP system identifies the trial by the last submitter and the last submitter organization. In the figure below, username CTRPDOC1 is affiliated with M D Anderson as per the account information in the figure above.

The screenshot shows a 'Trial Identification' page for 'NCI-2014-00543: Test of submitter organization'. It lists the following information:

Lead Organization Trial ID: M D A - 12	Principal Investigator: Autissier, Isabelle	Current Trial Status: Approved
Lead Organization: M D Anderson Cancer Center	Last Submitter: CTRPDOC1	Current Trial Status Date: 08/20/2014
Trial Category: Complete Trial	Last Submitter Organization: M D Anderson Cancer Center	Processing Status: Submitted
Submission Source: Registry		

If Isabelle Autissier changes her organization affiliation, the results depend on the extent of the change:

- If she changes her organization affiliation to another within the organization family such as U.T. M.D Anderson Cancer Center after having submitted the trial, she retains trial ownership and her *original* organization retains association with the trial.

The screenshot shows a 'My Account' form. The 'Last Name *' field contains 'Autissier'. The 'Organization Affiliation *' field contains 'U.T.M.D. Anderson Cancer Center'. Both fields are highlighted with a red border.

- If she changes her organization affiliation to an organization outside the organization family such as Vanderbilt-Ingram Cancer Center, she loses trial ownership of all trials affiliated with M D Anderson. Her trial will not be among the "Search My Trials" results. M D Anderson Cancer Center retains association with the trial; Vanderbilt-Ingram Cancer Center does not assume association with the trial despite the last submitter's new organization affiliation.


The screenshot shows a 'My Account' form. The 'Last Name *' field contains 'Autissier'. The 'Organization Affiliation *' field contains 'Vanderbilt-Ingram Cancer Center'. Both fields are highlighted with a red border.

i The example above involves Complete trials. The same principles apply to Abbreviated trials, but changes in affiliation affect association with the site record rather than association with the trial.

Assigning Trial Ownership

How to Assign and Unassign Trial Ownership

- On the toolbar, click **Administration > Trial Ownership > Manage**. The Manage Trial Ownership page displays the following lists:
 - At the top of the page: The names of users affiliated with your affiliated organization or its family member organization(s).
 - Below the list of names: Trials on which your organization is a lead organization or participating site.
- Under **Manage trial record ownership for**, select which role your affiliated organization or its family member organization(s) play(s).
 - For Complete trials, select **Lead Organization**.
 - For Abbreviated trials, select **Participating Site**.
- Indicate which users you want to give the ability to update and amend selected Complete trials; or update Abbreviated trials. To do so, select one or more user names on the list.

 **You can select or deselect all names, or filter the list of names**

To select all names, select the check box on the left side of the column heading. Click it again to deselect all names.

Manage Trial Ownership

Manage trial record ownership for: (select one)

Trials where the **Lead Organization** is from affiliated Organization's family. (includes only Complete trials)

Trials where a **Participating Site** is from affiliated Organization's family. (includes only Abbreviated trials)

Users affiliated with this site (M D Anderson Cancer Center)

Select this check box to select or deselect all users

Search:

<input type="checkbox"/>	Name	E-Mail
<input type="checkbox"/>	Jane Doe	ctrp_user@example.com
<input type="checkbox"/>	Jane Doe	ctrp_user@example.com
<input type="checkbox"/>	Jane Doe	ctrp_user@example.com

To filter the list of names, in the **Search** field, type one or more characters contained in a user's name or email address. The system filters the list as you type each character.

- In the list of trials at the bottom of the page, under **All Available Trials**, or **All Available Abbreviated Trials**, select the trials to assign to the user(s), and then click the Assign icon (>).

Trials where this site is the Lead Organization

A record owner of a trial listed below can amend or update that trial in CTRP

All Available Trials

Search:

<input type="checkbox"/>	NCI Identifier	Lead Org ID
<input type="checkbox"/>	NCI-2014-00454	LeadMay21
<input type="checkbox"/>	NCI-2014-00499	LEADORGID 123 K

Showing 1 to 2 of 2 entries

Trial Owner Assignments

Search:

Assign >

Unassign <

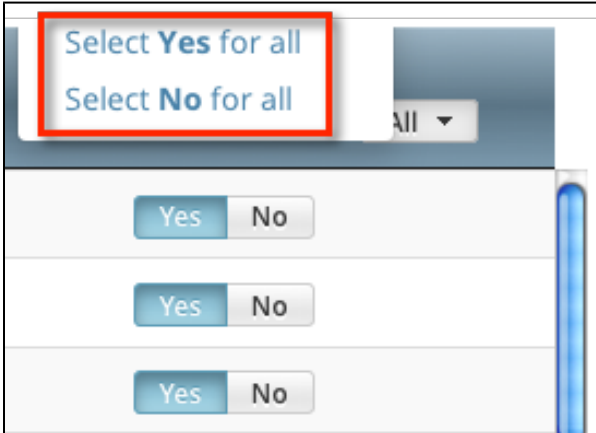
<input type="checkbox"/>	Name	NCI Identifier	Lead Org ID	Email Notification?
<input type="checkbox"/>	National Cancer Institute, xxxx	NCI-2014-00454	LeadMay21	<input type="button" value="Yes"/> <input type="button" value="No"/>
<input type="checkbox"/>	Jane Doe	NCI-2014-00454	LeadMay21	<input type="button" value="Yes"/> <input type="button" value="No"/>
<input type="checkbox"/>	Jane Doe	NCI-2014-00499	LEADORGID 123 K	<input type="button" value="Yes"/> <input type="button" value="No"/>

Showing 1 to 3 of 3 entries

- To unassign trials, under **Trial Ownership Assignments**, or **Site Owner Assignments**, select the user(s) you want to unassign, and click the Unassign icon (<).
- For Complete trials, indicate which trial owners should receive email notifications about the trial(s):
 - To indicate that a specific user should or should not receive email, in the **Email Notification?** column, in the row for that user, click **Yes** or **No**.

Name	NCI Identifier	Lead Org ID	Email Notification?
<input type="checkbox"/> Doe, Jane	NCI-2014-00454	LeadMay21	Yes <input type="button" value="No"/>
<input type="checkbox"/> Doe, Jane	NCI-2014-00499	LEADORGID 123 K	<input type="button" value="Yes"/> No

- To indicate that all owners should or should not receive email, in the **Email Notification?** column header, click **All** > **Select Yes/No for all**.



The **Select No for All** and **Select Yes for All** options apply globally to all trial owners, not just the ones currently visible in the list.

Displaying Trial Ownership

You can perform the following tasks on the trials you own:

- View trial details
- Update trials
- Amend Complete trials
- Access TSR and XML documents

As a Site Administrator, you can display trial ownership for any trial for which your organization or its family member organization is the lead organization. Additionally, you can indicate whether a user would like to receive system notifications, including TSRs and XML files, on a trial-by-trial basis.

How to Display Trial Ownership

1. On the toolbar, click **Administration > Trial Ownership > View**. The Display Trial Ownership page displays the current owner(s) of the trials for which your organization is the lead organization. It also indicates which of the owners, for each of the trials, receive system-generated email notifications.

Display Trial Ownership Hide Search Criteria

First Name:

Last Name:

E-Mail:

NCI Identifier:

Search Results

Show 10 << < 1 > >>

First Name	Last Name	E-Mail	NCI Identifier	Lead Org ID	Receive Email?	Action
Isabelle	Autissier	anthonel@mail.nih.gov	NCI-2014-00508	123456ABC	<input type="radio"/> Yes <input type="radio"/> No	<input type="button" value="Remove"/>


Showing 1 to 1 of 1 << < 1 > >>

2. You have the following search options:
 - To display all the trials owned by a given user, search for the user by first name, last name, or email address, and then click **Search**. The system lists all trials owned by the user in the **Search Results** list.
 - To display all owners of a given trial, enter the NCI Identifier in the field provided, and then click **Search**. The system lists all owners of the selected trial in the **Search Results** list.
3. You have the following options to manage trial ownership:
 - Indicate whether or not an owner of a trial should receive system-generated email messages. To do so, in the **Receive Email?** column, select **Yes** or **No**.
 - Selecting **Yes** indicates that you want the owner to receive *all* notifications regarding the specified trial.
 - Selecting **No** indicates that you do *not* want the owner to receive any notifications regarding the specified trial.
 - To revoke ownership of a trial, locate the user/trial in the **Search Results** list, and then click **Remove**.
4. You have the following additional options:
 - To filter the search results, in the **Search** field, type one or more characters contained in any of the fields. The system filters the list as you type each character. For details, refer to [Working with Tables and Search Results](#).
 - To create more space on the page, on the upper right corner of the page, select the **Hide Search Criteria** check box.

Adding Sites

As a site administrator, you can add participating sites as follows:

- Add your site to multiple *Abbreviated* trials
- Add a Family Member Organization as a participating site to multiple *Abbreviated* trials
- Add multiple Family Member Participating Sites to a given trial

 The system does not allow duplicate sites on trials.



How to Search for the Trials to which You Want to Add Participating Sites

1. On the toolbar, click **Register Trial > Add Sites**. The Search Trials page appears.
2. Enter a trial identifier (NCI, lead organization, or other) or enter all or part of a trial title.
3. Click **Search**. The system lists in the results table the *Abbreviated* trials with which your affiliated organization or its family members are not yet participating.

 The system can return up to 100 trials. If the system finds over 100 records in the database, it prompts you to narrow your search criteria.

4. Optionally, to sort the results, click the column ascending or descending arrows. This option is available only prior to adding your first site.

How to Add Organizations as Participating

1. On the toolbar, click **Register Trial > Add Sites**, and search for the trials to which you can add participating sites as described above. The *Abbreviated* trials with which your affiliated organization or its family members are not yet participating are listed in the results table.
2. In the row of the trial to which you want to add sites, click the **Plus** sign (). The trial record expands to display trial information. The Site field is pre-populated with your affiliated organization automatically.
For an *Abbreviated* trial where the participating site you are adding is a member of a cancer center family, the Program Code(s) field is available. The Program Code field lists all program codes available for that organization family.
3. Optionally, in the **Program Code(s)** field, select one or more program codes for the trial.
4. If you need to change the participating site, select one from the **Site** drop-down list. Only your family member organizations are listed.
5. If the Principal Investigator has not been selected, click the Look Up Person icon () and search for the investigator.
6. Enter the **Local Trial Identifier**.
7. (Optional) If the trial record does not already specify a contact for the trial at this participating site, you can do so in one of the following ways:
 - Next to the **Site Primary Contact** field, click the look up person icon to search for and select the site primary contact.
 - Next to the **Generic Contact** field, click the look up person icon to search for and select a CTRP person record.
8. (Optional) Consider whether the default contact information for the selected person record is appropriate for the trial at this participating site. The system accepts either the contact's primary telephone number or the contact's primary email address. You can provide both if available. Enter the phone number in the format 123-456-7890. You can provide an extension if available.
9. Select the **Site Recruitment Status** and the **Site Recruitment Status Date**. Click **Add Status**. The status record appears in the Site Recruitment Status History list.
10. If your organization belongs to a family, you can add to this trial any site within that family. To add another site to the same trial, in the **Site** column, click **Add Another Site**, and repeat the steps above to complete the trial/site information.
11. Scroll to the bottom of the page and click **Save**.

Managing Data Table 4 Information for Your Center

As a Site Administrator, you can manage Data Table 4 information for your organization family. You can manage this information for trials that meet all of the following criteria:

- Complete trials where a member of your cancer center family is the lead organization on the trial and/or a member of your cancer center family is a participating site on the trial.
- Abbreviated trials where a member of your cancer center family is a participating site.
- Trials with status other than Withdrawn.
- Trials with processing status other than Rejected or Submission Terminated.
- Trials that were active during the cancer center reporting period.

Keep in mind the following points about the entities in CTRP that represent NCI-designated Cancer Centers:

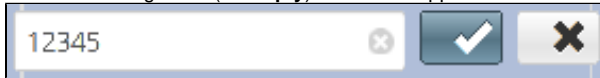
- A CTRP organization family represents an NCI-designated Cancer Center family of organizations. For brevity, this guide refers to this entity as a *Cancer Center family*, a *Cancer Center*, or an *organization family*.
- A CTRP organization that is a member of a Cancer Center family is considered a Cancer Center organization. For brevity, this guide refers to this entity as a *Cancer Center organization*.

For instructions, refer to the following pages:

Managing Targeted Accrual

If you are a Site Administrator, you can add the total number of participants expected to accrue at all of the sites within your organization family participating on a study. You can add this information to the trials described in [Managing Data Table 4 Information for Your Center](#).

1. On the toolbar, click **Administration > Manage DT4 Information > Manage DT4 Information for Your Center**. A page by that name appears.
2. In the row for the trial of interest, in the **Targeted Accrual for Your Center** column, specify the targeted accrual:
 - a. Click the existing value (or **Empty**). A text box appears.

A screenshot of a text input field. The field contains the number '12345'. To the right of the text is a small 'x' icon. Further right are two buttons: a blue button with a white checkmark and a grey button with a black 'X'.

- b. Change the value or enter a new one. When done, click the check mark. The system saves your changes.

This value appears in the Your Center Total column of the Data Table 4 report. For instructions on generating that report, refer to [Running CTRP Data Table 4 Reports](#).

Managing Program Codes

Each cancer center family uses program codes to group its clinical trials. As a Site Administrator, you can manage the set of program codes and program code assignments for your organization family. You can assign program codes to the trials described in [Managing Data Table 4 Information for Your Center](#).

For instructions, refer to the following pages:

Viewing Program Codes

1. On the toolbar, click **Administration > Manage DT4 Information > Manage Program Code Master List**. The Manage Program Codes Master List appears.

Program Code	Program Name	
1	Cell Biology	[edit] [delete] [refresh]
2	Developmental Therapeutics	[edit] [delete] [refresh]
3	Gene and Virus Therapy	[edit] [delete] [refresh]
4	Cancer Immunology and Immunotherapy	[edit] [delete] [refresh]
5	Gastrointestinal Cancer	[edit] [delete] [refresh]
6	Hematologic Malignancies	[edit] [delete] [refresh]
7	Neuro-oncology	[edit] [delete] [refresh]
8	Women's Cancer	[edit] [delete] [refresh]
9	Cancer Prevention and Control (CPC)	[edit] [delete] [refresh]
10	Genetic Epidemiology and Risk Assessment (GERA)	[edit] [delete] [refresh]

Showing 1 to 10 of 11

Excel CSV

2. Notice that this page displays information specific to your organization family.

Note Visible to Internal Users Only

Internal users with the Program Code Administrator role: From the **Organization Family** list, select an organization family. You can perform all of the functions available to a site administrator at the family you select.

Organization Family: Abramson Cancer Center

- Abramson Cancer Center
- Albert Einstein Cancer Center
- Arizona Cancer Center
- Cancer Therapy & Research Center

You can navigate through the list of program codes just like any other list of search results in the CTRP Registration application. For instructions, refer to [Working with Tables and Search Results](#).

Adding Program Codes

1. On the **Manage Program Codes Master List** page, in the **Program Code** field, enter a unique program code. This is likely to be a very short representation of the program.


Program Code *	Program Name	
<input type="text"/>	<input type="text"/>	<input type="button" value="+ Add Program Code"/>

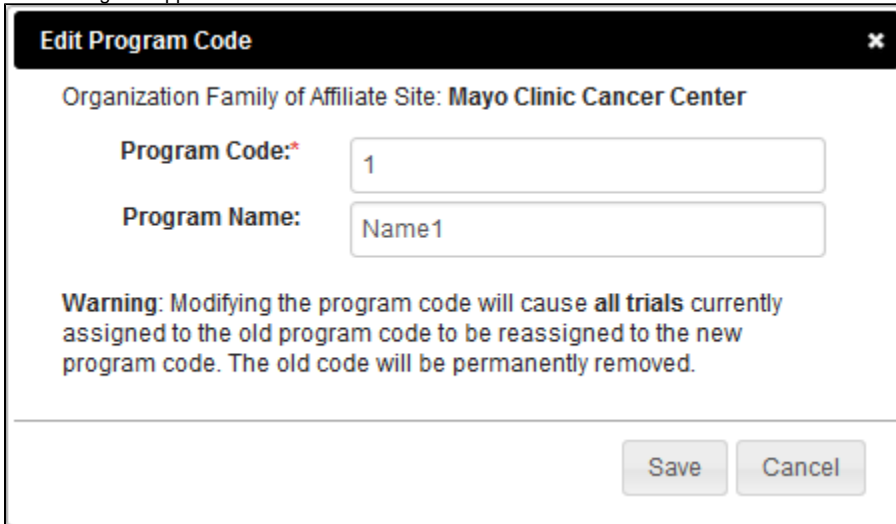
2. (Optional) In the **Program Name** field, enter a program name.
3. Click **Add Program Code**. The new program code appears in the list.

For each organization family, active program codes must be unique. The list may contain two entries with the same program code, if one is active and the other is inactive.

Editing Program Codes

When you change a program code, the system re-assigns to the new program code all trials (including closed trials) currently assigned to the old program code.

1. On the **Manage Program Codes Master List** page, in the row for the program code of interest, click the Edit icon (). The Edit Program Code dialog box appears.



Edit Program Code [X]

Organization Family of Affiliate Site: **Mayo Clinic Cancer Center**


Program Code:*

Program Name:

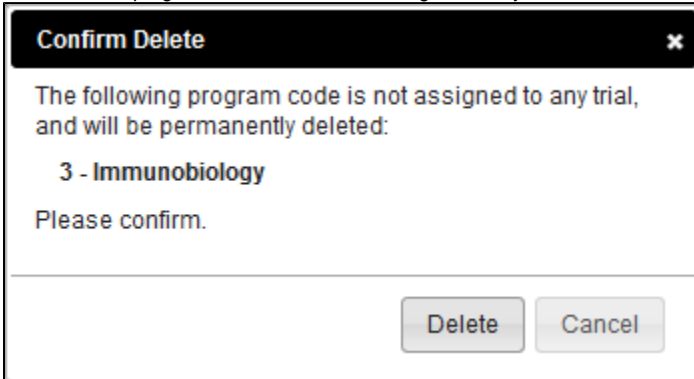
Warning: Modifying the program code will cause **all trials** currently assigned to the old program code to be reassigned to the new program code. The old code will be permanently removed.

2. Change the program code, program name, or both.
3. Click **Save**.
 - If you have changed only the program name, the list reflects your change.
 - If you have changed the program code, a confirmation message appears. If you want to proceed, click **Yes**. The list reflects your change.

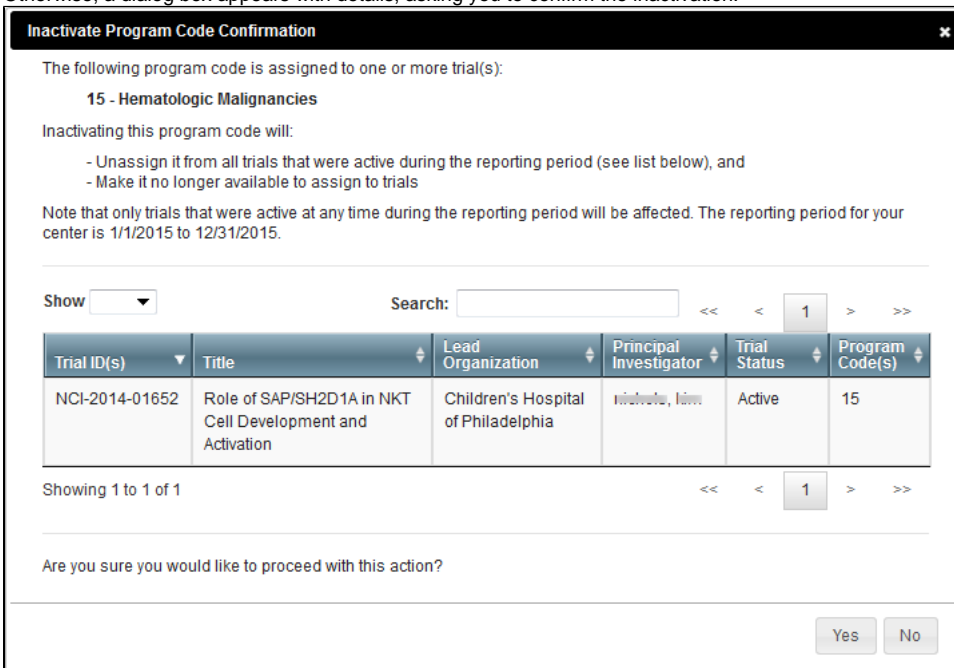
Deleting or Inactivating Program Codes

- On the **Manage Program Codes Master List** page, in the row for the program code of interest, click the Delete icon (). The system checks whether the selected program code has been assigned to any trials. What happens next depends on the result of that system check:

- If the selected program code has not been assigned to any trials, then a message appears, asking you to confirm the deletion.




- Otherwise, a dialog box appears with details, asking you to confirm the inactivation.



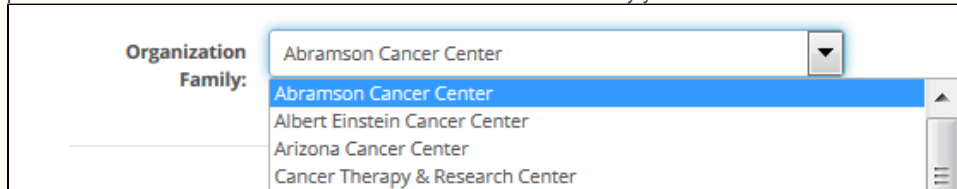
- After reading the provided information, confirm or cancel the action:
 - To confirm deletion, click **Delete**. To confirm inactivation, click **Yes**. The list changes to reflect your action:
 - If you deleted a program code, the system removes the program code completely.
 - If you inactivated a program code, the system removes the program code from *only* trials that were active at any time during the reporting period. (For instructions on changing the reporting period, refer to [Viewing the Assignments for a Program Code](#).) You can no longer assign this program code to trials. For trials with this program code outside of the reporting period, the system appends “-inactive” to the program code.
 - To cancel deletion, click **Cancel**. To cancel inactivation, click **No**.

Viewing the Assignments for a Program Code


1. On the **Manage Program Codes Master List** page, in the row for the program code of interest, click the View icon (). The Manage DT4 Information for Your Center page appears.
2. Notice that this page displays information specific to a date range:
 - The default end date is 12/31/2015. In the **Reporting Period End Date** field, consider specifying a different date.
 - The default reporting period length is 12 months. In the **Reporting Period Length** field, consider specifying a different number.
3. Notice that this page displays a list of trials that meet all the following criteria:
 - Trials in which any member of your organization family is a participant.

Note Visible to Internal Users Only

Internal users with the Program Code Administrator role: From the **Organization Family** list, select an organization family. You can perform all of the functions available to a site administrator at the family you select.



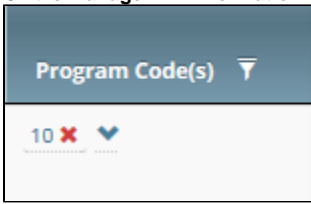
The screenshot shows a dropdown menu for "Organization Family". The menu is open, displaying a list of organization families: "Abramson Cancer Center", "Albert Einstein Cancer Center", "Arizona Cancer Center", and "Cancer Therapy & Research Center". The "Abramson Cancer Center" option is currently selected and highlighted in blue. The dropdown is positioned over a form field that currently contains "Abramson Cancer Center".

- Trials assigned the program code that you selected on the Manage Program Codes Master List page.
 - Trials with any of the following statuses at any time within the reporting period, as specified on this page:
 - In Review
 - Approved
 - Active
 - Enrolling by Invitation
 - Temporarily Closed to Accrual
 - Temporarily Closed to Accrual and Interventions
4. If you want to adjust the list filter, instructions depend on whether the list is already filtered:
 - a. If the list has been filtered, in the **Program Code(s)** column header, click the button that indicates the number of program codes selected. The list includes all program codes for the organization family and other options.
 - b. If the list has not been filtered yet, in the **Program Code(s)** column header, click the filter icon (). The Select Program Code(s) button appears. Click **Select Program Code(s)**. The list includes all program codes for the organization family and other options.
 5. Select one or more program codes from the list. (To select all program codes or deselect all program codes, toggle the **Select/Deselect All** option. To display trials that have not been assigned to program codes, select **None**.) The system updates the list of trials to reflect your selections.

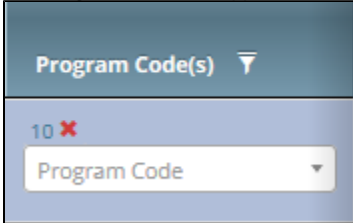
You can navigate through the list of trials just like any other list of search results in the CTRP Registration application. For instructions, refer to [Working with Tables and Search Results](#). On the **Manage Program Code Assignments** page, in the **Search** box, if you include the search term in double quote marks (for example "cancer"), the search results include trials that have an exact match in any of the first five columns.

Assigning a Program Code to a Single Trial

1. On the **Manage DT4 Information for Your Center** page, in the row for the trial of interest, in the **Program Code(s)** column, click the v icon.



The Program Code field appears.



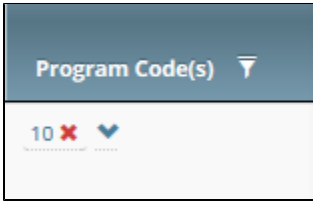
2. Click the **Program Code** field. The list includes all program codes for the organization family, but the ones already assigned to the selected trial are unavailable for selection.
3. Select the target program code. The Program Code(s) column reflects your changes.

You can also assign a program code to a trial while performing the following tasks:

- Registering, amending, or updating a Complete trial. For instructions, refer to [Registering New Trials](#), specifically [Recording Data Table 4 Information](#).
- Adding your site after importing a trial. For instructions, refer to [Registering Abbreviated \(Industrial and Other\) Trials](#).
- Adding a participating site to an Abbreviated trial or updating such a site (as a site affiliate). For instructions, refer to [Adding Your Site to Abbreviated Trials](#).
- Adding participating sites to Abbreviated trials (as a Site Administrator). For instructions, refer to [Adding Sites](#).

Unassigning a Program Code from a Single Trial

On the **Manage DT4 Information for Your Center** page, in the row for the trial of interest, in the **Program Code(s)** column, click the **x** for the program code you want to unassign. The Program Code(s) column reflects your changes.

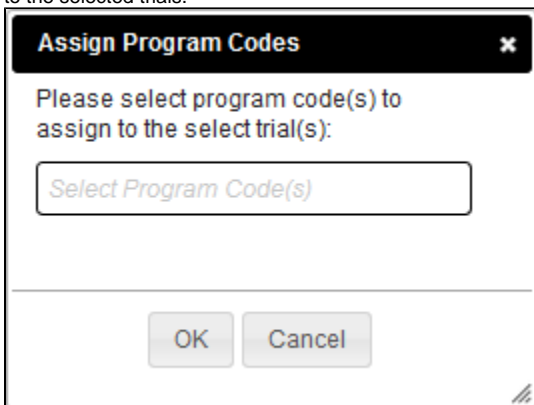


You can also unassign a program code from a trial while performing the following tasks:

- Amending or updating a Complete trial. For instructions, refer to [Registering New Trials](#), specifically [Recording Data Table 4 Information](#).
- Adding a participating site to an Abbreviated trial or updating such a site (as a site affiliate). For instructions, refer to [Adding Your Site to Abbreviated Trials](#).
- Adding participating sites to Abbreviated trials (as a Site Administrator). For instructions, refer to [Adding Sites](#).

Assigning Program Codes to Multiple Trials

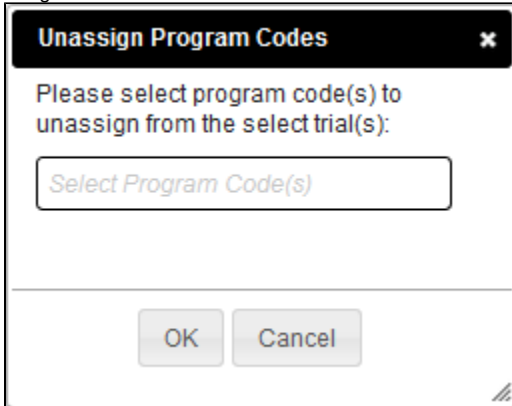
1. On the **Manage DT4 Information for Your Center** page, select one or more trials of interest.
2. Click **Assign** (at the bottom of the page). The Assign Program Codes dialog box appears. The list includes all program codes that you can assign to the selected trials.



3. In the list, select one or more target program codes.
4. Click **OK**. The Program Code(s) column reflects your changes.

Unassigning Program Codes from Multiple Trials

1. On the **Manage DT4 Information for Your Center** page, select one or more trials that have been assigned to program codes.
2. Click **Unassign** (at the bottom of the page). The Unassign Program Codes dialog box appears with a list of all program codes, but only the ones assigned to the selected trials are available for selection.



3. In the list, select one or more program codes.
4. Click **OK**. The Program Code(s) column reflects your changes.

Replacing a Program Code

1. On the **Manage DT4 Information for Your Center** page, select one or more trials that have been assigned to program codes.
2. Click **Replace** (at the bottom of the page). The Replace Program Code Assignments dialog box appears with two lists. The first list includes all program codes assigned to any selected trial.

Replace Program Code Assignments ✕

Only one program code can be replaced at a time. Select the program code that you want to replace:

1

Select one or more target program codes:

Select Program Code(s)

OK Cancel

3. In the first list, select the program code that you want to replace. The second list includes all program codes for the organization family. However, the one you selected in the first list becomes unavailable for selection in the second list.
4. In the second list, select one or more target program codes.
5. Click **OK**. The Program Code(s) column reflects your changes.

Viewing Your Participation

1. On the **Manage DT4 Information for Your Center** page, in the row for the trial of interest, in the **Lead Organization** column, click **Show my participation**. The Participating Sites dialog box appears, listing only the participating organizations that are members of your organization family.

Site Name	Investigators
Mayo Clinic	Test, Test
Mayo Clinic Hospital	Person, Test

2. When you are done viewing the list of participating sites, click **Close**.

Specifying the Center Principal Investigator

If you are a Site Administrator, you can specify the Center Principal Investigator for the trials described in [Managing Data Table 4 Information for Your Center](#).

1. On the toolbar, click **Administration > Manage DT4 Information > Manage DT4 Information for Your Center**. A page by that name appears.
2. If you want to specify a different person, in the row for the trial of interest, in the **Center Principal Investigator** column, click **Look Up**. For instructions, refer to [Looking Up Registered Persons](#).

This value appears in the PI columns (Last Name, First Name, Middle Initial) of the Data Table 4 report. For instructions on generating that report, refer to [Running CTRP Data Table 4 Reports](#).

Managing Local Trial IDs

If you are a Site Administrator, you can specify the local trial ID for each of the trials described in [Managing Data Table 4 Information for Your Center](#).

1. On the toolbar, click **Administration > Manage DT4 Information > Manage DT4 Information for Your Center**. A page by that name appears.
2. In the row for the trial of interest, in the **Local Trial ID** column, enter your site's ID for the trial:
 - a. Click the existing value (or **Empty**). A text box appears.
 - b. Change the value or enter a new one. When done, click the check mark. The system saves your changes.

The system does not use the Local Trial ID column to generate the Data Table 4 Report. Field values will not be copied into the Center Local Trial ID field (in Registration) of the Data Table 4 report. For instructions on generating that report, refer to [Running CTRP Data Table 4 Reports](#).

Verifying Trial Data

NCI requires that trial owners, trial submitters, and members of the Clinical Trials Reporting Office (CTRO) staff verify their open trial records twice per year to ensure that information is accurate and up-to-date.

This requirement applies to Interventional trials that have the following attributes:

- Trial processing status is either Abstraction Verified - No Response or Abstraction Verified - Response
- Trial status is anything other than the following:
 - Withdrawn
 - Administratively Complete
 - Complete

The system sends trial owners, trial submitters, and site administrators a verification reminder 30 and 15 days before their trial data verification due dates. It sends reminders to CTRO staffs 7 days before the due date.



CTRO staffs are responsible for verifying the types of trials below. Trial owners and submitters are responsible for verifying all others.

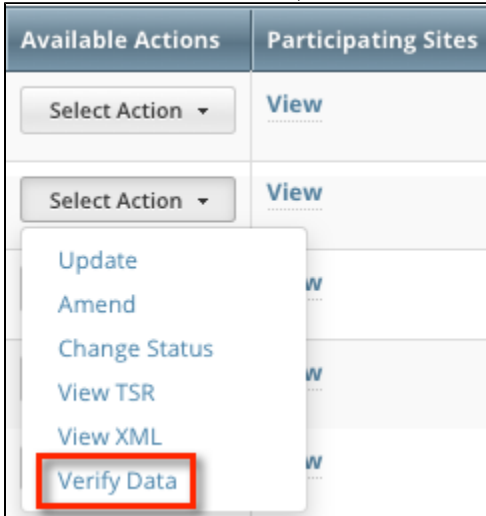
- NCI-managed trials (trials with DCP or CTEP IDs)
- NCI-sponsored trials
- Trials imported from [ClinicalTrials.gov](https://clinicaltrials.gov)
- Trials submitted by users affiliated with the National Cancer Institute or National Cancer Institute Division of Cancer Prevention
- Trials submitted by the NCI Center for Cancer Research (CCR)

Each time you verify a trial, the CTRP system records your name and date of verification. This is true for original as well as updated trials. You can view these records at any time, but cannot change them.

For additional instructions, refer to the following pages:

How to Access the Trial Data Verification Page

1. Search for the trial by the identifier noted in the email reminder you received, or use the **Search My Trials** feature.
2. In the **Available Actions** column, click **Select Action > Verify Data**.



The Trial Data Verification page appears.

Trial Data Verification

NCI Trial Identifier: NCI-2014-00318
ClinicalTrials.gov Identifier: NCT01804465
Lead Organization Trial Identifier: 12557
Title: A Randomized Phase 2 Trial of Immediate versus Delayed Anti-CTLA4 Blockade Following Sipuleucel-T Treatment for Prostate Cancer Immunotherapy

One item found.1

Date	Verification method	Verified By
2014-02-19 10:55:33.322	Abstraction Verified Response	CTRO Staff

Add Data Verification Record

I have reviewed the data for this trial :

✔ An asterisk (*) at the end of a trial title indicates that the trial has alternate titles.

Trial Data Verification

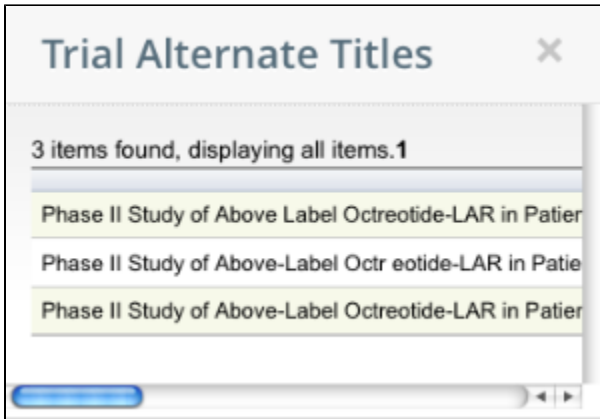
NCI Trial Identifier: NCI-2013-02396
ClinicalTrials.gov Identifier: NCT01886287
Lead Organization Trial Identifier: MCC 17410
Title: Phase II Study of Above-Label Octreotide-LAR in Patients with Insufficiently Controlled Carcinoid Syndrome*

One item found.1

Date	Verification method
2014-01-07 14:40:21.259	Abstraction Verified Response

An asterisk (*) at the end of the title is highlighted with a red box and labeled 'Alternate Title(s) indicator'.

3. To view the alternate titles, click the asterisk (*)



How to Verify Trial Data

1. On the **Trial Data Verification** page, under **Add Data Verification Record**, click **Save Verification Record**.
2. Confirm that you would like to save the record by clicking **OK** in the pop-up message.

The Trial Data Verification page displays all verification records to date.

Trial Data Verification

Message: Record was saved successfully.

NCI Trial Identifier: NCI-2014-00318
ClinicalTrials.gov Identifier: NCT01804465
Lead Organization Trial Identifier: 12557
Title: A Randomized Phase 2 Trial of ... Cancer Immunotherapy

2 items found, displaying all items.1

Date	Verification method	Verified By
2014-04-20 21:31:06.86	Manual Verification Entered	Lauren Anthonie
2014-02-19 10:55:33.322	Abstraction Verified Response	CTRO Staff

Callouts:

- The system records this when the trial owner or submitter verifies the trial** (points to 'Manual Verification Entered')
- Trial record owner or submitter** (points to 'Lauren Anthonie')
- The system records this automatically when the trial has reached the Abstraction Verified Response/No Response processing status** (points to 'Abstraction Verified Response')

Buttons: Save Verification Record, Cancel

Working With Persons and Organizations

This section provides instructions for looking up persons and organizations registered in the Clinical Trials Reporting Program (CTRP), and for adding new persons and organizations to it.

For instructions, refer to the following pages:

Looking up Registered Organizations

The procedure for searching for an organization registered in the CTRP is the same throughout the application, whether you are searching for a lead organization, funding source, or other role. You can enter a series of characters in any of the search fields (except the PO ID, which must be an exact match) to narrow the search results.

How to Look Up Registered Organizations

1. Click the **Search Organizations** tab, or on the toolbar, select **Search > Organizations**. The Search Organizations page appears.

2. Provide as much information as you can about the organization you are looking for. You can enter the Organization Identifier (PO ID) or Cancer Therapy Evaluation Program (CTEP) Identifier. You must enter search criteria in at least one field. The PO ID you enter for your search criterion must be exact and complete. That is, do not use partial IDs or wildcards.
3. Click **Search**. The search results appear in a new tab.

PO-ID	CTEP ID	Name	Family Name	City	State	Country	Zip
		Mayo Clinic in Arizona	Mayo Clinic Cancer Center	Scottsdale	AZ	United States	85259
		Mayo Clinic in Florida	Mayo Clinic Cancer Center	Jacksonville	FL	United States	32224-9980
		Mayo Clinic	Mayo Clinic Cancer Center	Rochester	MN	United States	55905
		Mayo Phase 2 Consortium	Mayo Clinic Cancer Center	Rochester	MN	United States	55905
		Mayo Clinic Scottsdale-Phoenix	Mayo Clinic Cancer Center	Scottsdale	AZ	United States	85259
		Mayo Clinic Cancer Center	Mayo Clinic Cancer Center	UNKNOWN	UM	United States	96960

To control which columns appear in your search results, click **Choose Columns**. A list of the available columns appear. Clear the check boxes for those columns you do not want to display.

Search: <input type="text"/>		Choose columns	First	Pre
Family Name		<input checked="" type="checkbox"/> PO-ID		
Mayo Clinic Cancer Center	S	<input checked="" type="checkbox"/> CTEP ID		U
Mayo Clinic Cancer Center	J	<input checked="" type="checkbox"/> Name		U
Mayo Clinic Cancer Center	R	<input checked="" type="checkbox"/> Family Name		U
Mayo Clinic Cancer Center	M	<input checked="" type="checkbox"/> City		U
Mayo Clinic Cancer Center	A	<input checked="" type="checkbox"/> State		U
Mayo Clinic Cancer Center	R	<input checked="" type="checkbox"/> Country		U
Mayo Clinic Cancer Center	R	<input checked="" type="checkbox"/> Zip		U

If the lead 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 the one you are searching for, you can narrow your search by providing more information.

4. If the organization does not appear in the results table, do one of the following to modify your search:
 - a. 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 -
 - b. 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 state in your original search, you may want to search by city in addition to the state.
5. If you still don't find your organization in the system, you can ask the CTRO to create the organization record. To do so, follow the instructions in [Requesting Creation of an Organization Record](#).
6. To link to an organization to the trial, click its **PO-ID** value.
The organization's name you selected appears in the Family Name field.


Requesting Creation of an Organization Record

If an organization record that you need for trial registration does not seem to be in the CTRP system, you can request that the CTRO create one.

1. Contact the CTRO at ncictro@mail.nih.gov and provide the following information:
 - The organization's name
 - The organization's street address
 - The organization's city
 - The organization's state or province
 - The organization's country
 - The organization's phone number
 - The organization's email address
2. Wait for a response. After resolving the request, the CTRO will send you an email message.

Looking Up Registered Persons

The procedure for searching for the name of a person registered in the Clinical Trials Reporting Program is the same throughout the application, whether you are searching for principal investigators, responsible parties, or other roles. To link a person to a role, you select the person's record from a list of search results.

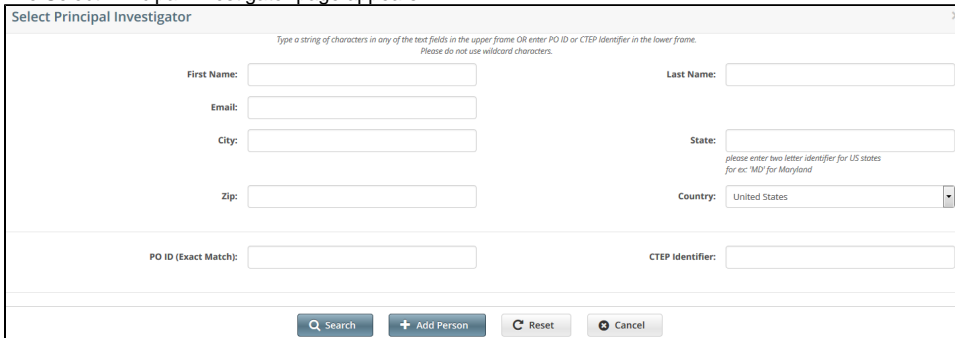
 The procedure below uses the principal investigator role as an example. The same search criteria may not appear in all search windows however.

Using wildcard characters (%)

You can enter a series of characters in any of the search fields to narrow the search results, but do not use wildcards.

How to Look Up Registered Persons

1. Next to any field for a person, such as **Principal Investigator**, click **Look Up Person**. The **Select Principal Investigator** page appears.



The screenshot shows a search form titled "Select Principal Investigator". It contains several input fields: First Name, Last Name, Email, City, State, Zip, PO ID (Exact Match), and CTEP Identifier. There are also buttons for Search, Add Person, Reset, and Cancel. A note at the top says "Type a string of characters in any of the text fields in the upper frame OR enter PO ID or CTEP Identifier in the lower frame. Please do not use wildcard characters." The State field has a note: "please enter two letter identifier for US states for ex: 'MD' for Maryland". The Country field is set to "United States".

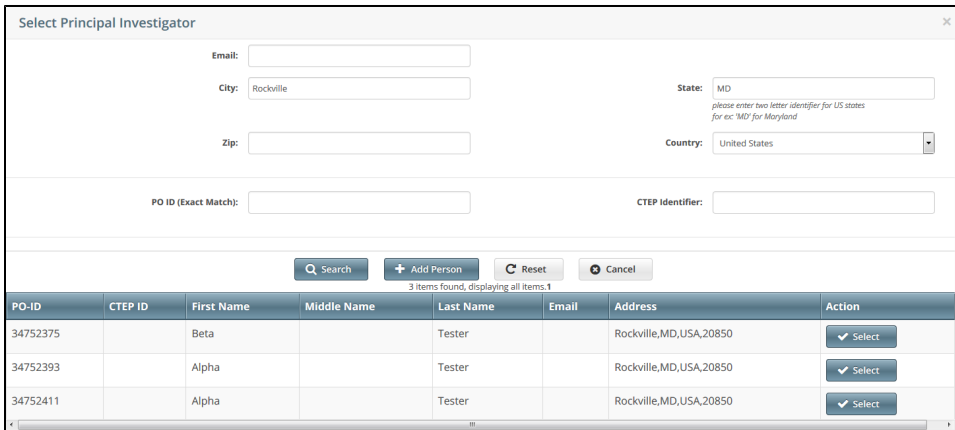
2. Provide as much information as you can about the person you are searching for, or, enter the Person/Organization (PO) ID or Cancer Therapy Evaluation Program (CTEP) Identifier. You must enter search criteria in at least one field.

Searching by PO ID

The PO ID you enter for your search criterion must be exact and complete. That is, do not use partial IDs or wildcards.

3. Click **Search**.

The **Select Principal Investigator** window displays the results of your search.



The screenshot shows the search results for the "Select Principal Investigator" window. The search criteria are: Email, City: Rockville, State: MD, Zip, Country: United States. The results table shows 3 items found, displaying all items. The table has columns for PO-ID, CTEP ID, First Name, Middle Name, Last Name, Email, Address, and Action.

PO-ID	CTEP ID	First Name	Middle Name	Last Name	Email	Address	Action
34752375		Beta		Tester		Rockville,MD,USA,20850	Select
34752393		Alpha		Tester		Rockville,MD,USA,20850	Select
34752411		Alpha		Tester		Rockville,MD,USA,20850	Select

Tip

If your principal investigator is not listed, you may have searched too narrowly (that is, 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 the one you are searching for, you can narrow your search by providing more information. Refer to the Step below for instructions.

4. 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 both first and last names 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 information about your investigator. For example, if you searched by last name only in your original search, you may want to search by first name as well.
5. If you still don't find your investigator in the system, you can ask the CTRO to create the person record. To do so, follow the instructions in [Requesting Creation of a Person Record](#).
 6. To associate a person with the role, scroll through the results list until you locate the principal investigator's record, and then click **Select**. The investigator's name you selected appears in the Principal Investigator field.

Requesting Creation of a Person Record


If a person record that you need for trial registration does not seem to be in the CTRP system, you can request that the CTRO create one.

1. Contact the CTRO at ncictro@mail.nih.gov and provide the following information:
 - The person's first name (given name)
 - The person's last name (inherited name)
 - The person's email address
 - The person's city
 - The person's state or province
 - The person's country
 - The organization with which the person is affiliated
2. Wait for a response. After resolving the request, the CTRO will send you an email message.

Viewing Trial Summary Reports and XML Documents

This section provides instructions for viewing Trial Summary Reports (TSRs) and XML documents.

- You can view the Trial Summary Report (TSR) for *Complete* trials you own.

 The View TSR link is available even if the CTRO has not accepted the trial.

- You can view the XML document for a trial you own if it meets the following criteria:
 - Trial category is *Complete*
 - Processing status is one of the following:
 - Abstraction Verified Response*
 - Abstraction Verified No Response*
 - On Hold* (if the trial was put on hold after it reached either of the two statuses above)

How to View TSR and XML Documents

- If you intend to use an XML file to upload your trial record from CTRP to ClinicalTrials.gov, make sure your trial record in CTRP has all of the trial attributes required by ClinicalTrials.gov. For details on which attributes are required, refer to <https://prsinfo.clinicaltrials.gov/definitions.html>. If you need to add or change any attributes in your trial, refer to the following pages or contact the CTRO at NCICTRO@mail.nih.gov:
 - [Updating Trials](#)
 - [Amending Complete Trials](#)

- Search for the trial(s) for which you want to view a TSR or XML document. The Submitted Clinical Trials Search Results table displays the trial(s) you searched for. Available actions are listed (if any) for each record.

Available Actions	Participating Sites	Available Actions	Participating Sites
Select Action ▾	View	Select Action ▾	View
Select Action ▾	View	Select Action ▾	View
<ul style="list-style-type: none">UpdateAmendChange StatusView TSRView XMLVerify Data	W	<ul style="list-style-type: none">UpdateAmendChange StatusView TSRView XMLVerify Data	W

- In the **Available Actions** column, click **Select Action > View TSR** or **Select Action > View XML**.

Managing Your Account

This page tree provides instructions for modifying your CTRP account.

Changing Your Password

If you know the password for your CTRP user account, you can change it.

1. On the Registration login page (<https://trials.nci.nih.gov/registration>), click **Reset Password**. On the Reset Password tab, click the CTRP Password Self Service Station link. The Change Your Password page appears. (For a more direct route to this page, visit <https://trials.nci.nih.gov/ctrp-password>.)
2. Enter your CTRP username, old password, and new password. The new password must meet the following requirements:
 - Must be 8-15 characters.
 - Must have at least one uppercase letter (A-Z), one lowercase letter (a-z), one digit (0-9), and one special character. Special characters include the following:
! " # \$ % & ' () * + , - . / : ; < = > ? @ [\] ^ _ ` { | } ~
 - Must not match any of the previous 6 passwords for this account.
3. Enter the new password again to confirm.
4. Click **Submit**. If the new password met all requirements, a confirmation page appears. Passwords remain in effect for 60 days.

If you have forgotten the password for your CTRP user account, refer to [Resetting Your Password](#).

If you have questions or want to report any issues, contact us at ctrp_support@nih.gov.

Resetting Your Password

If you have forgotten the password for your CTRP user account, or if you want to reset it for any reason, you can reset it.

1. On the Registration login page (<https://trials.nci.nih.gov/registration>), click **Reset Password**. On the Reset Password tab, click the CTRP Password Self Service Station link. The Change Your Password page appears. (For a more direct route to this page, visit <https://trials.nci.nih.gov/ctrp-password>.)
2. Click **Email a Password Reset Link**. The Email a Password Reset Link page appears. (For a more direct route to this page, visit <https://trials.nci.nih.gov/ctrp-password/?action=sendtoken>.)
3. Enter your CTRP username and the email address associated with that account.
4. Click **Submit**. If the email address matches the username, the system sends an email message to that address.
5. Click the link inside that message. A page appears prompting for the new password.
6. Enter your CTRP username and new password. The new password must meet the following requirements:
 - Must be 8-15 characters.
 - Must have at least one uppercase letter (A-Z), one lowercase letter (a-z), one digit (0-9), and one special character. Special characters include the following:
! " # \$ % & ' () * + , - . / : ; < = > ? @ [\] ^ _ ` { | } ~
 - Must not match any of the previous 6 passwords for this account.
7. Enter the new password again to confirm.
8. Click **Submit**. If the new password met all requirements, a confirmation page appears. Passwords remain in effect for 60 days.

If you have questions or want to report any issues, contact us at ctrp_support@nih.gov.

Managing Your User Account Profile

You can update your account information after you have registered for an account and have logged in to Registration.

Changing your Organizational Affiliation results in loss of privileges

If you change your organizational affiliation, the system revokes your existing Site Admin and Accrual Submission privileges.

How to Edit Your Account Information

1. Visit the CTRP Registration home page at <https://trials.nci.nih.gov/registration>.
2. Log in.
3. On the top right corner of any page, click **Your Username > My Account**.
The My Account page appears, populated with the information you previously supplied for your account.
4. In the **Your Account Profile** section, make any changes as necessary, and then click **Save**.

Keep your account up to date

The PRS organization name is required for uploading trial records to ClinicalTrials.gov via a system-generated file. The PRS organization name you include in your profile is included in that file. This precludes having to update the PRS name in the file. Therefore it is very important for you to update your account whenever there is a change in PRS.

Viewing Trial-Related Documents

This section provides instructions for accessing and viewing trial documents.

Trial-related documents include, but are not limited to the following types:

- *Complete* Protocol document
- IRB Approval
- List of Participating Sites (if not included in the protocol document). Multi-site trials require a list of participating sites and contact information.
- Informed Consent

Only trial owners and administrators can view/download trial-related documents.

How to Download Trial-Related Documents

1. Click the **NCI Trial Identifier** link associated with the trial of interest.
The metadata for the selected trial is displayed in a new page.
2. In the section at the bottom of the page, click the 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 a location of your choice.
3. Follow your browser/operating system instructions to view or save the document.



If a trial has been updated or amended, there is likely to be more than one (1) [Trial Summary Report](#) (TSR) listed. You can view and download each of them separately. To access Trial Summary Reports and XML documents, see [Viewing Trial Summary Reports and XML Documents](#).

Working with Tables and Search Results

The system lists search results in tables. You can navigate through the records in several ways, and choose which columns are of interest to you. Additionally, you can filter the results by typing a string of characters in a search field.

To do this...	Do this...
Move horizontally across the page	Press the Left arrow (←) or Right arrow (→) on your keyboard
Sort your results by column	Click the Sort icons
Move to the first page of results	Click <<
Move to the previous page of results	Click < or click the preceding page number
Move to the next page of results	Click > or click the next page number
Move to the last page of results	Click >>
Move to a specific page of results	Click a specific page number
Choose how many rows you want to display per page	Select the number of rows from the Show selector
Choose which columns to display	Click Choose columns . A list of available columns appears. Check or clear the boxes to indicate which columns you want to show or hide.
Search the list of results by keywords	In the Search field, type one or more characters contained in your keyword(s). The results are filtered as you type subsequent characters.
Export search results to a file	At the bottom of the page, click CSV to export the search results to a comma-separated file or Excel to export to a file in Microsoft Excel format.

The screenshot shows the 'Clinical Trials Search Results' page. The search term 'phase III' is entered in the search field. The 'Show' selector is set to 25. A dropdown menu for 'Choose columns' is open, showing options like 'Title', 'Current Trial Status', 'Lead Organization', 'Principal Investigator', 'Other Identifiers', 'Sites', and 'Available Actions'. The table below displays search results with columns for NCI Trial Identifier, Title, Current Trial Status, Lead Organization, Principal Investigator, and NCT ID.

NCI Trial Identifier	Title	Current Trial Status	Lead Organization	Principal Investigator	NCT ID
NCI-2014-00264	A Phase II, Double Blind, Randomized Trial of Sorafenib in Desmoid Tumors Fibrosarcoma (D7/D9)	Approved	Cancer and Leukemia Group B	Miller, Mirinal	NCT02060181
NCI-2014-00176	A Phase I Study of HDAC Inhibitor Panobinostat (LBH 589) Administered in Combination with Ipilimumab in Subjects with Unresectable Stage III or Stage IV Melanoma	Active	H. Lee Moffitt Cancer Center and Research Institute	Lee, Jeffrey	NCT02032810
NCI-2014-00118	A Randomized Phase III Study of Ibrutinib (PCI-32765)-based Therapy vs Standard Fludarabine, Cyclophosphamide, and Rituximab (FCR) Chemotherapy in Untreated Younger Patients with Chronic Lymphocytic Leukemia (CLL)	Approved	Eastern Cooperative Oncology Group	Wfelt, Tait	NCT02048813
NCI-2013-02312	Phase III Study of Metastatic Cancer that Expresses NY-ESO-1 Using Lymphodepleting Conditioning Followed by Infusion of Gene Engineered Lymphocytes Cotransduced with Genes Encoding IL-12 and Anti-NY-ESO-1 TCR	Complete	NCI - Center for Cancer Research	Shenberg, Steven	NCT01457131
NCI-2013-02288	A Randomized, Phase III Study of Intra-anal Imiquimod 2.5% vs. Topical 5-Fluorouracil 5% vs. Observation for the	Approved	AIDS - Associated Malignancies Clinical	Timothy	NCT02059499

For more instructions, refer to [Filtering Registration Search Results](#).

Filtering Registration Search Results

To filter the search results, in the **Search** field, type one or more characters contained in any of the fields. The list is filtered as you type subsequent characters.

For example, in the figure below, the results list has been filtered to display only trials that contain "004" in the NCI Identifier.

The screenshot shows a search results interface. At the top, there is a search bar with the text "Search: 004". Below the search bar is a table with the following columns: First Name, Last Name, E-Mail, NCI Identifier, Lead Org ID, Receive Email?, and Action. The table contains two rows of data:

First Name	Last Name	E-Mail	NCI Identifier	Lead Org ID	Receive Email?	Action
Isabelle	Autissier	anthonel@mail.nih.gov	NCI-2014-00499	LEADORGID 123 K	Yes No	Remove
Lauren	Anthone	example@example.com	NCI-2014-00454	LeadMay21	Yes No	Remove

Adding one more character, as shown below, filtered out the remaining trial because the number "9" was not included in the NCI Identifier.

The screenshot shows the same search results interface, but the search bar now contains "Search: 0049". The table now only contains one row of data:

First Name	Last Name	E-Mail	NCI Identifier	Lead Org ID	Receive Email?	Action
Isabelle	Autissier	anthonel@mail.nih.gov	NCI-2014-00499	LEADORGID 123 K	Yes No	Remove

Below the table, the text "Showing 1 to 1 of (filtered from 4 total entries)" is displayed.

CTRP Registration Reference

The following pages provide tables and other reference material relevant to CTRP Registration:

CTRP Trial Categories, Study Sources

Trials are categorized by type of Data Table 4 Funding Sponsorship or Trial Submission Category (study source). For more information, refer to <https://cancercenters.cancer.gov/GrantsFunding/eData#dt4>.

- **Complete Trials:**
 - **National:** NCI National Clinical Trials Network (NCTN) and other NIH-supported National Trial Networks.
 - **Externally Peer-Reviewed:** R01s, SP0RES, U01s, U10s, P01s, CTEP, or any other clinical research study mechanism supported by the NIH or organizations on this list: [Organizations with Peer Review Funding Systems](#).
 - **Institutional:** In-house clinical research studies authored or co-authored by Cancer Center investigators and undergoing scientific peer review solely by the Protocol Review and Monitoring System of the Cancer Center. The Cancer Center investigator has primary responsibility for conceptualizing, designing, and implementing the clinical research study and reporting results.
 - It is acceptable for industry and other entities to provide support (such as drug, device, or other funding), but the trial should clearly be the intellectual product of the center investigator.
 - This category may also include:
 - Institutional studies authored and implemented by investigators at another Center in which your Center is participating.
 - Multi-Institutional studies authored and implemented by investigators at your Center. (Note: National and externally peer-reviewed studies should be listed with those categories, not as Institutional studies.)
- **Abbreviated Trials:**
 - **Industrial/Other:** A pharmaceutical company controls the design and implementation of these clinical research studies.

Keep in mind the following points about the entities in CTRP that represent NCI-designated Cancer Centers:

- A CTRP organization family represents an NCI-designated Cancer Center family of organizations. For brevity, this guide refers to this entity as a *Cancer Center family*, a *Cancer Center*, or an *organization family*.
- A CTRP organization that is a member of a Cancer Center family is considered a Cancer Center organization. For brevity, this guide refers to this entity as a *Cancer Center organization*.

Data Table 4 Anatomic Site Values

CTRP uses the following values to identify the anatomic sites on which each trial or study is focused:

- Anus
- Bones and Joints
- Brain and Nervous System
- Breast - Female
- Breast - Male
- Cervix
- Colon
- Corpus Uteri
- Esophagus
- Eye and Orbit
- Hodgkin's Lymphoma
- Ill-Defined Sites
- Kaposi's Sarcoma
- Kidney
- Larynx
- Leukemia, not otherwise specified
- Leukemia, other
- Lip, Oral Cavity and Pharynx
- Liver
- Lung
- Lymphoid Leukemia
- Melanoma, Skin
- Multiple
- Multiple Myeloma
- Mycosis Fungoides
- Myeloid and Monocytic Leukemia
- Non-Hodgkin's Lymphoma
- Other Digestive Organ
- Other Endocrine System
- Other Female Genital
- Other Hematopoietic
- Other Male Genital
- Other Respiratory/Intrathoracic Organs
- Other Skin
- Other Urinary
- Ovary
- Pancreas
- Prostate
- Rectum
- Small Intestine
- Soft Tissue / Sarcoma
- Stomach
- Thyroid
- Unknown Sites
- Urinary Bladder

Expanded Access Statuses

Trial status refers to the current stage or state of participant/patient enrollment in a clinical trial relative to other stages. CTRP uses the same statuses at the trial level and at the participating site level. The following table lists the valid Expanded Access trial statuses used in CTRP and in ClinicalTrials.gov. For information on other trial statuses used in CTRP and in ClinicalTrials.gov, refer to [Trial Status Values in the CTRP and ClinicalTrials.gov](#).

Current trial status definitions

#	Trial Status Values	Status Category	Definition
1	Available	Open	Expanded access is currently available.
2	No longer available	Terminal	Expanded access was available previously but is not currently available and is not expected to be available in the future.
3	Temporarily not available	Open	Expanded access was previously available, is not currently available, but is expected to be available in the future.
4	Approved for marketing	Terminal	Expanded access was available previously, but is not currently available because the product has been approved, licensed, or cleared by the U.S. Food and Drug Administration.

Funding Mechanism Code Values

CTRP allows you to specify the funding mechanism for a trial as a unique three-character code. NIH assigns one of these codes to each area of extramural research activity. This code identifies the funding mechanism of a grant on a trial. The following table provides the name for each code:

Funding Mechanism Code	Funding Mechanism Name
B01	Preventive Health Services
B08	Substance Abuse Prevention and Treatment Block Grant
B09	Mental Health Services Block Grant
C06	Research Facilities Construction Grant
D43	International Training Grants in Epidemiology
D71	International Training Program Planning Grant
DP1	NIH Director's Pioneer Award (NDPA)
DP2	NIH Director's New Innovator Awards
DP3	Type 1 Diabetes Targeted Research Award
E11	Grants for Public Health Special Projects
F05	International Research Fellowships (FIC)
F30	Individual Predoctoral NRSA for M.D./Ph.D. Fellowships (ADAMHA)
F31	Predoctoral Individual National Research Service Award
F32	Postdoctoral Individual National Research Service Award
F33	National Research Service Awards for Senior Fellows
F34	MARC (NRSA) Faculty Fellowships
F37	Medical Informatics Fellowships
F38	Applied Medical Informatics Fellowships
G07	Resources Improvement Grant
G08	Resources Project Grant (NLM)
G11	Extramural Associate Research Development Award (EARDA)
G12	Research Centers in Minority Institutions Award
G13	Health Sciences Publication Support Awards (NLM)
G20	Grants for Repair, Renovation and Modernization of Existing Research Facilities (NCRR)
G94	Administrative Support for Public Health Service Agency Foundations
H13	Conferences
H23	Immunization Program
H25	Venereal Disease Control
H28	State and Community-Based Injury Control Programs
H50	Maternal and Child Health Services Project, RB Funds
H57	Indian Health Service Loan Repayment Program
H62	Services or Education on AIDS
H64	State and Community-Based Childhood Lead Poisoning Prevention Program
H75	Health Investigations/Assessments of Control/Preven. Methods
H79	Mental Health and/or Substance Abuse Services Grants
HD4	Drug Use/Alcohol Abuse Prevention Demo: Community Partnership Study

HR1	State Mental Health and Substance Abuse Data Resource Projects
HS5	Child Mental Health Services Initiative: Comprehensive Community Mental Health Services for Children and Adolescents with Serious Emotional Disturbances
I01	Non-DHHS Research Projects
K01	Research Scientist Development Award - Research & Training
K02	Research Scientist Development Award - Research
K05	Research Scientist Award
K06	Research Career Awards
K07	Academic/Teacher Award (ATA)
K08	Clinical Investigator Award (CIA)
K12	Physician Scientist Award (Program) (PSA)
K14	Minority School Faculty Development Awards
K18	The Career Enhancement Award
K21	Scientist Development Award
K22	Career Transition Award
K23	Mentored Patient-Oriented Research Career Development Award
K24	Midcareer Investigator Award in Patient-Oriented Research
K25	Mentored Quantitative Research Career Development Award
K26	Midcareer Investigator Award in Biomedical and Behavioral Research
K30	Clinical Research Curriculum Award (CRCA)
K99	Career Transition Award
KD1	Mental Health and/or Substance Abuse KD&A Grants
KL1	Linked Research Career Development Award
KL2	Mentored Career Development Award
KM1	Institutional Career Enhancement Awards - Multi-Yr Funding
L30	Loan Repayment Program for Clinical Researchers
L32	Loan Repayment Program for Clinical Researchers from Disadvantaged Backgrounds
L40	Loan Repayment Program for Pediatric Research
L50	Loan Repayment Program for Contraception and Infertility Research
L60	Loan Repayment Program for Health Disparities Research
M01	General Clinical Research Centers Program
N01	Research and Development Contracts
N02	Resource and Support Contracts - Awarded in the ICD
N03	Station Support Contracts - Awarded by the Division of Procurement
N43	Small Business Innovation Research - Phase I (Contract)
N44	Small Business Innovation Research - Phase II (Contract)
P01	Research Program Projects
P20	Exploratory Grants
P30	Center Core Grants
P40	Animal (Mammalian and Nonmammalian) Model, and Animal and Biological Material Resource Grants (NCRR)
P41	Biotechnology Resource Grants

P42	Hazardous Substances Basic Research Grants Program (NIEHS)
P50	Specialized Center
P51	Primate Research Center Grants (NCRR)
P60	Comprehensive Center
P76	Projects to Design and implement Health Exhibits/Materials for Public Education
PL1	Linked Center Core Grant
PN1	Concept Development Award
PN2	Research Development Center
R00	Research Transition Award
R01	Research Project
R03	Small Research Grants
R04	Anthrop. Fellow Res. Support (old
R06	Translations
R08	Development of Innovative Technology for Measurement of Lead
R13	Conference
R15	Academic Research Enhancement Awards (AREA)
R17	Mental Health Career Investigator Grants Active
R18	Research Demonstration and Dissemination Projects
R21	Exploratory/Developmental Grants
R24	Resource-Related Research Projects
R25	Education Projects
R30	Preventive Health Service - Venereal Disease Research, Demonstration, and Public Information and Education Grants
R33	Exploratory/Developmental Grants Phase II
R34	Clinical Trial Planning Grant
R36	Dissertation Award
R37	Method to Extend Research in Time (MERIT) Award
R41	Small Business Technology Transfer (STTR) Grants - Phase I
R42	Small Business Technology Transfer (STTR) Grants - Phase II
R43	Small Business Innovation Research Grants (SBIR) - Phase I
R44	Small Business Innovation Research Grants (SBIR) - Phase II
R49	Injury Control Research and Demonstration Projects and Injury Prevention Research Centers
R55	James A. Shannon Director's Award
R56	High Priority, Short Term Project Award
R90	Interdisciplinary Regular Research Training Award
RC1	NIH Challenge Grants and Partnerships Program
RC2	High Impact Research and Research Infrastructure Programs
RC3	Biomedical Research, Development, and Growth to Spur the Acceleration of New Technologies (BRDG-SPAN) Program
RC4	High Impact Research and Research Infrastructure Programs Multi Year Funding
RL1	Linked Research project Grant
RL2	Linked Exploratory/Development Grant
RL5	Linked Education Project

RL9	Linked Research Training Award
RS1	Programs to Prevent the Emergence and Spread of Antimicrobial Resistance in the United States
S06	Minority Biomedical Research Support - MBRS
S10	Biomedical Research Support Shared Instrumentation Grants (NCRR)
S11	Minority Biomedical Research Support Thematic Project Grants
S21	Research and Institutional Resources Health Disparities Endowment Grants -Capacity Building
S22	Research and Student Resources Health Disparities Endowment Grants - Educational Programs
SC1	Research Enhancement Award
SC2	Pilot Research Project
SC3	Research Continuance Award
T01	Graduate Training Program
T02	Undergraduate Training Program
T03	Combined Undergraduate and Graduate Training Program
T06	Minority Supplements to Clinical Training Grants
T09	Scientific Evaluation
T14	Conferences
T15	Continuing Education Training Grants
T32	Institutional National Research Service Award
T34	MARC Undergraduate NRSA Institutional Grants
T35	NRSA Short -Term Research Training
T36	MARC Ancillary Training Activities (Grant) (NIGMS) <Title Revised>
T37	Minority International Research Training Grants (FIC)
T42	Educational Resource Center Training Grants
T90	Interdisciplinary Research Training Award
TL1	Linked Training Award
TU2	Institutional National Research Service Award with Involvement of NIH Intramural Faculty
U01	Research Project--Cooperative Agreements
U09	Scientific Review and Evaluation--Cooperative Agreements
U10	Cooperative Clinical Research--Cooperative Agreements
U11	Study (in China) of Periconceptional Vitamin Supplements to Prevent Spina Bifida and Anencephaly Cooperative Agreements
U13	Conference--Cooperative Agreements
U14	Public Health Leadership Institute Cooperative Agreement
U17	Applied Methods in Violence-Related or Accidental Injury Surveillance Cooperative Agreements
U18	Research Demonstration--Cooperative Agreements
U19	Research Program--Cooperative Agreements
U1A	Capacity Building for Core Components of Tobacco Prevention and Control Programs Cooperative Agreements
U1Q	Emergency Disaster Relief Relating to CDC Programs Cooperative Agreement
U1S	Emergency Disaster Relief Relating to SAMHSA Programs Cooperative Agreements
U1T	Violence Prevention Training for Minority Medical Students Cooperative Agreement
U1V	Capacity Building for Core Components of Tobacco Prevention and Control Programs Cooperative Agreements
U21	Immunization Service for Racial and Ethnic Minorities, Cooperative Agreements

U22	HIV/STD Preventive Services for Racial and Minorities
U23	TB Prevention and Control Services for Racial and Ethnic Minorities Cooperative Agreements
U24	Resource-Related Research Related Cooperative Agreements
U27	Surveillance of Complications of Hemophilia Cooperative Agreements
U2G	Global HIV/AIDS Non-Research Cooperative Agreements
U2R	International Training Cooperative Agreement
U30	Prev. Health Services: Venereal Disease Research, Demonstration, and Public Information and Education Projects
U32	State-based Diabetes Control Programs
U34	Clinical Planning Grant Cooperative Agreement
U36	Program Improvements for Schools of Public Health
U38	Uniform National Health Program Reporting System
U41	Biotechnology Resource Cooperative Agreements
U42	Animal (Mammalian and Nonmammalian) Model, and Animal and Biological Materials Resource Cooperative Agreements (NCRR)
U43	Small Business Innovation Research (SBIR) Cooperative Agreements - Phase I
U44	Small Business Innovation Research (SBIR) Cooperative Agreements - Phase II
U45	Hazardous Waste Worker Health and Safety Training Cooperative Agreements (NIEHS)
U47	Laboratory/Other Diagnostic Medical Quality Improvement Cooperative Agreements
U48	Health Promotion and Disease Prevention Research Centers
U49	Coop: Injury Control Res. and Demo and Injury Prevention
U50	Special Cooperative Investigations/Assessment of Control/Prevention Methods
U51	Health Planning Strategies/National Academy of Sciences Activities
U52	Cooperative Agreement for Tuberculosis Control
U53	Capacity Bldg: Occupational Safety/Community Environmental Health
U54	Specialized Center--Cooperative Agreements
U55	Core Support For American Council on Transplantation Active
U56	Exploratory Grants--Cooperative Agreements
U57	State-Based Comprehensive Breast/Cervical Cancer Control Program Cooperative Agreements
U58	Chronic Disease Control Cooperative Agreement
U59	Disabilities Prevention Cooperative Agreement Program
U60	Cooperative Agreements in Occupational Safety and Health Research, Demonstrations, Evaluation and Education Research, Demonstrations, Evaluation and Education
U61	Preventive Health Activities Regarding Hazardous Substances
U62	Prevention/Surveillance Activities/Studies of AIDS
U65	Minority/Other Community-based HIV Prevention Project, Cooperative Agreements
U66	Immunization Demonstration Projects Cooperative Agreements
U75	National Cancer Registries Cooperative Agreements
U79	Mental Health and/or Substance Abuse Services Cooperative Agreements
U81	Injury Community Demonstration Projects: Evaluation of Youth Violence Prevention Program
U82	Enhancement of State and Local Capacity to Assess the Progress toward Healthy People 2010 Objectives
U83	Research to Advance the Understanding of the Health of Racial and Ethnic Populations or Subpopulations Cooperative Agreements
U84	Cooperative Agreements for Fetal Alcohol Syndrome Prevention Research Programs

U87	State Demonstration: Comprehensive School Health Program to Prevent Sexual Behaviors that Result in HIV Infection and to Improve Educational Outcome Cooperative Agreements
U88	Services Demonstration Cooperative Agreements
U90	Cooperative Agreements for Special Projects of National Significance (SPNS)
UA1	AIDS Research Project Cooperative Agreement
UC1	NIH Challenge Grants and Partnerships Program - Phase II-Coop.Agreement
UC2	High Impact Research and Research Infrastructure Cooperative Agreement Programs
UC3	Biomedical Research, Development, and Growth to Spur the Acceleration of New Technologies (BRDG-SPAN) Cooperative Agreement Program
UC6	Construction Cooperative Agreement
UC7	National Biocontainment Laboratory Operation Cooperative Agreement
UD1	Mental Health and/or Substance Abuse KD&A Cooperative Agreements
UE1	Studies of Environmental Hazards and Health Effects
UE2	Emergency and Environmental Health Services
UH1	HBCU Research Scientist Award
UH2	Exploratory/Developmental Cooperative Agreement Phase I
UH3	Exploratory/Developmental Cooperative Agreement Phase II
UL1	Linked Specialized Center Cooperative Agreement
UR1	Cooperative Agreements for Resources and Technical Assistance Projects to Support Mental Health and Substance Abuse Services
UR3	School Health: Findings from Evaluated Programs Cooperative Agreements
UR6	Prevention Intervention Research on Substance Abuse in Children Cooperative Agreements
UR8	Applied Research in Emerging Infections-(including Tick-borne Diseases) Cooperative Agreements
US3	Hantaviral Reservoir Studies Cooperative Agreements
US4	Community-Based Primary Prevention Programs: Intimate Partner Violence Cooperative Agreements
UT1	Small Business Technology Transfer (STTR) – Cooperative Agreements - Phase I
UT2	Small Business Technology Transfer (STTR) – Cooperative Agreements - Phase II
VF1	Rape Prevention and Education Grants
X01	Resource Access Award
X02	Preapplication
X06	Projects for Assistance in Transition from Homelessness
X98	Protection and Advocacy for Mentally Ill Individuals
Y01	NIH Inter-Agency Agreements
Y02	NIH Intra-Agency Agreements
Z01	Intramural Research
Z02	Intramural Research Resources
Z1A	Investigator-Initiated Intramural Research Projects

NCI Division and Program Values

The following table provides the NCI values used to identify the name of the NCI division or program responsible for a grant.

Division/Program Value	Definition
CCR	Center for Cancer Research
CCT/CTB	Center for Cancer Training/Cancer Training Branch
CDP	Cancer Diagnosis Program
CIP	Cancer Imaging Program
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
DCP	Division of Cancer Prevention
DEA	Division of Extramural Activities
DESP	Division of Extramural Science Programs
DTP	Developmental Therapeutics Program
OD	Office of the Director, NCI, NIH
OSB/SPORE	Organ Systems Branch/Specialized Programs of Research Excellence
RRP	Radiation Research Program
TRP	Translational Research
N/A	Not applicable

NIH Grant Institute Code Values

The following table lists each two-letter code identifying the organization that supports an NIH grant, contract, or inter-agency agreement. The support may be financial or administrative. You can associate the NIH institute with a trial, in a grant record.

Code	Organization
AA	National Institute on Alcohol Abuse and Alcoholism (NIAAA)
AE	Office of the Assistant Secretary for Planning and Evaluation
AF	Administration for Children and Families
AG	National Institute on Aging (NIA)
AI	National Institute of Allergy and Infectious Diseases Extramural Activities (NIAID)
AM	National Institute of Arthritis, Diabetes, Digestive, and Kidney Diseases
AO	NIAID Research Support
AR	National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)
AT	National Center for Complementary and Integrative Health (NCCIH)
BC	Division of Basic Sciences (NCI)
BX	Biomedical Laboratory Research and Development
CA	National Cancer Institute (NCI)
CB	Division of Cancer Biology and Diagnosis (NCI)
CD	Office of the Director, Centers for Disease Control and Prevention
CE	National Center for Injury Prevention and Control
CH	Coordinating Center for Infectious Diseases
CI	National Center for Infectious Diseases (NCID)
CK	National Center for Zoonotic, Vector-borne, and Enteric Diseases
CL	Clinical Center (CLC)
CM	Division of Cancer Treatment (NCI)
CN	Division of Cancer Prevention and Control (NCI)
CO	Office of the Director (NCI)
CP	Division of Cancer Epidemiology and Genetics (NCI)
CR	Cooperative Research and Development Agreements (NCI)
CT	Center for Information Technology (CIT)
CU	Cooperative Studies Program
CX	Clinical Science Research and Development
DA	National Institute on Drug Abuse (NIDA)
DC	National Institute on Deafness and Other Communication Disorders (NIDCD)
DD	Centers for Disease Control and Prevention
DE	National Institute of Dental and Craniofacial Research (NIDCR)
DK	National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)
DP	National Center for Chronic Disease Prevention and Health Promotion
EB	National Institute of Biomedical Imaging and Bioengineering (NIBIB)
EH	National Center for Environmental Health
EM	Environmental Health Services

EP	Epidemiology Program Office
ES	National Institute of Environmental Health Sciences (NIEHS)
EY	National Eye Institute (NEI)
FD	Food and Drug Administration
GD	Office of Genomics and Disease Prevention
GH	Coordinating Office of Global Health
GM	National Institute of General Medical Sciences (NIGMS)
GW	Genome Association Studies (GAS)
HB	Division of Blood Diseases and Resources (NHLBI)
HC	Division of Epidemiology and Clinical Applications (NHLBI)
HD	National Institute of Child Health and Human Development (NICHD)
HG	National Human Genome Research Institute (NHGRI)
HI	Division of Intramural Research (NHLBI)
HK	Office of National Center for Public Health Informatics
HL	National Heart, Lung, and Blood Institute (NHLBI)
HM	National Center for Health Marketing
HO	Office of the Director (NHLBI)
HP	Health Resources and Services Administration / Bureau of Health Professions
HR	Division of Lung Diseases (NHLBI)
HS	Agency for Healthcare Research and Quality
HV	Division of Heart and Vascular Diseases (NHLBI)
HX	Health Services Research and Development
HY	Office of Health and Safety
IP	National Center for Immunization and Respiratory Diseases
JT	Joint Funding
LM	National Library of Medicine (NLM)
MD	National Institute on Minority Health and Health Disparities (NIMHD)
MH	National Institute of Mental Health (NIMH)
MN	Office of Minority Health
NB	Neuroscience Blueprint (NB)
NH	National Institutes of Health
NR	National Institute of Nursing Research (NINR)
NS	National Institute of Neurological Disorders and Stroke (NINDS)
NU	Division of Nursing
OA	Office of the Administrator (SAMHSA)
OC	Office of the National Coordinator for Health Information Technology, OS, HHS
OD	Office of the Director (NIH)
OF	Office of Research Facilities Development and Operations (ORFDO)
OH	National Institute for Occupational Safety and Health
OL	Office of Logistics and Acquisition Operations (OLAO)
OR	Office of Research Services (ORS)

PC	Division of Cancer Control and Population Science (NCI)
PH	Public Health Practice Program Office
PR	Office of Chief Public Health Practice
PS	National Center for HIV, Viral Hepatitis, STD, and TB Prevention
RC	Center for Cancer Research (CCR)
RD	Office of Research and Development
RG	Center for Scientific Review (CSR)
RM	NIH Roadmap Initiative, Office of the Director (RMOD)
RR	National Center for Research Resources (NCRR)
RX	Rehabilitation Research and Development
SC	Division of Clinical Sciences (NCI)
SF	Superfund Basic Research Program (SBRP)
SH	National Center for Health Statistics
SM	Center for Mental Health Services
SP	Center for Substance Abuse Prevention
SU	Substance Abuse and Mental Health Services Administration
TI	Center for Substance Abuse Treatment
TP	Coordinating Office for Terrorism Preparedness and Emergency Response
TR	National Center for Advancing Translational Sciences (NCATS)
TS	Agency for Toxic Substances and Disease Registry
TW	John E. Fogarty International Center (FIC)
VA	Veterans Affairs
WC	Office of Workforce and Career Development
WH	Women's Health Initiative (WHI, OD)
WT	Worker Education Training Program (WETP)

NIH Institution Code Values

The following table lists NIH institution codes. You can associate the NIH institution with a trial, in an IND or IDE record.

Valid Value	Definition
NEI	National Eye Institute
NHLBI	National Heart, Lung, and Blood Institute
NHGRI	National Human Genome Research Institute
NIA	National Institute on Aging
NIAAA	National Institute on Alcohol Abuse and Alcoholism
NIAID	National Institute of Allergy and Infectious Diseases
NIAMS	National Institute of Arthritis and Musculoskeletal and Skin Diseases
NIBIB	National Institute of Biomedical Imaging and Bioengineering
NICHHD	Eunice Kennedy Shriver National Institute of Child Health and Human Development
NIDCD	National Institute on Deafness and Other Communication Disorders
NIDCR	National Institute of Dental and Craniofacial Research
NIDDK	National Institute of Diabetes and Digestive and Kidney Diseases
NIDA	National Institute on Drug Abuse
NIEHS	National Institute of Environmental Health Sciences
NIGMS	National Institute of General Medical Sciences
NIMH	National Institute of Mental Health
NINDS	National Institute of Neurological Disorders and Stroke
NINR	National Institute of Nursing Research
NLM	National Library of Medicine
CIT	Center for Information Technology
CSR	Center for Scientific Review
FIC	John E. Fogarty International Center for Advanced Study in the Health Sciences
NCCAM	National Center for Complementary and Alternative Medicine
NCMHD	National Center on Minority Health and Health Disparities
NCRR	National Center for Research Resources (NCRR)
CC	NIH Clinical Center
OD	Office of the Director

Primary Purpose Value Definitions

CTRP allows you to choose one of the following values when specifying the main reason for conducting the trial.

CTRP Primary Purpose Value	Definition
Treatment	Protocol is designed to evaluate one or more interventions for treating a disease, syndrome, or condition.
Prevention	Protocol is designed to assess one or more interventions aimed at preventing the development of a specific disease or health condition.
Supportive Care	Protocol is 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 is 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).
Diagnostic	Protocol is designed to evaluate one or more interventions aimed at identifying a disease or health condition.
Health Services Research	Protocol is designed to evaluate the delivery, processes, management, organization, or financing of health care.
Basic Science	Protocol is designed to examine the basic mechanism of action (e.g., physiology, biomechanics) of an intervention.
Device Feasibility	Protocol is designed to evaluate an intervention of a device product, to determine the feasibility of the product or to test a prototype device and not health outcomes. Such studies are conducted to confirm the design and operating specifications of a device before beginning a full clinical trial.
Other	Any purpose not described above.

Status Rules for Trial Dates

Valid dates for a given trial status depend on the other values you have entered, and whether those dates are *Actual* or *Anticipated*. The following table illustrates these rules:

Status	Start Date Type	Primary Completion Date Type	Completion Date Type
<ul style="list-style-type: none"> • In Review • Approved • Withdrawn • Active • Enrolling by Invitation 	Can be Actual or Anticipated.	Can be Actual or Anticipated.	Must be Anticipated.
<ul style="list-style-type: none"> • Temporarily Closed to Accrual • Temporarily Closed to Accrual and Intervention • Closed to Accrual • Closed to Accrual and Intervention 	Must be Actual.	Can be Actual or Anticipated.	Can be Actual or Anticipated.
<ul style="list-style-type: none"> • Complete • Administratively Complete 	Must be Actual.	Must be Actual.	Can be Actual or Anticipated.

The general rules for Study Date types are as follows:

- If the date is in the past, the type must be Actual.
- If the date is today, the type could be Actual or Anticipated.
- If the date is in the future, the type must always be Anticipated.


The general rules for Study Date values are as follows:

- The Trial Start Date can be in the past, present, or future.
- The Primary Completion Date is always the same as, or later than, the Trial Start Date.
- If the Primary Completion Date is *Actual*, it can be earlier than the Current Trial Status Dates *Complete* or *Administratively Complete*.
- The Completion Date is always the same as, or later than, the Primary Completion Date.

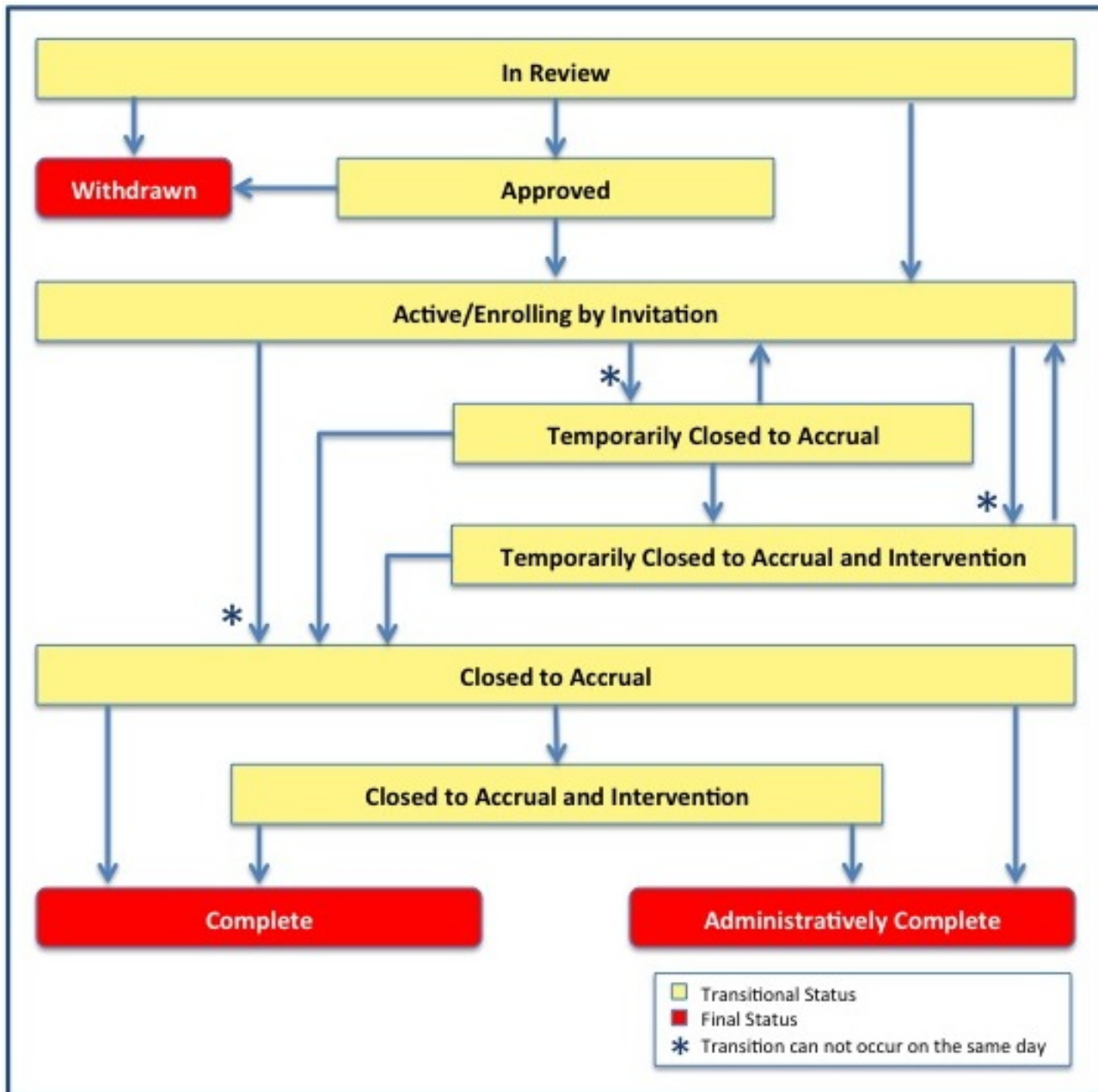
Status Transition Rules

The table and diagram below provide rules for ensuring that you record valid transitions between trial statuses and participating site statuses.

Trial Status Flow Relationships

A trial can proceed from this status...	Directly to this status	Or to this status
In Review	<ul style="list-style-type: none"> Approved Withdrawn 	Active/Enrolling by Invitation <div style="border: 1px solid #ccc; padding: 5px; margin-top: 10px;">  This can occur when the trial has been Approved and is Active /Enrolling by Invitation on the same day </div>
Approved	<ul style="list-style-type: none"> Active/Enrolling by Invitation Withdrawn 	NA
Active/Enrolling by Invitation	Closed to Accrual	<ul style="list-style-type: none"> Temporarily Closed to Accrual Temporarily Closed to Accrual and Intervention Closed to Accrual and Intervention Administratively Completed Completed
Closed to Accrual	Closed to Accrual and Intervention	Administratively Completed
Closed to Accrual and Intervention	<ul style="list-style-type: none"> Completed Administratively Completed 	NA
Temporarily Closed to Accrual	Temporarily Closed to Accrual and Intervention	<ul style="list-style-type: none"> Active/Enrolling by Invitation Closed to Accrual Closed to Accrual and Intervention Administratively Completed
Temporarily Closed to Accrual and Intervention	Administratively Completed	<ul style="list-style-type: none"> Active/Enrolling by Invitation Closed to Accrual Closed to Accrual and Intervention

The diagram below illustrates the flow and transitions among trial statuses. The system records the statuses in the order indicated by the arrows. Double-ended arrows indicate that a transition between statuses can be recorded in either order. For example, a status can transition from Active/Enrolling by Invitation to Temporarily Closed to Accrual and Intervention, or conversely, from Temporarily Closed to Accrual and Intervention to Active/Enrolling by Invitation.



Trial Status Transitions

Trial Phase Value Definitions

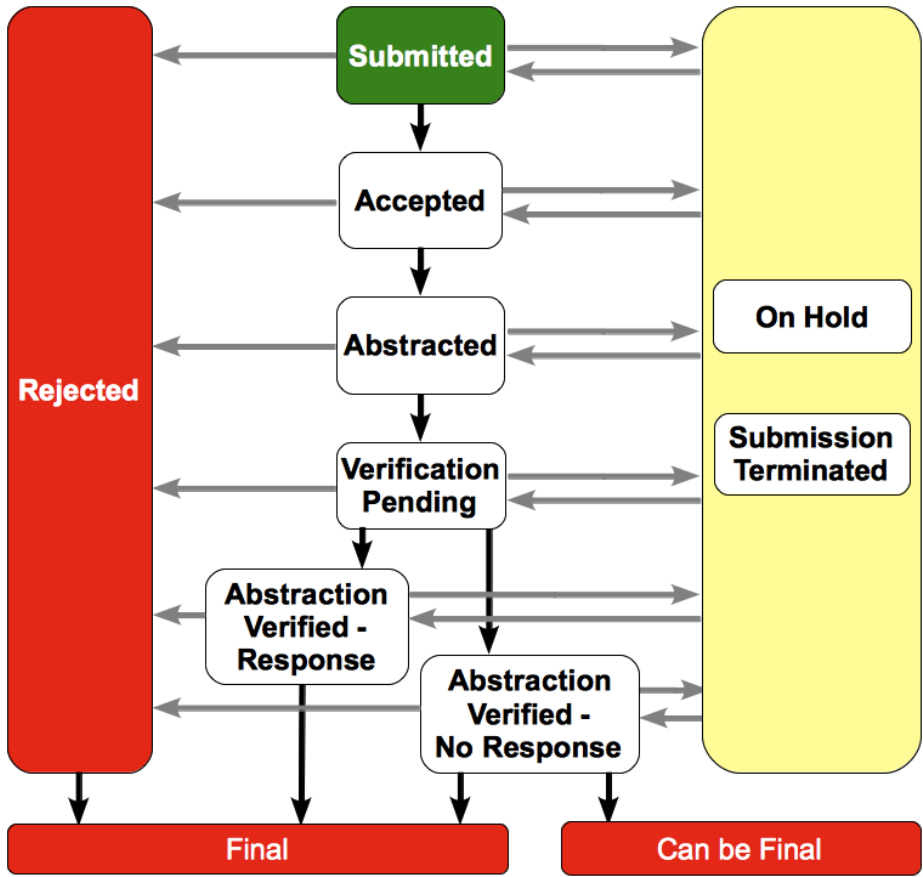
When you specify trial data in CTRP, the system requires you to specify the phase of investigation, as defined by the US FDA for trials involving investigational new drugs. The following table provides a definition of each phase and maps the ClinicalTrials.gov values to the CTRP values:

CTRP Phase Value	ClinicalTrials.gov Phase Value	Definition
Early Phase I	Early Phase 1 (Formerly listed as "Phase 0")	Exploratory trials, involving very limited human exposure, with no therapeutic or diagnostic intent (e.g., screening studies, microdose studies). See FDA guidance on exploratory IND studies for more information.
I	Phase 1	Includes initial studies to determine the metabolism and pharmacologic actions of drugs in humans, the side effects associated with increasing doses, and to gain early evidence of effectiveness; may include healthy participants and /or patients.
I/II	Phase 1/Phase 2	Trials that are a combination of phases 1 and 2.
II	Phase 2	Includes controlled clinical studies conducted to evaluate the effectiveness of the drug for a particular indication or indications in participants with the disease or condition under study and to determine the common short-term side effects and risks.
II/III	Phase 2/Phase 3	Trials that are a combination of phases 2 and 3.
III	Phase 3	Includes trials conducted after preliminary evidence suggesting effectiveness of the drug has been obtained, and are intended to gather additional information to evaluate the overall benefit-risk relationship of the drug.
IV	Phase 4	Studies of FDA-approved drugs to delineate additional information including the drug's risks, benefits, and optimal use.
NA	N/A	Trials without phases (for example, studies of devices or behavioral interventions).

Trial Processing Statuses

The following table provides the definitions of each of the statuses that occur during the course of the trial processing work flow. The diagram (after the table) illustrates the work flow so that you can see the relationships between the trial statuses.

Trial Processing Status	Definition
All	Any processing status.
Submitted	Original trial submitted but not validated.
Amendment Submitted	Amendment submitted but not validated.
Accepted	Trial passed validation.
Rejected	Trial did not pass validation. These trials are displayed in PA but not in trial search results in the Registration application.
Abstracted	Trial has been abstracted.
Verification Pending	Trial has been abstracted, and the Trial Summary Report (TSR) has been sent to the trial submitter for abstraction verification.
Abstraction Verified Response	Submitter has verified the abstraction as per the TSR, and has returned feedback to the CTRO within five business days after receiving the TSR. (A business day is any weekday that is not a Federal holiday. For a list of Federal holidays, refer to the U.S. Office of Personnel Management's list of Federal Holidays .)
Abstraction Verified No Response	Submitter has not responded or returned verification feedback to the CTRO within five business days after receiving the TSR.
On-Hold	Trial has been delayed, or there is not enough information to process the submission.
Submission Terminated	Trial processing has been terminated in PA. (For example, a Registration application user may have requested termination.) These trials are displayed in PA but not in trial search results in the Registration application.
Submission Reactivated	Trial processing has resumed in PA.



Trial Status Values in the CTRP and ClinicalTrials.gov

Trial status refers to the current stage or state of participant/patient enrollment in a clinical trial relative to other stages. CTRP uses the same statuses at the trial level and at the participating site level. The following table lists the valid trial statuses used in CTRP and maps each value to the corresponding ClinicalTrials.gov-defined recruitment value.

For information on Expanded Access trial statuses, refer to [Expanded Access Statuses](#).

Current trial status definitions

#	CTRP Trial Status Values	ClinicalTrials.gov Trial Status Values	Status Category	Definition
01	In Review	Not yet recruiting	Review	Participants are not yet being recruited.
11	Withdrawn	Withdrawn	Terminal	Study halted prematurely, prior to enrollment of first participant.
02	Approved	Not yet recruiting	Review	Participants are not yet being recruited.
03	Active	Recruiting	Open	Participants are currently being recruited, whether or not any participants have yet been enrolled.
04	Enrolling by Invitation	Enrolling by Invitation	Open	Participants are being (or will be) selected from a predetermined population.
08	Temporarily Closed to Accrual	Suspended	Open	Study halted prematurely but potentially will resume.
09	Temporarily Closed to Accrual and Intervention	Suspended	Open	Study halted prematurely but potentially will resume.
05	Closed to Accrual	Active, not recruiting	Closed	Study is continuing, meaning participants are receiving an intervention or being examined, but new participants are not currently being recruited or enrolled.
06	Closed to Accrual and Intervention	Active, not recruiting	Closed	Study is continuing, meaning participants are receiving an intervention or being examined, but new participants are not currently being recruited or enrolled.
10	Administratively Complete	Terminated	Terminal	Study halted prematurely and will not resume; participants are no longer being examined or receiving intervention.
07	Complete	Completed	Terminal	The study has concluded normally; participants are no longer receiving an intervention or being examined (that is, last participant's last visit has occurred).

Trial Summary Report and XML File Data Elements

The CTRP system captures the trial data you submit, and from them generates two types of trial documents: a Trial Summary Report (TSR), formatted for user consumption; and an XML file formatted for upload to ClinicalTrials.gov. Both documents contain a subset of trial data elements captured in the CTRP. However, the TSR contains more elements than the XML because ClinicalTrials.gov-required fields are different from those in CTRP. Some data that appear in the TSR do not appear in the XML, and vice versa. The documents are described below.

- **Trial Summary Report (TSR)** – Report that presents a summary of key abstracted data from the trial you registered, in an easy-to-read format. The CTRP system sends the TSR as an attachment in an email to the trial submitter/owner with instructions to review the TSR for accuracy and to report any changes to the CTRO staff.




When a trial has been amended, the system sends a modified TSR to the submitter that reflects the changes.

- **XML File** – File that contains abstracted data in the format suitable for submission to ClinicalTrials.gov. You may want to make sure the trial record in CTRP has all of the trial attributes required for ClinicalTrials.gov before you use CTRP to generate an XML file from that trial record, to avoid having to make corrections/additions in ClinicalTrials.gov.

The following sections compare the TSR data elements with those in the XML.


For instructions on viewing these trial documents, refer to [Viewing Trial Summary Reports and XML Documents](#).

TSR-XML Data Element Comparisons

 Use the horizontal scroll bar to display hidden columns

If you don't see all four columns in the table below, scroll down to the bottom of the table and use the horizontal scroll bar to display them.

Data Fields	Sample TSR Data	Sample Corresponding XML Data	Comments
Record Verification Date	2013-03	<verification_date>2013-03</verification_date>	NA
Trial Category	Complete	(Not included in the XML file)	ClinicalTrials.gov does not capture this field
Trial Type	Interventional	<study_type>Interventional</study_type>	NA
NCI Trial Identifier	NCI-2011-9999	<id_info> <secondary_id> <id>NCI-2011-99999</id> <id_type>Registry Identifier</id_type> <id_domain>CTRP (Clinical Trial Reporting Program)</id_domain> </secondary_id> </id_info>	NA
ClinicalTrials.gov Identifier	NCT01234567	(Not included in the XML file)	NA
Lead Organization (Trial) Identifier	CCCCWFU 12345	<org_study_id>CCCCWFU 12345</org_study_id> and <id_info> <secondary_id> <id>CCCCWFU 12345</id> <id_type>Other Identifier</id_type> <id_domain>Wake Forest University Health Sciences</id_domain> </secondary_id> </id_info>	Wake Forest University Health Sciences is the Lead Organization in this example
DCP Identifier	WFU-01-01-06	<id_info> <secondary_id> <id>WFU-01-01-06</id> <id_type>Registry Identifier</id_type> <id_domain>DCP</id_domain> </secondary_id> </id_info>	ClinicalTrials.gov captures all other identifiers as <secondary_id>
CTEP Identifier	WFU-01-01-06	<id_info> <secondary_id> <id>WFU-01-01-06</id> <id_type>Registry Identifier</id_type> <id_domain>CTEP</id_domain> </secondary_id> </id_info>	ClinicalTrials.gov captures all other identifiers as <secondary_id>
CCR Identifier	CCR-123	(Not included in the XML file)	ClinicalTrials.gov captures all other identifiers as <secondary_id>
Amendment Date	02/10/2003	(Not included in the XML file)	ClinicalTrials.gov does not capture this field
Amendment Number	35	(Not included in the XML file)	ClinicalTrials.gov does not capture this field
Type	Interventional	<study_type>Interventional</study_type>	NA
Official Title	A Phase II Double-Blind Feasibility Study of Armodafinil...	<official_title> A Phase II Double-Blind Feasibility Study of Armodafinil... </official_title>	NA
Brief Title	Armodafinil in Treating Fatigue Caused By Radiation Therapy in Patients With Primary Brain Tumors	<brief_title> Armodafinil in Treating Fatigue Caused By Radiation Therapy in Patients With Primary Brain Tumors </brief_title>	NA
Acronym	ABC	<acronym>	NA
Brief Summary	This clinical trial is studying how well Armodafinil works...	<brief_summary> <textblock> This clinical trial is studying how well	NA

		Armodafinil works... <textblock> <brief_summary>	
Detailed Description	Detailed Description...	<detailed_description> <textblock> Detailed Description... </textblock> </detailed_description>	NA
Primary Objectives	I. To estimate...	<detailed_description> <textblock> PRIMARY OBJECTIVES: I. To estimate... </textblock> </detailed_description>	NA
Secondary Objectives	I. To obtain a preliminary estimate...	<detailed_description> <textblock> SECONDARY OBJECTIVES: To obtain a preliminary estimate... </textblock> </detailed_description>	NA
Outline	OUTLINE: This is a multicenter study...	<detailed_description> <textblock> OUTLINE: This is a multicenter study... </textblock> </detailed_description>	NA
Keywords	Feasibility Armodafinil; narcolepsy	<keyword>Feasibility Armodafinil</keyword> <keyword>narcolepsy</keyword>	NA
Reporting Dataset Method	Complete	(Not included in the XML file)	Not required for the ClinicalTrials.gov schema
Sponsor	National Cancer Institute	<sponsors> <lead_sponsor> <agency>National Cancer Institute</agency> </lead_sponsor> </sponsors>	NA
Lead Organization	Wake Forest University Health Sciences	<overall_official> <first_name>Jane</first_name> <last_name>Doe</last_name> <role>Principal Investigator</role> <affiliation>Wake Forest University Health Sciences</affiliation> </overall_official>	NA
Principal Investigator	Jane Doe	<overall_official> <first_name>Jane</first_name> <last_name>Doe</last_name> <role>Principal Investigator</role> <affiliation>Wake Forest University Health Sciences</affiliation> </overall_official>	NA
Responsible Party	Sponsor	<resp_party_type>Sponsor</resp_party_type>	NA
Overall Official	Jane Doe (Principal Investigator) Wake Forest University Health Sciences	<overall_official> <first_name>Jane</first_name> <last_name>Doe</last_name> <role>Principal Investigator</role> <affiliation>Wake Forest University Health Sciences</affiliation> </overall_official>	NA
Current Trial Status	Closed to Accrual and Intervention as of 08/01/2012	<overall_status>Active, not recruiting</overall_status>	NA
Trial Start Date	08/01/2010-Actual	<start_date>2010-08</start_date> <start_date_type>Actual</start_date_type>	NA
Primary Completion Date	01/11/2014-Actual	<primary_compl_date>2014-01</primary_compl_date> <primary_compl_date_type>Actual</primary_compl_date_type>	NA
Completion Date	02/04/2014-Actual	<last_follow_up_date>2014-02</last_follow_up_date>	Not required for the ClinicalTrials.gov schema
		 If no data are available, the "<last_follow_up_date>" does not appear in the XML file.	
Regulatory Information >	Yes	<oversight_info>	NA

Studies a U.S. FDA-regulated Drug Product		<fda_regulated_drug>Yes</fda_regulated_drug></oversight_info>	
Regulatory Information > Studies a U.S. FDA-regulated Device Product	Yes	<oversight_info><fda_regulated_device>Yes</fda_regulated_device></oversight_info>	NA
Regulatory Information > Unapproved/Uncleared Device?	Yes	<delayed_posting>Yes</delayed_posting>	NA
Regulatory Information > Post Prior to U.S. FDA Approval or Clearance	Yes	<oversight_info><post_prior_to_approval>Yes</post_prior_to_approval></oversight_info>	NA
Regulatory Information > Pediatric Post-market Surveillance (of a Device Product)	Yes	<oversight_info><ped_postmarket_surv>Yes</ped_postmarket_surv></oversight_info>	NA
Regulatory Information > Product Exported from the U.S.	Yes	<oversight_info><exported_from_us>Yes</exported_from_us></oversight_info>	NA
Regulatory Information > FDA Regulated Intervention?	Yes	<is_fda_regulated>Yes</is_fda_regulated>	NA
Regulatory Information > Section 801?	Yes	<is_section_801>Yes</is_section_801>	NA
Regulatory Information > DMC Appointed?	Yes	<oversight_info><has_dmc>Yes</has_dmc></oversight_info>	NA
Regulatory Information > IND /IDE Study?	Yes	<is_ind_study>Yes</is_ind_study>	NA
Board Approval Status	Submitted, approved	<irb_info><approval_status>Approved</approval_status></irb_info>	NA
Board Approval Number	IRB00012856	<irb_info><approval_number>IRB00012856</approval_number></irb_info>	NA
Board	Wake Forest University Health Sciences	<irb_info><name>Wake Forest University Health Sciences</name></irb_info>	NA
Affiliation	Wake Forest University Health Sciences	<irb_info><affiliation>Wake Forest University Health Sciences</affiliation></irb_info>	NA
IND/IDE > Type	IND	<ind_info>	Applies to IND and IDE
IND/IDE > Grantor	CBER	<ind_grantor>CBER</ind_grantor>	NA
IND/IDE > Number	119999	<ind_number>119999</ind_number>	NA
IND/IDE > Holder Type	NCI	(Not included in the XML file)	NA
IND/IDE > Availability of Expanded Access	Yes	<has_expanded_access>Yes</has_expanded_access>	NA
IND/IDE > Expanded Access Record	NCT12345678	<expanded_access_nct_id>NCT12345678</expanded_access_nct_id>	NA
NIH Grants > Funding Mechanism	U10	<secondary_id><id>U10CA88888</id><id_type>NIH Grant Number</id_type></secondary_id>	NA
NIH Grants > NIH Institution Code	CA	<secondary_id><id>U10CA88888</id><id_type>NIH Grant Number</id_type></secondary_id>	NA
NIH Grants > Serial Number	88888	<secondary_id><id>U10CA88888</id><id_type>NIH Grant Number</id_type></secondary_id>	NA
NIH Grants > NCI Division /Program Code	DCP	(Not included in the XML file)	NA

Data Table 4 Information > Funding Category	Externally Peer-Reviewed	(Not included in the XML file)	Not required for the ClinicalTrials.gov schema
Data Table 4 Information > Funding Sponsor/Source	National Cancer Institute	(Not included in the XML file)	Not required for the ClinicalTrials.gov schema
Data Table 4 Information > Program Codes	2, 5, 12	(Not included in the XML file)	NA
Anatomic Site Code	Prostate	(Not included in the XML file)	Not required for the ClinicalTrials.gov schema
Collaborator Name	National Cancer Institute	<collaborator> <agency>National Cancer Institute</agency> </collaborator>	Not required for the ClinicalTrials.gov schema
Collaborator Role	Funding Source	(Not included in the XML file)	ClinicalTrials.gov does not capture this field
Disease/Condition Name	Prostate Carcinoma	<condition>Prostate Carcinoma</condition>	NA
Trial Design > Type	Interventional	<study_type>Interventional</study_type> and <study_design>Interventional</study_design>	NA
Trial Design > Expanded Access	(Not included in the TSR)	(Not included in the XML file)	Data field in Protocol Abstraction
Trial Design > Primary Purpose	Prevention	<study_design> <interventional_design> <interventional_subtype>Prevention</interventional_subtype> </interventional_design> </study_design>	NA
Trial Design > Phase	II	<study_design> <interventional_design> <phase>II</phase> </interventional_design> </study_design>	NA
Trial Design > Interventional Study Model	Parallel	<study_design> <interventional_design> <assignment>Parallel Assignment</assignment> </interventional_design> </study_design>	NA
Trial Design > Model Description	Lorem ipsum dolor sit amet ...	<study_design> <interventional_design> <model_description> <textblock>Lorem ipsum dolor sit amet ... </textblock> </model_description> </interventional_design> </study_design>	NA
Trial Design > Number of Arms	2	<study_design> <interventional_design> <number_of_arms>2</number_of_arms> </interventional_design> </study_design>	NA
Trial Design > Masking	Participant, Investigator, Care Provider, Outcomes Assessor	<study_design> <interventional_design> <no_masking>No</no_masking> <masked_assessor>Yes</masked_assessor> <masked_caregiver>Yes</masked_caregiver> <masked_investigator>Yes</masked_investigator> <masked_subject>Yes</masked_subject> </interventional_design> </study_design>	NA
Trial Design > Masking Description	Lorem ipsum dolor sit amet ...	<study_design> <interventional_design> <masking_description> <textblock>Lorem ipsum dolor sit amet ... </textblock> </masking_description> </interventional_design> </study_design>	NA
Trial Design > Allocation	Randomized Controlled Trial	<study_design> <interventional_design> <allocation>Randomized Controlled Trial</allocation>	NA

		/allocation> </interventional_design> </study_design>	
Trial Design > Target Enrollment	100	<enrollment>100</enrollment>	NA
Eligibility Criteria > Accepts Healthy Volunteers?	No	<eligibility> <healthy_volunteers>No</healthy_volunteers> </eligibility>	NA
Eligibility Criteria > Sex	Female	<eligibility> <gender>Female</gender> </eligibility>	NA
Eligibility Criteria > Gender Based	Yes	<eligibility> <gender_based>Yes</gender_based> </eligibility>	NA
Eligibility Criteria > Gender Eligibility Description	Lorem ipsum dolor sit amet ...	<eligibility> <gender_description> <textblock>Lorem ipsum dolor sit amet ... </textblock> </gender_description> </eligibility>	NA
Eligibility Criteria > Minimum Age	18 Years	<eligibility> <minimum_age>18 years</minimum_age> </eligibility>	NA
Eligibility Criteria > Maximum Age	N/A	<eligibility> <maximum_age>N/A</maximum_age> </eligibility>	NA
Eligibility Criteria > Inclusion Criteria	Family history of prostate cancer...	<eligibility> <criteria> <textblock>Inclusion Criteria: Family history of prostate cancer...</textblock> </criteria> </eligibility>	NA
Eligibility Criteria > Exclusion Criteria	Patient must not have had radiation therapy in the pelvic area...	<eligibility> <criteria> <textblock>Exclusion Criteria: Patient must not have had radiation therapy in the pelvic area...</textblock> </criteria> </eligibility>	NA
Intervention(s) > Type	Drug	<intervention_type>Drug</intervention_type>	NA
Intervention(s) > Name	Armodafinil	<intervention_name>Armodafinil</intervention_name>	NA
Intervention(s) > Alternate Name	2-(difluoromethyl)-DL-ornithine, 2-(difluoromethyl)-dl-ornithine Hydrochloride,...	<intervention_other_name> 2-(difluoromethyl)-DL-ornithine, 2-(difluoromethyl)-dl-ornithine Hydrochloride,... </intervention_other_name>	NA
Intervention(s) > Description	Given orally	<intervention_description> <textblock>Given orally</textblock> </intervention_description>	NA
Arm/Group(s) > Type	Placebo Comparator	<arm_type>Placebo Comparator</arm_type>	NA
Arm/Group(s) > Label	Arm II	<arm_group_label>Arm II</arm_group_label>	NA
Arm/Group(s) > Description	Patients receive oral Armodafinil once daily...	<arm_group_description> <textblock>Patients receive oral Armodafinil once daily...</textblock> </arm_group_description>	NA
Primary Outcome Measures > Title	Accrual rate estimated as the number of patients ...	<primary_outcome> <outcome_measure>Accrual rate estimated as the number of patients ...</outcome_measure> </primary_outcome>	NA
Primary Outcome Measures > Description	Estimated using an analysis of covariance (ANCOVA) model which includes...	<outcome_description> <textblock>Estimated using an analysis of covariance (ANCOVA) model which includes...</textblock> </outcome_description>	NA
Primary Outcome Measures > Time Frame	Up to 2 years	<outcome_time_frame>Up to 2 years</outcome_time_frame>	NA
Secondary Outcome Measures	Incidence of toxicity incidents...	<secondary_outcome>	NA

> Title		<outcome_measure>Incidence of toxicity incidents assessed...</outcome_measure> <secondary_outcome>	
Secondary Outcome Measures > Description	NA	<outcome_description>	NA
Secondary Outcome Measures > Time Frame	Up to 2 years	<outcome_time_frame>Up to 2 years</outcome_time_frame>	NA
Sub-groups Stratification Criteria > Label	(Not included in the TSR)	(Not included in the XML file)	Data field in Protocol Abstraction
Sub-groups Stratification Criteria > Description	(Not included in the TSR)	(Not included in the XML file)	Data field in Protocol Abstraction
Markers > Marker Name	(Not included in the TSR)	(Not included in the XML file)	Data field in Protocol Abstraction
Markers > Evaluation Type	(Not included in the TSR)	(Not included in the XML file)	Data field in Protocol Abstraction
Markers > Assay Type	(Not included in the TSR)	(Not included in the XML file)	Data field in Protocol Abstraction
Markers > Biomarker Use	(Not included in the TSR)	(Not included in the XML file)	Data field in Protocol Abstraction
Markers > Biomarker Purpose	(Not included in the TSR)	(Not included in the XML file)	Data field in Protocol Abstraction
Markers > Specimen Type	(Not included in the TSR)	(Not included in the XML file)	Data field in Protocol Abstraction
Participating Sites > Facility	Wake Forest University Health Sciences Winston-Salem, NC 27106 United States	<location> <facility> <name>Wake Forest University Health Sciences</name> <address> <city>Winston-Salem</city> <state>NC</state> <zip>27106</zip> <country>United States</country> </address> </facility> </location>	NA
Participating Sites > Contact	Doe, Jane, M. phone:123-123-1234 Email:jmd@domain.com	<location> <contact> <first_name>Jane</first_name> <middle_name>M</middle_name> <last_name>Doe</last_name> <phone>123-123-1234</phone> <email>jmd@domain.com</email> </contact> </location>	NA
Participating Sites > Recruitment Status and Dates	Enrolling by Invitation as of 05/09/2014	<location> <status>Enrolling by Invitation</status> </location>	NA
Participating Sites > Target Accrual	40	(Not included in the XML file)	ClinicalTrials.gov does not capture this field
Participating Sites > Investigators	Doe, Jane, Principal Investigator	<investigator> <first_name>Jane</first_name><last_name>Doe</last_name><role>Principal Investigator</role> </investigator>	NA

Trial Summary Report Data Elements by Section

Each of the following sections contain mapping tables, in the order in which they appear in the TSRs.

For information, refer to the following pages:

Trial Identification

TSR Data Elements	XML Data Elements
Trial Category	(Not included in the XML file)
Trial Type	<study_type>
NCI Trial Identifier	<secondary_id>
Other Trial Identifiers	<secondary_id>
Lead Organization (Trial) Identifier	<org_study_id>
ClinicalTrials.gov Identifier	(Not included in the XML file)
DCP Identifier	<secondary_id>
CTEP Identifier	<secondary_id>
CCR Identifier	(Not included in the XML file)
Duplicate NCI Identifier	<secondary_id>
Obsolete ClinicalTrials.gov Identifier	(Not included in the XML file)
Other Identifier	<secondary_id>
Amendment Date	(Not included in the XML file)
Amendment Number	(Not included in the XML file)

General Trial Details

TSR Data Elements	XML Data Elements
Type	<study_type>
Official Title	<official_title>
Alternate Title	(Not included in the XML file)
Brief Title	<brief_title>
Acronym	<acronym>
Brief Summary	<brief_summary>
Detailed Description	<detailed_description>
Keywords	<keyword>
Reporting Dataset Method	(Not included in the XML file)
Sponsor	<lead_sponsor>
Lead Organization	<overall_official>
Principle Investigator	<resp_party>
Responsible Party	<resp_party_type>
Overall Official	<overall_official>
Central Contact	<overall_contact>

Status/Dates

TSR Data Elements	XML Data Elements
Current Trial Status	<overall_status>
Trial Start Date	<start_date> <start_date_type>
Primary Completion Date	<primary_compl_date> <primary_compl_date_type>
Trial Completion Date	<last_follow_up_date> <last_follow_up_date_type>

Regulatory Information/Oversight Information

TSR Data Elements	XML Data Elements
Studies a U.S. FDA-regulated Drug Product	<fda_regulated_drug>
Studies a U.S. FDA-regulated Device Product	<fda_regulated_device>
Unapproved/Uncleared Device?	<delayed_posting>
Post Prior to U.S. FDA Approval or Clearance	<post_prior_to_approval>
Pediatric Post-market Surveillance	<ped_postmarket_surv>
Product Exported from the U.S.	<exported_from_us>
FDA Regulated Intervention?	<is_fda_regulated>
Section 801?	<is_section_801>
DMC Appointed?	<has_dmc>
IND/IDE Study?	<is_ind_study>

Human Subject Safety/Regulatory Authority

TSR Data Elements	XML Data Elements
Board Approval Status	<approval_status>
Board Approval Number	<approval_number>
Board	<irb_info>
Affiliation	<affiliation>

IND/IDE

TSR Data Elements	XML Data Elements
Type	<ind_info>
Grantor	<ind_grantor>
Number	<ind_number>
Holder Type	(Not included in the XML file)
Holder	(Not included in the XML file)
Availability of Expanded Access	<has_expanded_access>
Expanded Access Record	<expanded_access_nct_id>

NIH Grants

TSR Data Elements	XML Data Elements
Funding Mechanism	<secondary_id>
NIH Institute Code	<secondary_id>
Serial Number	<secondary_id>
NCI Division/Program Code	<secondary_id>

Data Table 4 Information

TSR Data Elements	XML Data Elements
Funding Category	(Not included in the XML file)
Funding Sponsor/Source	(Not included in the XML file)
Program Codes	(Not included in the XML file)
Anatomic Site Code	(Not included in the XML file)

Collaborators

TSR Data Elements	XML Data Elements
Name	<collaborator>
Role	(Not included in the XML file)

Disease/Condition

TSR Data Elements	XML Data Elements
Name	<condition>

Trial Design

TSR Data Elements	XML Data Elements
Type	<study_type>
Primary Purpose	<interventional_subtype>
Secondary Purpose	(Not included in the XML file)
Phase	<phase>
Interventional Study Model	<assignment>
Model Description	<model_description>
Number of Arms	<number_of_arms>
Masking	<no_masking> <masked_assessor> <masked_caregiver> <masked_investigator> <masked_subject>
Masking Description	<masking_description>
Allocation	<allocation>
Target Enrollment	<enrollment>

Eligibility Criteria

TSR Data Elements	XML Data Elements
Accepts Healthy Volunteers?	<healthy_volunteers>
Sex	<gender>
Gender Based	<gender_based>
Gender Eligibility Description	<gender_description>
Minimum Age	<minimum_age>
Maximum Age	<maximum_age>
Inclusion Criteria	<criteria>
Exclusion Criteria	<criteria>

Intervention(s)

TSR Data Elements	XML Data Elements
Type	<intervention_type>
Name	<intervention_name>
Alternate Name	(Not included in the XML file)
Description	<intervention_description>

Arm/Group(s)

TSR Data Elements	XML Data Elements
Type	<arm_type>
Label	<arm_group_label>
Description	<arm_group_description>

Primary and Secondary Outcome Measures

TSR Data Elements	XML Data Elements
Title	<outcome_measure>
Description	<outcome_description>
Time Frame	<outcome_time_frame>

Sub-groups Stratification Criteria

TSR Data Elements	XML Data Elements
Label	(Not included in the XML file)
Description	(Not included in the XML file)

Markers

TSR Data Elements	XML Data Elements
Marker Name	(Not included in the XML file)
Evaluation Type	(Not included in the XML file)
Assay Type	(Not included in the XML file)
Biomarker Use	(Not included in the XML file)
Biomarker Purpose	(Not included in the XML file)
Specimen Type	(Not included in the XML file)

Participating Sites

TSR Data Elements	XML Data Elements
PO ID	(Not included in the XML file)
Facility	<facility>
Contact	<contact>
Recruitment Status and Dates	<status>
Target Accrual	(Not included in the XML file)
Investigator(s)	<investigator>

Excerpts from Example TSR and Example XML File

The images below are excerpts from an example TSR:

Trial Summary Report

Date: 03/23/2015

Record Verification Date: 02/24/2015

Trial Identification	
Trial Category	Complete
Trial Type	Interventional
NCI Trial Identifier	NCI-2009-00533
Other Trial Identifiers	
Lead Organization Identifier	E2804
ClinicalTrials.gov Identifier	NCT00378703
DCP Identifier	No Data Available
CTEP Identifier	E2804
CCR Identifier	No Data Available
Other Identifier	ECOG-E2804
Other Identifier	CDR0000499788
Amendment Number	27
Amendment Date	01/08/2015

PRIMARY OBJECTIVES:

I. To assess progression-free survival on each arm of combination targeted therapy (CTT) compared to that of bevacizumab alone.

SECONDARY OBJECTIVES:

I. To assess the significance of changes in tumor size over early time points as a predictor of progression-free survival (PFS).

II. To quantify the number and percent of patients who have stable disease at 6 months of therapy (failure to progress) in each treatment arm of CTT in patients with metastatic renal cell carcinoma (RCC).

III. To evaluate the safety of each treatment arm of combination targeted therapy (CTT) in patients with metastatic RCC.

IV. To assess overall survival in each arm of the study.

V. To assess the objective response rate in each treatment arm of CTT in patients with metastatic RCC.

VI. To assess pathology, angiogenesis histology and to assess activation status of mitogen activated protein (MAP) kinase and vascular endothelial growth factor receptor 2 (VEGFR2) pathways and relate to clinical outcome.

Inclusion Criteria

- Patients will be required to have the clear cell variant of renal cell carcinoma with less than 25% of any other histology (including, but not limited to, papillary or chromophobe or oncocytic); there must be histologic confirmation by treating center of either primary or metastatic lesion
- Patients will be required to have measurable metastatic disease that is not curable by standard radiation therapy or surgery; all sites must be assessed within 4 weeks prior to study entry
- Previous nephrectomy is required with the following exceptions:
 - * Primary tumor \leq 5 cm, or
 - * Extensive liver ($>$ 30% of liver parenchymal) or multiple ($>$ 5) bone metastases, making nephrectomy a clinically questionable procedure
 - * Unresectable primary tumor due to invasion into adjacent organs or encasing the aorta or vena cava
- No prior cytotoxic chemotherapy; a maximum of one prior regimen of either vaccine or cytokine-based immunotherapy disease is permitted
- No prior anti-angiogenic therapy including, but not limited to, SU11248, ZD6474 or VEGF Trap; no prior therapy with bevacizumab, mammalian target of rapamycin (mTOR) inhibitors (including, but not limited to, temsirolimus), or sorafenib will be allowed; thalidomide or interferon alpha (IFNalpha) are allowed either for adjuvant therapy or stage IV disease

The images below are excerpts from an example XML file. XML files contain all abstracted data in code format that can be submitted to ClinicalTrials.gov for registration.

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1 <?xml version="1.0" encoding="UTF-8"?>
2 <clinical_study>
3   <study_type>Interventional</study_type>
4   <id_info>
5     <org_study_id>NCI-2009-00533</org_study_id>
6     <secondary_id>
7       <id>NCI-2009-00533</id>
8       <id_type>Registry Identifier</id_type>
9       <id_domain>CTRP (Clinical Trial Reporting Program)</id_domain>
10    </secondary_id>
11    <secondary_id>
12      <id>ECOG-E2804</id>
13    </secondary_id>
14    <secondary_id>
15      <id>CDR0000499788</id>
16    </secondary_id>
17    <secondary_id>
18      <id>E2804</id>
19      <id_type>Other Identifier</id_type>
20      <id_domain>ECOG-ACRIN Cancer Research Group</id_domain>
21    </secondary_id>
22
23   <textblock>PRIMARY OBJECTIVES:&#13;
24   I. To assess progression-free survival on each arm of combination targeted therapy (CTT) compared to that of bevacizumab alone.&#13;
25
26   SECONDARY OBJECTIVES:&#13;
27   I. To assess the significance of changes in tumor size over early time points as a predictor of progression-free survival (PFS).
28
29   II. To quantify the number and percent of patients who have stable disease at 6 months of therapy (failure to progress) in each treatment arm of combination targeted therapy (CTT) in patients with metastatic renal cell carcinoma (RCC).
30
31   III. To evaluate the safety of each treatment arm of combination targeted therapy (CTT) in patients with metastatic RCC.
32
33   IV. To assess overall survival in each arm of the study.
34
35   V. To assess the objective response rate in each treatment arm of CTT in patients with metastatic RCC.
36
37   VI. To assess pathology, angiogenesis histology and to assess activation status of mitogen activated protein (MAP) kinase and vascular endothelial growth factor receptor 2 (VEGFR2) pathways and relate to clinical outcome.
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78 I. To assess progression-free survival on each arm of combination targeted therapy (CTT) compared to that of bevacizumab alone.&#13;
79
80 SECONDARY OBJECTIVES:&#13;
81 I. To assess the significance of changes in tumor size over early time points as a predictor of progression-free survival (PFS).
82
83 II. To quantify the number and percent of patients who have stable disease at 6 months of therapy (failure to progress) in each treatment arm of combination targeted therapy (CTT) in patients with metastatic renal cell carcinoma (RCC).
84
85 III. To evaluate the safety of each treatment arm of combination targeted therapy (CTT) in patients with metastatic RCC.
86
87 IV. To assess overall survival in each arm of the study.
88
89 V. To assess the objective response rate in each treatment arm of CTT in patients with metastatic RCC.
90
91 VI. To assess pathology, angiogenesis histology and to assess activation status of mitogen activated protein (MAP) kinase and vascular endothelial growth factor receptor 2 (VEGFR2) pathways and relate to clinical outcome.
92
```

307 <eligibility>
308 <criteria>
309 <textblock>
310 Inclusion Criteria:
311 - Patients will be required to have the clear cell variant of renal cell carcinoma with less than 25% of any other histology (incl
chromophobe or oncocytic); there must be histologic confirmation by treating center of either primary or metastatic lesion
312 - Patients will be required to have measurable metastatic disease that is not curable by standard radiation therapy or surgery; al
prior to study entry
313 - Previous nephrectomy is required with the following exceptions:
314 * Primary tumor =< 5 cm, or
315 * Extensive liver (> 30% of liver parenchymal) or multiple (> 5) bone metastases, making nephrectomy a clinically questionab
316 * Unresectable primary tumor due to invasion into adjacent organs or encasing the aorta or vena cava
317 - No prior cytotoxic chemotherapy; a maximum of one prior regimen of either vaccine or cytokine-based immunotherapy disease is per
318 - No prior anti-angiogenic therapy including, but not limited to, SU11248, ZD6474 or VEGF Trap; no prior therapy with bevacizumab,
inhibitors (including, but not limited to, temsirolimus), or sorafenib will be allowed; thalidomide or interferon alpha (IFNalpha) a
stage IV disease
319 - No immunotherapy within 4 weeks of randomization; toxicities from immunotherapy must have resolved and a minimum of two weeks mu
320 - Prior radiation therapy is permitted, but toxicities from radiation must have resolved and a minimum of 2 weeks must pass prior
321 - No history or clinical evidence of central nervous system (CNS) disease, including primary brain tumor, seizures not controlled

Trial Types and Subtypes

Trial type refers to the nature of the investigation. The CTRP includes the following types:

- **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.
- **Non-Interventional.** 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.

The non-interventional category includes observational and ancillary/correlative studies:

- **Observational.** Studies among cancer patients and healthy populations that involve no interventions or alteration of the participants. Biomedical and/or health outcome(s) are assessed in pre-defined groups of participants. The participants in the study may receive diagnostic, therapeutic, or other interventions but the investigator of the observational study is not responsible for assigning specific interventions to the participants of the study.
- **Ancillary-Correlative.** A trial that is secondary to another trial, or a type of trial that tests for a relationship between a condition and a potential causal factor of the condition.
 - **Ancillary.** 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 must be linked to an active clinical research study and should include only patients accrued to that clinical research study. Report only those studies that can be linked to individual patient or participant data.
 - **Correlative.** Laboratory-based studies using specimens to assess cancer risk, clinical outcomes, response to therapies, etc. Report only those studies that can be linked to individual patient or participant data.