NCI CTRP Registration Site Help Topics

Topic Links

ⓘ **This page is simply a wiki shortcut.**

This page displays subject matter that is included, in context, in many of the web pages that constitute the CTRP application user's guides.

✅ You can send this page to a printer or convert it to a PDF, HTML, or Word document. Refer to Printing and Exporting Wiki Pages.

Getting Help

This page contains select topics that help you to understand and use the NCI CTRP Registration application. You can find more comprehensive documentation in the NCI CTRP Registration User Guide.

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.

Adding Sites

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 CTRP System Rules for Study Status and 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. _Warnings_ indicate that fixing the status record is optional; you do not have to resolve the transitions. However, _Errors_ 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.

Amending Trials

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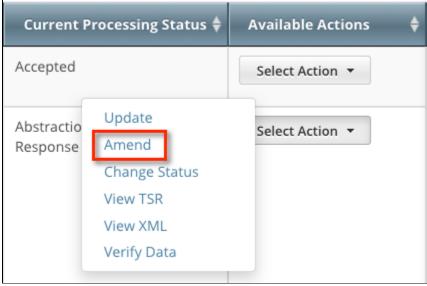
The following are examples of amendments that the Amend Trial feature accommodates.

- **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.

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.

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Converting Documents to PDF

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**.

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Displaying Trial Ownership
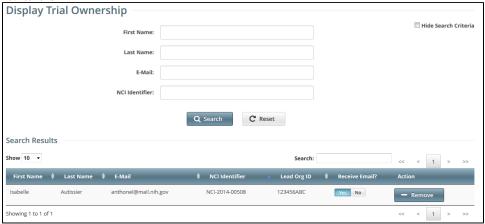
You can perform the following tasks on the trials you own:

- 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.

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.

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Editing Trial 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.

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Granting and Revoking Administrative Authority

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
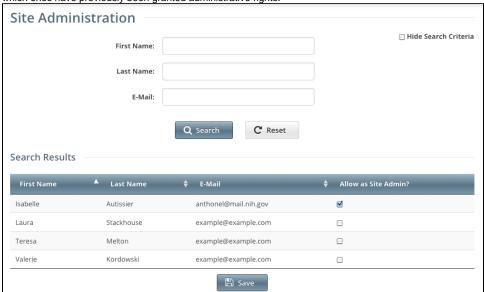 - Revoke own administrative rights

> ⚠ **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.

   ## Site Administration

First Name:	
Last Name:	
E-Mail:	

   ☐ Hide Search Criteria

   [🔍 Search] [↻ Reset]

   ### Search Results

First Name ▲	Last Name ⬍	E-Mail ⬍	Allow as Site Admin?
Isabelle	Autissier	anthonel@mail.nih.gov	☑
Laura	Stackhouse	example@example.com	☐
Teresa	Melton	example@example.com	☐
Valerie	Kordowski	example@example.com	☐

   [💾 Save]

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**.

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Managing Access to the Subject Accrual Application

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?	- 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	- 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?	- By trial - By organization - By organization family member 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.	- 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?	- 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	- All Abbreviated trials registered by the submitter's participating site only - Trials currently registered in CTRP - Trials that the organization registers in CTRP in the future, once abstracted

For instructions, refer to the following pages:
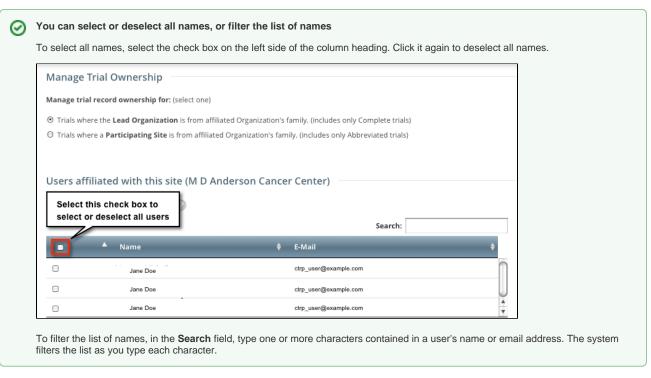
Return to top of page

Managing Participating Site Record Ownership

How to Assign and Unassign Trial Ownership

1. 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.

2. Under **Manage trial record ownership for**, select which role your affiliated organization or its family member organization(s) play(s).

> a. For Complete trials, select **Lead Organization**.
> b. For Abbreviated trials, select **Participating Site**.

3. 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: [   ]

☐	▲ Name	⬍ E-Mail	⬍
☐	Jane Doe	ctrp_user@example.com	
☐	Jane Doe	ctrp_user@example.com	
☐	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.

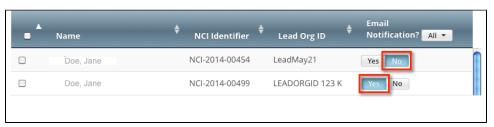4. In the list of trials at the bottom of the page, under **All Available Trials**, or **All Available Abbreviated Trials**, select the trials to assign to the user (s), and then click the Assign icon (**>**).

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: [ ]			
☐	▲ NCI Identifier	⬍ Lead Org ID	⬍
☐	NCI-2014-00454	LeadMay21	
☐	NCI-2014-00499	LEADORGID 123 K	

Showing 1 to 2 of 2 entries

Assign [>]

Unassign [<]

❓	Trial Owner Assignments			
				Search: [ ]
☐	▲ Name	⬍ NCI Identifier	⬍ Lead Org ID	⬍ Email Notification? All ▾
☐	National Cancer Institute, xxxx	NCI-2014-00454	LeadMay21	Yes No
☐	Jane Doe	NCI-2014-00454	LeadMay21	Yes No
☐	Jane Doe	NCI-2014-00499	LEADORGID 123 K	Yes No

Showing 1 to 3 of 3 entries

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5. To unassign trials, under **Trial Ownership Assignments**, or **Site Owner Assignments**, select the user(s) you want to unassign, and click the Unassign icon (**<**).
6. 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? All ▾
☐	Doe, Jane	NCI-2014-00454	LeadMay21	Yes **No**
☐	Doe, Jane	NCI-2014-00499	LEADORGID 123 K	**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.

Managing Program Codes and Targeted Accrual

This section describes how to:

- Manage the set of program codes and program code assignments for the organization family. Most of this section provides instructions for that task.
- Manage targeted accrual, the total number of participants expected to accrue at all of the sites within your organization family participating on a study. For instructions, refer to Managing Targeted Accrual.
- Specify the Center Principal Investigator for a trial. For instructions, refer to Specifying the Center Principal Investigator.
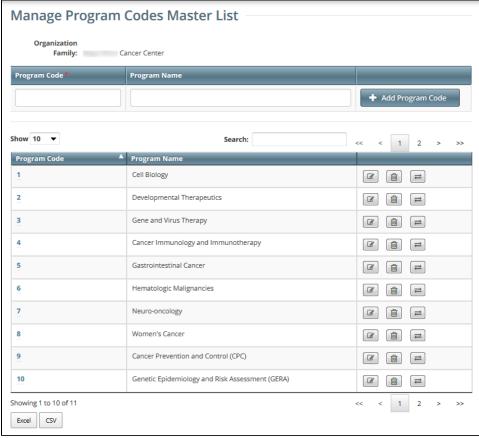- Specify the local trial ID for a trial. For instructions, refer to Managing Local Trial IDs.

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:

Using the Manage Program Codes Master List Page

Viewing Program Codes

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

Manage Program Codes Master List

Organization
Family: ▭▭▭▭ Cancer Center

Program Code *	Program Name	
		+ Add Program Code

Show 10 ▼　　　　　　　　　　　Search: [ ]　　<< < **1** 2 > >>

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

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Excel　CSV

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

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.
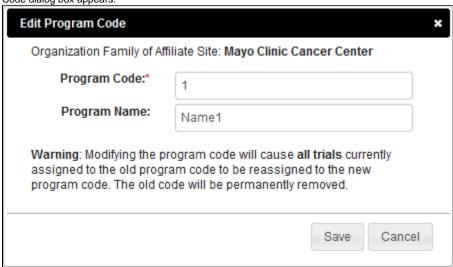
Program Code *	Program Name	
		+ Add Program Code

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 ✕

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

Program Code:*   1

Program Name: Name1

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.

Save   Cancel

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

1. 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.
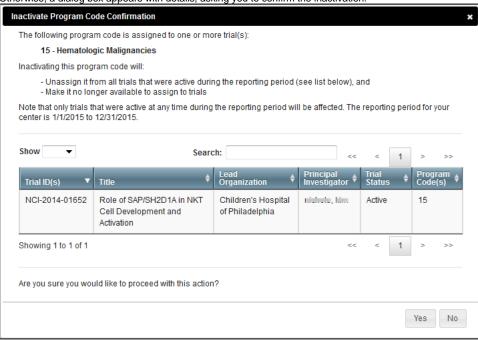
Confirm Delete ✕

The following program code is not assigned to any trial, and will be permanently deleted:

   3 - Immunobiology

Please confirm.

Delete   Cancel

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

Inactivate Program Code Confirmation   ✕

The following program code is assigned to one or more trial(s):

15 - Hematologic Malignancies

Inactivating this program code will:

- Unassign it from all trials that were active during the reporting period (see list below), and
- Make it no longer available to assign to trials

Note that only trials that were active at any time during the reporting period will be affected. The reporting period for your center is 1/1/2015 to 12/31/2015.

Show ▼   Search: [   ]   << < 1 > >>

Trial ID(s) ▼	Title	Lead Organization	Principal Investigator	Trial Status	Program Code(s)
NCI-2014-01652	Role of SAP/SH2D1A in NKT Cell Development and Activation	Children's Hospital of Philadelphia	mchele, law	Active	15

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

Are you sure you would like to proceed with this action?

[Yes] [No]

2. 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.
    - 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.
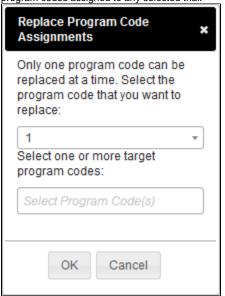
You can navigate through the list of trials just like any other list of search results in the CTRP Registration application. For instructions, refer to Working with Tables and Search Results. On the **Manage Program Code Assignments** page, in the **Search** box, if you include the search term in double quote marks (for example "cancer"), the search results include trials that have an exact match in any of the first five columns.

Using the Manage DT4 Information for Your Center Page

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.

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.

Assign Program Codes ✖

Please select program code(s) to assign to the select trial(s):

| Select Program Code(s) |

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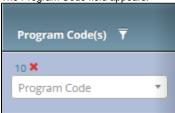
3. In the list, select one or more target program codes.
4. Click **OK**. The Program Code(s) column reflects your changes.

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.
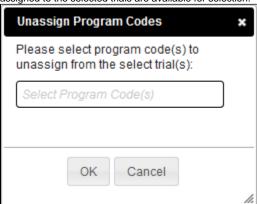

The Program Code field appears.

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 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.

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.

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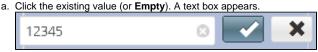
2. When you are done viewing the list of participating sites, click **Close**.

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.

   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.

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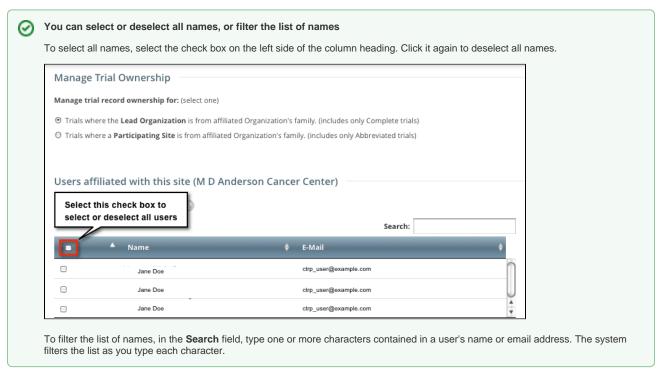
The system does not use the Local Trial ID column to generate the Data Table 4 Report. Field values will not be copied into the Center Local Trial ID field (in Registration) of the Data Table 4 report. For instructions on generating that report, refer to Running CTRP Data Table 4 Reports.
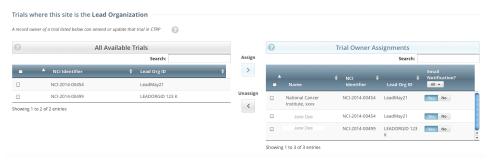
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Managing Trial Ownership

How to Assign and Unassign Trial Ownership

1. 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.

2. Under **Manage trial record ownership for**, select which role your affiliated organization or its family member organization(s) play(s).
   a. For Complete trials, select **Lead Organization**.
   b. For Abbreviated trials, select **Participating Site**.
3. 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.

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.

---

4. 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 (**>**).

5. To unassign trials, under **Trial Ownership Assignments**, or **Site Owner Assignments**, select the user(s) you want to unassign, and click the Unassign icon (**<**).
6. 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**.

- 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.

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Managing Your Account

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.

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Registering 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.

ℹ️ 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.

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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	In the various fields, specify information as appropriate according to the detailed instructions provided for each of the following sections: a. Recording Trial Identification Information b. Recording Trial Details c. Recording Lead Organizations and Principal Investigators 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	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. 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.
Review Trial	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. The Review Trial Details page is read-only. To make changes to the trial data, follow the instructions in Editing Trial Details.
Cancel	Click to cancel the registration. A pop-up message prompts you to confirm cancellation.

⚠️

> ⚠ If you choose to cancel the registration, you will lose all data that you may have entered.

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.
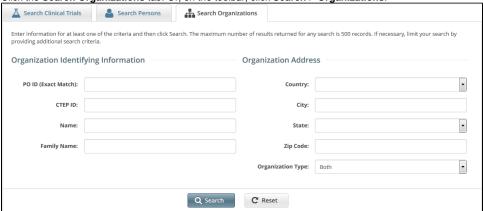
Searching for Organization Records

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**.

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.
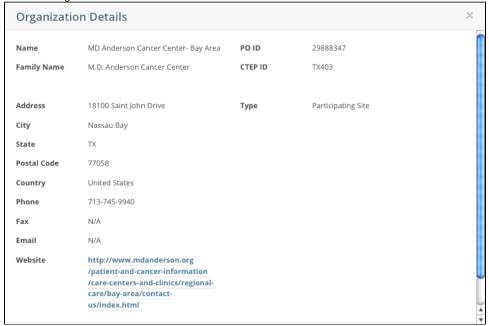

> ✓ **Tip**
>
> If the organization you are searching for is not listed, you may have searched too narrowly (that is, you may have provided too much information about the organization). If the list of results is very long and contains many organizations that are similar to the one you are searching for,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

4. 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.
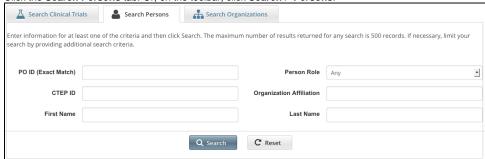

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Searching for Person Records

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**.

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.
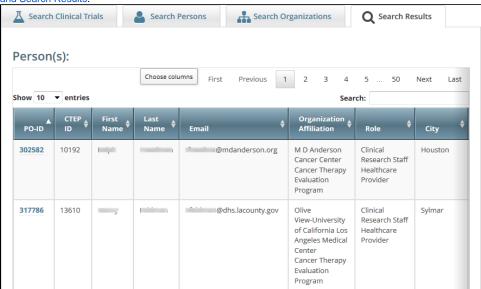
   ✅ **Using wildcard characters (%)**

   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.
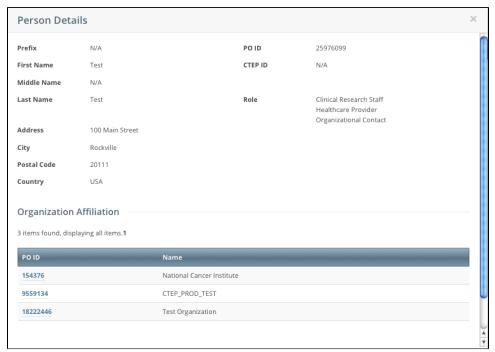

   ✅ **Tip**

   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.

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

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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.
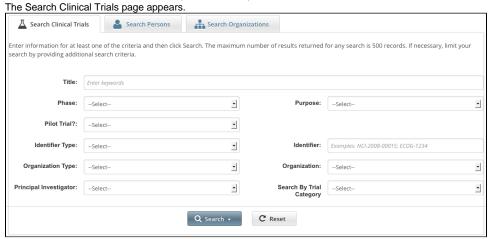
| Search Option	Search All Trials	Search My Trials	Search Saved Drafts
Types of Trials Returned	All trials	• Trials you own that are on hold • Trials you own, including those conducted at an affiliated site.	Partial Submissions
Actions Permitted	• View Trial Details • Add/Update My Site (Abbreviated trials only) • Verify Trials (for trials you submitted but may not own) ⓘ The results of this search may include a subset of trials that you own or submitted.	• View Trial Details • Update Trials • Amend Trials • Request TSR/XML • Change Status • Add/Update My Site (Abbreviated trials only) • Verify Trials	• View Trial Details • Complete Submissions • Add/Update My Site (Abbreviated trials only)
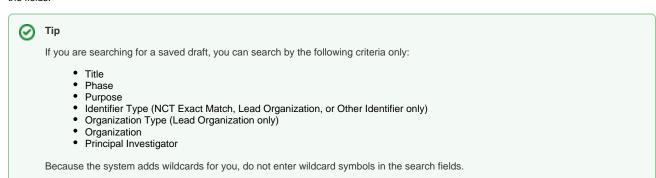
ⓘ All registered users can search trials with the "Accepted" and subsequent processing status. Additionally, you can search for trials that you own that have not been validated. These trials are indicated by the "Submitted" status. See Trial Processing Statuses for information about statuses that occur 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	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). > ✓ **Avoid specifying the entire title in the search field** > 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.
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?	To narrow the search by this trial attribute, specify whether the trial is a pilot trial. - 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	To narrow the search by both identifier and the type of trial identifier, specify both. Valid identifier types are as follows: - **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 *exact* 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.

	The **Identifier Type** field is optional, even when specifying an identifier.
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.
Organizat ion Type	To narrow the search by both organization and organization type, specify both. Valid organization types are as follows: • **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 ⊘ You can change the Organization Type without affecting any other search criteria you may have selected previously.
Organizat ion	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. ⊘ 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.
Principal Investigat or	To narrow the search by this trial attribute, specify the Look Up Person. 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**.
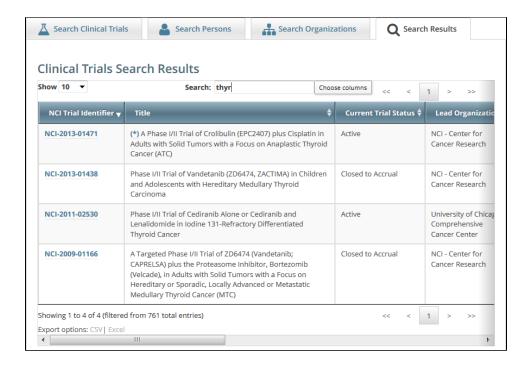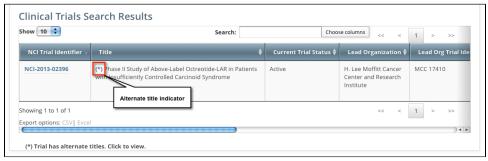
     ⊘ **Allow sufficient time for the system to conduct your search before you run your search again**

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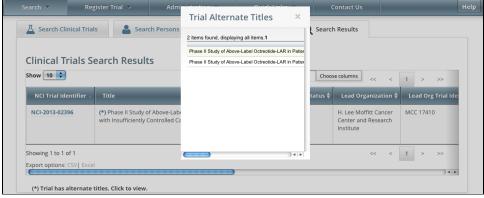
Trials may have more than one title. For example, the CTRO staffs may add an alternate title if they find a misspelling in the registered title. Any trial identified by more than one title is identified in the search results table by an asterisk (*) in the Title column.

5. 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.

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.

6. 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:

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Trial Status Rules for Start and Completion 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
- In Review - Approved - Withdrawn - Active - Enrolling by Invitation	Can be Actual or Anticipated.	Can be Actual or Anticipated.	Must be Anticipated.
- 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.
- 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.

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Updating Trials

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.

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.

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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
> - 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.
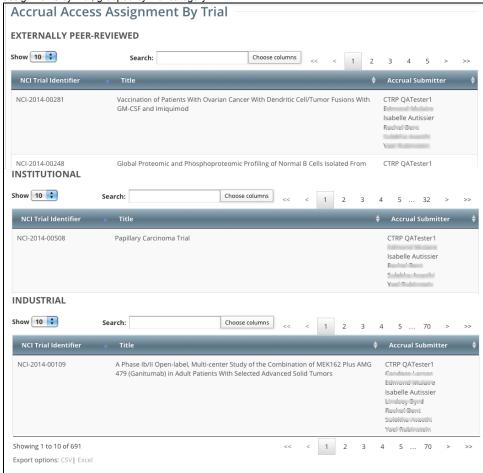
For additional instructions, refer to the following pages:

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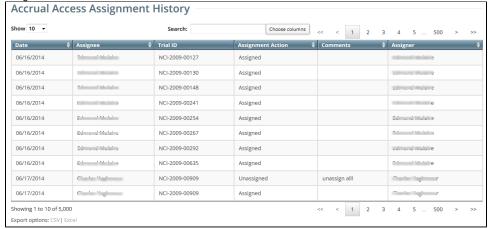
2. To navigate the table, refer to Working with Tables and Search Results.
3. To export the assignment history to a file, click **CSV** (comma-separated values) or **Excel** in the bottom left corner. Your browser prompts you to open or save the file.

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Viewing Accrual Assignment History in Registration

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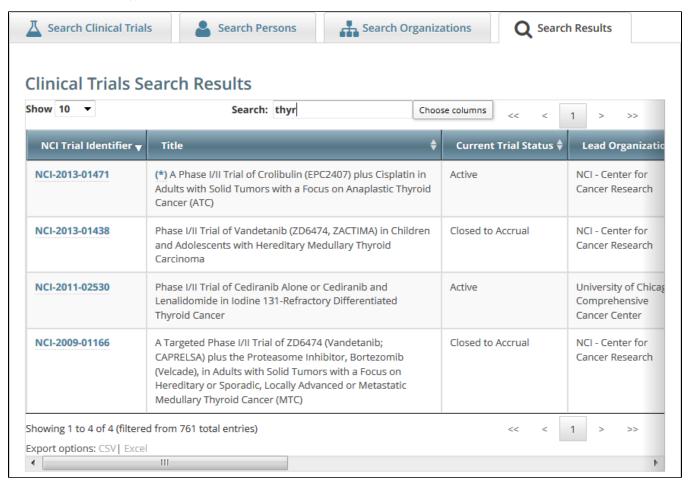
2. To navigate the table, refer to Working with Tables and Search Results.
3. To export the assignment history to a file, click **CSV** (comma-separated values) or **Excel** in the bottom left corner. Your browser prompts you to open or save the file.

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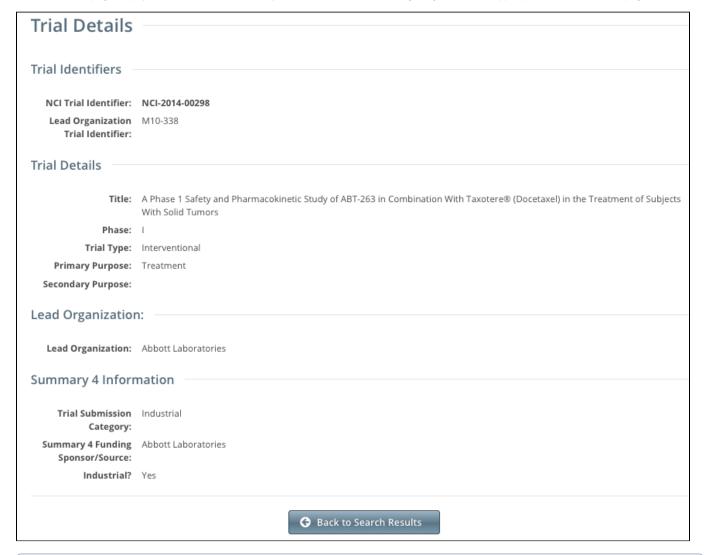
The Submitted Clinical Trials Search Results table lists the trials that match your search criteria, as well as additional criteria. For information on that additional criteria, refer to Types of Trials Included in Trial Search Results.

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 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.**

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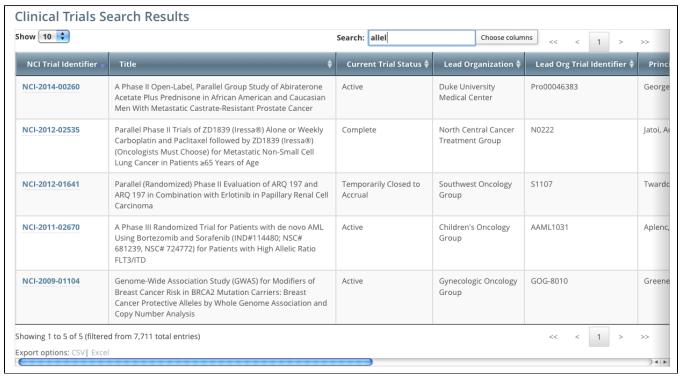
The search results table lists the trials that match your search criteria, as well as the following criteria:

- 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: [allel] [Choose columns]   << < 1 > >>

NCI Trial Identifier	Title	Current Trial Status	Lead Organization	Lead Org Trial Identifier	Princi
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, A
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	Twardc
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	Aplenc,
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.

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