NCI Clinical Trials Reporting Program (CTRP) User's Guides

NCI Clinical Trials Reporting Program (CTRP) User's Guides

User's Guides for the CTRP Registry and the CTRP Accrual Web Applications

- NCI CTRP Registration User's Guide
- NCI CTRP Accrual User's Guide

User's Guides for CTRP Web Applications Used Internally

- NCI CTRP Protocol Abstraction User's Guide
- NCI CTRP Person and Organization Curation User's Guide
- NCI CTRP Reports Reference Guides

⚠ The CTRP Protocol Abstraction User's Guide, CTRP Person and Organization Curation User's Guide, and CTRP Reports Reference Guides are designed for internal users. You must be logged in to access these guides.

User's Guides for the CTRP Registration and the CTRP Accrual Web Applications

User's Guides for the CTRP Registration and the CTRP Accrual Web Applications

- NCI CTRP Registration User's Guide v4.3
- NCI CTRP Accrual User's Guide v4.3

NCI CTRP Registration User's Guide v4.3

NCI CTRP Registration User's Guide v4.3

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- Audience
- Navigating Registration
- Application Support

> ⊘ **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 the Application Support section below.

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.

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.

Navigating Registration

Using the Toolbar

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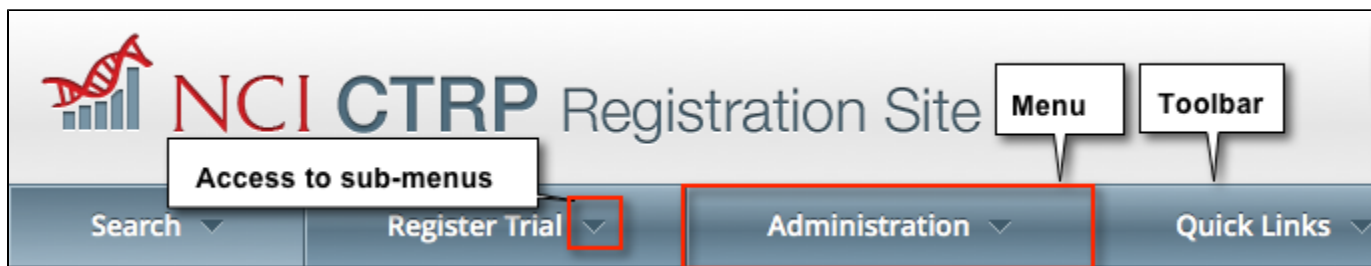
Your name appears on the upper right corner of the page and the associated arrow provides access to the My Account page.

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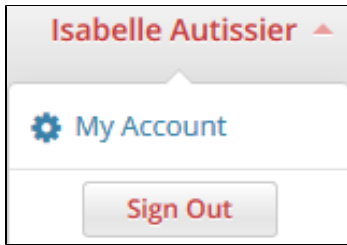
Getting Help

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

Hover your cursor over the Help icon next to it.
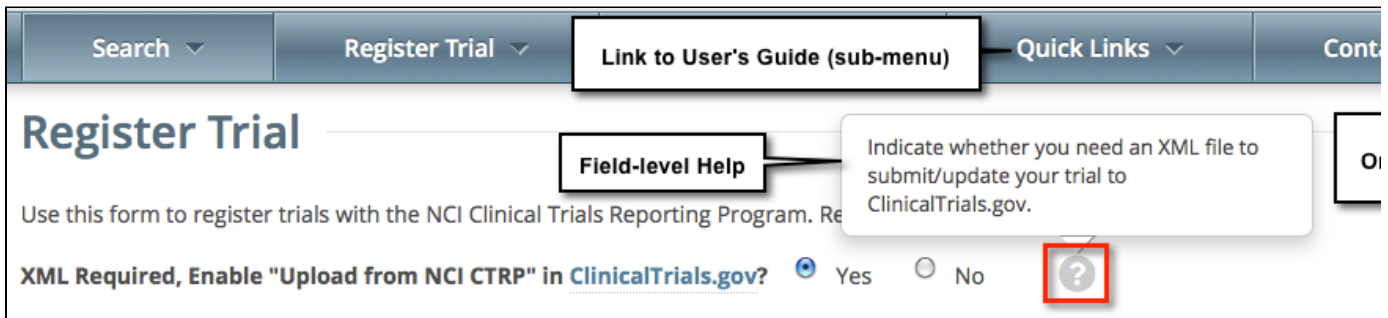
Online Help provides instruction/information for the topic you are working on.

How to Launch Online Help

Below your name on the toolbar, click **Help**.
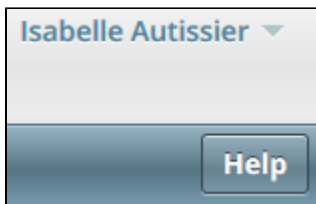
How to access the User's Guide

On the toolbar, click **Quick Links > Registration User's Guide**.

Changing the Color Scheme

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

How to Change the Color Scheme

1. On the top right corner of any page, click **(User Name) > My Account**.
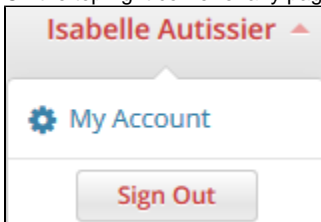
2. Scroll to the bottom of the **My Account** window and select one of the five color schemes.
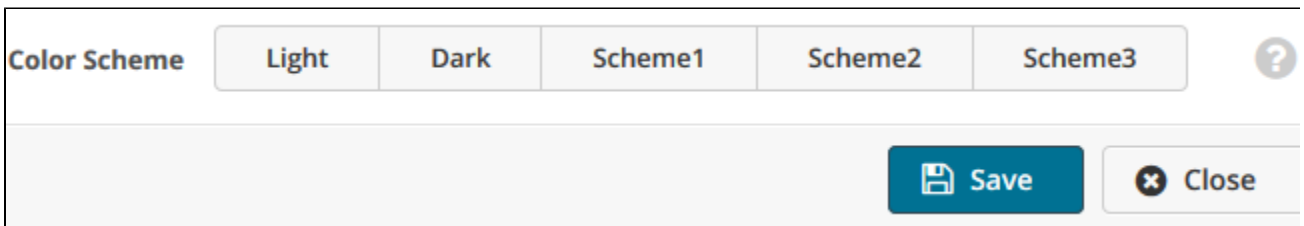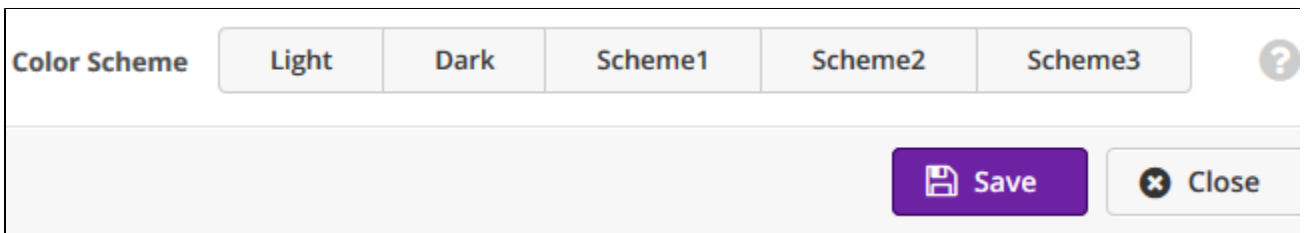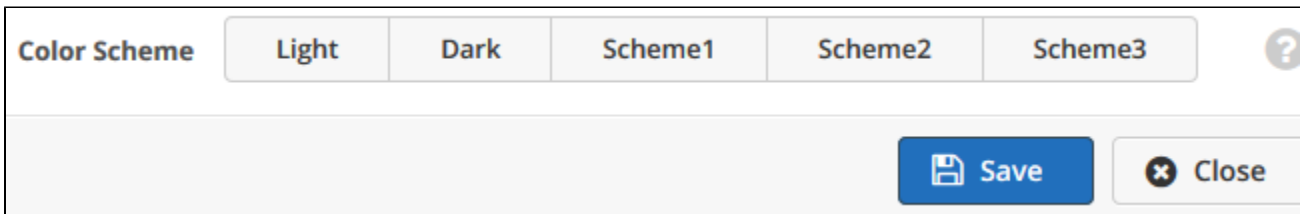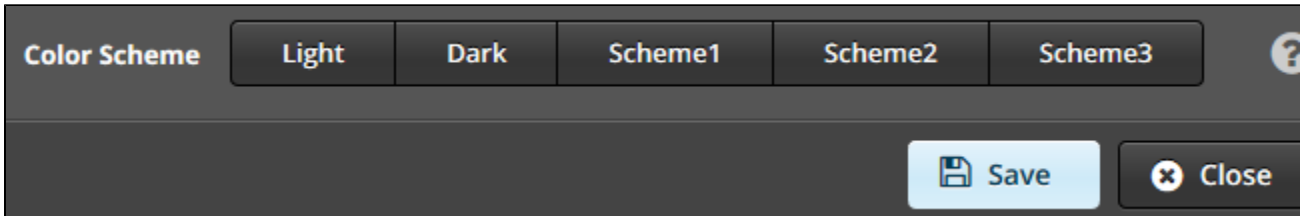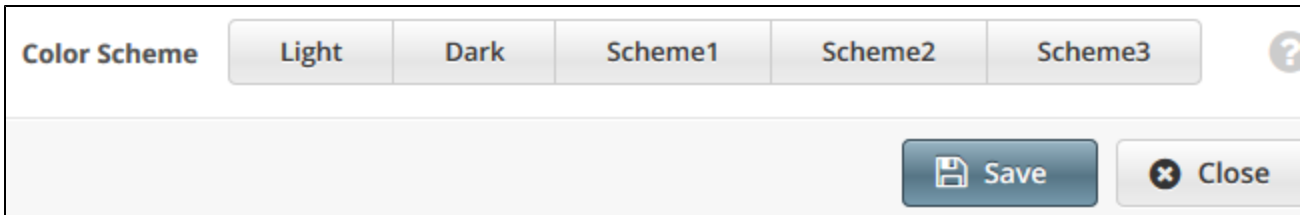
3. Click **Save**.

Application Support

- Email: ncicbiit@mail.nih.gov
- Call: 240-276-5541

When submitting support requests, please include:

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

Contacting the Clinical Trials Reporting Office

If you have questions or comments regarding this document, or other CTRP topics, contact the Clinical Trials Reporting Office (CTRO) at ncictro @mail.nih.gov.

Contents - NCI CTRP Registration User's Guide v4.3

Contents - NCI CTRP Registration User's Guide v4.3
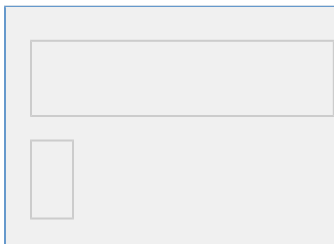
Opening Linked Pages

- To op en the top ic in thi s tab , cli ck the rel ev ant top ic lin k.

  - or -

- To op en the top ic in a ne w tab , rig ht- cli ck the top ic lin k an d the n cli

ck **Open Link in New Tab**.

Getting Started with Registration v4.3

Topic Links
• About Registration
• About Clinical Trial Details
• What's New in this Release of Registration
• Typical Life Cycle of a Trial
• Role-Based Tasks in Registration
• Trial Categories (Study Sources)
• Creating CTRP Accounts
• Creating New CTRP Accounts via Email
• Creating New CTRP Accounts Using NIH or NCI Credentials
• Requesting Organization Admin Rights
• Managing Registration Email Notifications

ⓘ **Tested Browsers**
- This version of the Registration and Accrual applications have been tested on Internet Explorer v10.
- This version of the Protocol Abstraction application and the Person and Organization Curation application have been tested on Internet Explorer v10 and the latest version of Firefox.

CTRP should work with all recent browsers. However, please note that it has been tested only on the browsers listed. If you discover a browser related issue in a non-tested browser, please submit it to Application Support at ncicbiit@mail.nih.gov. Please include your browser version, OS version, and, when possible, a screen shot illustrating the difficulty.

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

About Registration

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 or in batches consisting of multiple trials, 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.

About Clinical Trial Details

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).

What's New in this Release of Registration

This version of the CTRP Trial Registration application has the following new features and improvements:

Issue Type	Development #	Documentation #	Description	Link to Content in this User's Guide	Comments
Bug	PO-9266	NA	Unable to Submit Amendment for NCI-2011-02028 in CTRP application	NA	NA
Bug	PO-9198	NA	Re: CTRO#45527: Trial update notification for NCI-2014-02556	NA	NA
Bug	PO-9182	NA	Add Site in Registry: blank entries followed by "java.lang.NullPointerException".	NA	NA
Bug	PO-9116	NA	Major: CCC Wake Forest University submitter unable to save P30 grant information (EW#43395)	NA	NA
Improvement	PO-9106	NA	Update Study Protocols REST Service to support additional trial identifiers	NA	NA
Improvement	PO-9100	PO-9181	Allow user to specify any organization in Family as participating site at time of importing Industrial Trial	• Registering Abbreviated (Industrial and Other) Trials • Using the Add My Site Feature	NA
Improvement	PO-9087	NA	Improve performance of Update Trial screen in Registry for trials with many sites, which was hurt significantly by recent Program Code changes	NA	NA
Improvement	PO-9072	PO-9224	Add "NA" as a type for Primary Completion Date	NA	The only documentation changes for this issue were in the PA User's Guide.
Bug	PO-9055	NA	It shall not open Registry links if account setup is not done in CTRP	NA	NA
Task	PO-9042	PO-9119	Add Z1A to Funding Mechanism LOV for PA and Registry	Trial Registration Funding Mechanism Codes v4.3	NA
Improvement	PO-9003	PO-9117	Add TR as a valid value for NIH Institution Code when adding/editing grants in Registry and PA	NIH Grant Institute Codes v4.3	Also refer to Institute or Center (IC) section of Glossary of NIH Terms.
Task	NA	PO-8990	Add details to the Registry Users Guide to show typical lifecycle of trials in CTRP	Typical Life Cycle of a Trial	NA

| Bug	PO-8971	NA	Registry User administration privilege breach	NA	NA
Task	PO-8968	PO-9119	Addition to "Trial Funding" tab in CTRP	Trial Registration Funding Mechanism Codes v4.3	NA
New Feature	NA	PO-8951	CTRP 4.3 Documentation	(Refer to other links in this column.)	NA
Bug	PO-8934	NA	Registry: Registering a trial gives HTTP 500 error if Cancel is selected in Look up Person	NA	NA
Improvement	PO-8815	PO-8955	Restrict updating the Delayed Posting Indicator to the CTRO staff only	Registering New Trials v4.3	In Registering New Trials v4.3, refer to the Recording Regulatory Information section.
Improvement	PO-8814	NA	Eliminate MailManager in Registry and refactor to use MailManagerBeanLocal.	NA	NA
Bug	PO-8798	PO-9322	Inconsistent use of terms "Institute" and "Institution" in GRANT and IND/IDE sections of PA and Registration UI	• Abstracting INDs and IDEs • Abstracting Funding	NA
Improvement	PO-8732	NA	Improve the search performance when the user searches for trials with a specific participating site (Registration)	NA	NA
Epic	PO-8330	PO-9053	Improvements to Industrial/Other trials	NA	The only documentation changes for this issue were in the PA User's Guide.
Bug	PO-8028	NA	NCT ID can be imported into CTRP more than once if import button hit multiple times quickly	NA	NA

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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. If appropriate, the system also sends an Abstracted XML file of the trial. (XML documents are available for trials that have been designated for import into ClinicalTrials.gov.) 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 diagram illustrates the typical life cycle of a trial and the relationship between actions and processing statuses:

CTRP Trial Processing Life Cycle
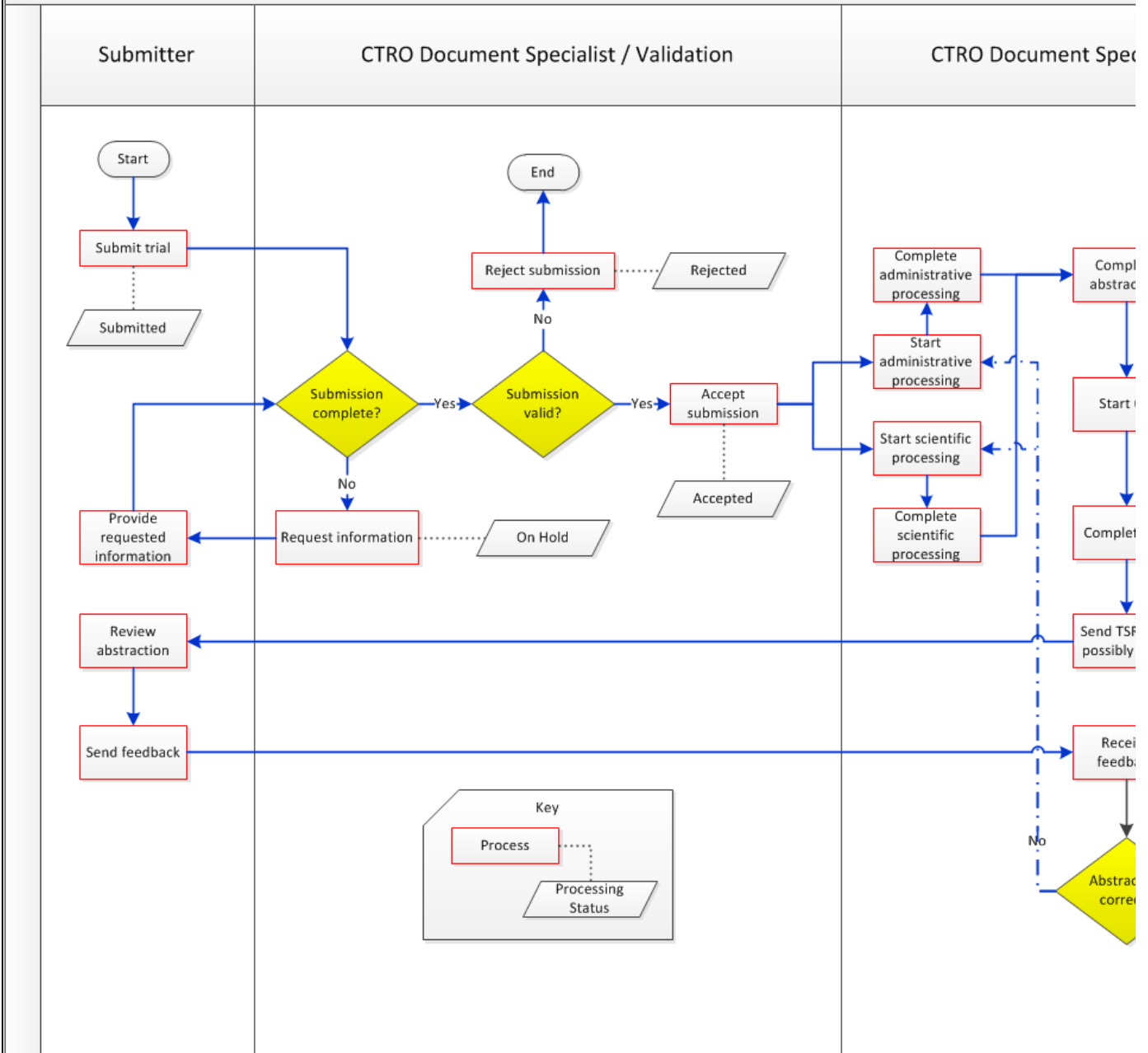
For more information, refer to Trial Processing Statuses and Amendment Process Life Cycle.

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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 • 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 Administrator's organization's or family member organization's trials.
Display Trial Ownership	No	Yes For any trial owned by 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.
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

Trial Categories (Study Sources)

Trials are categorized by type of Data Table 4 Funding Sponsorship or Trial Submission Category. Refer to http://cancercenters.cancer.gov/GrantsFunding/DataGuide#dt4 for further information.

- **Complete Trials**:
    - **National**: NCI National Clinical Trials Network (NCTN) and other NIH-supported National Trial Networks.
    - **Externally Peer-Reviewed**: R01s, SPORES, 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.

Creating CTRP Accounts

Although you already have an NIH (or NCI) account, you must register for an associated CTRP account. The CTRP account identifies your organization affiliation, whether or not you own a particular trial record, and other such details. You can create both types of accounts using Registration's account creation feature, in one of two ways, as follows:

- If you are a new user AND you *do not have* an NIH/NCI account, request one via Registration. Follow the instructions in Creating New CTRP Accounts via Email .
- If you are a new user AND you *have* an NIH/NCI account, use your current credentials to register for a CTRP account via Registration. Follow the instructions in Creating New CTRP Accounts Using NIH or NCI Credentials .

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

Additionally, you can request authorization from the CTRO to use the batch upload feature to register, update, and amend multiple new trials conducted at a given site. Follow the instructions in Registering Multiple Trials .
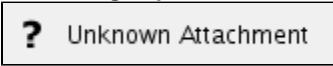
Return to top of page

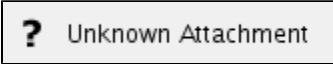**Creating New CTRP Accounts via Email**

If you are new to Registration and you do not have an NCI account, request a CTRP account via the Registration account creation feature.
How to Create a New CTRP Account

1. Navigate to the CTRP Registration home page at http://trials.nci.nih.gov/registration.
2. Click the **Sign Up** tab.

   ❓ Unknown Attachment

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.

   ❓ Unknown Attachment

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 `None` in the **Zip Code** field.
Organization Affiliation*	Click **Look Up** and select the appropriate organization from the list of search results. If your trial's affiliated organization is not listed, you can register it in the system at this point. To search for and register an organization, follow the instructions in Looking up Registered Organizations. > ⓘ 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).
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://prsinfo.clinicaltrials.gov/prs_organizations.html. > ⚠ **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.

Receive Email Notifications	Select this check box if you want the CTRP system to send you an email message whenever some aspect of a trial you have submitted or own has changed.
Submit	Click to register your information with CTRP. The system sends you an account confirmation email message.

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 NCI CBIIT Application Support directly by sending an email to ncicbiit@mail.nih.gov or by calling 888-478-4423.
>
> (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.)
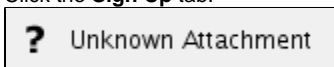
5. Open the account information email when it arrives, and click the embedded link to the **My Account** page.

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Creating New CTRP Accounts Using NIH or NCI Credentials

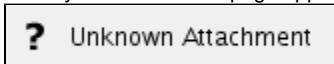### How to Create a New CTRP Account Using NIH Credentials

1. Navigate to the CTRP Registration home page at http://trials.nci.nih.gov/registration.
2. Click the **Sign Up** tab.

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3. Because you already have an NIH account, click the **here** link.
   The Sign Up tab displays username and password fields.

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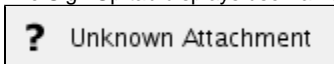
4. Enter your username and password, and then click **Next**.
   The My Account Profile page appears, pre-populated automatically with all the information associated with your NIH/NCI account.

? Unknown Attachment

5. 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 *None* in the **Zip Code** field.
Organization Affiliation	Click **Look Up** and select the appropriate organization from the list of search results. If your trial's affiliated organization is not listed, you can register it in the system at this point. To search for and register an organization, follow the instructions in Looking up Registered Organizations. > ⓘ 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).
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://prsinfo.clinicaltrials.gov/prs_organizations.html.
	⚠ **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.
Receive Email Notifications	Select this check box if you want the CTRP system to send you an email message whenever some aspect of a trial you have submitted or own has changed.
Submit	Click to register your information with CTRP. The system sends you an account confirmation email message.

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 your organization's trials to other registered users within your organization
- **Accrual Access** - Assign and unassign access to Accrual to registered users within your organization

ⓘ **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. On the top right corner of any page, click **Your Username > My Account**.
   The My Account page displays all of your Registration account information.
2. Select the **Request for Admin Access** check box.

Managing Registration Email Notifications

The Registration system automatically sends you an email message whenever some aspect of a trial you have submitted or own has changed. For example, the system notifies you when the CTRO has accepted a trial that you submitted. It sends 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. On the top right corner of any page, click **Your Username > My Account**.
   The My Account page displays all of your Registration account information.
2. To receive all system messages, select the **Receive Email Notifications** radio button.
3. To opt out, clear the radio button.

Searching for Trials, Organizations, and Persons in the CTRP System v4.3

Searching for Trials, Organizations, and Persons in the CTRP System v4.3

This section 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. This section also provides instructions for reviewing trial-related documents and downloading Trial Summary Reports (TSRs) and XML documents.

Searching for Trials

You can retrieve existing trial records once you have registered for an account. See Creating CTRP Accounts.

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. See Working with Search Results for rules that determine which trial details are displayed.

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, search by **Phase**, **Purpose**, or **Title** only. Because the system adds wildcards for you, do not enter wildcard symbols in the search fields.

Trial Search Criteria

To search by this...	Do this...
Title	Enter one or more words from the long title or name of the trial provided by the principal investigator or sponsor.
	✅ **Avoid copying and pasting, or typing the entire title into 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	Select the trial phase from the drop-down menu. Valid values are as follows: • **0** - Exploratory trials, involving very limited human exposure, with no therapeutic or diagnostic intent (e.g., screening studies, micro dose studies). See FDA guidance on exploratory IND studies for more information. • **I** - Includes initial studies to determine the metabolism and pharmacologic actions of a medical approach in humans, the side effects associated with increasing doses or exposure, and to gain early evidence of effectiveness; may include healthy participants and/or patients. • **I/II** - Includes trials that are a combination of phases I and II. • **II** - Includes controlled clinical studies conducted to evaluate the effectiveness of the medical approach for a particular indication or indications in patients with the disease or condition under study and to determine the common short-term side effects and risks. • **II/III** - Trials that are a combination of phases II and III. • **III** - Includes expanded controlled and uncontrolled trials after preliminary evidence suggesting effectiveness of the medical approach has been obtained, and are intended to gather additional information to evaluate the overall benefit-risk relationship of the drug and provide an adequate basis for physician labeling. • **IV** - Studies of FDA-approved drugs, interventions, tests or diagnostic procedures to delineate additional information including the medical approach risks, benefits, and optimal use. • **NA** (Not applicable) - All non-interventional or pilot studies.
Pilot Trial?	If the trial is a pilot, select **Yes**.
Purpose	Select the primary purpose of the trial from the drop-down list. Valid values are as follows: • **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. • **Other**. Any purpose not described above.
Identifier Type	Select the type of trial identifier from the drop-down list. Valid values are as follows: • **NCI** - NIH National Cancer Institute identifier • **ClinicalTrials.gov (ClinicalTrials.gov Identifier)** - Provide the *exact* number, including the ClinicalTrials.gov Identifier prefix. Example: NCT00012345 • **Lead Organization** - Enter 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 > ✓ **Selecting a Trial Identifier Type is not required** > You can enter an identifier in the **Identifier** field without first having to choose an Identifier Type.
Identifier	Enter the unique identifier assigned to the trial by the NCI, ClinicalTrials.gov, PRS, or the identifier assigned to it by the lead organization. For Inter-Group trials, enter the Lead Group's trial number.
Organization Type	Select one of the following organization roles from the drop-down list: • **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.

Organization	ⓘ The system suggests organizations as you type.
	Enter the initial letter(s) of the organization and then 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 Investigator	ⓘ The system suggests names as you type.
	Enter the initial letter(s) of the principal investigator's last name and then select the investigator name from the list of suggestions.
Search by Trial Category	To restrict your search by trial category, select *Abbreviated* or *Complete* from the drop-down list. Otherwise, select **Both**.

3. Click **Search.**
   The Search menu options are displayed.
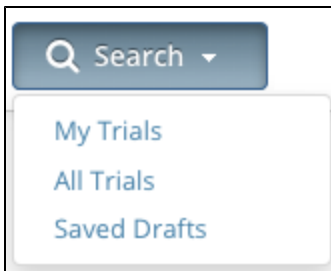
4. Do one of the following:
   - To search all registered trials in the system, click **All Trials**.
     -or-
   - To search only the trials that you submitted or own, click **My Trials**. This feature enables access to all the trials that you have submitted, including those that are currently on hold. (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.

Clinical Trials Search Results

Show 10 ▼   Search: thyr| Choose colu

NCI Trial Identifier ▼	Title	Cu
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)	Activ
NCI-2013-01438	Phase I/II Trial of Vandetanib (ZD6474, ZACTIMA) in Children and Adolescents with Hereditary Medullary Thyroid Carcinoma	Clos
NCI-2011-02530	Phase I/II Trial of Cediranib Alone or Cediranib and Lenalidomide in Iodine 131-Refractory Differentiated Thyroid Cancer	Activ
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)	Clos

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

Export options: CSV | Excel

Clinical Trials Search Results

Show 10 ▲▼   Search: Choose colu

NCI Trial Identifier ▼	Title	Current Trial Status ▲	Le
NCI-2013-02396	(*) Phase II Study of Above-Label Octreotide-LAR in Patients with Insufficiently Controlled Carcinoid Syndrome	Active	H. L Cen Inst

Alternate title indicator

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.

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. See Viewing Trial Details.

Return to top of page

Searching for Organizations

You can search for organizations that are currently registered with the Clinical Trials Reporting Program 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

> ⊘ You can use this search feature to identify organizations when you use the batch upload template to register multiple trials simultaneously.

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.

PO-ID	CTEP ID	Name	Family Name	City	
24827	AK001	Anchorage Medical and Surgical Clinic		Anchorage	A
24856	AK002	Providence Alaska Medical Center		Anchorage	A
24885	AK003	Anchorage Radiation Therapy Center		Anchorage	A

> ⊘ **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.

Organization Details

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 Persons

You can search for persons that are currently registered with the Clinical Trials Reporting Program.

> ⊘ You can use this search feature to identify persons when you use the batch upload template to register multiple trials simultaneously.

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.

Person(s):

PO-ID	CTEP ID	First Name	Last Name	Email	Organization Affiliation
302582	10192	▓	▓	▓@mdanderson.org	M D Anderson Cancer Center Cancer Therapy Evaluation Program
317786	13610	▓	▓	▓@dhs.lacounty.gov	Olive View-University of California Los Angeles Medical Center Cancer Therapy Evaluation Program

Choose columns   First   Previous   1   2   3   4

Show 10 entries   Sea

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

> ⊘ **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.

Return to top of page

Clinical Trial Search Results

The Clinical Trials Reporting Office (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/abstraction process:

- 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.

The trials that match your search criteria are listed in search results tables. Which of the search results are displayed is determined by the following criteria:

- Processing status of the trial at the time of the search. Trial statuses are listed and defined in Trial Processing Statuses.
  - **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 not displayed.
  - **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

- **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.)

Clinical Trials Search Results

Show 10 ◆   Search: allel   Choos

NCI Trial Identifier ▾	Title	Current Trial Status ◆	Lead Organiza
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
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 Ca Treatment Group
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 Oncol Group
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 Oncol Group
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 Onc Group

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

Export options: CSV | Excel

To navigate the search results table, see Working with Tables and 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.

ⓘ No data are displayed for Private trials with a processing status of Rejected nor for Public trials with a processing status of Submitted or Rejected.

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

Column	Displayed for Public trials?	Description
NCI Trial Identifier	Yes	Unique identifier assigned to the trial by the CTRP

Title	Yes	Official name of the protocol provided by the study principal investigator or sponsor (same as in the protocol document)
Lead Organization	Yes	Organization responsible for the overall scientific and administrative coordination, study monitoring, and data management activities of a given clinical trial
Lead Org (Organization) Trial Identifier	Yes	Unique identification assigned to the protocol 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	Appointed investigator responsible for conducting the clinical trial, or, for multi-site trials, the study chair
ClinicalTrials.gov Identifier	Yes	Number assigned to the trial by PRS (ClinicalTrials.gov) (for trials that have been submitted to ClinicalTrials.gov previously)
Other Identifiers	Yes	Identifiers other than Lead Organization Trial Identifier or ClinicalTrials.gov Identifier
Current Trial Status	Yes	Code that represents the status of a trial in relation to the ability to enroll participants/patients
Current (Trial) Processing Status	No	Stage in the trial processing work flow
Available Actions	Yes	Actions that are applicable to the trial according to the processing rules • Update - Link used to initiate trial updates • Amend - Link used to initiate trial amendments. Available for trials with processing statuses abstraction verified (response/no response). • Change Status - Link used to initiate a change to the trial status and status dates • Add My Site - Link used to initiate adding an organization as a participating site • Update My Site - Link available to Participating Site Record owners to initiate participating site information changes • Request TSR and XML documents (for complete trials) - Documents are sent via email to all trial owners • Verify Trial Data - Link used to verify open trial records twice per year to ensure that information is accurate and up-to-date ⚠ The actions available for a trial depend on its processing status and participating site record ownership.
Accrual Disease Terminology	No	The disease terminology currently in use for accruals. 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.
(Participating) Sites	Yes	One or more organizations participating in the trial. Click **View** in the **Sites** column to view participating site details.
Phase	No	Phase of the investigation, as defined by the US FDA for trials involving investigational new drug
Primary Purpose	No	Main purpose of the trial
Category	No	Data Table 4 Funding Sponsorship or Trial Submission Category
Trial Start Date	No	Date on which the trial starts
Responsible Party	No	Responsible party, as defined by FDAAA
Sponsor	No	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	Trial category selected for trial submission
Record Verification Date	No	Date on which the CTRO validated the trial submission
Submitter	No	Name of person who submitted the trial

Primary Completion Date	No	Date on which the trial reaches/reached its primary completion date
Last Update Submitted	No	Date on which the trial was last updated
Last Updater Name	No	Name of the person who last updated the trial
Last Amendment Submitted	No	Date on which the trial was last amended
Last Amender Name	No	Name of person who amended the trial
On-Hold Reason	No	Reason why the trial was placed on hold

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	Unique identifier that the system assigned to the saved draft
Title	Official name of the protocol provided by the study principal investigator or sponsor (same as in the protocol document)
Lead Organization	Organization responsible for the overall scientific and administrative coordination, study monitoring, and data management activities of a given clinical trial
Lead Organization Trial Identifier	Unique identification assigned to the protocol by the sponsoring organization. Multiple studies conducted under the same grant must each have a unique number
Action	- 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.

Return to top of page

Viewing Trial Details

Trials you search for are listed in the Submitted Clinical Trials Search Results table as shown below.

Clinical Trials Search Results

	Search Clinical Trials		Search Persons		Search Organizations	Q

Show 10 ▼   Search: thyr| Choose columns   <<

NCI Trial Identifier ▼	Title	↕	Current Trial St
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-2013-01438	Phase I/II Trial of Vandetanib (ZD6474, ZACTIMA) in Children and Adolescents with Hereditary Medullary Thyroid Carcinoma		Closed to Accrual
NCI-2011-02530	Phase I/II Trial of Cediranib Alone or Cediranib and Lenalidomide in Iodine 131-Refractory Differentiated Thyroid Cancer		Active
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

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

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 trial ownership (private or public) and Data Table 4 Category (*Complete* or *Abbreviated*).

The Trial Details page displays the metadata as entered by a trial submitter. The upper part of the Trial Details page is shown below. Refer to the Glossary of CTRP Terms for a description of the metadata.

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 Tre 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

ⓘ   Responsible party, IND/IDE, NIH grant information and trial-related documents are only displayed for Private trials.

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

Return to top of page

Exporting Search Results

You can export the results from any search you conduct in a format suitable for 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.xsl** file
   A download pop-up dialog box appears.
3. Follow your browser/operating system instructions to view or save the document.

Return to top of page

Registering New Trials v4.3

Registering New Trials v4.3

This section describes how to register new *National*, *Externally Peer-Reviewed* and *Institutional* trials (collectively referred to as *Complete* trials) in the CTRP system, and 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 CBIIT Application Support at ncicbiit@mail.nih.gov , or phone: 240-276-5541 or toll free: 888-478-4423. If you have forgotten your password, see Resetting Your NCI Password .

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.

Guidelines for Complete Trials

If your trial is *Complete*, follow the instructions in Registering New Complete Trials.

- Cancer Center trials must meet the following criteria to be eligible for registration:
    - 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:
    - If NCI-managed, trials must have been active as of January 1, 2009 or any time thereafter.
    - If NCI-sponsored, trials either must have been *Completed* as of December 2007 or opened anytime thereafter).

    ⚠ Cancer Centers do not register PIO-managed trials. These trials are submitted to CTRP directly by CTEP and DCP.

Guidelines for Abbreviated Trials

If your trial is *Abbreviated*, registration differs according to a combination of the following trial attributes:

- 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

Guidelines for Trials with NCT IDs

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.

- If your organization is not an NCI-designated Cancer Center, NIH institute, or pharmaceutical company, you will need to import the trial directly from ClinicalTrials.gov. Instructions for this process can be found under Registering Abbreviated (Industrial and Other) Trials.

ⓘ The system assigns the trial you import from ClinicalTrials.gov the Data Table 4 Category (funding source) *Industrial/Other*. To specify whether the trial is *Industrial*, or to specify if an *Other* trial is *National* or *Externally Peer-Reviewed*, contact the CTRO for assistance at ncictro@mail.nih.gov. For funding source definitions, see http://cancercenters.cancer.gov/GrantsFunding/DataGuide#dt4.

- If your organization is the Lead Organization on a trial, and your organization is an NCI-designated Cancer Center, do not import the trial from ClinicalTrials.gov. Instead, submit the trial to CTRP as a Complete trial, as described in Registering New Complete Trials.
- If your organization is the Lead Organization for any trial on anything other than an NCI-designated Cancer Center, NIH institute, or pharmaceutical company trial, the CTRO contacts the Center and further categorizes the trial as *Other/National* or *Other/Externally Peer-Reviewed* based on whether your trial is conducted under an NIH grant, as follows:
    - If your trial is conducted under an NCI grant, the CTRO categorizes it as a *Consortia* trial.
    - If your trial is not conducted under an NCI grant, the CTRO categorizes it as follows:
        - *Other/National,* for trials sponsored by an NIH institute
        - *Other/Externally Peer-Reviewed*, for trials managed by a hospital or a center other than one designated by the NCI

Guideline for Trials without NCT IDs

If your trial is *Abbreviated* but does **not** have an NCT ID, please contact the CTRO for assistance at ncictro@mail.nih.gov. CTRO registers these trials manually.

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Registering New Complete Trials

ⓘ Before you begin to register a trial, ensure that the trial does not exist in the system already by searching for trials using any of the criteria as per the instructions in Searching for Trials . The system uses the Lead Organization ID, Lead Organization Trial ID, and the ClinicalTrials.gov Identifier to detect duplicates. If a duplicate is detected, the system will not record your trial.

How to Register New Complete Trials

1. 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**.

   ✓ 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 http://cancercenters.cancer.gov/GrantsFunding/DataGuide#dt4.
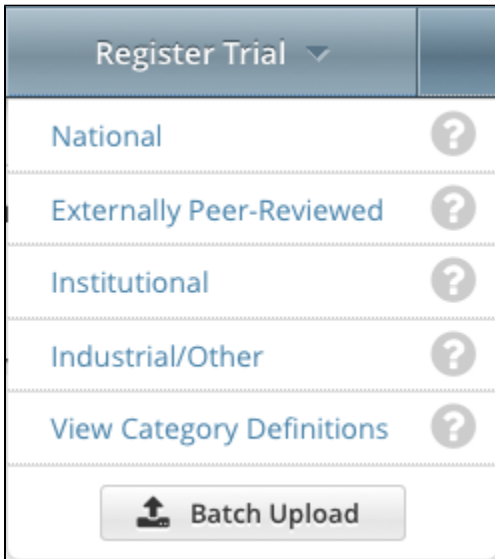
The Register Trial page appears.

Register Trial

Use this form to register trials with the NCI Clinical Trials Reporting Program. Required fields are marked

XML Required, Enable "Upload from NCI CTRP" in ClinicalTrials.gov? ◉ Yes ○ No

⊖ Collapse All

Trial Identifiers*

Lead Organization Trial Identifier:* [   ] ❓

30 characters left

ClinicalTrials.gov Identifier: [   ] ❓

Other Identifiers

Other Trial Identifier [   ] ➕ Add Oth

The system can create an XML document that is formatted to facilitate trial registration with ClinicalTrials.gov. The document it creates contains all the information that you submit during registration and all the trial data abstracted by the CTRO. If you indicate that you do not need to register the trial with ClinicalTrials.gov, you will not be asked to provide regulatory and responsible party information.

> ✅ **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**.
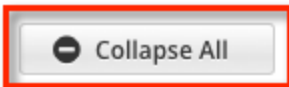
Register Trial

Use this form to register trials with the NCI Clinical Trials Reporting Program. Required fields are marked

XML Required, Enable "Upload from NCI CTRP" in ClinicalTrials.gov? ● Yes ○ No

[−] Collapse All — **Click to collapse all sections**

Trial Identifiers*

Click to collapse this se

Lead Organization Trial Identifier:* [   ] ❓

30 characters left

ClinicalTrials.gov Identifier: [   ] ❓

Register Trial

Use this form to register trials with the NCI Clinical Trials Reporting Program. Required fields are marked

XML Required, Enable "Upload from NCI CTRP" in ClinicalTrials.gov? ● Yes ○ No

⊕ Expand All ← Click to expand all sections

Trial Identifiers*   Click to expand this sec

Other Identifiers

Trial Details*

Lead Organization/Principal Investigator*

Sponsor/Responsible Party*

Summary 4 Information*

NIH Grant Information (for NIH funded Trials)*

Status/Dates*

FDA IND/IDE Information for applicable trials

Regulatory Information *

Trial Related Documents *

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

⊘ **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. Later you can return to complete the registration in another session.

Instructions for registering Complete *trials*

XML required. Enable "Upload from NCI CTRP" in ClinicalTrials.gov?	If you require an XML document to register your trial with ClinicalTrials.gov, select **Yes**. If you are not going to submit your trial to ClinicalTrials.gov, select **No**. The option you select here dictates which sections you will be required to complete. For example, if you select **No**, you will not be required to complete responsible party and regulatory information. If you select **Yes**, NCI will be added as a collaborator to the Funding Source.

Various	Select or enter the appropriate information in the text fields and drop-down lists as appropriate according to the detailed instructions provided for each of the following sections:
	
	   a. Recording Trial Identification Information
	   b. Recording Interventional Trial Details
	   c. Recording Non-interventional Trial Details
	   d. Recording Lead Organizations and Principal Investigators
	   e. Recording Sponsors and Responsible Parties
	   f. Recording Data Table 4 Information
	   g. Recording NIH Grants
	   h. Recording Trial Statuses
	   i. Recording Trial Dates
	   j. Recording INDs and IDEs
	   k. Recording Regulatory Information
	   l. Recording 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 Recording Interventional Trial Details and Recording Non-Interventional 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.

3. Correct any errors if indicated, and repeat the previous steps as many times as necessary until the trial is error-free.
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

1. Indicate whether or not you require an XML document for registration with ClinicalTrials.gov. The default is **Yes**. If you select **No**, you will not be asked to provide regulatory and responsible party information.
2. 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	If the trial has been submitted to ClinicalTrials.gov previously, enter the number assigned to the trial by PRS (ClinicalTrials.gov). ⚠ The CTRP renamed the previous identifiers "NCT Number" and "NCT ID" to "ClinicalTrials.gov Identifier". ⚠ 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. ⓘ 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.
Other Trial Identifier	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 *Other Identifier* list. To delete an identifier you have added, in the **Action Column**, click **Delete**.

Recording Interventional Trial Details

How to Complete the Trial Details 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 Interventional Trial Details

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. The following list provides valid values. • **0** - Exploratory trials, involving very limited human exposure, with no therapeutic or diagnostic intent (e.g., screening studies, micro dose studies). See FDA guidance on exploratory IND studies for more information. • **I** - Includes initial studies to determine the metabolism and pharmacologic actions of a medical approach in humans, the side effects associated with increasing doses or exposure, and to gain early evidence of effectiveness; may include healthy participants and/or patients. • **I/II** - Includes trials that are a combination of phases I and II. • **II** - Includes controlled clinical studies conducted to evaluate the effectiveness of the medical approach for a particular indication or indications in patients with the disease or condition under study and to determine the common short-term side effects and risks. • **II/III** - Trials that are a combination of phases II and III. • **III** - Includes expanded controlled and uncontrolled trials after preliminary evidence suggesting effectiveness of the medical approach has been obtained, and are intended to gather additional information to evaluate the overall benefit-risk relationship of the drug and provide an adequate basis for physician labeling. • **IV** - Studies of FDA-approved drugs, interventions, tests or diagnostic procedures to delineate additional information including the medical approach risks, benefits, and optimal use. • **NA** (Not applicable) - All non-interventional or pilot studies.
Is this a Pilot?* ⓘ This field is displayed only if you selected **NA** from the **Phase** drop-down list.	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. **Interventional** is the default.
Primary Purpose*	1. Select the primary reason for conducting the trial. The following list provides valid values. • **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. • **Other**. Any purpose not described above. 2. Optionally, if the primary purpose is **Other**, type a detailed description of the trial's purpose in the text field provided. ⓘ 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.

Secondary Purpose	1. Select one of the following reasons for conducting the trial.
	
	• **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.
	• **Other**. Any purpose other than Ancillary-Correlative.
	
	2. If the secondary purpose is **Other**, enter a detailed description of the trial's purpose in the text field provided.

Accrual Disease Terminology*	Click to select the disease terminology used to report subject accruals for this trial.

Recording Non-Interventional Trial Details

How to Complete the Trial Details Section

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.

Instructions for recording Trial Details

Field Label	Description/Instructions
Title*	Enter the official name of the protocol provided by the study principal investigator or sponsor. 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. The following list provides valid values. ⓘ Select **N/A** for observational and ancillary-correlative trials. • **0** - Exploratory trials, involving very limited human exposure, with no therapeutic or diagnostic intent (e.g., screening studies, micro dose studies). See FDA guidance on exploratory IND studies for more information. • **I** - Includes initial studies to determine the metabolism and pharmacologic actions of a medical approach in humans, the side effects associated with increasing doses or exposure, and to gain early evidence of effectiveness; may include healthy participants and/or patients. • **I/II** - Includes trials that are a combination of phases I and II. • **II** - Includes controlled clinical studies conducted to evaluate the effectiveness of the medical approach for a particular indication or indications in patients with the disease or condition under study and to determine the common short-term side effects and risks. • **II/III** - Trials that are a combination of phases II and III. • **III** - Includes expanded controlled and uncontrolled trials after preliminary evidence suggesting effectiveness of the medical approach has been obtained, and are intended to gather additional information to evaluate the overall benefit-risk relationship of the drug and provide an adequate basis for physician labeling. • **IV** - Studies of FDA-approved drugs, interventions, tests or diagnostic procedures to delineate additional information including the medical approach risks, benefits, and optimal use. • **NA** (Not applicable) - All non-interventional or pilot studies.
Is this a Pilot?* ⓘ This field is displayed only if you selected **NA** from the **Phase** drop-down list.	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. **Non-Interventional** is selected by default.

Non-Interventional Trial Type*	Select one of the following trial types:
	
	• **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.

Primary Purpose*	1. Select the primary reason for conducting the trial. The following list provides valid values. • **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. • **Other**. Any purpose not described above. 2. If none of the values is appropriate, select **Other**, and then enter the same Non-Interventional Study Type you selected earlier, either *Observational* or *Ancillary -Correlative* , in the text field. ⓘ 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.
Study Model Code*	1. Select the primary strategy for subject identification and follow-up. The following list provides valid values. • **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 2. If the study model is **Other**, type a detailed description of the trial's study model in the text field provided. ⓘ The text field is displayed only after you have selected Other.
Time Perspective Code*	1. Select the temporal relationship of observation period to time of subject enrollment. The following list provides valid values. • **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 2. If the time perspective is **Other**, type a detailed description of the trial's time perspective in the text field provided. ⓘ 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.
Site Principal Investigator*	Click **Look Up Person** and search for the principal investigator. See 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 Organizatio

Principal Investigator:*

Sponsor/Responsible Party*

Sponsor * Please Select the Sponsor Organiz

Responsible Party:* --Select--

How to Complete the Lead Organization/Principal Investigator Section

1. 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:*

Current User's Affiliated Organization ID

Principal Investigator:*

Please Select the Lead Organ

PO ID	CTEP ID	Name
129345	244600	M D Ar
129374	74097525	MD An
9200000	544612	M D Ar
18478	79966622	M D Ar
227400	244689	M D Ar
129345	244600	M D Ar
29888347	119380965	MD An
70797	74253034	UF Can
16984721	74353788	U.T.M.I
227050	74191123	MD An
213790	423638	M D Ar

Sponsor/Responsible Party*

Sponsor *

Responsible Party:*

Click to search for other organizations

Search...

Summary 4 Information*

2. 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 .
   a. If the search does not return your trial's lead organization, you can register it in the system at this point. To register an organization, follow the instructions in Adding Organizations to the CTRP.
3. Next to **Principal Investigator** click **Look Up Person**, and search for the principal investigator as per the instructions in Looking Up Registered Persons.
   a. If your trial's principal investigator's name is not listed, you can register it in the system at this point. To register an investigator, follow the instructions in Adding Persons to the CTRP.

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Recording Sponsors and Responsible Parties

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

⊘ The system will not display this section unless you indicate that you require an XML document.

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, see http://prsinfo.clinicaltrials.gov/Elaborations OnDefinitions.pdf.

You must complete all fields in the Sponsor/Responsible Party section. The fields displayed depend on your selection of the Responsible Party role, as shown in the images below.

If you select **Sponsor** (above), you do not submit any further information about the Responsible Party.

If you select **Principal Investigator** (above), 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.

Lead Organization/Principal Investigator*

Lead Organization:* **MD Anderson Cancer Center- Bay**

Principal Investigator:* A▮▮▮▮,Isabelle

Sponsor/Responsible Party*

Sponsor * **National Cancer Institute**

Responsible Party:* Sponsor-Investigator

Investigator:* T▮▮▮▮,Pam

Investigator Title:* Principal Investigator

Investigator Affiliation:* National Cancer Institute

If you select **Sponsor-Investigator** (above), 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.

> ⊘ Before you begin, complete the Lead Organization/Principal Investigator section. Doing so will ensure that the Sponsor/Responsible party section is pre-populated when applicable.

How to Complete 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. All fields in this section are required.

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: 1. **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. 2. **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. 3. **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.

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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 an NCI-designated cancer center.

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. See Looking Up Registered Organizations. (If your trial's funding sponsor is not listed, you can register it in the system at this point. To register an organization, see Adding Organizations to the CTRP.)

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

> ⓘ 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.
4. In the **Program Code** field, enter the code that includes the study.

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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 member of an NCI-Designated Cancer Center, you must record a valid P30 grant.

For a complete guide to NIH grant information, see 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	Enter the initial letter(s) and or number(s) in the Funding Mechanism field and then select the NIH unique identifier f⎯ activity applied to funding mechanisms. ✅ **Tip** Click the down arrow in the field, and then use the up and down arrow keys on your keyboard to scroll up ar⎯ For a list of valid codes, see Funding Mechanism Codes.
Institute Code	Select the two-letter code identifying the first major-level subdivision, the organization that supports an NIH grant, c⎯ For a list of valid codes, see NIH Grant Institute Codes .
Serial Number	Enter the five- or six-digit number generally assigned sequentially to a series within an Institute, Center, or Division, ⎯ match the sequence of serial numbers as you type them one-by-one. By selecting a grant from the list, you ensure t⎯ **Institute Code** **Serial Number** CA 123 123099 - UNIVERSITY OF TENNESS⎯ Metastasis; TIFFANY SEAGROVES 123649 - UNIVERSITY OF CALIFORI⎯ Mark Lim 123660 - NORTHWESTERN UNIVER⎯ elect-- CISZEK
NCI Division/Program Code	Enter the initial letter(s) of the division or program code, and then select the code for the organizational unit that pro⎯ For a list of Division and Program codes, see NCI Division and Program Codes .

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**.

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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 trials used in CTRP are mapped to ClinicalTrials.gov-defined recruitment values. ClinicalTrials.gov status definitions are provided in Trial Status Values in the CTRP and ClinicalTrials.gov.

⚠ **Errors and Warnings**
The system validates each new status as you add it, as well as when you review the trial information before submitting the trial for registration.

If you add a status that does not conform to the rules provided in Trial Status Transitions , the system displays errors and/or warnings. *Warnings* indicate that fixing the record is optional. However, *Errors* indicate that you must correct an invalid transition in order to submit the trial for registration.

If you register a trial after it has reached the status *Active* or *Closed to Accrual*, you must create a complete Trial Status History by adding all previous statuses in order, as per the rules provided in Trial Status Transitions.

How to Complete the Trial Status 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.

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. Valid values are as follows: • **In Review** - Trial is currently under IRB review. • **Withdrawn** - Trial has been withdrawn from development and review prior to enrollment of the first participant. • **Approved** - Trial has been approved, but is not yet recruiting or enrolling participants. • **Active** - Trial is open for accrual and enrollment. • **Enrolling by Invitation** - Participants are being (or will be) selected from a predetermined population. • **Temporarily Closed to Accrual** - Participant recruitment or enrollment has been halted prematurely but may resume. Participants already on trial continue to receive intervention. • **Temporarily Closed to Accrual and Intervention** - Participant recruitment or enrollment has been halted prematurely but may resume. Participants already on trial do not receive intervention. • **Closed to Accrual** - Trial has been closed to participant accrual, but trial is ongoing (i.e., participants continue to receive treatment and/or examination). • **Closed to Accrual and Intervention** - Trial has been closed to participant accrual. Participants already on trial do not receive treatment, but continue to be monitored for endpoints such as long-term survival. • **Administratively Complete** - Participant recruitment or enrollment has been halted prematurely (for example, due to poor accrual, insufficient drug supply, IND closure, etc.), and will not resume. Participants already on the trial do not receive further treatment or examination. • **Complete** - 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.
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.

Status Date ❓	Status ❓	Why Study Stoppe
mm/dd/yyyy 📅	--Select-- ▾ *Participants are being (or will be) selected from a predetermined population.*	 *Administratively Com* *Closed statuses only*

Please refer to the **Trial Status Transition Rules.**

Trial Status History

Show 10 ▾ entries

Status Date	Status	Comments
12/01/2014	Enrolling by Invitation	

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 ✖

Status Date:*	02/03/2015 📅
Status:*	Enrolling by Invitation ▾
Why Study Stopped:	
	1000 characters left *Administratively Complete, Withdrawn and* *Temporarily Closed statuses only*
Comment:*	
	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.

ⓘ If a *Complete* trial reaches any of the statuses below, the system closes the trial at all participating sites, and sets their trial statuses to match those of the trial that closed.

   - Closed to Accrual
   - Closed to Accrual and Intervention
   - Administratively Complete
   - Complete

The system displays the following warning if you enter any of the statuses above:

The trial has open sites

⚠ Since you are closing the trial, all open sites will be closed as well as a result. For your information, below is a list of currently open sites that will be affected by this operation.

Show 10 ⬦ entries

PO ID ▲	Name ▼	Status ▼	Status Date
9772429	Virginia Commonwealth University/Massey Cancer Center	Enrolling by Invitation	05/06/201

Showing 1 to 1 of 1 entries   Previous 1 Ne

Proceed   Ca

Trial Status Transitions

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

Trial Status Flow Relationships

A trial can proceed from this status…	Directly to this status	Or to this status
In Review	• Approved • Withdrawn	Active/Enrolling by Invitation ⓘ This can occur when the trial has been Approved and is Active/Enrolling by Invitation on the same day
Approved	• Active/Enrolling by Invitation • Withdrawn	NA
Active/Enrolling by Invitation	Closed to Accrual	• 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	• Completed • Administratively Completed	NA
Temporarily Closed to Accrual	Temporarily Closed to Accrual and Intervention	• Active/Enrolling by Invitation • Closed to Accrual • Closed to Accrual and Intervention • Administratively Completed
Temporarily Closed to Accrual and Intervention	Administratively Completed	• 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

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Recording Trial Dates

The Trial Dates section captures start, primary completion, and completion dates as they occur according to the rules specified in Start, Primary Completion, and Completion Date Rules.

How to Complete the Trial Dates Section

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

Valid trials used in CTRP are mapped to ClinicalTrials.gov-defined recruitment values. ClinicalTrials.gov status definitions are provided in Trial Status Values in the CTRP and ClinicalTrials.gov.

Start, Primary Completion, and Completion Date Rules

Valid dates for a given trial status depend on the other values you have entered, and whether those dates are *Actual* (current, or past) or *Anticipated* (future).

The following diagram illustrates these rules. The arrow at the top of the diagram represents a time line for the life of a trial. The three horizontal bands in the lower section of the diagram represent, from top to bottom, the relative date (actual or anticipated) rules for trial Start Date types, Primary Completion Date types, and Completion Date types.

The following table provides the rules for trial status dates as diagrammed.

Rules for Status/Dates relationships

If this is true...	Follow this rule
Current Trial Status is anything *other than* In Review, Approved, or Withdrawn	Trial Start Date must be Actual (solid band)
Current Trial Status is Approved or In Review	Trial Start Date could be Actual or Anticipated (diagonal stripes band)
Current Trial Status is Complete	All date types must be Actual (solid band)

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
- The Primary Completion Date can be earlier than the Current Trial Status Dates *Complete* or *Administratively Complete* if the Primary Completion Date is *Actual*
- The Completion Date is always the same as, or later than, the Primary Completion Date

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) ⊘ **IND number formats** 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.

IND/IDE Grantor*	Select one of the following organizations that holds the IND/IDE approval:
	
	1. For IND trials:
	   a. Center for Drug Evaluation and Research
	   b. Center for Biologics Evaluation and Research
	2. For IDE trials:
	   a. Center for Devices and Radiological Health
	   b. Center for Biologics Evaluation and Research

IND/IDE Holder Type*	Select one of the following holder types: 1. Investigator 2. Organization 3. Industry 4. NIH 5. NCI

NIH Institution, NCI Division/Program Code* (required if the holder type is NIH or NCI)	Select a code from the drop-down list. - If you selected **NIH** from the IND/IDE Holder Type list, see NIH Institution Codes for valid values. - If you selected **NCI** from the IND/IDE Holder Type list, see NCI Division/Program Codes for valid values.
Expanded Access?	If an experimental drug or device is available outside any clinical trial protocol, select **Yes**.
Expanded Access Type* (required if you selected the **Yes** check box in the **Expanded Access?** column)	Select one of the following access types: **Available** - Expanded access is currently available for this treatment **No Longer Available** - Expanded access was available for this treatment previously but is not currently available and will not be available in the future **Temporarily not available -** Expanded access is not currently available for this treatment, but is expected to be available in the future **Approved for Marketing** - This treatment has been approved for sale to the public
Exempt?	Select the **Yes** check box in the **Exempt?** column if the investigational product does not require FDA approval .

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 indicated that you require an XML document to register your trial with ClinicalTrials.gov.

> ⓘ   The system will not display this section if you indicated that you do not require an XML document for ClinicalTrials.gov.

Regulatory Information *

Trial Oversight Authority Country :*   -Select- ▼   ❓

Trial Oversight Authority Organization Name :*   [   ] ▼   ❓

FDA Regulated Intervention Indicator :*   ◯ No   ◯ Yes   ❓

Section 801 Indicator :*   ◯ No   ◯ Yes   ❓

Data Monitoring Committee Appointed Indicator :   ◯ No   ◯ Yes   ❓

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. See the ClinicalTrials.gov Protocol Data Element Definitions for definitions for these fields.

Instructions for recording regulatory information

Field Label	Description/Instructions
Trial Oversight Authority Country*	Select the name of the country in which the oversight authority organization is located. After you make your selection, the oversight authorities registered in the country you selected are listed in the Trial Oversight Authority Organization Name field.

Trial Oversight Authority Organization Name*	Select the name of the organization that oversees the trial from the drop-down list.
FDA Regulated Intervention Indicator*	Indicate whether the trial is regulated by the FDA by selecting **Yes** or **No**. ⚠️ You must select **YES** in the FDA Regulated Intervention Indicator field if the trial includes an IND or IDE. If the trial is interventional and you indicated that it is regulated by the FDA, the Regulatory Information section displays fields for Section 801. You are required to complete these fields.
Section 801 Indicator*	For interventional trials, indicate whether the FDA-regulated interventional trial is an applicable trial as defined in US Public Law 110-85, Title VIII, Section 801 by selecting **Yes** or **No**. ⚠️ If you indicated that the trial is applicable under Section 801, the **Delayed Posting Indicator** field becomes available and defaults to No. This field is read-only. You may request a change in its value by submitting a request to the CTRO at ncictro@mail.nih.gov.
Delayed Posting Indicator*	This indicator becomes available only when you indicate that the trial is applicable under Section 801. Only the CTRO can modify this indicator's value: • A **No** value indicates that any devices in the trial have already been approved or cleared by the US FDA, and so there is no need to delay posting of trial information information on ClinicalTrials.gov. • A **Yes** value indicates that the release of trial information on ClinicalTrials.gov is being delayed until after an interventional device has been approved or cleared. To change this indicator's value, submit a request to the CTRO at ncictro@mail.nih.gov.
Data Monitoring Committee Appointed Indicator	Optionally, indicate whether a data monitoring committee has been appointed for this trial by selecting **Yes** or **No**. ⓘ 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.

Recording Trial-Related Documents

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

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

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

⚠️ **Special processing for PDF files**
Adobe PDF files require special processing. See the information about creating PDFs in Converting Documents to PDFs .

Trial Related Documents *

To ensure successful registration, upload a Protocol document and an IRB Approval document. If the Protocol document does not i.
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 addit
*You can use the **Participating Sites template** to submit your list of participating sites.*

Tips for creating CTRP compatible PDF documents

Protocol Document:*	Browse... No file selected.	?
IRB Approval:*	Browse... No file selected.	?
List of Participating Sites:	Browse... No file selected.	?
Informed Consent Document:	Browse... No file selected.	?
Other:	Browse... No file selected.	?

Add more...

💾 Save as Draft   📄 Review Trial   ❌ Cancel

How to Submit Trial Related Documents

1. Next to the document-type field, (*e.g.*, **Protocol Document**), click **Browse**.
2. Navigate to, and select, the appropriate document, and then click **Open**.

   ⓘ   Depending on your operating system, you may see a different command name for "Open."

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 **Ad d More** link. A new **Other** document field is displayed.

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Converting Documents 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 *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 the search term "save file as pdf".

You don't 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 (.doc, .xls, etc.)
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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Registering Multiple Complete Trials in Batch Files

You can submit multiple trials for registration by recording trial data in pre-formatted Excel spreadsheets called batch templates. There are separate templates for *Complete* trial information and participating sites.

As an authorized CTRP submitter you can use the CTRP batch upload feature to register multiple new *Complete* trials that were conducted at a given site, and to update and/or amend them as necessary. The batch upload template, a predefined Excel spreadsheet, provides the structure for recording your trial data. When you have recorded the data and have prepared trial-related documents, upload them for submission using the CTRP batch upload feature. CTRO staffs use the information you provide in these documents to register your trials.

ⓘ **Before You Begin**
Request authorization from the CTRP to upload batches. Send your request via email to the CTRO. Once you have received approval, you do not have to request approval for subsequent uploads.

Upload each of the following types of files whenever you register multiple trials:

1. Data documents – Documents that contain all the requisite information about the trial.
2. Trial-related documents – Protocol and IRB documents, among others. You are not required to upload these types of documents when updating registered trial records.

Main Steps for Uploading Your Complete Trial Data

1. Prepare the trial data file. See Preparing Batch Data Files.
2. Prepare the trial documents Zip file. See Preparing Trial Document ZIP Files.
3. Upload your files to the CTRP system via the NCI Trial Registration batch upload web page at https://trials.nci.nih.gov/registry/admin/batchUpload.action. See Submitting Trial Document Zip Files.

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Preparing Data Files

The CTRP website provides a batch upload template, valid data values, data definitions, examples, and rules for registering batches of trials and trial amendments/updates. This section contains a summary of the information required for the .xls file. See Using CTRP Registration Templates .

ⓘ You must provide trial data in the Microsoft Excel format, .xls.

How to Prepare Trial Data Files

1. Download the following batch upload templates (Excel spreadsheets) containing the mandatory and optional data for multiple trial registration and participating sites from CTRP Trial Registration Batch File Templates . For instructions, see Downloading Trial Registration Templates.
2. Enter the trial data elements as specified in the templates. For participating sites, see Using CTRP Registration Templates .

> ⓘ The .xls file that contains the trial data you want to register via the CTRP batch upload feature, and the trial-related documents associated with it, must meet certain requirements for successful registration. Refer to the specifications below and in Preparing Trial Document ZIP Files.

Trial Requirements

To ensure successful submission, ensure that your trials conform to the following criteria:

Study Type	1. Complete 2. Interventional only
Data Table 4 Funding Sponsor Categories	1. National 2. Externally Peer-Reviewed 3. Institutional
Processing Statuses for Trial Amendments	1. Abstraction Verified Response 2. Abstraction Verified No Response
Processing Statuses for Trial Updates	Accepted and beyond

Data File Requirements

Ensure that the batch data files conform to the following criteria:

Number of Trials per File	100 maximum
Number of Grants per Trial	Multiple
Number of IND/IDEs per Trial	Multiple
Responsible Party or Sponsor Options	1. Contact 2. Generic Contact
Number of "Other" Trial Identifiers	Multiple
Data Submission Options	1. XML file is required for trial submission to ClinicalTrials.gov 2. XML file is not required for trial submission to ClinicalTrials.gov
Person and Organization Information Options	1. PO-ID for the person or organization 2. Set of mandatory attributes for person or organization ✅ You can request a list of CTRP persons and organizations along with PO-IDs from the CTRO at ncictro@mail.nih.gov. Or, you can use the search organization/person feature in Registration to ascertain PO-IDs.

Template Requirements

1. List trial elements required for registration in the order specified in the Batch Upload Data Element Spec tab in the batch upload template.
2. Do not change the spelling of data elements, valid values, or the order of the columns in the spreadsheet. Changes to spelling or to the order of the trial elements will cause the upload to fail. Similarly, the addition of new/extra trial elements will also cause a failure. The column headings are not case-sensitive. For example, a heading could be "Lead Organization" or "LEAD ORGANIZATION".
3. Conform to the valid values guidelines when entering trial data. Valid values for each of the trial elements, where applicable, are listed in the Batch Upload Data Element Spec tab and the Valid Values tab in the batch upload template.
4. Identify each trial uniquely. For example, append your cancer center unique trial identifier to the file name.
5. Select and delete any columns that do not have column headings.

> ⓘ You can enter dates in the following formats:
>
> 1. MM/dd/yyyy
> 2. MM-dd-yyyy

3. yyyy/MM/dd
4. yyyy-mm-dd

Preparing Trial Document ZIP Files

Trial documents include Protocol, IRB approval, Informed Consent, Participating Sites, Change Memo, and other document types. Upload these files together in one Zip file.

> ⓘ You are not required to upload trial-related documents when updating existing trial records.

How to Prepare Trial-Related Document ZIP Files

1. List the document names (including their extensions) in the file containing the trial data. You can specify up to seven (7) files in one single trial record.
2. Zip together all applicable trial documents (e.g., Protocol, IRB approval, Informed Consent, Participating Sites, Change Memo) for the trials in the data file. (The Batch Upload application does not support the native MacOS X file compression utility.) If you are uploading trial amendments, provide either a Change Memo or Protocol Highlight document. Be sure to include the Change Memo or Protocol Highlight document file names in your data file (.xls).

> ⊘ Do not include the following items in Zip files that you intend to upload:
>
> a. Folders or other Zip files
> b. Path names. Some ZIP/compression tools provide an option to include the entire file path name when compressing a file. Path names describe the location of the file.

Trial-Related Document Requirements

Basic criteria for trial-related documents include the following:

File Types	1. Microsoft Word (.doc) 2. Adobe PDF CTRO staffs use the information in the submitted trial documents to register the details of your trial. They often copy and paste this information during the registration process. They can copy text from Word documents, but not from scanned documents. If you intend to submit your Word documents as PDFs (for example, to prevent editing), do not scan them. Instead, convert them to PDFs. For instructions see Converting Files to PDFs .
File Names	Trial document file names must be unique. To avoid overwriting existing files when the system extracts your latest upload, rename the document files if they are not unique. For example, prefix files with a unique trial identifier such as `XXXX_document name.doc`. ⚠ If using trial identification prefixes, ensure that each of a given trial's document file names is unique.
Number of Files Permitted per Trial	7 maximum

Submitting Trial Document ZIP Files

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

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

- **Data documents** - Documents that contain all the requisite information about the protocol.
- **Trial-related documents** - Protocol and IRB documents, among others.

How to Upload Trial Registration Batch Files

1. Navigate to the batch upload URL that you received from the CTRO. The Batch Trial Upload page appears. An asterisk (*) indicates a

required field.

Batch Trial Upload

Register multiple trials in the NCI Clinical Trials Reporting Program by uploading the Trial Data file and th
file that contains trial documents. Note the following requirements:

1. Use this form to submit complete trials only

2. The trial data file must conform to the specifications in the CTRP Registry Complete Batch Upload
   Template, available on the **CTRP Trial Registration Batch File Templates** page

3. You must submit a Zip file that contains trial documents for each new and amended trial

4. You do not have to submit a Zip file that contains trial documents for updates to registered trials

Organization Name:*

Trial Data:*   Browse…   No file selected.

Documents Zip: Browse…   No file selected.

⬆ **Upload Trials**   ⊗ Clos

Batch Trial Upload Page

2. In the **Organization Name** field, type the name of the organization associated with the trials you want to register.
3. Next to the **Trial Data** field, click **Browse** and navigate to the file that contains all of the trial data.
4. Next to the **Documents Zip** field, click **Browse** and navigate to the `.zip` file that contains all of the trial-related documents. You do not have to upload a Zip file if you are updating a trial.
5. Click **Upload Trials**. The Batch Trial Upload Confirmation page appears.

Batch Trial Upload Confirmation

The batch trial data you submitted is being processed. You will receive an e-mail notification after the

Please click here to submit another file.

6. To upload more files, click the **click here** link, which directs you back to the Batch Trial Upload window.
   The batch upload program generates a report after processing the batch data and emails it to the submitter. The report includes a brief summary and the detailed status of each trial.

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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.
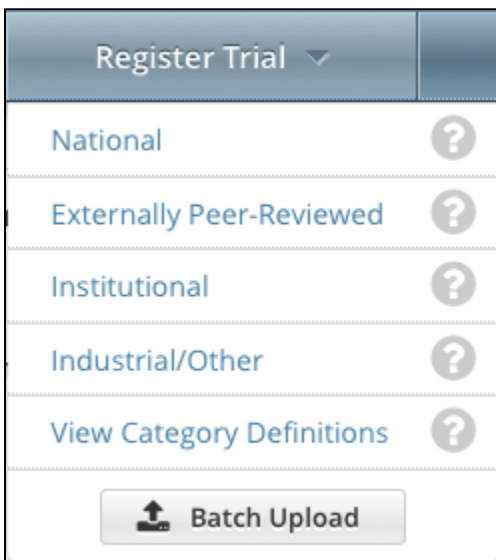
The Import ClinicalTrials.gov Trials page appears.

Import ClinicalTrials.gov Trials

To register a trial under the Industrial/Other submission category in CTRP, please enter the ClinicalTria
Studies. If you do not have the ClinicalTrials.gov identifier or if the trial does not have one yet th
ncictro@mail.nih.gov.

ClinicalTrials.gov Identifier: [   ] 🔍

Note: Any trials imported using this feature will be registered as Abbreviated in CTRP system. If the trial shou be classified as "Other" then please contact the Clinical T Reporting Office staff at ncictro@mail.nih.gov after importing/registering this trial in the CTRP system.

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.

Import ClinicalTrials.gov Trials

No match was found in CTRP system using the ClinicalTrials.gov identifier specified. However, a match has been found in review the following trial details and click 'Import Trial From ClinicalTrials.gov' button if you wish to proceed and register Otherwise, click 'Cancel' to stop.

Studies on ClinicalTrials.gov

One item found.**1**

ClinicalTrials.gov Identifier	Status	Study
NCT01744106	Recruiting	A Multicenter, Randomized, Placebo-Controlled Study of Pseud Temporary Relief of Nasal Congestion in Children With the Com **Condition(s)**: Nasal Congestion Associated With the Common (**Intervention(s)**: Drug: pseudoephedrine hydrochloride 30 mg Placebo tablets

[⬇ Import Trial From ClinicalTrials.gov]   [✖ Cancel]

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.

Trial Details

Message: Trial NCT01106534 has been imported and registered in CTRP system successfully. A unique NCI id assigned to this trial with a processing status of Submitted. Once the CTRO staff validates and accepts this tria trial via CTRP Registration application. Please contact CTRO staff for any further assistance.

+ Add My Site

Trial Identifiers

NCI Trial Identifier:	NCI-2014-00491
Lead Organization Trial Identifier:	06-374C

Trial Details

Title:	XIENCE V® Everolimus Eluting Coronary Stent System USA Post- Approval Study (XIENCE V
Phase:	IV
Trial Type:	Interventional
Primary Purpose:	Treatment
Secondary Purpose:	

5. To add your site as a participant in the trial, click **Add My Site**. The Add Participating Site page appears.

Add Participating Site

NCI Trial Identifier: NCI-2015-00763

Lead Org Trial Identifier: 1000008727

Title: The Implementation of a Gastroenteritis Education Program

Because your organization belongs to a family, you can add to this trial any site within that family. Please select the site you would like to add below:

Participating Site:*   Mayo Clinic ▾

> Next   ⊗ Cancel

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.

Add Participating Site

NCI Trial Identifier: NCI-2015-00763

Lead Org Trial Identifier:* 1000008727

Title: The Implementation of a Gastroenteritis Education Program

Organization Name:* Mayo Clinic

Local Trial Identifier:*

Site Principal Investigator:*

Site Specific Program Code:

Site Recruitment Status Date:*

mm/dd/yyyy

Please refer to the **Site Status Transition Rules**.

Site Recruitment Status:*

--Select--

➕ Add

Note: Site Recruitment Status of Active or Enrolli...
Invitation indicates that the Site is Open for Pati...
Closed to Accrual Site Status indicates that the S...
Patient Accruals.

💾 Save   ⊗ Cancel

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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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**.

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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**.

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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, see Searching for Trials .)
   Saved draft records are listed on the Search Results page.

Saved Draft Search Results

Show 10 ⇕			Search:

Temp Trial Identifier ▼	Title ⇕	Lead Organization ⇕	Lead Org Trial
137847524	Phase II trial of saved drafts	National Cancer Institute	LEADORGID 1234

Showing 1 to 1 of 1

Export options: CSV| Excel

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 a Complete Trial.

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Updating Trials v4.3

This section describes how to update trials that are currently registered and verified in CTRP.

About Trial Updates

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

You can also update the trial status and trial status start/completion dates without having to update other trial details. See Changing Trial Status Information for instructions.

> ⓘ Use the Update Trial feature when changes to the trial are not a consequence of changes to the protocol document. Use the Amend Trial feature---for *Complete* trials only---when changes to the trial involve changes to the protocol document that require IRB approval. You can update both trial and participating site information for Industrial/Other trials using the Available Actions column.

Updating Trial Information

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 and site program code for abstracted trial sites. See Recording Trial Statuses and Dates .
- **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 and Dates .

⊘ **Tip**
You can also update trials in batches. See Registering Multiple Complete Trials in Batch Files .

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, see Viewing Trial Details .

"Available Actions" Columns for Complete trials - Select Action List

"Available Actions" Columns for Industrial trials - Select Action List

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

Update Trial page for Complete trials

Update Trial page for Industrial trials

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

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

5. If applicable, enter an ClinicalTrials.gov Identifier, and then click **Add ClinicalTrials.gov Identifier**.

> ⚠ 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.

> ⓘ 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.

6. Make changes to the fields as necessary. Instructions for recording each of the fields are provided in Registering New Trials .
7. If appropriate, upload any new or updated documents. See Recording 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).
8. 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.
9. If necessary, correct any errors, and click **Review Trial**. Repeat this cycle until your update is error-free.
10. Submit the trial update.
    The system sends you an update notification—with the details of what has changed—whenever you update accepted trials.

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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, as well as when you review the trial information before submitting the update.

If you add a status that does not conform to the rules provided in Status Transitions, 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 by following the instructions in Searching for Trials .
   The Search Results table displays the results of your search and actions available (if any) for each record.

2. 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-- ▾ 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.	9 Administratively Complete, With... Temporarily Closed statuses only

Please refer to the **Trial Status Transition Rules**.

Trial Status History

Show 10 ⬍ entries

Status Date	Status	Comments	Validation Mes
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

3. Edit or add a new status as necessary (see Recording Trial Statuses). If you changed the status to *Administratively Complete*, *Withdrawn*, or *Temporarily Closed*, enter the reason for the status change.

> ⓘ If a *Complete* trial reaches any of the statuses below, the system closes the trial at all participating sites, and sets their trial statuses to match those of the trial that closed.
>
> - Closed to Accrual
> - Closed to Accrual and Intervention
> - Administratively Complete
> - Complete

The system displays the following warning if you enter any of the statuses above:

4. 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 it, as well as when you review the trial information before submitting the trial for registration.

If you update or add a status that does not conform to the rules provided in Recording Trial Statuses and Dates, 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-- ▾ *Participants are being (or will be) selected from a predetermined population.*	 100 Administratively Complete, Withdrawn and Te... Closed statuses only

*Please refer to the **Trial Status Transition Rules**.*

Trial Status History

Show 10 ⇕ entries

Status Date	Status	Comments	Validation Messages
12/01/2014	Enrolling by Invitation		WARNING: Interim st... REVIEW] is missing WARNING: Interim st... [APPROVED] is missi...

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.

Trial Status History

❗ Status Transition **Errors** and **Warnings** were found. This trial cannot be submitted until all Status Transition Errors action icons below to make corrections.

Show 10 ⇕ entries

Status Date	Status	Comments	Validation Messages
10/16/2014	Approved		
12/16/2014	Enrolling by Invitation		
12/17/2014	Complete	Invalid transition	ERROR: Interim status [CLOSED ACCRUAL] is missing WARNING: Interim status [CLO... ACCRUAL AND INTERVENTION]...

6. Fix any errors as necessary, and then click **Review**.
7. Click **Submit**. See Recording Trial Statuses and Dates for detailed instructions.

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Updating the Trial Start, Primary Completion, and Completion Dates

The trial status dates section captures start, primary completion, and completion dates as they occur according to the rules specified in Start, Primary Completion, and Completion Date Rules.

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

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**.

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. Valid values are as follows: • **In Review** - Trial is currently under IRB review. • **Withdrawn** - Trial has been withdrawn from development and review prior to enrollment of the first participant. • **Approved** - Trial has been approved, but is not yet recruiting or enrolling participants. • **Active** - Trial is open for accrual and enrollment. • **Enrolling by Invitation** - Participants are being (or will be) selected from a predetermined population. • **Temporarily Closed to Accrual** - Participant recruitment or enrollment has been halted prematurely but may resume. Participants already on trial continue to receive intervention. • **Temporarily Closed to Accrual and Intervention** - Participant recruitment or enrollment has been halted prematurely but may resume. Participants already on trial do not receive intervention. • **Closed to Accrual** - Trial has been closed to participant accrual, but trial is ongoing (i.e., participants continue to receive treatment and/or examination). • **Closed to Accrual and Intervention** - Trial has been closed to participant accrual. Participants already on trial do not receive treatment, but continue to be monitored for endpoints such as long-term survival. • **Administratively Complete** - Participant recruitment or enrollment has been halted prematurely (for example, due to poor accrual, insufficient drug supply, IND closure, etc.), and will not resume. Participants already on the trial do not receive further treatment or examination. • **Complete** - 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.
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.

Valid trials used in CTRP are mapped to ClinicalTrials.gov-defined recruitment values. ClinicalTrials.gov status definitions are provided in Trial Status Values in the CTRP and ClinicalTrials.gov.

Start, Primary Completion, and Completion Date Rules

Valid dates for a given trial status depend on the other values you have entered, and whether those dates are *Actual* (current, or past) or *Anticipat*

ed (future).

The following diagram illustrates these rules. The arrow at the top of the diagram represents a time line for the life of a trial. The three horizontal bands in the lower section of the diagram represent, from top to bottom, the relative date (actual or anticipated) rules for trial Start Date types, Primary Completion Date types, and Completion Date types.

The following table provides the rules for trial status dates as diagrammed.

Rules for Status/Dates relationships

If this is true...	Follow this rule
Current Trial Status is anything *other than* In Review, Approved, or Withdrawn	Trial Start Date must be Actual (solid band)
Current Trial Status is Approved or In Review	Trial Start Date could be Actual or Anticipated (diagonal stripes band)
Current Trial Status is Complete	All date types must be Actual (solid band)

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
- The Primary Completion Date can be earlier than the Current Trial Status Dates *Complete* or *Administratively Complete* if the Primary

Completion Date is *Actual*
* The Completion Date is always the same as, or later than, the Primary Completion Date

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 Transitions below.

For Abbreviated trials, see 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.

If you add a status that does not conform to the rules provided in Status Transitions, 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 by following the instructions in Searching for Trials . The Search Results table displays the results of your search and actions available (if any) for each record.

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.

3. Select new statuses and enter dates as necessary.
4. You also have the option to specify a program code for each site.
5. Click **Review Trial.**
   If you entered invalid values, error messages display instructions for correcting the statuses and/or dates.

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

If a *Complete* trial reaches any of the statuses below, the system closes the trial at all participating sites, and sets their trial statuses to match those of the trial that closed.

- Closed to Accrual
- Closed to Accrual and Intervention
- Administratively Complete
- Complete

Status Transitions

The rules that apply to trial status transitions also apply to participating site status transitions.

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

Trial Status Flow Relationships

A trial can proceed from this status…	Directly to this status	Or to this status
In Review	- Approved - Withdrawn	Active/Enrolling by Invitation ⓘ This can occur when the trial has been Approved and is Active/Enrolling by Invitation on the same day
Approved	- Active/Enrolling by Invitation - Withdrawn	NA
Active/Enrolling by Invitation	Closed to Accrual	- 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	- Completed - Administratively Completed	NA
Temporarily Closed to Accrual	Temporarily Closed to Accrual and Intervention	- Active/Enrolling by Invitation - Closed to Accrual - Closed to Accrual and Intervention - Administratively Completed
Temporarily Closed to Accrual and Intervention	Administratively Completed	- 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

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, see Editing Updated Details.

4. Click **Submit**.

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 follow the instructions in Reviewing and Submitting Trial Updates .

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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, see 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**.

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Amending Complete Trials v4.3

Amending Complete Trials v4.3

Topic Links
• About Trial Amendments • Amendment Process Life Cycle • Amending Trials 　• Reviewing and Submitting 　　Trial Amendments 　• Editing Amended Trials 　• Printing Amended Trial 　　Information

This section describes how to amend trials currently registered and verified in CTRP.

About Trial Amendments

In your role as trial owner, you can amend National, Externally Peer-Reviewed, and Institutional trials that have been registered with the CTRP previously and have reached the Abstraction Verified Response/No Response processing status. (See Trial Processing Statuses.) You can amend a trial you submitted or own if the trial status is *In Review* or *Approved*. (See Trial Status Values.)

The CTRO reviews and abstracts amended trial data just as it does with original submissions.

> ⚠ **The ability to amend a trial is restricted by its trial status**
> You can not amend trials in the *Complete*, *Administratively Complete, Withdrawn,* or *Terminated* statuses.

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.

You can also amend trials in batches. See Preparing Data Files .

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. (If appropriate, the CTRO also sends an XML document with all the newly-modified data. XML documents are available for trials that have been designated for import into ClinicalTrials.gov.)
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 (and XML document, if appropriate).

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.

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. See 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 documents are required with submission:
  - Amendment Protocol

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

    > ⓘ   **Accepted Documents**
    > You can submit clean (original) amendment protocol documents or documents that have been marked up, with or without using the Track Changes feature.

  - Change Memo – Contains a summary of changes to the original, or last amended, trial submission
    (One or the other of the *Change Memo* and *Protocol Highlight* documents is required. You do not have to submit both of these documents.)
  - Protocol Highlighted Document
  - IRB Approval for the amended protocol

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

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.

Current Processing Status ⬍	Available Actions ⬍
Accepted	Select Action ▾
Abstractio Response	Update **Amend** Change Status View TSR View XML Verify Data Select Action ▾

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

Amendment Trial

Use this form to register trials with the NCI Clinical Trials Reporting Program. Required fields are marked by asterisks (*

XML Required, Enable "Upload from NCI CTRP" in ClinicalTrials.gov? ● Yes ○ No ?

⊕ Expand All

Amendment Details

Trial Identifiers*

Other Identifiers*

Trial Details*

| Title:* | Papillary Carcinoma Trial | ? |
| | 3975 characters left | |

Phase:* I/II ▾ ?

Trial Type:* ● Interventional ○ Non-interventional

Primary Purpose:* Treatment ▾ ?

Secondary Purpose: Ancillary-Correlative ▾

Accrual Disease Terminology: ICD-O-3 ▾

4. Select or enter the appropriate information in the text fields and drop-down lists, following the instructions provided in Registering New Trials .

ⓘ If a *Complete* trial reaches any of the statuses below, the system closes the trial at all participating sites, and sets their trial statuses to match those of the trial that closed.

- Closed to Accrual
- Closed to Accrual and Intervention
- Administratively Complete
- Complete

The system displays the following warning if you enter any of the statuses above:

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

> ⚠ You can select a different disease code only if the trial has not accrued any subjects to date.

5. Review the amendment. See 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.

Return to top of page

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 Amennd 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**.

Return to top of page

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 .

> (i) **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.

Return to top of page

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**.

Return to top of page

Adding Your Site to Abbreviated Trials v4.3

Adding Your Site to Abbreviated Trials v4.3

Topic Links
• Using the Add My Site Feature
• Viewing Participating Sites
• Updating Participating Site Organization Records

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, ensure that you have indicated your affiliated organization in the CTRP**
> To verify that you have indicated your current organization affiliation, on the top right corner of any page, click **Your Username > My Account** and review your account information. You can add/update your affiliation by following the instructions in Creating CTRP Accounts .

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
- Site-specific program code
- 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.

Add Participating Site

NCI Trial Identifier: NCI-2015-00763

Lead Org Trial Identifier:* 1000008727

Title: The Implementation of a Gastroenteritis Education Program

Organization Name:* Mayo Clinic

Local Trial Identifier:*

Site Principal Investigator:* 🔍

Site Specific Program Code:

Site Recruitment Status Date:*   **Site Recruitment Status:***

mm/dd/yyyy 📅   --Select-- ▼   ✚ Add

Please refer to the **Site Status Transition Rules**.

Note: Site Recruitment Status of Active or Enrollin Invitation indicates that the Site is Open for Pati Closed to Accrual Site Status indicates that the S Patient Accruals.

💾 Save   ✖ Cancel

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.

Field	Description/Instructions
Local Trial Identifier*	Enter the identifier used at the participating site.
Site Principal Investigator*	Click Look Up to search for, and select, the site principal investigator.
Site Specific Program Code	Optionally, enter a program code for the participating site.

5. 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 Trial Status Date Rules in the CTRP.
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 Trial Status Transition Rules in the CTRP, 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.

Site Recruitment Status- No Warnings or
Errors

Site Recruitment Status- With Warnings
and an Error

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.

6. 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.

Edit Trial Status

Status Date:*	02/03/2015 📅
Status:*	Enrolling by Invitation ▾
Why Study Stopped:	

1000 characters left

Administratively Complete, Withdrawn and Temporarily Closed statuses only

| Comment:* | |

1000 characters left

[Save] [Cancel]

     b. 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.

8. Click **Save**. Your information is added to the trial details.

Return to top of page

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.

Participating Sites

View

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	[▓▓▓▓▓▓▓▓ - Principa Pending]
59969	University of Colorado Cancer Center - Anschutz Cancer Pavilion	[▓▓▓▓▓▓ - Principal In Pending]

[💾 Close]

Updating Participating Site Organization Records

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

- Appointed participating site record owner(s) and the trial owner(s) can update information about their respective organizations in the same trial record.
- If your affiliated organization is a member of the parent organization's family (that is, a Cancer Center's family), you can also update your organization's sibling sites (that is, other participating sites in the Cancer Center's family).
- If you are affiliated with the Cancer Center that is acting as the parent organization, you can update any organization in the family.
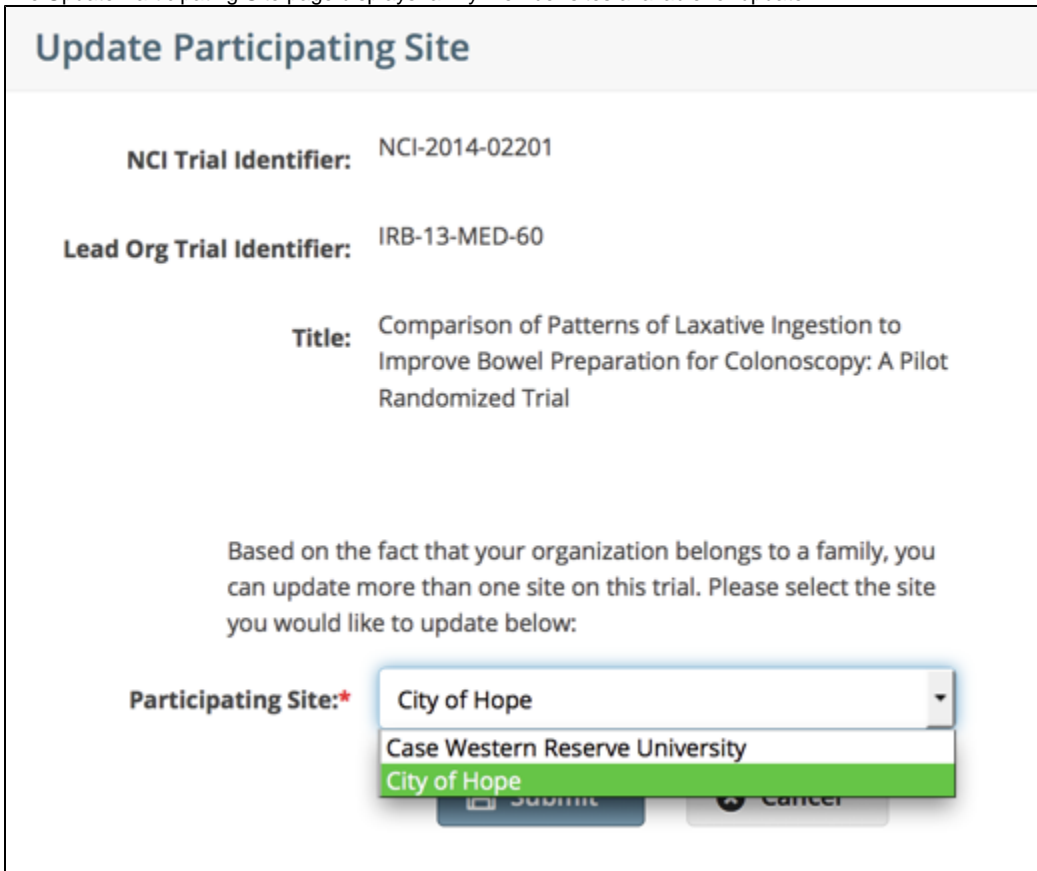
For information about appointed participating site records, see Managing Trial Ownership .

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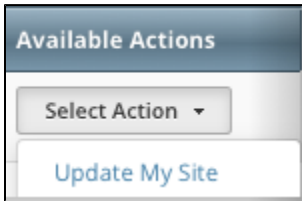
The Update Participating Site page displays family member sites available for update.

3. From the **Participating Site** drop-down list, select the site you want to update.
4. Click **Submit**. The Update Participating Site page appears. The Organization Name field is pre-populated with the organization you selected on the previous page.

Title:	Phase 1/1b, First-in-Human, Dose-Escalation and Expansion Study of FLX925 Administered Orally to Subjects With Relapsed or Refractory Acute Myeloid Leukemia
Organization Name:*	Mayo Clinic
Local Trial Identifier:*	LA_12345
Site Principal Investigator:*	___,Isabelle
Site Specific Program Code:	

Site Recruitment Status Date:*

mm/dd/yyyy 📅

Please refer to the *Site Status Transition Rules*.

Site Recruitment Status:*

--Select-- ▾

Note: Site Recruitment Status of Active or Enrolling by Invitation indicates that the Site is Open for Patien... that the Site is Closed to Patient Accruals.

Site Recruitment Status History

Show 10 ▾ entries

Status Date	Status	Comments	Validation Messages
11/03/2014	Closed to Accrual		ERROR: Interim status	missing WARNING: Interim stat REVIEW] is missing WARNING: Interim stat [APPROVED] is missing
11/04/2014	Enrolling by Invitation	status invalid	ERROR: Invalid status t from [CLOSED TO ACC [ENROLLING BY INVITA

Showing 1 to 2 of 2 entries

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

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Registration Site Administration v4.3

Registration Site Administration v4.3

This page provides instructions for site administrators. A site administrator is a user with administrative privileges who is responsible for reviewing and updating user access to trials owned by the organization, and for assigning site administrator status to other users in the organization. This page introduces you to site administration management and provides instructions for granting and revoking administrative authority.

About Site Administration

Each organization registered in the CTRP system can have more than one site administrator. You can request primary site administration authority from the CTRO via the "Request for Admin Access" feature on the "My Account" page when you first complete your account profile and provide your organization affiliation. Refer to Creating CTRP Accounts . Otherwise, request administration authority from the current site administrator.

> ⓘ To display the administrator(s) currently assigned to your organization, on the **My Account** page, below the **Organization Affiliation** field, click **View Admins**. This feature is displayed only for those users whose affiliated organizations currently have registered admins.

Granting and Revoking Administrative Authority

The relationships between administrators and trials in a single organization are as follows:

- An organization can have the following:
    - One original site administrator
    - Many site administrators appointed by the original administrator
    - Many trials, providing that the organization plays the lead organization role
    - Many users affiliated with the site who can submit and own trials
- A trial can have the following:
    - One submitter
    - One organization affiliation, defined by the lead organization
    - Many trial owners

Site administrators are trial owners by default if the site administrator's affiliated organization is the trial's lead organization. A site administrator can be added explicitly as an owner of any trial. Refer to Managing Trial 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**
> System-generated emails (including TSRs) are sent 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 on the *My Account* page.

As a site site administrator, you can grant and revoke administrative rights to other users in your organization. (You can grant/revoke administrative authority 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 see and access the Site Administration menu.

How to Grant and Revoke Site Administrator Rights

1. On the toolbar, click **Administration** > **Site Administration**.
   The Site Administration page appears, listing the administrators to whom administrator rights have previously been granted, if applicable.

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 under the **Allow as Site Admin?** column.
3. Click **Save**.

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

How to View Accrual Assignment History by Trial

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

NCI Trial Identifier ▼	Title
NCI-2014-00281	Vaccination of Patients With Ovarian Cancer With Dendritic Cell/Tumor Fusions Wi GM-CSF and Imiquimod
NCI-2014-00248	Global Proteomic and Phosphoproteomic Profiling of Normal B Cells Isolated Fron

INSTITUTIONAL

Show 10 ↕   Search: [   ] [Choose columns]   <<   <   1   2   3

NCI Trial Identifier ▼	Title
NCI-2014-00508	Papillary Carcinoma Trial

INDUSTRIAL

Show 10 ↕   Search: [   ] [Choose columns]   <<   <   1   2   3

NCI Trial Identifier ▼	Title
NCI-2014-00109	A Phase Ib/II Open-label, Multi-center Study of the Combination of MEK162 Plus AM 479 (Ganitumab) in Adult Patients With Selected Advanced Solid Tumors

Showing 1 to 10 of 691   <<   <   1   2   3

Export options: CSV| Excel

To navigate the table, refer to Working with Tables and Search Results.

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 (Institutional and Externally Peer Reviewed), the organization must be a lead; for *Abbreviated* trials (Institutional), 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.

> ⓘ Access to CTEP and DCP trial accruals is restricted to the CTRO only.

The table below outlines the access and trial assignment rules for *Complete* (Institutional and Externally Peer-Reviewed) 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
Who can be assigned 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 be assigned?	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 is access assigned?	- 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 the Organization Family Accrual Submitter's organization is removed from the organization family in the future.	- By trial - By participating site
Who can submit accrual data?	Any assigned user, for any organization trials for which the assigner's organization is the Lead Organization	Any assigned user affiliated with the participating site
Which trials can the Organization Family Accrual Submitter submit accrual data to?	- 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

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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.

How to Assign Accrual Access

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

2. Select an assignment type.
    - Select **Assign user access to individual trials** to assign specific trials to specific users. If you select this option, the **Select a trial category** list appears where you can narrow the list of trials to a category.
    - Select **Make user a Site Submitter** to grant users rights to submit accruals for all trials in CTRP that have been submitted or will be submitted by the affiliated site.
    - Select **Make user an Org Family Submitter** to 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.
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.

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

4. From the **Not Assigned** trial list, select the trial to which the user will 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 others. Then click the single arrow (**>**) under **Assign**.

A comment box appears.

Comments

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

[Save]   [Cancel]

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

> ⓘ Comments are optional. You can leave the comment field blank and still save it. To abort the assignment, click **Cancel** instead.

A message confirms your assignment. The assigned trial(s) appear in the Assigned list.

6. 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 (**<<**).

7. Optionally, enter a comment in the **Comments** box, and then click **Save**.
The trial(s) you selected are moved to the Not Assigned list, and the user will no longer have access to them.
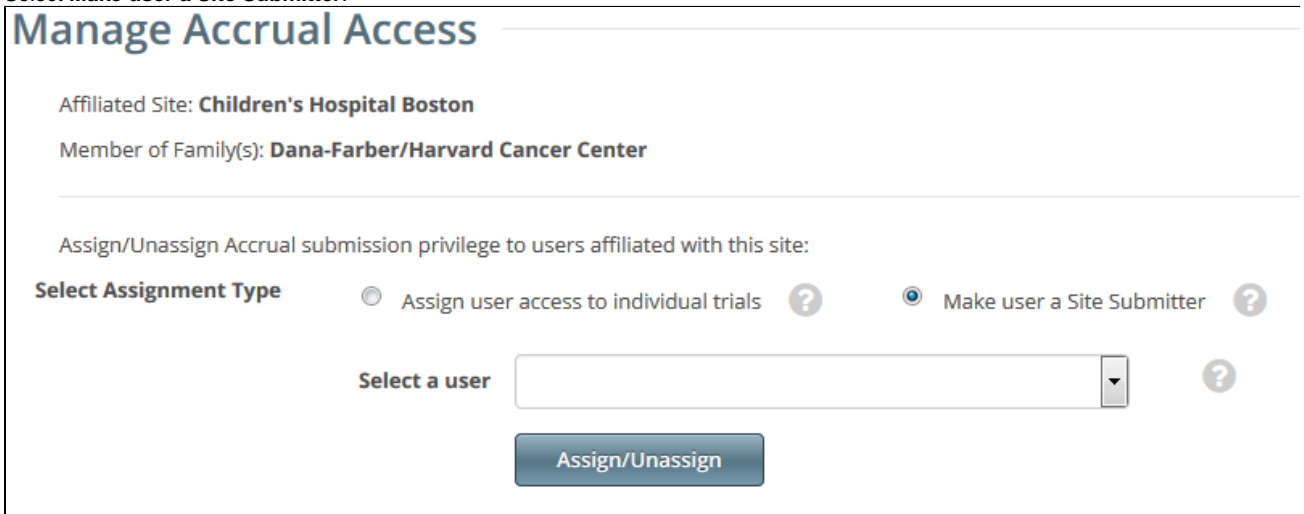
Assigning and Unassigning Accrual Access by Site

As a site administrator, you can assign a user Accrual access globally by site.

How to Assign Accrual Access by Site

1. On the toolbar, click **Administration > 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 ❓

Select a user   [▾] ❓

[Assign/Unassign]

3. Select the user from the **Select a user** drop-down list.
4. Click **Assign/Unassign**.

5. To unassign access, click **Assign/Unassign** again.

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Assigning and Unassigning Accrual Access by Organization Family

As a site administrator, you can assign a user Accrual access globally by organization family.

How to Assign Accrual Access

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

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

Return to top of page

Viewing Accrual Assignment History

As a site administrator, you can view a history of your organization's trials to which users have been assigned/unassigned user access.

How to View Accrual Assignment History

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

Accrual Access Assignment History

Show 10 ▼   Search: [_____]   [Choose columns]   << <

Date	Assignee	Trial ID	Assignment Action	Comments
06/16/2014	~~Edmond McLaine~~	NCI-2009-00127	Assigned	
06/16/2014	~~Edmond McLaine~~	NCI-2009-00130	Assigned	
06/16/2014	~~Edmond McLaine~~	NCI-2009-00148	Assigned	
06/16/2014	~~Edmond McLaine~~	NCI-2009-00241	Assigned	
06/16/2014	~~Edmond McLaine~~	NCI-2009-00254	Assigned	
06/16/2014	~~Edmond McLaine~~	NCI-2009-00267	Assigned	
06/16/2014	~~Edmond McLaine~~	NCI-2009-00292	Assigned	
06/16/2014	~~Edmond McLaine~~	NCI-2009-00635	Assigned	
06/17/2014	~~Charles Yaghmour~~	NCI-2009-00909	Unassigned	unassign all
06/17/2014	~~Charles Yaghmour~~	NCI-2009-00909	Assigned	

Showing 1 to 10 of 5,000   << <

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.

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Managing Trial Ownership

Trials are associated 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. And M D Anderson is the last Submitter Organization and trial owner.

My Account

Last Name * [Autissier]

Organization Affiliation * **M D Anderson Cancer Center**

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.

Trial Identification

NCI-2014-00543: Test of submitter organization

Lead Organization Trial ID: M D A - 12
Lead Organization: M D Anderson Cancer Center
Trial Category: Complete Trial
Submission Source: Registry

Principal Investigator: Autissier, Isabelle
Last Submitter: CTRPDOC1
Last Submitter Organization: M D Anderson Cancer Center

Curren
Curren
Proces

If Isabelle Autissier changes her organization affiliation to another within the organization family such as U.T. M.D Anderson Cancer Center after having submitted the trial, both she and her *original* organization retain trial ownership.

My Account

Last Name *   Autissier

Organization Affiliation *   **U.T.M.D. Anderson Cancer Center**

However, if Isabelle Autissier 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 trial ownership; Vanderbilt-Ingram Cancer Center does not assume trial ownership despite the Last Submitter's new organization affiliation.

My Account

Last Name *   Autissier

Organization Affiliation *   **Vanderbilt-Ingram Cancer Center**

> ⓘ The example above is based on *Complete* trials. The same principals apply to *Industrial* trials but site record ownership rather than trial ownership is affected by affiliate changes.

Assigning 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 indicate which of the owners you assign will receive notifications about the trial(s) via email.

> ⓘ 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's local trial identifier
- Site principal investigator
- Site-specific program code
- Site recruitment status and dates

Trial ownership requirements
You may not be able to change trial ownership using the Manage Trial Ownership functionality in certain circumstances. 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 Site Recruitment Statuses and Dates .) However, you can request trial ownership changes by contacting the CTRO. When requesting trial ownership changes, include the new owner's first name, last name, and email address. Ensure that the user has registered in CTRP or has a valid CTRO account.

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

My Account

Last Name *	Autissier
Organization Affiliation *	**M D Anderson Cancer Center**

You can assign any trial submitted by your affiliated organization or it family member organizations. For example, if you are affiliated with the M D Anderson Cancer Center, you can manage trial assignments for trials that M D Anderson International and UF Cancer Center at Orlando Health own.

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

___

How to Assign and Unassign Trial Ownership

1. On the toolbar, click **Administration > Trial Ownership > Manage**.
   The Manage Trial Ownership page displays the names of your affiliated organization or it's family member organization(s) users on the top of the page, and trials that your organization owns as a Lead Organization or Participating Site below the list of 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
☐	Morgan, Michelle	example@example.com
☐	Kratz, Anna	example@example.com
☐	Autissier, Isabelle	anthonel@mail.nih.gov

2. Under **Manage trial 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. To indicate which users will have the ability to update and amend selected *Complete* trials; or update *Abbreviated* trials, 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 list is filtered as you type subsequent characters.

4. In the list of trials at the bottom of the page, under **All Available Trials**, or **All 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). In the **Email Notifications?** column, click the **Yes** or **No** button. To indicate that all owners should receive/not receive email, in the **Email Notification** column header, click **All > Select Yes/No for all**.

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Displaying Trial Ownership

As a site administrator, you can display trial ownership for any trial owned by your site for which your organization or its family member organization is the lead organization. Trial owners can view trial details, update trials, and amend *Complete* trials. Additionally, you can indicate

whether a user would like to receive system notifications, including TSRs and XML files, on a trial-by-trial basis.

ⓘ **TSR and XML distribution**
Trial owners can access TSR and XML documents.

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, will receive system-generated email notifications.

Display Trial Ownership

First Name:	
Last Name:	
E-Mail:	
NCI Identifier:	

🔍 Search   ↻ Reset

Search Results

Show 10 ▾   Search:

First Name ⬍	Last Name ⬍	E-Mail ⬍	NCI Identifier ▾	Lead Org ID ⬍	Rec
Isabelle	Autissier	anthonel@mail.nih.gov	NCI-2014-00508	123456ABC	Yes

Showing 1 to 1 of 1

2. 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**.
   All trials owned by the user are listed in the Search Results list.
3. To display all owners of a given trial, enter the NCI Identifier in the field provided, and then click **Search**.
   All owners of the selected trial are listed in the Search Results list.

✅ **You can filter the search results and create more space to display the 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 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.

---

4. To indicate whether or not an owner of a trial should receive system-generated email messages, in the **Receive Email?** column, select **Yes** or **No**.

ⓘ Selecting **Yes** indicates that the owner will receive *all* notifications regarding the specified trial.

Selecting **No** indicates that the owner will *not* receive any notifications regarding the specified trial.

---

5. To revoke ownership of a trial, locate the user/trial in the **Search Results** list, and then click **Remove**.

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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.

   ## Search Trials

   NOTE: Search results include only those eligible Abbreviated Trials with which your affiliated organiz...

   NCI, Lead Org, or Other Trial Identifier: | *Examples: NCI-2008-00015; ECOG-1234* | **Trial Title:** | a...

   [🔍 Search]   [↻ Reset]

2. Enter the **NCI**, **Lead Organization**, or **Other** trial identifier; or, enter all or part of the **Trial Title**.
3. Click **Search**.
   The *Abbreviated* trials with which your affiliated organization or its family members are not yet participating are listed in the results table.

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

	Trial Identifier ⬍	Trial Title ⬍
➕	NCI-2013-01383	A Phase Ib/II, Multicenter, Trial Of CVX-060, A Selective Angiopoietin-2 (ANG-2) Binding, An Advanced Renal Cell Carcinoma
➕	NCI-2013-01264	A PHASE 1B DOSE-ESCALTION STUDY OF TRC105 IN COMBINATION WITH AXITINIB IN PAT...
➕	NCI-2013-00717	An International Phase 3 Randomized Trial of Autologous Dendritic Cell Immunotherapy ((ADAPT)

4. Optionally, to sort the results, click the column ascending or descending arrows. This option only is available 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 per the previous topic.
   The *Abbreviated* trials with which your affiliated organization or its family members are not yet participating are listed in the results table.
2. Click the **Plus** sign (➕) to add participating sites to a trial.

   The trial record expands to display trial information. The Site field is pre-populated with your affiliated organization automatically.

3. If you need to change the participating site, select one from the **Site** drop-down list. Only your family member organizations are listed.

4. If the Principal Investigator has not been selected, click the **Look Up Person** icon (   ) and search for the investigator.

5. Enter the **Local Trial Identifier**.

6. Optionally, in the **Program Code** field, enter a program code for the site.

7. Select the **Current Recruitment Status** and the **Current Recruitment Status Date**.

8. Optionally, select the **Date Opened for Accrual** and **Date Closed for Accrual**.

9. 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.

10. Scroll to the bottom of the page and click **Save**.

Verifying Trial Data v4.3

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

> (i) 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)

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.

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.

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**.
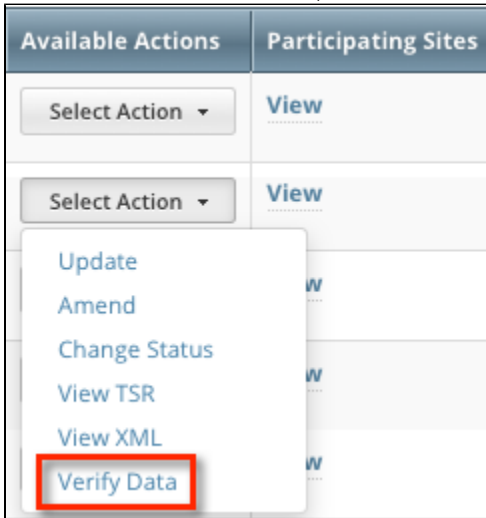
The Trial Data Verification page appears.

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 Sipu Cancer Immunotherapy

One item found. **1**

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

Add Data Verification Record

I have reviewed the data for this trial :

💾 Save Verification Record   ⊗ Cancel

✅   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

Alternate Title(s) indicator

Title: Phase II Study of Above-Label Octreotide-LAR in Patients with Insufficien Controlled Carcinoid Syndrome (*)

One item found. **1**

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

3. To view the alternate titles, click the asterisk (*)
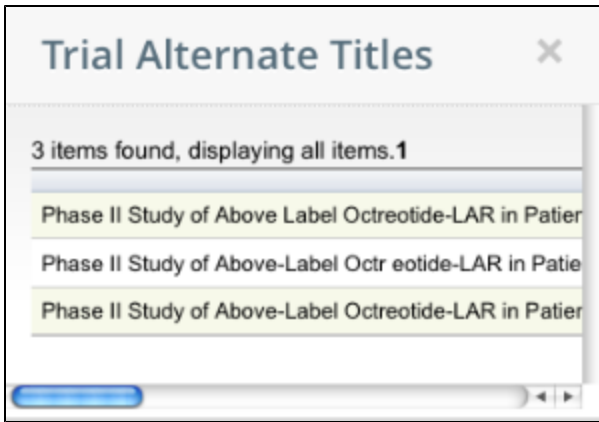
How to Verify Trial Data

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.

Working With Persons and Organizations v4.3

Working With Persons and Organizations v4.3

Topic Links
• Looking up Registered Organizations
• Adding Organizations to the CTRP
• Looking Up Registered Persons
• Adding Persons to the CTRP

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.

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.

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.

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.

> ✓ If you still don't find your organization in the system, you can add it using the **Add Org** feature.

c. 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.
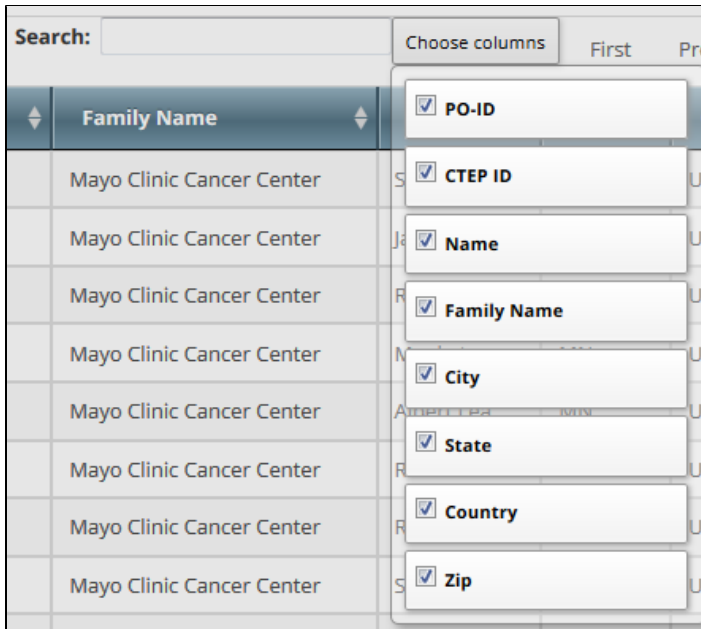
4. To link to an organization to the trial, click its **PO-ID** value.
   The organization's name you selected appears in the Family Name field.

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Adding Organizations to the CTRP

If you are unable to find an organization, you can add a Lead Organization, Data Table 4 Funding Sponsor, etc. when you register, update, or amend a trial .

> ✅ **Check for duplicate organizations first**
> Be sure to search the system's registered organizations first before you register a new one. This will ensure that you do not create a duplicate record in the system.

When you register an organization, the CTRO staff curate the organization's record, then add it to the list of registered organizations in the CTRP.

> ⓘ The procedure below uses the Lead Organization as an example. The same fields may not appear in all Add Organization windows however.

How to Add Organizations to the CTRP

1. Hover your mouse over any field for an organization, such as **Please Select the Lead Organization**.
   A list of organizations appears.

PO ID	CTEP ID	Name
120894	MA042	Children's Hospital Boston (Your Affiliation)
120807	MA038	Beth Israel Deaconess Medical Center
121010	MA046	Brigham and Women's Faulkner Hospital
120778	MA037	Brigham and Women's Hospital
120748	MA036	Dana-Farber Cancer Institute
3456936		Dana-Farber Harvard Cancer Center
10687496	MA188	Dana-Farber/Brigham and Women's Cancer C
9631998	MA185	Dana-Farber/Brigham and Women's Cancer C
120836	MA039	Harvard Medical School
9594250		Mass General/North Shore Cancer Center
123441	MA148	Massachusetts General Hospital
120689	MA034	Massachusetts General Hospital Cancer Cent
7252235	NH043	The Dana-Farber Cancer Institute at Londond

Search...

2. At the bottom of the list, click **Search**.
   The Select Lead Organization page (or Select Sponsor page, if you started there) appears.

Select Lead Organization

Type a string of characters in any of the text fields in the upper frame, o

Organization Name:

Organization Family Name:

State:

please enter two letter identifier for US states, for ex: 'MD' for Maryland

Click Add Org if the organization you searched for does not appear in the search results

PO ID (Exact Match):

🔍 Search   ➕ Add Org   ⟳

3. Click **Add Org**.
   The Add Organization window appears.

Select Lead Organization

Add Organization

Organization Name :* [   ]   Cou

Street Address :* [   ]

State : [-Select a State-   ▾]

Email : [   ]   Phone Nu

URL : [   ]

Fax Number : [   ]

[💾 Save]   [🔍 Search

4. In the **Organization Name** field, type the full name of the organization.
5. Select or enter the appropriate information in the text fields and drop-down lists. An asterisk (*) indicates a required field.

   ⓘ   ZIP Codes are required for organizations in the USA, Canada, and Australia.

6. Click **Save**.
   The organization you added is saved in the system and is displayed in a table at the bottom of the page.
7. In the organization record, click **Select**.
   The **Organization Name** field is populated with the organization you just added.

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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.

Select Principal Investigator

Type a string of characters in any of the text fields in the upper frame OR enter PO ID or CTEP Identifier in the lo...
Please do not use wildcard characters.

First Name:

Email:

City:

Zip:

PO ID (Exact Match):

CT

[Q Search] [+ Add Person] [C Reset] [⊗ Cancel]

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.

Select Principal Investigator

Email:

City: Rockville   State

Zip: Country

PO ID (Exact Match):   CTEP Identifie

[Q Search] [+ Add Person] [C Reset] [⊗ Cancel]
3 items found, displaying all items.**1**

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

✓ **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.

    > ⊘ **Tip**
    > If you still don't find your investigator in the system, you can add the person.

5. 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.

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Adding Persons to the CTRP

f you are unable to find a person, you can add one when you register, update, or amend a trial .

> ⊘ **Check for duplicate names first**
> Be sure to search the system's registered names first before you register a new one. This will ensure that you do not create a duplicate record in the system.

When you register a person, the CTRO staff curate the person's record, then add it to the list of registered persons in CTRP.

> ⓘ The procedure below uses the principal investigator role on the Register Trial page as an example. The same fields may not appear in all Add Person windows however.

How to Add Persons to CTRP

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

2. Click **Add Person**. The Add Person window appears.

Select Principal Investigator

Add Person

Please provide professional contact information only.

First Name :*		Last Name :*	
Prefix :		Middle Name :	
Suffix :		Country :*	Unit
Street Address :*		City :*	
State :	-Select a State- ▾	ZIP :	
Email :		Phone :	
URL :		TTY :	
Fax :			

Contact information required for internal administrative use only; not revealed to public

[💾 Save] [🔍 Search] [⊗ Cancel]

3. Select or enter the appropriate information in the text fields and drop-down lists. An asterisk (*) indicates a required field. Use professional contact information only. For U.S. and Canadian contacts, type phone and fax numbers in the format ***xxx-xxx-xxxx***. For all others, you can use spaces or dashes as separators, or no separators at all. Include phone number extensions where applicable.

> ⓘ **Privacy concerns**
> The information you provide is not revealed to the public.

> ⓘ ZIP Codes are required for organizations in the USA, Canada, and Australia.

4. Click **Save**.

> ⚠ **Avoid creating duplicate records**
> To prevent creating a duplicate record, do not click **Save** more than once. If you have to make changes after you click **Save**, do not use your browser's back button to make changes, and submit the record again. Instead, contact the CTRO.

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

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Viewing Trial Summary Reports and XML Documents v4.3

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

have been designated for import into ClinicalTrials.gov.
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)
- XML Required, Enable "Upload from NCI CTRP in ClinicalTrials.gov?" indicator is *Yes*

How to View TSR and XML Documents

1. 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.
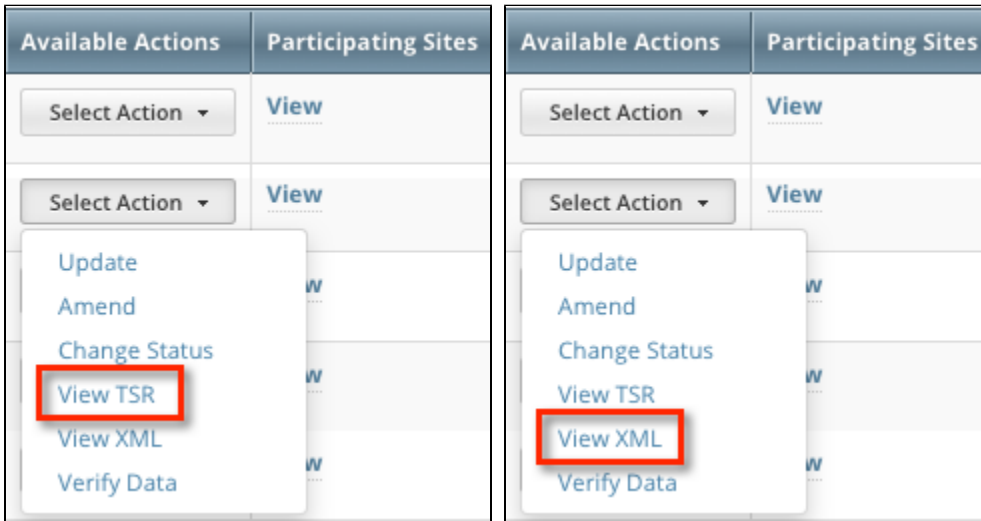
2. In the **Available Actions** column, click **Select Action > View TSR** or **Select Action > View XML.**

Managing Your Account v4.3

Topic Links
- Resetting Your NCI Password
- Retrieving Your Username
- Managing Your User Account Profile

This section provides instructions for resetting and modifying your CTRP account.

Resetting Your NCI Password

How to Reset Your NCI Password

- Navigate to the NCI Password Station at http://password.nci.nih.gov. Once you have logged in to the NCI Password Station, use the **Change Password** feature to create a new password.
  - or -
- On the Registration login page, click **Forgot Your Password?**.
  A pop-up window provides instructions for resetting your password and a link to the NCI Password Station.

Retrieving Your Username

How to Retrieve Your Username

1. On the **Login Page**, click the **Forgot Your Username?** link.
   The Retrieve User Name page is displayed.
2. Enter the email address associated with your account, and click **Submit**.
   The system sends your username to the email address you provided.

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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. 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.
2. 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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Using CTRP Registration Templates v4.3

Topic Links
• Downloading Trial Registration Templates
• Using the Complete Trial Participating Sites Template
• Main Steps for Submitting Your Complete Trial Participating Sites Data
• Preparing Participating Sites Data Files
• Trial Requirements
• Data Specification Requirements
• Submitting Participating Sites Files

This section provides instructions for submitting multiple trials in batches.

The CTRP provides templates and other resources on their website, and on the CTRP Batch Trial Template page, that you can use to facilitate trial information gathering and registration. See Registering Multiple Complete Trials in Batch Files . You can also use the templates to update and amend *Complete* trials that you have registered previously. CTRO staff use the information you provide in these documents to abstract your trials.

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

Downloading Trial Registration Templates

You can download the following templates (MS Excel files) for *Complete* trials directly from the [CTRP Trial Registration Batch File Templates](#) page, or from the [CTRP website](#):

- CTRP Registration *Complete* Batch Upload Template. Use this template as a guide to record trial data required for registering multiple interventional *Complete* trials, updates, and amendments in batches. See [Registering Multiple Complete Trials in Batch Files](#) .

- CTRP Registration *Complete* Participating Sites Template. Use this template to record interventional trial participating site data, especially if site-specific data is not included in the trial protocol, or if you need to make changes to the original participating sites information.

> (i) For information about trial updates and amendments, see [About Trial Amendments](#) and [About Trial Updates](#) .

How to Download CTRP Trial Registration Templates

1. Navigate to the [CTRP Trial Registration Batch File Templates](#) page.
2. Click the link for the appropriate template.
3. Follow your browser/operating system instructions to view or save the document.

> (i) If you have difficulty locating or downloading the templates, send a request for the files to application support at ncicbiit@mail.nih.gov.

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Using the Complete Trial Participating Sites Template

The participating sites template is designed for recording additional participating site and collaborator data for interventional trials, especially if site-specific data is not included in the trial protocol.

Main Steps for Submitting Your *Complete* Trial Participating Sites Data

How to Submit Your Complete Trial Participating Sites Data

1. Prepare the trial data file. See [Preparing Participating Sites Data Files](#).
2. Upload the file via the trial-related document feature in Registration. See [Submitting Participating Sites Files](#).

> (i) The .xls file that contains the trial data you want to register must meet certain requirements for successful registration. Ensure that you use this template for single complete interventional trials only.

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Preparing Participating Sites Data Files

The Participating Sites template includes data element requirements, valid values, rules and examples for registering complete trial participating site and collaborator information.

How to Prepare Complete Trial Participating Sites Data Files

Download the Complete Trial Participating Sites Template (Excel spreadsheet). See [Downloading Trial Registration Templates](#) .
Enter the trial data elements as specified in the template.

> (i) The .xls file that contains the trial data you want to register must meet certain requirements for successful registration as listed below and in the template itself.

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Trial Requirements

To ensure successful submission, ensure that your trials conform to the following criteria:

Study Type	- Complete - Interventional only

Data Table 4 Funding Sponsor Categories	• National • Externally Peer-Reviewed • Institutional
Processing Statuses for Trial Amendments	• Abstraction Verified Response • Abstraction Verified No Response
Processing Statuses for Trial Updates	Accepted and beyond

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Data Specification Requirements

The Participating Sites template includes data element requirements, valid values, rules and examples for registering complete trial participating site and collaborator information.

How to Prepare Complete Trial Participating Sites Data Files

1. Download the Complete Trial Participating Sites Template (Excel spreadsheet). See Downloading Trial Registration Templates .
2. Enter the trial data elements as specified in the template.

> ⓘ The .xls file that contains the trial data you want to register must meet certain requirements for successful registration as listed below and in the template itself.

You must adhere to the following requirements:

- List trial elements required for registration in the order specified in the template.
- Do not change the spelling of data elements or valid values.
- Conform to the valid values guidelines when entering trial data.
- Identify each trial uniquely.
- Participating site information must include the following data elements:
    - Study participating site data
    - At least one study site investigator's information
    - Participating site primary or central contact information. Generic contact information is accepted.
    - Organization attribute
    - Current recruitment status
    - Status date
    - Target accrual. This is mandatory if the target accrual is for a study at a participating site or if the lead organization is an NCI-designated Cancer Center.

    > ⓘ Optionally, provide a local trial identifier.

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

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

- Participating site contact information is optional if the contact person is the investigator, or if the central contact information is provided.
- List persons and organizations with PO-IDs.

> ✅ You can request a list of CTRP persons and organizations along with PO-IDs from the CTRO at ncictro@mail.nih.gov. Or, you can use the organization/person look-up features in Registration to search for PO-IDs.

> ⚠ **Program Code Updates**
> Although you can update Program Codes via Registration, you can not do so via the Participating Sites batch template.

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Submitting Participating Sites Files

You can submit the data file when you register your trial via Registration.

How to Submit Complete Trial Participating Sites Files

1. In Microsoft Excel, list the trial elements required for registration in the order specified in the template. To access the template, see Downloading Trial Registration Templates .
2. Once you have completed the template, upload it via the **Trial Related Documents** section on the **Register Trial** page in Registration. For upload instructions, see Recording Trial-Related Documents.

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Viewing Trial-Related Documents v4.3

Viewing Trial-Related Documents v4.3

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 v4.3

Working with Tables and Search Results v4.3

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.
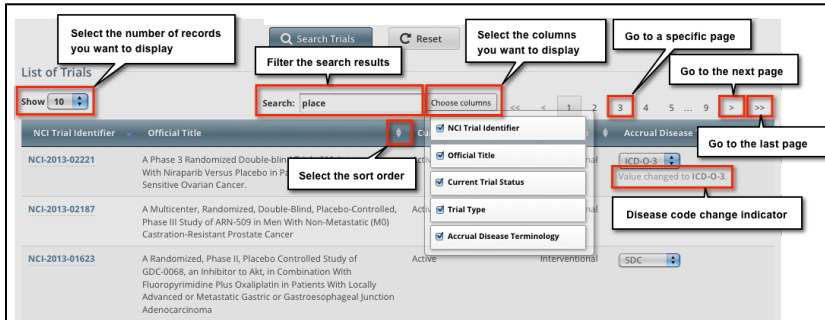
Filtering Search Results

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.

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

CTRP Trial Categories (Study Sources) v4.3

CTRP Trial Categories (Study Sources) v4.3

Trials are categorized by type of Data Table 4 Funding Sponsorship or Trial Submission Category (study source). Refer to http://cancercenters.cancer.gov/GrantsFunding/DataGuide#dt4 for further information.

- **Complete Trials**:
  - **National**: NCI National Clinical Trials Network (NCTN) and other NIH-supported National Trial Networks.
  - **Externally Peer-Reviewed**: R01s, SPORES, 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.

NCI Division and Program Codes v4.3

NCI Division and Program Codes v4.3

Division/Program Code	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
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 Institution Codes v4.3

NIH Institution Codes v4.3

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
NICHD	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

NIH Grant Institute Codes v4.3

NIH Grant Institute Codes v4.3

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)

Trial Phase Value Definitions v4.3

Trial Phase Value Definitions v4.3

- **0** - Exploratory trials, involving very limited human exposure, with no therapeutic or diagnostic intent (e.g., screening studies, micro dose studies). See FDA guidance on exploratory IND studies for more information.
- **I** - Includes initial studies to determine the metabolism and pharmacologic actions of a medical approach in humans, the side effects associated with increasing doses or exposure, and to gain early evidence of effectiveness; may include healthy participants and/or patients.
- **I/II** - Includes trials that are a combination of phases I and II.
- **II** - Includes controlled clinical studies conducted to evaluate the effectiveness of the medical approach for a particular indication or indications in patients with the disease or condition under study and to determine the common short-term side effects and risks.
- **II/III** - Trials that are a combination of phases II and III.
- **III** - Includes expanded controlled and uncontrolled trials after preliminary evidence suggesting effectiveness of the medical approach has been obtained, and are intended to gather additional information to evaluate the overall benefit-risk relationship of the drug and provide an adequate basis for physician labeling.
- **IV** - Studies of FDA-approved drugs, interventions, tests or diagnostic procedures to delineate additional information including the medical approach risks, benefits, and optimal use.
- **NA** (Not applicable) - All non-interventional or pilot studies.

Trial Processing Statuses v4.3

Trial Processing Statuses v4.3

This section provides the definitions of each of the statuses that occur during the course of the trial processing work flow. It also 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.
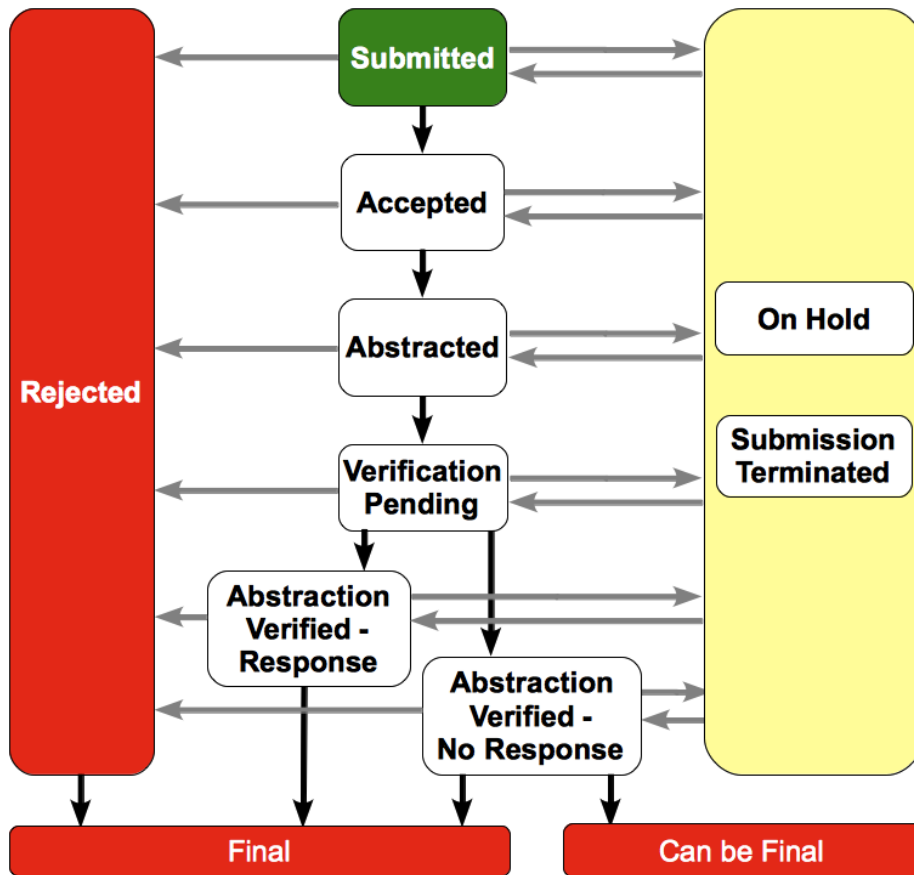
Milestone Workflow

Trial Registration Funding Mechanism Codes v4.3

Trial Registration Funding Mechanism Codes v4.3

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 Educati onal 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

Trial Status Date Rules in the CTRP v4.3

Valid dates for a given trial status depend on the other values you have entered, and whether those dates are *Actual* (current, or past) or *Anticipated* (future).
The following diagram illustrates these rules. The arrow at the top of the diagram represents a time line for the life of a trial. The three horizontal bands in the lower section of the diagram represent, from top to bottom, the relative date (actual or anticipated) rules for trial Start Date types, Primary Completion Date types, and Completion Date types.

The following table provides the rules for trial status dates as diagrammed.

Rules for Status/Dates relationships

If this is true...	Follow this rule
Current Trial Status is anything *other than* In Review, Approved, or Withdrawn	Trial Start Date must be Actual (solid band)
Current Trial Status is Approved or In Review	Trial Start Date could be Actual or Anticipated (diagonal stripes band)

Current Trial Status is Complete	All date types must be Actual (solid band)

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
- The Primary Completion Date can be earlier than the Current Trial Status Dates *Complete* or *Administratively Complete* if the Primary Completion Date is *Actual*
- The Completion Date is always the same as, or later than, the Primary Completion Date

Trial Status Transition Rules in the CTRP v4.3

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

Trial Status Flow Relationships

A trial can proceed from this status…	Directly to this status	Or to this status
In Review	- Approved - Withdrawn	Active/Enrolling by Invitation ⓘ This can occur when the trial has been Approved and is Active/Enrolling by Invitation on the same day
Approved	- Active/Enrolling by Invitation - Withdrawn	NA
Active/Enrolling by Invitation	Closed to Accrual	- 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	- Completed - Administratively Completed	NA
Temporarily Closed to Accrual	Temporarily Closed to Accrual and Intervention	- Active/Enrolling by Invitation - Closed to Accrual - Closed to Accrual and Intervention - Administratively Completed
Temporarily Closed to Accrual and Intervention	Administratively Completed	- 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 Status Values in the CTRP and ClinicalTrials.gov v4.3

Trial Status Values in the CTRP and ClinicalTrials.gov v4.3

This section maps each of the CTRP trial status values to their counterparts in ClinicalTrials.gov.

Trial status refers to the current stage or state of a clinical trial 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 as listed in the table below.

Current trial status definitions

CTRP Trial Status Values	ClinicalTrials.gov Trial Status Values	Definition
In Review	Not yet recruiting	Trial is currently under IRB review.
Withdrawn	Withdrawn	Trial has been withdrawn from development and review prior to enrollment of the first participant.
Approved	Not yet recruiting	Trial has been approved, but is not yet recruiting or enrolling participants.

Active	Recruiting	Trial is open for accrual and enrollment.
Enrolling by Invitation	Enrolling by Invitation	Participants are being (or will be) selected from a predetermined population.
Temporarily Closed to Accrual	Suspended	Participant recruitment or enrollment has been halted prematurely but may resume. Participants already on trial continue to receive intervention.
Temporarily Closed to Accrual and Intervention	Suspended	Participant recruitment or enrollment has been halted prematurely but may resume. Participants already on trial do not receive intervention.
Closed to Accrual	Active, not recruiting	Trial has been closed to participant accrual, but trial is ongoing (i.e., participants continue to receive treatment and/or examination).
Closed to Accrual and Intervention	Active, not recruiting	Trial has been closed to participant accrual. Participants already on trial do not receive treatment, but continue to be monitored for endpoints such as long term survival.
Administratively Complete	Terminated	Participant recruitment or enrollment has been halted prematurely (for example, due to poor accrual, insufficient drug supply, IND closure, etc.), and will not resume. Participants already on the trial do not receive further treatment or examination.
Complete	Completed	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.

Trial Summary Report and XML File Data Elements v4.3

Topic Links

- TSR-XML Data Element Comparisons
- Trial Summary Report Data Elements by Section
    - Trial Identification Data Elements
    - General Trial Details
    - Status/Dates
    - Regulatory Information/Oversight Information
    - Human Subject Safety/Regulatory Authority
    - NIH Grants
    - Data Table 4 Information
    - Collaborators
    - Disease/Condition
    - Trial Design
    - Eligibility Criteria
    - Intervention(s)/Intervention(s)
    - Arm and Group(s)
    - Primary and Secondary Outcome Measures
    - Participating Sites
- Excerpts from Example TSR and Example XML File

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. This document is sent only to trial submitters/owners who indicated that an XML file is required for submission to ClinicalTrials.gov when they registered the trial.

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

TSR-XML Data Element Comparisons

> ⊘ **Use the horizontal scroll bar to display "missing" 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
Record Verification Date	2013-03	`<verification_date>2013-03</verification_date>`
Trial Category	Complete	Not included in the XML file
Trial Type	Interventional	`<study_type>Interventional</study_type>`

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>`

ClinicalTrials.gov Identifier	NCT01234567	Not included in the XML file

Lead Organization Identifier	CCCCWFU 12345	`<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>`

DCP Identifier	WFU-01-01-06	`<secondary_id><id>WFU-01-01-06</id></secondary_id>`
		`<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>`

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>`

CCR Identifier	CCR-123	Not included in the XML file
Amendment Date	02/10/2003	Not included in the XML file
Amendment Number	35	Not included in the XML file
Type	Interventional	`<study_type>Interventional</study_type>`
Official Title	A Phase II Double-Blind Feasibility Study of Armodafinil...	`<official_title>A Phase II Double-Blind Feasibility Study of Armoda`
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 Th` `Primary Brain Tumors</brief_title>`
Acronym	ABC	Not included in the XML file

Brief Summary	This clinical trial is studying how well Armodafinil works....	`<brief_summary><textblock>`
		`This clinical trial is studying how well Armodafinil works..../>`
		`<textblock><brief_summary>`

Detailed Description	Detailed Description...	`<detailed_description><textblock>`
		`Detailed Description...`
		`</textblock></detailed_description>`

Primary Objectives	I. To estimate....	`<detailed_description><textblock>`
		`PRIMARY OBJECTIVES: I. To estimate....`
		`<textblock><detailed_description>`

Secondary Objectives	I. To obtain a preliminary estimate....	`<detailed_description><textblock>`
		`SECONDARY OBJECTIVES: To obtain a preliminary estimate....`
		`</textblock></detailed_description>`

Outline	OUTLINE: This is a multicenter study....	`<detailed_description><textblock>`
		`OUTLINE: This is a multicenter study....`
		`</textblock></detailed_description>`

Keywords	Feasibility Armodafinil; narcolepsy	`<keyword>Feasibility Armodafinil</keyword>` `<keyword>narcolepsy</keyword>`
Reporting Dataset Method	Complete	Not included in the XML file

| Sponsor | National Cancer Institute | ```<sponsors>
<lead_sponsor>
<agency>National Cancer Institute</agency>
</lead_sponsor>
</sponsors>``` |
|---|---|---|
| Lead Organization | Wake Forest University Health Sciences | ```<overall_official>
<first_name>PI First Name</first_name>
<last_name>PI Last Name</last_name>
<role>Principal Investigator</role>
<affiliation>Wake Forest University Health Sciences </affiliation>
</overall_official>``` |
| Principal Investigator | Autissier, Isabelle affiliated with Wake Forest University Health Sciences in the role of Principal Investigator | ```<overall_official>
<first_name>Isabelle Name</first_name>
<last_name>Autissier</last_name>
<role>Principal Investigator</role>
<affiliation>Wake Forest University Health Sciences</affiliation>
</overall_official>``` |
| Responsible Party | Sponsor | ```<resp_party_type>Sponsor</resp_party_type>``` |
| Overall Official | Autissier, Isabelle affiliated with Wake Forest University Health Sciences in the role of Principal Investigator | ```<overall_official>
<first_name>Isabelle Name</first_name>
<last_name>Autissier</last_name>
<role>Principal Investigator</role>
<affiliation>National Cancer Institute External</affiliation>
</overall_official>``` |
| Current Trial Status | Closed to Accrual and Intervention as of 08/01/2012 | ```<overall_status>Active, not recruiting</overall_status>``` |
| Trial Start Date | 08/01/2010-Actual | ```<start_date>2010-08</start_date>``` |
| Primary Completion Date | 01/11/2014-Actual | ```<primary_compl_date>2014-01</primary_compl_date>
<primary_compl_date_type>Actual</primary_compl_date_type>``` |
| Completion Date | 02/04/2014-Actual | `<last_follow_up_date>2014-02</last_follow_up_date>`

ⓘ If no data are available, the "<last_follow_up_date>" does not appear in the XML fil |
| Oversight Authorities | United States: Food and Drug Administration | ```<oversight_info>
<regulatory_authority>United States : Food and Drug Administration<
</oversight_info>``` |
| FDA Regulated Intervention? | Yes | ```<is_fda_regulated>Yes</is_fda_regulated>``` |
| Section 801? | Yes | ```<is_section_801>Yes</is_section_801>``` |
| DMC Appointed? | No Data Available | ```<oversight_info>
<has_dmc>Yes</has_dmc>
</oversight_info>``` |
| IND/IDE Study? | Yes | ```<is_ind_study>Yes</is_ind_study>``` |
| Board Approval Status | Submitted, approved | ```<irb_info>
<approval_status>Approved</approval_status>
<irb_info>``` |

Board Approval Number	IRB00012856	`<irb_info>`
		`<approval_number>IRB00012856</approval_number>`
		
		`<irb_info>`

Board	Wake Forest University Health Sciences	`<irb_info>`
		`<name>Wake Forest University Health Sciences</name>`
		`<irb_info>`

Affiliation	Wake Forest University Health Sciences	`<irb_info>`
		`<affiliation>Wake Forest University Health Sciences</affiliation>`
		`<irb_info>`

IND/IDE > Type	IND	`<ind_info>`
IND/IDE > Grantor	CBER	`<ind_grantor>CBER</ind_grantor>`
IND/IDE > Number	119999	`<ind_number>119999</ind_number>`
IND/IDE > Holder Type	NCI	Not included in the XML file
IND/IDE > Expanded Access	Yes	`<has_expanded_access>Available</has_expanded_access>`
IND/IDE Expanded Access Status	Not included in the TSR	Not included in the XML file
IND/IDE > Exempt Indicator	No	Not included in the XML file
NIH Grants > Funding Mechanism	U10	`<secondary_id><id>`**U10**`CA12345</id><id_type>NIH Grant Number</id_type></secondary_id><secondary_id>`

NIH Grants > NIH Institution Code	CA	`<secondary_id>`
		`<id>U10`**CA** `012345</id>`
		`<id_type>NIH Grant Number</id_type>`
		`</secondary_id>`

NIH Grants > Serial Number	88888	`<secondary_id>`
		`<id>U10CA`**8888**`</id>`
		`<id_type>NIH Grant Number</id_type>`
		`</secondary_id>`

NIH Grants > NCI Division/Program Code	DCP	Not included in the XML file
Data Table 4 Information > Funding Category	Externally Peer-Reviewed	Not included in the XML file
Data Table 4 Information > Funding Sponsor/Source	National Cancer Institute	Not included in the XML file
Anatomic Site Code	Prostate	Not included in the XML file

Collaborator Name	National Cancer Institute	`<collaborator>`
		`<agency>National Cancer Institute</agency>`
		`</collaborator>`

Collaborator Role	Funding Source	Not included in the XML file
Disease/Condition Name	Prostate Carcinoma	`<condition>`Prostate Carcinoma`</condition>`
Trial Design > Type	Interventional	`<study_type>`Interventional`</study_type>` and `<study_design>`Interventional`</study_design>`
Trial Design > Primary Purpose	Prevention	`<study_design>` `<interventional_design>` `<interventional_subtype>`Prevention`</interventional_subtype>` `</interventional_design>` `</study_design>`
Trial Design > Phase	II	`<study_design>` `<interventional_design>` `<phase>`II`</phase>` `</interventional_design>` `</study_design>`
Trial Design > Intervention Model	Parallel	`<study_design>` `<interventional_design>` `<assignment>`Parallel Assignment`</assignment>` `</interventional_design>` `</study_design>`
Trial Design > Number of Arms	2	`<study_design>` `<interventional_design>` `<number_of_arms>`2`</number_of_arms>` `</interventional_design>` `</study_design>`
Trial Design > Masking	Double Blind	`<study_design>` `<interventional_design>` `<masking>`Double Blind`</masking>` `</interventional_design>` `</study_design>`
Trial Design > Allocation	Randomized Controlled Trial	`<study_design>` `<interventional_design>` `<allocation>`Randomized Controlled Trial`</allocation>` `</interventional_design>` `</study_design>`
Trial Design > Classification	Safety/Efficacy	`<study_design>` `<interventional_design>` `<endpoint>`Safety Efficacy Study`</endpoint>` `</interventional_design>` `</study_design>`
Trial Design > Target Enrollment	100	`<enrollment>`54`</enrollment>`
Eligibility Criteria > Accepts Healthy Volunteers?	No	`<eligibility criteria >` `<healthy_volunteers>`No`</healthy_volunteers>` `</eligibility>`
Eligibility Criteria > Gender	Both	`<eligibility criteria >` `<gender>`Both`</gender>` `</eligibility>`

Eligibility Criteria > Minimum Age	18 Years	`<eligibility criteria >` `<minimum_age>18 years</minimum_age>`

Eligibility Criteria > Maximum Age	N/A	`<eligibility criteria >`
		`<maximum_age>N/A</maximum_age>`
		`</eligibility>`

Eligibility Criteria > Inclusion Criteria	Family history of prostate cancer...	`<eligibility>`
		`<criteria>`
		`<textblock>Inclusion Criteria: Family history of prostate cancer...`
		`</criteria>`
		`</eligibility>`

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 area....</textblock>`
		`</criteria>`
		`</eligibility>`

Intervention(s) > Type	Drug	`<intervention_type>Drug</intervention_type>`
Intervention(s) > Name	Armodafinil	`<intervention_name>Armodafinil</intervention_name>`
Intervention(s) > Alternate Name	2-(difluoromethyl)-DL-ornithine, 2-(difluoromethyl)-dl-ornithine Hydrochloride,...	`<intervention_other_name>2-(difluoromethyl)-DL-ornithine, 2-(difluo Hydrochloride,...</intervention_other_name>`
Intervention(s) > Description	Given orally	`<intervention_description><textblock>Given orally</textblock></inte`
Arm/Group(s) > Type	Placebo Comparator	`<arm_type>Placebo Comparator</arm_type>`
Arm/Group(s) > Label	Arm II	`<arm_group_label>Arm II</arm_group_label>`

Arm/Group(s) > Description	Patients receive oral Armodafinil once daily....	`<arm_group_description>`
		`<textblock>Patients receive oral Armodafinil once daily....</textbl`
		`</arm_group_description>`

Primary Outcome Measures > Title	Accrual rate estimated as the number of patients	`<primary_outcome>`
		`<outcome_measure>Accrual rate estimated as the number of patients .`
		`</primary_outcome>`

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 includes....</textblock>`
		`</outcome_description>`

Primary Outcome Measures > Time Frame	Up to 2 years	`<outcome_time_frame>Up to 2 years</outcome_time_frame>`

Secondary Outcome Measures > Title	Incidence of toxicity incidents....	`<secondary_outcome>`
		`<outcome_measure>Incidence of toxicity incidents assessed....</outc`
		`<secondary_outcome>`

Secondary Outcome Measures > Description	NA	`<outcome_description>`

Secondary Outcome Measures > Time Frame	Up to 2 years	`<outcome_time_frame>Up to 2 years</outcome_time_frame>`
Secondary Outcome Measures > Safety Issue?	No	`<outcome_safety_issue>No</outcome_safety_issue>`
Sub-groups Stratification Criteria > Label	Not included in the TSR	Not included in the XML file
Sub-groups Stratification Criteria > Description	Not included in the TSR	Not included in the XML file
Markers > Marker Name	Not included in the TSR	Not included in the XML file
Markers > Evaluation Type	Not included in the TSR	Not included in the XML file
Markers > Assay Type	Not included in the TSR	Not included in the XML file
Markers > Biomarker Use	Not included in the TSR	Not included in the XML file
Markers > Biomarker Purpose	Not included in the TSR	Not included in the XML file
Markers > Specimen Type	Not included in the TSR	Not included in the XML file

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>`

Participating Sites > Contact	Autissier, Isabelle, M.
	
	phone:123-123-1234
	
	Email:ia@domain.com
		`<location>`
		`<contact>`
		`<first_name>Isabelle</first_name>.<middle_name>M</middle_name><last`
		`<phone>123-123-1234></phone>`
		`<email>ia@domain.com</email>..`
		`</ contact>`
		`</location>`

Participating Sites > Recruitment Status and Dates	Enrolling by Invitation as of 05/09/2014	`<location>`
		`<status>Enrolling by Invitation</status>`
		`</location>`

Participating Sites > Target Accrual	40	Not included in the XML file

| Participating Sites > Investigators | Autissier, Isabelle, Principal Investigator | `<investigator>`
`<first_name>Isabelle</first_name><last_name>Autissier</last_name><r`
`Investigator</role>`
`</investigator>` |

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.

Trial Identification Data Elements

TSR Data Elements	XML Data Elements
Trial Category	Not included in the XML file
Trial Type	`<study_type>`
NCI Trial ID	`<secondary_id><id>`
Other Trial ID	`<id_type>`
Organization ID	`<org_study_id>`
ClinicalTrials.gov ID	Not included in the XML file
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
Study Type	`<study_type>`
Official Title	`<official_title>`
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>`

Status/Dates

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

Regulatory Information/Oversight Information

TSR Data Elements	XML Data Elements
Oversight Authorities	`<oversight_info>`
FDA Regulated Intervention?	`<is_fda_regulated>`
Delayed Posting Indicator?	`<delayed_posting>`
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>`

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
Anatomic Site Code	Not included in the XML file

Collaborators

TSR Data Elements	XML Data Elements
Collaborator Name	`<collaborator>`- `<agency>`
Role	Not included in the XML file

Disease/Condition

TSR Data Elements	XML Data Elements
Disease/Condition Name	`<condition>`

Trial Design

TSR Data Elements	XML Data Elements
Type	`<study_type>`
Primary Purpose	`<interventional_subtype>`
Phase	`<phase>`
Intervention Model	`<assignment>`
Number of Arms	`<number_of_arms>`
Masking	`<masking>`
Allocation	`<allocation>`
Classification	`<endpoint>`
Target Enrollment	`<enrollment>`

Eligibility Criteria

TSR Data Elements	XML Data Elements
Accepts Healthy Volunteers?	`<healthy_volunteers>`
Gender	`<gender>`
Minimum Age	`<minimum_age>`
Maximum Age	`<maximum_age>`

Inclusion Criteria	`<criteria>`
Exclusion Criteria	`<criteria>`

Intervention(s)/Intervention(s)

TSR Data Elements	XML Data Elements
Type	`<intervention_type>`
Name	`<intervention_name>`
Alternate Name	`<intervention_other_name>`
Description	`<intervention_description>`

Arm and Group(s)

TSR Data Elements	XML Data Elements
Number of arms	Not included in the XML file

Primary and Secondary Outcome Measures

TSR Data Elements	XML Data Elements
Title	`<outcome_measure>`
Description	`<outcome_description>`
Time Frame	`<outcome_time_frame>`
Safety Issue?	`<outcome_safety_issue>`

Participating Sites

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

Excerpts from Example TSR and Example XML File

The images below are excerpts from an example TSR:

Trial Summary Report

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 =< 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.

```xml
1  <?xml version="1.0" encoding="UTF-8"?>
2  <clinical_study>
3      <study_type>Interventional</study_type>
4      <id_info>
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```
<textblock>PRIMARY OBJECTIVES:&#13;
I. To assess progression-free survival on each arm of combination targeted thera

SECONDARY OBJECTIVES:&#13;
I. To assess the significance of changes in tumor size over early time points as

II. To quantify the number and percent of patients who have stable disease at 6
metastatic renal cell carcinoma (RCC).

III. To evaluate the safety of each treatment arm of combination targeted therap

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 patient

VI. To assess pathology, angiogenesis histology and to assess activation status
(VEGFR2) pathways and relate to clinical outcome.


    <eligibility>
        <criteria>
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Inclusion Criteria:
  - Patients will be required to have the clear cell variant of renal cell carci
chromophobe or oncocytic); there must be histologic confirmation by treating cen
  - Patients will be required to have measurable metastatic disease that is not
prior to study entry
  - Previous nephrectomy is required with the following exceptions:&#13;
  * Primary tumor =&lt; 5 cm, or&#13;
  * Extensive liver (&gt; 30% of liver parenchymal) or multiple (&gt; 5) bone me
  * Unresectable primary tumor due to invasion into adjacent organs or encasing
  - No prior cytotoxic chemotherapy; a maximum of one prior regimen of either va
  - No prior anti-angiogenic therapy including, but not limited to, SU11248, ZD6
inhibitors (including, but not limited to, temsirolimus), or sorafenib will be a
stage IV disease
  - No immunotherapy within 4 weeks of randomization; toxicities from immunother
  - Prior radiation therapy is permitted, but toxicities from radiation must hav
  - No history or clinical evidence of central nervous system (CNS) disease, inc
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