NCI Clinical Trials Reporting Program Registration Site User's Guide

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☑ **You can convert the wiki version of this guide to PDF for viewing and printing**

For instructions refer to Printing multiple pages. If you want to print a single page, refer to Printing a page.
Some longer links may appear truncated when viewed in PDFs, but they work regardless.

Application Support

If you have problems with the program or have suggestions for any of the CTRP User 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 the NCI Clinical Trials Reporting Program Trial Registration Site (CTRP Registration Site) and instructions for using its tools and resources to search for and view details of existing clinical trials. Additionally, users can submit new clinical trials and amend and/or update those currently registered and

verified in the CTRP.

Audience

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

Topics Covered

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

- 1 - Getting Started introduces you to the CTRP Registration Site and provides instructions for registering for an account and for logging in to the system.
- 2 - Searching for Trials, Organizations, and Persons in the CTRP System provides instructions for searching for existing trials, persons, and organizations that have been registered the CTRP system.
- 3 - Registering New Trials describes how to register, Institutional, National, and Externally Peer-Reviewed trials using the CTRP Registration Site. It also provides instructions for registering multiple trials in batches.
- 4 - Updating Trials describes how to update complete and abbreviated trials that are currently registered and verified in CTRP.
- 5 - Amending Trials describes how to submit amendments to complete trials currently registered and verified in the CTRP.
- 6 - Adding Your Site to Abbreviated Trials provides instructions for adding your organization as a participating site to Industrial (abbreviated) trials.
- 7 - Managing Participating Site Record Ownership provides instructions for assigning and un-assigning participating site record ownership to other registered CTRP users from your organization for abbreviated trials in which your organization is a participant.
- 8 - Managing Site Administration Within Your Organization introduces you to site administration management and provides instructions for granting and revoking administrative authority.
- 9 - Displaying Trial Ownership provides instructions for site administrator to view trial ownership.
- 10 - Managing Trial Ownership provides instructions for managing trial ownership.
- 11 - Managing Access to Subject Accruals provides instructions for assigning and un-assigning access to the Subject Accruals application.
- 12 - Managing Your Account provides instructions for modifying your CTRP Registration Site account.
- 13 - Using CTRP Registration Templates and Resources provides instructions for submitting participating site information for complete and abbreviated trials; and disease/condition and intervention information for abbreviated trials.
- A - Working With Persons and Organizations provides instructions for looking up persons and organizations registered in the CTRP system, and for adding new persons and organizations to it.
- B - Common Tasks and Data Element Formats provides detailed instructions for tasks that are common to many of the procedures for recording trial information in the Clinical Trials Reporting Program (CTRP). It also provides a key to the user interface (icons, buttons, etc.) and valid formats for entering information such as dates and phone numbers.
- C - Funding Mechanism Codes provides the values for funding mechanism codes, the NCI codes used to identify areas of extramural research activity applied to various funding mechanisms.
- D - Institute Codes provides the values for institute codes, the NCI codes used to identify the name of the primary organization responsible for funding the trial.
- E - NCI Division and Program Codes provides the values for Division codes, the NCI codes used to identify the name of the NCI Division responsible for a grant.
- F - Trial Processing Statuses provides definitions for 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.
- G - Trial Phase Value Definitions provides definitions for each of the trial phases.

- [H - Trial Summary Reports and XML Files](#) provides definitions and examples of the system-generated Trial Summary Report and XML files.
- [I - Clinical Trial Summary 4 Categories](#) provides definitions of CTRP trial categories.

Application Support

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 as per the instructions below.

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

1 - Getting Started

1 - Getting Started

This section introduces you to the NCI Clinical Trials Reporting Program Trial Registration Site (CTRP Registration Site) and provides instructions for registering for an account and logging in to the system. It also provides information for accessing templates and other resources.

This section includes the following topics:

- [About the CTRP Registration Site](#)
- [What's New in This Release](#)
- [About Clinical Trial Details](#)
- [Creating CTRP Registration Site Accounts](#)
- [Requesting Organization Admin Rights](#)
- [Logging In to the CTRP Registration Site](#)

> 🛈 **Browser Support**
>
> This version of the application supports Firefox 14.0.1, and Internet Explorer 8. Although tested on these browsers alone, CTRP applications should work with all popular browsers. However, if you use another browser to access CTRP applications, you may experience problems.

About the CTRP Registration Site

About the CTRP Registration Site

The CTRP Registration Site provides cancer clinical trial access to researchers who have Clinical Trials Reporting Program (CTRP) accounts. It enables these users to view details of existing trials submitted by members of the cancer research community, and to register, amend, and update trials one-at-a-time or in batches consisting of multiple trials. Currently you can register [complete](#) and [abbreviated](#) interventional trials. Future releases of this product will enable you to register observational, ancillary, and correlative studies as well.

Related Topics

- [About Clinical Trial Details](#)
- [Accessing Registered Trials](#)

What's New in This Release

What's New in This Release

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

- **Accrual Access Management**
    - You can now assign and un-assign access to the CTRP Subject Accrual application to users in your organization

- **Email Messages and Trial Ownership**
    - Email messages that are sent to trial owners who have updated or amended their trials contain details of the changed elements
    - You can now indicate whether a user would like to receive system notifications, including TSRs and XML files, on a trial-by-trial basis

- **Navigation and User Interface Improvements**
    - A "Back to Search Results" button enables you to return to your search results after leaving the Search Results page

- **Person and Organization Search Features and Improvements**
    - You can now search for organizations and persons by their PO IDs

About Clinical Trial Details

About Clinical Trial Details

The CTRP Registration Site captures clinical trial details, a sanctioned set of key data elements, entered into the system by trial protocol submitters. This set of recorded data enables the research community to share and analyze standardized clinical trial details.

> 🛈 **Tip**
>
> The glossary on the CTRP web site at http://www.cancer.gov/clinicaltrials/ctrp/page12 provides definitions, attributes, and examples of metadata associated with trials.

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).

Creating CTRP Registration Site Accounts

Creating CTRP Registration Site Accounts

To search for and submit individual clinical trial protocol details, you must have an NIH (or NCI) account and a Clinical Trials Reporting Program account. You can create both types of accounts using the Registration

application's account creation feature. The way in which you create a new account in the CTRP Registration Site depends on whether you have a current NIH account, as follows:

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

> ℹ️ 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](#).

Creating New CTRP Registration Site Accounts Using NIH or NCI Credentials

Creating New CTRP Registration Site Accounts Using NIH or NCI Credentials

Although you already have an NIH (or NCI) account, you must register for an associated CTRP Registration Site account. The CTRP account identifies your organization affiliation, whether or not you own a particular trial, and other such details specific to the NCI Clinical Trials Reporting Program Trial Registration Site.

How to Create New CTRP Registration Site Accounts Using NIH Credentials

1. Navigate to the CTRP Registration Site home page at http://trials.nci.nih.gov/registration.
2. Click **Create an account**.
   The Register for a CTRP Account page appears.

Register for a CTRP Account Page

3. Because you already have an NIH account, click the **here** link.
   The Register for a CTRP Account page displays username and password fields.

Register for a CTRP Account Page

4. Enter your username and password, and then click **Next**.

    The My Account Page appears, pre-populated automatically with all the information associated with your NIH/NCI account.

My Account

To register for NCI Clinical Trials Reporting Program, please begin by creating an account.
Please note: asterisks (*****) indicate required fields.
Please provide professional contact information only.

Your Account Profile

Email Address:*	user@mail.nih.gov
First Name:*	Isabelle
Middle Initial:	
Last Name:*	Autissier
Street Address:*	
City:*	
State:*	--Select--
ZIP/Postal Code:*	
Country:*	United States
Phone Number:*	
Organization Affiliation:*	🔍 **Look Up**
PRS Organization Name :	

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

👤 **Submit**

My Account Page

5. Select or enter the appropriate information in the text fields and drop-down lists in **Your Account Profile**. Fields with an asterisk (*) are required.

> ℹ️ **Privacy concerns**
>
> Contact information is required for internal administrative use only. Your information is not revealed to the public.

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 Persons. Once organization affiliation is assigned, 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 access. Otherwise the **View Admins** link that enables you to display the name of the current admins appears. (The link appears only if the organization you are affiliated with already has one or more registered admins.)
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.
Submit	Click to register your information with CTRP. The system sends you an account confirmation email message.

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

Related Topics

Creating New CTRP Registration Site Accounts via Email
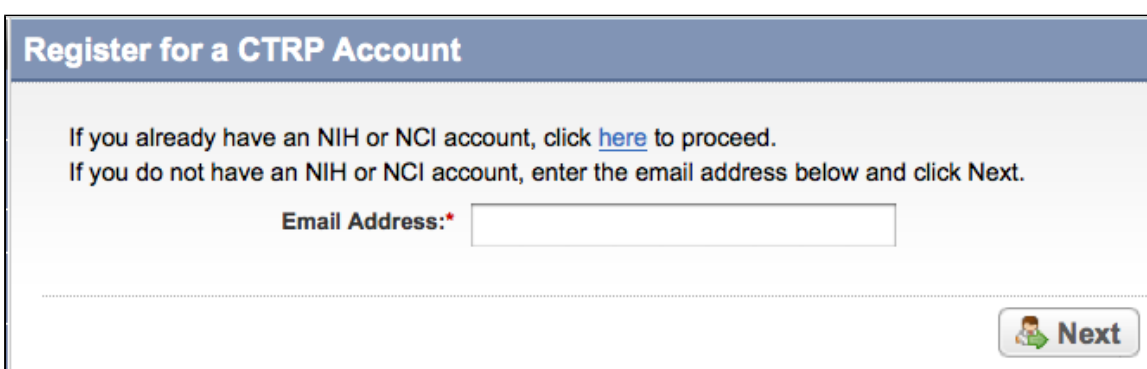
Creating New CTRP Registration Site Accounts via Email

If you are new to the NCI Clinical Trials Reporting Program Trial Registration Site and you do not have an NCI account, request a CTRP Registration Site account via the CTRP Registration Site account creation feature.

How to Create a New CTRP Registration Site Account

1. Navigate to the CTRP Registration Site home page at http://trials.nci.nih.gov/registration.
2. Click **Create an account**.
   The Register for a CTRP Account page appears.

Register for a CTRP Account Page

3. In the **Email Address** field, type the email address you will use for registering trials (this should be your business email address), and then click **Next**.
   The system sends you a message stating that you will receive an email notification with instructions for activating your account.

   > ℹ️ **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 ncicb@pop.nci.nih.gov or by calling 888-478-4423.

4. Open the account information email when it arrives, and click the embedded link to the **My Account** page.
   The My Account page appears, pre-populated with the email address you provided.

Your Account Profile

Email Address:*	autissieri@myorg.com
First Name:*	
Middle Initial:	
Last Name:*	
Street Address:*	
City:*	
State:*	--Select--
ZIP/Postal Code:*	
Country:*	United States
Phone Number:*	
Organization Affiliation:*	🔍 Look Up
PRS Organization Name :	

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

My Account Page--Your Account Profile

5. Select or enter the appropriate information in the text fields and drop-down lists in **Your Account Profile**. Fields with an asterisk (*) are required.

> ℹ **Privacy concerns**
>
> Contact information is required for internal administrative use only. Your information is not revealed to the public.

Field Name	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 Persons](). Once organization affiliation is assigned, 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 access. Otherwise the **View Admins** link that enables you to display the name of the current admins appears. (The link appears only if the organization you are affiliated with already has one or more registered admins.)
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. <table><tr><td>⚠️ **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.</td></tr></table>
Submit	Click to register your information with CTRP. The system sends you an account confirmation email message.

Requesting Organization Admin Rights

Requesting Organization Admin Rights

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

- Site Administration - Enables you to accept or reject requests for Admin rights from other users within your organization.
- Trial Ownership management - Enables you to assign and un-assign ownership of your organization's trials to other registered users within your organization.

> ℹ **Condition**
>
> The **Request for Admin Access** check-box on the **My Account** page is displayed if no one in your organization has been granted administrative (admin) access.

How to Request Admin Access

Do one of the following on the **My Account** page to request admin access:

- Select the **Request for Admin Access** check box, and then click **Submit**.
  -or-
- Click the **View Admins** link, and contact one of the current Affiliated Organization Administrators to request admin aceess.

> ℹ The CTRO will send you an email message when your request has been approved or rejected. If approved, you can access all trials for your affiliated organization, review and update trial ownership, and assign new administrator status to other users in your organization.

Logging In to the CTRP Registration Site

Logging In to the CTRP Registration Site

Once you have created a CTRP Registration Site account, you can log in to search for and submit clinical trial details.

> ✅ **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 also 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 NCICB Support at ncicb@pop.nci.nih.gov , or phone: 301-451-4384 or toll free: 888-478-4423. If you have forgotten your password, see Resetting Your NCI Password.

How to Log In to the CTRP Registration Site

1. Navigate to the CTRP Registration Site home page at http://trials.nci.nih.gov/registration.
2. On the **Home** page, click the **Log In** link.

> ℹ You can also display the **Login** page by clicking **Log In** on the navigation pane on the left side of the page or on the banner at the top of the page on the right side.

The Login page appears.

CTRP Registration Site – Login page

3. Type your username and password in the fields provided. If you do not have a registered username and password, see Creating CTRP Registration Site Accounts. If you have forgotten your password or username, or have been locked out of your account, see the instructions in Managing Your Account.
4. Click **Log In**.
   The notification regarding respondent burden appears.
5. After you read the public reporting burden notice, click **Accept**.
   The **Search Trials** page appears.
6. After you have logged in to CTRP Registration Site, you can proceed to search for and/or add clinical trials in the system.

Related Topics

- Searching for Trials
- Registering New Trials

2 - Searching for Trials, Organizations, and Persons in the CTRP System

2 - Searching for Trials, Organizations, and Persons in the CTRP System

The CTRP Registration Site enables you to search for trials, persons, and organizations that have been registered with the CTRP system. In each case you are presented with a pre-defined set of search criteria that is appropriate for the type of search you are conducting. For example, when you search for a trial, the set of criteria includes Title, Trial Phase, and Purpose, whereas a set of criteria for searching for a person will include Last name and First Name.

> ☑ All criteria are presented as fields in which you type attributes, or as drop-down lists from which you select them. You can run your search once you have selected or typed an attribute for at least one criterion.

This section includes the following topics:

- Searching for Trials
- Searching for Organizations
- Searching for Persons
- Working with Search Results
- Viewing Trial Details
- Viewing Trial-Related Documents
- Exporting Search Results

Related Topics

- [Working With Persons and Organizations](#)
- [About Clinical Trial Details](#)

Searching for Trials

Searching for Trials

You can retrieve existing interventional trials once you have registered for an account. See [Creating CTRP Registration Site 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 have submitted or 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.
- Use the **Search On Hold Trials** to search for trials that the CTRO has placed on hold.

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 All Trials	Search My Trials	Search Saved Drafts
Types of Trials Returned	All trials	- Trials on hold - Trials for which you are the trial submitter or owner	Partial Submissions

Actions Permitted	• View Trial Details • Add/Update My Site (Abbreviated trials only) ⓘ If you are the trial submitter or owner of a trial in the search results, you can perform the same actions as you would when using the **Search My Trials** feature.	• View Trial Details • Update Trials • Amend Trials • Request TSR/XML • Change Status • Add/Update My Site (Abbreviated trials only)	• View Trial Details • Complete Submissions • Add/Update My Site (Abbreviated trials only)
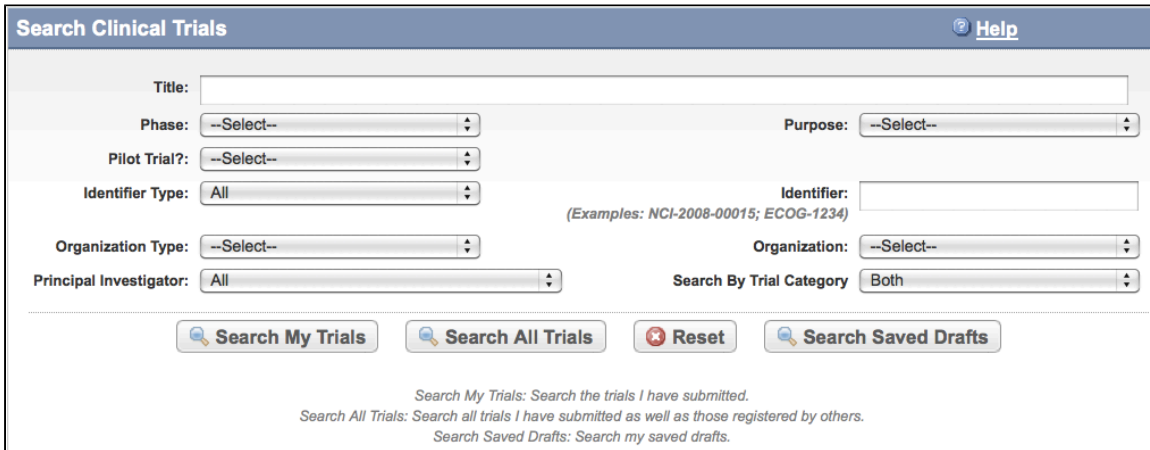
> ℹ️ All registered users can search trials with the "Accepted" and subsequent processing status. Additionally, you can search trials that you registered or own which have not been validated. These trials are indicated by the "Submitted" status.

How to Search for Existing Trials

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

Search Clinical Trials Page

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

> ✔️ **Tip**
>
> If you are searching for a saved draft, search by Phase, Purpose, Title, or Identifier only. Because the system adds wildcards for you, do not type wildcard symbols in the search fields.

Trial Search Criteria

To search by this...	Do this...

Title	Type one or more words from the long title or name of the trial provided by the principal investigator or sponsor.
	✅ **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. See Trial Phase Value Definitions. * Phase 0 * Phase I * Phase I/II * Phase II * Phase II/III * Phase III * Phase IV * N/A
Pilot Trial?	If the trial is a pilot, select **Yes**.
Purpose	Select the primary purpose of the trial from the drop-down menu. * Treatment * Prevention * Supportive Care * Screening * Diagnostic * Health Services Research * Basic Science * Other – Any other type of trial not included in this list

Identifier Type	Select the type of trial identifier from the drop-down list. * NCI – NIH National Cancer Institute identifier * NCT (Exact Match) – National Clinical Trial identifier (NCT Number). Provide the exact number, including the NCT prefix. Example: NCT00012345 * Lead Organization – Type the unique identifier assigned to the trial by the lead organization. * Other identifier > ☑ **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	Type the unique identifier assigned to the trial by the NCI, NCT, PRS, or the identifier assigned to it by the lead organization. For Inter-Group trials, type the Lead Group's trial number.
Organization Type	Select either **Lead Organization**, **Participating Site**, or **Both** from the drop-down list.
Organization	Type the initial letter(s) of your organization and then select the name of your organization from the drop-down list. > ☑ To search for trials by organization without having to specify what role the organization plays in the trial, select **Either or Both** from the **Organization Type** list, and then select the name of the organization of interest.
Principal Investigator	Type the initial letter(s) of the principal investigator's last name and then select the investigator's name from the drop-down list
Search by Trial Category	To restrict your search by trial category, select **Abbreviated** or **Complete** from the drop-down list. Otherwise, select **Both**.

3. Do one of the following:

- To search all registered trials in the system, click **Search All Trials**.
  -or-
- To search only the trials that you submitted or own, click **Search My Trials**. This feature enables access to all the trials that you have submitted, including those that are currently on hold[1]
  -or-

- To search only the trials that you have saved for later completion, click **Search Saved Drafts**.
  -or-
- To clear all search criteria and begin a new search, click **Reset**.

The Search Trials page refreshes and displays a list of search results. For more information on navigating and working with search results, see <u>Navigating Search Results Lists</u>.

4. To view the trial, click the link corresponding to the NCI Trial Identifier.
The Trial Details page appears. For more information on viewing trial details, see <u>Viewing Trial Details</u>.

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

null

Related Topics

- <u>Working with Search Results</u>
- <u>Adding Organizations as Participating Sites to Registered Industrial Trials</u>
- <u>Searching for Organizations</u>
- <u>Searching for Persons</u>
- <u>Exporting Search Results</u>

Searching for Organizations

Searching for Organizations

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

> ✅ 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. On the navigation pane, click **Search Organizations**.
The Search Organizations window appears.

Search Organizations Window

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 type 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 (%) between characters of the string as necessary..

3. Click **Search**.
   The Search Organizations window displays the results of your search.

Search Organizations Window – Search Results

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

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

search by city in addition to the state.
5. To view the details of any organization in the search results list, click its **PO-ID**.
   The Organization Details window displays current information about the organization, including an email link that you can use to contact the organization.

Organization Details Window

Searching for Persons

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 Look Up Registered Persons

1. On the navigation pane, click **Search Persons**.
   The Search Persons window appears.

Search Persons Window

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 type 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 (%) between characters of the string as necessary..

3. Click **Search**.
   The Search Persons window displays the results of your search.
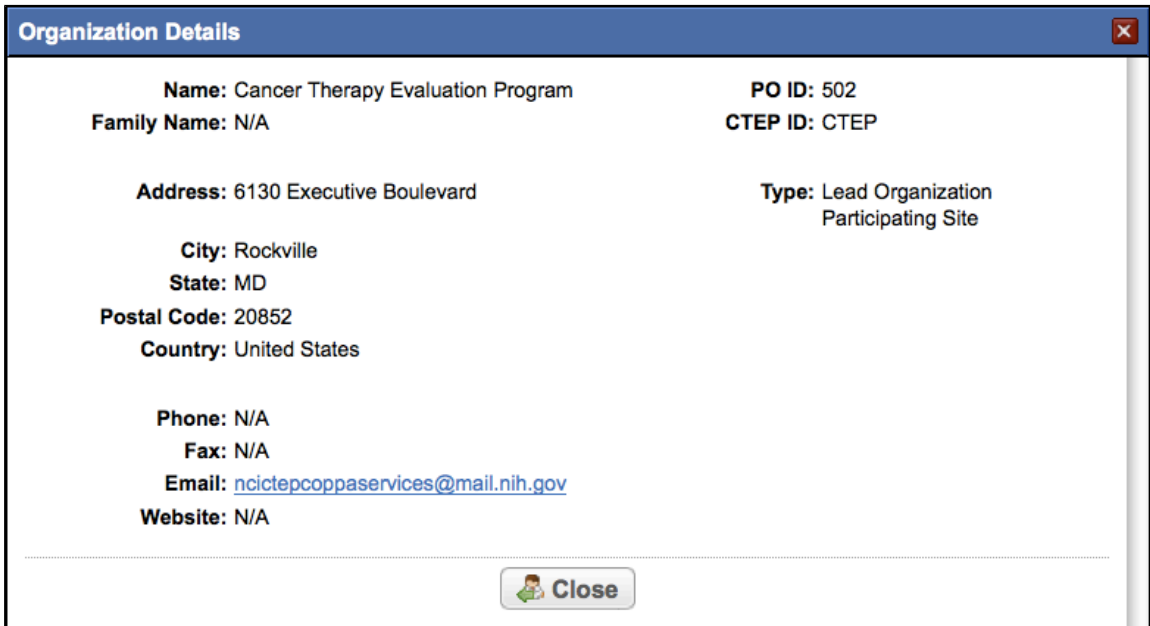

Search Persons Window – Search Results

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

4. If the person does not appear in the results table, do one of the following to modify your search:
   - To broaden your search so that more persons are listed in the search results, delete one or more of your criteria. For example, if you searched by part of the person's name, city, state, and zip code in your original search, you may want to search by state alone.

- or -
- To narrow your search so that fewer persons are listed in the search results, provide more about your person. For example, if you searched by state in your original search, you may want to search by city in addition to the state.

5. To view the details of any person in the search results list, click its **PO-ID** link.
   The Person Details window displays current information about the person.

Prefix: Dr.	**PO ID:** 13623979
First Name: Naomi	**CTEP ID:** 5582
Middle Name: N/A	
Last Name: Alazraki	**Role:** Healthcare Provider

Address: 1350 LA JOLLA VILLAGE	
NUCLEAR MEDICINE DEPARTMENT	
City: San Diego	
State: CA	
Postal Code: 92161	
Country: USA	

Organization Affiliation

2 items found, displaying all items.**1**

PO ID	Name
38803	University of California San Diego - Veterans Administration
502	Cancer Therapy Evaluation Program

[Close]

Person Details Window

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

Working with Search Results

Working with 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 a status of "accepted," and the system notifies the site 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 a status of "rejected," and the system sends the submitter an email message indicating the status and reason for the rejection.
  Reviewers may also reject a trial for the following reasons:
  - CTEP/DCP/CCR has approved the trial. NCI transfers these trials internally.
  - The trial is non-interventional. Non-interventional trials will be supported in future releases.

> ℹ If you have questions about a rejected trial, contact the CTRO at ncictro@nih.nci.gov.

The trials that match your search criteria are listed in the Submitted Clinical Trials Search Results table. 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 illustrated 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 the CTRP Registration Site
  - Public trials – Trials submitted by other registered users

> ⓘ 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.

Submitted Clinical Trials Search Results

5 trials found, displaying all trials.1

NCI Trial Identifier	Title	Lead Organization	Lead Org Trial Identifier	Principal Investigator	NCT Number	Other Identifiers	Current Trial Status	Current Processing Status	Available Actions	Participating Sites	Phase	Primary Purpose
NCI-2012-00448	Complete trial Doc2	Example	CTRP-DOC2	Tester1, Doc			Enrolling by Invitation	Submitted		View	I	BASIC_SCIENCE
NCI-2012-00447	Industrial Trial	Example	CTRP-DOC1					Submitted		View	II	DIAGNOSTIC
NCI-2012-00446	Alaska Cancer Research Test	Cancer Treatment Center	CTC TEST					Accepted	Select action ∇	View	I_II	TREATMENT
NCI-2012-00390	Example of trial registration	Example	6542	Autissier, Isabelle	2012	'12345'	Active	Accepted	Select action ∇	View	I	SUPPORTIVE_CARE
NCI-2012-00380	Trial registration search for on-hold trials	Example	123456	Autissier, Isabelle	000012		Enrolling by Invitation	Submitted		View	I_II	TREATMENT

Export options: CSV | Excel

Search Results Table - Columns on the Left Side

Category	Trial Start Date	Responsible Party	Sponsor	Summary 4 Funding Sponsor Type	Record Verification Date	Submittter	Primary Completion Date	Last Update Submitted	Last Updater Name	Last Amendment Submitted	Last Amender Name	On-Hold Reason
Complete	05/03/2011	Doc,Tester1	Cancer Treatment Center	INSTITUTIONAL		Test, Doc	05/02/2014					
Abbreviated				INDUSTRIAL		Test, Doc						
Abbreviated				INDUSTRIAL		Test, Doc						
Complete	04/09/2012	Isabelle,Autissier	Cancer Therapy Evaluation Program	NATIONAL		Test, Doc	04/03/2015					
Complete	04/02/2012			EXTERNALLY_PEER_REVIEWED		Test, Doc	04/30/2013					

Search Results Table - Columns on the Right Side

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. Column headers in **bold italic text** below indicate the information that is displayed for Public trials.

- ***NCI Trial Identifier*** – Unique identifier assigned to the trial by the CTRP
- ***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, usually an accession number or a variation of a grant number. Multiple studies conducted under the same grant must each have a unique number.
- ***Principal Investigator*** – Appointed investigator responsible for conducting clinical trial, or for multi-site trials, the study chair
- ***NCT Number*** - Number assigned to the trial by PRS (ClinicalTrials.gov) (for trials that have been submitted to ClinicalTrials.gov previously.
- **Other Identifiers_** - Identifiers other than Lead Organization Trial Identifier or NCT Number
- ***Current Trial Status*** – Code that represents the status of a trial in relation to the ability to enroll participants/patients
- Current Trial Processing Status - Stage in the trial processing work flow
- ***Available Actions*** - 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). The documents are sent via email to all trial owners

> ⚠ The actions available for a trial depend on its processing status and participating site record ownership.

- ***Participating Sites*** - One or more organizations participating in the trial. Click **View** in the **Participating Sites** column to view participating site details
- Phase - Phase of the investigation, as defined by the US FDA for trials involving investigational new drug
- Primary Purpose - Main purpose of the trial
- Category - Summary 4 Funding Sponsorship or Trial Submission Category

- Trial Start Date - Date on which the trial starts
- Responsible Party - Responsible party, as defined by FDAAA
- Sponsor - Primary organization that oversees the implementation of the study and is responsible for data analysis as defined in 21 CFR 50.3
- Summary 4 Funding Type - Trial category selected for trial submission
- Record Verification Date - Date on which the CTRO validated the trial submission
- Submitter - Name of person who submitted the trial
- Primary Completion Date - Date on which the trial reaches/reached its primary completion date
- Last Update Submitted - Date on which the trial was last updated
- Last Amendment Submitted - Date on which the trial was last amended
- Last Amender Name - Name of person who amended the trial
- On-Hold Reason - 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:

- 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

> ℹ 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.

Related Topics

- Navigating Search Results Lists
- Exporting Search Results

Viewing Trial Details

Viewing Trial Details

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

NCI Trial Identifier	Title	Lead Organization	Lead Org Trial Identifier	Principal Investigator	NCT Number	Other Identifiers	Current Trial Status	Current Processing Status	Available Actions	Participating Sites	Phase
NCI-2012-00452	a test	Cancer Therapy Evaluation Program	a test	Lee, Eudocia			In Review	Submitted		View	I_II
NCI-2012-00451	Example National Trial	Cancer Therapy Evaluation Program	LEAD ID	Tester1, Doc			Enrolling by Invitation	Submitted		View	NA
NCI-2012-00448	Complete trial Doc2	Example	CTRP-DOC2	Tester1, Doc			Enrolling by Invitation	Submitted		View	I

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 Summary 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.

NCI Trial Identifier	Title	Lead Organization	Lead Org Trial Identifier	Principal Investigator	NCT Number	Other Identifiers	Current Trial Status	Current Processing Status	Available Actions	Participating Sites	Phase

Trial Details

Trial Identifiers

NCI Trial Identifier: **NCI-2012-00451**

Lead Organization Trial Identifier: LEAD ID

NCT Number:

Trial Details

Title: Example National Trial

Phase: NA

Pilot Trial?: Pilot

Primary Purpose: Basic Science

Lead Organization / Principal Investigator

Lead Organization: Cancer Therapy Evaluation Program

Principal Investigator: Tester1, Doc

Summary 4 Information

Summary 4 Funding Sponsor Type: National

Summary 4 Funding Sponsor/Source: National Cancer Institute

Status / Dates

Current Trial Status: Enrolling by Invitation

Why the Study Stopped:

Current Trial Status Date: 05/17/2012

ⓘ 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.**

Related Topics

- Viewing Trial Details
- Searching for Trials, Organizations, and Persons in the CTRP System
- Navigating Search Results Lists

Viewing Trial-Related Documents

Viewing Trial-Related Documents

Only trial owners and system 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 the instructions for your browser and operating system to view or save the document.

> ℹ️ 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.

Related Topics

- [Viewing Trial Details](#)
- [Working with Search Results](#)

Exporting Search Results

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** table, 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. Open or save the file.

3 - Registering New Trials

3 - Registering New Trials

This section describes how to register new *National*, *Externally Peer-Reviewed* and *Institutional* interventional protocols (collectively referred to as *complete* trials), and Industrial trials, (referred to as *abbreviated* trials), in the CTRP system.

This section includes the following topics.

- [Main Steps for Registering Trials](#)
- [Recording Trial Identifiers](#)

Main Steps for Registering Trials

Main Steps for Registering Trials

The CTRP Registration Site provides a user-friendly interface through which you can register and update complete and abbreviated trials. Additionally, it enables you to amend complete interventional protocols in the CTRP system.
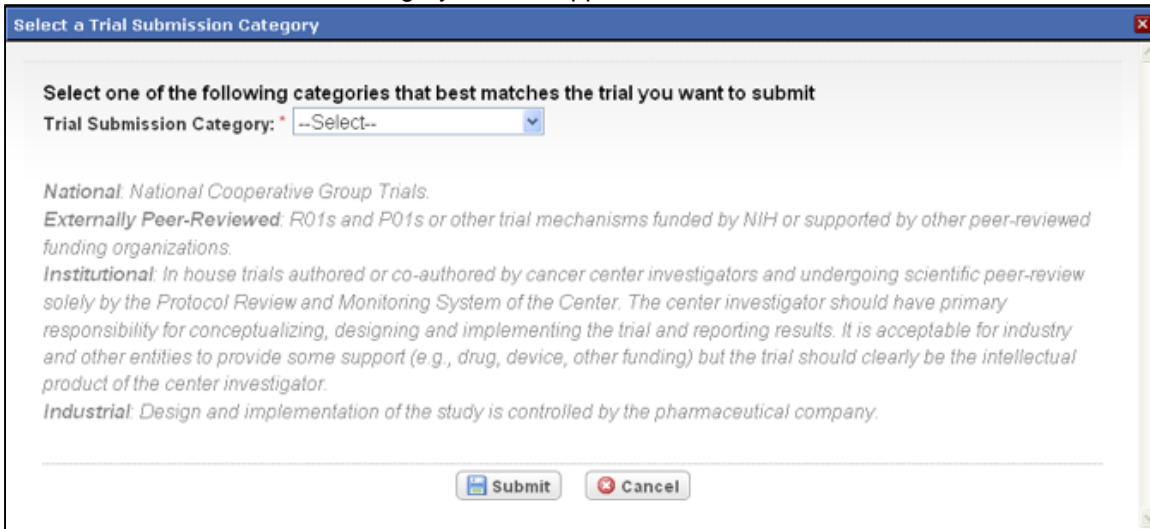
- **Complete**. Trials in this category include the following types of interventional trials:
    - **National**. National Cooperative Group Trials. These trials are conducted by the following cooperative groups:
        - American College of Radiology Imaging Network
        - American College of Surgeons Oncology Group
        - Cancer and Leukemia Group B
        - Children's Oncology Group
        - Eastern Cooperative Oncology Group
        - European Organization for Research and Treatment of Cancer
        - Gynecologic Oncology Group
        - National Cancer Institute of Canada, Clinical Trials Group
        - National Surgical Adjuvant Breast and Bowel Project
        - North Central Cancer Treatment Group
        - Radiation Therapy Oncology Group
        - Southwest Oncology Group
    - **Externally Peer-Reviewed**. R01s and P01s or other trial mechanisms funded by NIH or supported by other peer-reviewed funding organizations.
    - In-house trials authored or co-authored by cancer center investigators and undergoing scientific peer-review solely by the Protocol Review and Monitoring System of the Center. The center investigator should have primary responsibility for conceptualizing, designing and implementing the trial and reporting results. It is acceptable for industry and other entities to provide some support (e.g., drug, devices, other funding) but the trial should clearly be the intellectual product of the center investigator.
- **Abbreviated**. Trials in this category are Industrial trials. The design and implementation of these studies is controlled by the pharmaceutical company.

> ⚠ **Check for duplicate trials first**
>
> Before you begin to register a trial, ensure that the trial does not exist in the system already. You can do this by searching for trials using any of the criteria as per the instructions in Searching for Trials. The system uses the Lead Organization ID, Lead Organization Trial ID, and the NCT number to detect duplicates. If a duplicate is detected, the system will not record your trial.

How to Register New Trials

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

Select a Trial Submission Category Window

2. Trials are categorized by Summary 4 Trial Submission Category. Select **National**, **Externally Peer-Reviewed**, **Institutional**, or **Industrial**, and then click **Submit**.
   The Register Trial page appears. Information displayed on the Register Trial page differs according to the category of trial you selected.

Register Trial Page – Complete Trials, Upper Section

For complete trials, 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.

3. 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 CTRP Registration Site 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 trials

Field Label	Description/Instructions
XML required for ClinicalTrials.gov? (complete trials only)	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 will dictate which other 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: * Recording Trial Identifiers (complete trials) * Recording Trial Identification Information (abbreviated trials) * Recording Trial Details (complete and abbreviated trials) * Recording Lead Organizations and Principal Investigators (complete trials) * Recording Sponsors and Responsible Parties * Recording Summary 4 Information for NIH-Funded Trials (complete and abbreviated trials) * Recording NIH Grant Information (complete trials) * Recording Trial Statuses and Dates (complete trials) * Recording Site Recruitment Statuses and Dates (abbreviated trials) * Recording IND and IDE Information (complete trials) * Recording Regulatory Information (complete trials) * Recording Trial-Related Documents (complete and abbreviated trials)
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 CTRP Registration Site and retrieve your draft later to complete the registration. The system stores the draft for 30 days.
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 Trial Details.

4. Correct any errors if indicated, and repeat the previous steps as many times as necessary until the trial is error-free.
5. 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.

> ℹ️ 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.

Related Topics

- [Printing Trial Information](#)
- [Completing and Deleting Saved Drafts](#)
- [Registering Multiple Trials in a Batch](#)

Recording Trial Identifiers

Recording Trial Identifiers

This section pertains to complete trials only. You must provide a Lead Organization trial identifier for each trial you register. Optionally, provide an NCT number in addition.

Register Trial Page – Trial Identifiers Section

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. Fields are described in the following table. Items with an asterisk are required fields.
   Instructions for recording Trial Identifiers

Field Label	Description/Instructions

Lead Organization Trial Identifier*	Type the ID 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`
NCT Number	Type the NCT number in the field provided. This number is assigned to trials that have been submitted to ClinicalTrials.gov previously.
Other Trial Identifier	Type 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 Trial Identification Information

Recording Trial Identification Information

This section pertains to abbreviated trials only. You must provide a Lead Organization trial identifier for each trial you register. Optionally, provide an NCT number in addition.

Register Trial Page – Trial Identification Section

How to Complete the Trial Identifiers Section
Select or enter the appropriate information in the text fields and drop-down lists. Fields are described in the following table. All fields are required.

Instructions for Recording the Trial Identifiers section

Field Label	Description/Instructions
Lead Organization	Next to **Lead Organization**, click **Look Up Org**, and select the principal administrative organization responsible for the research protocol from the list of search results. ✅ **Tip** If your trial's lead organization is not listed, you can register it in the system at this point. To search for and register an organization, follow the instructions in Looking Up Registered Organizations and Adding Organizations to CTRP.
Lead Organization Trial Identifier	Type the unique identification used to identify, name, or characterize the protocol document, exactly the same 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. Example: `NSABP-B-40`
Submitting Organization Name	Next to **Submitting Organization Name**, click **Look Up Org**, and select the name of the organization that submitted the trial from the list of search results. ✅ **Tip** If your trial's lead organization is not listed, you can register it in the system at this point.
Submitting Organization Local Identifier	Type the ID exactly the same as it appears in the protocol document.
NCT Number Mandatory if an NCT number has been assigned to the trial.	If the trial has been submitted to ClinicalTrials.gov previously, enter the number assigned to the trial by PRS (ClinicalTrials.gov).

Recording Trial Details

Recording Trial Details

This section pertains to complete and abbreviated trials. Not all trial details pertain to them both however, as indicated in the instructions below.

Add Trial Page – Trial Details Section, Complete Trial

Add Trial Page – Trial Details Section, Abbreviated Trial

How to Complete the Trial Details Section

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

Instructions for recording Trial Details

Field Label	Trial Category	Description/Instructions
Title	Complete and Abbreviated	Type the trial title up to a maximum of 4000 characters. For example: "Study of Recombinant Vaccinia Virus That Expresses Prostate Specific Antigen in Metastatic Adenocarcinoma of the Prostate"
Trial Type	Complete and Abbreviated	You can not select "Observational" at this time.[1]
Phase	Complete and Abbreviated	Select a phase from the drop-down list.

- **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/11** - 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) - For epidemiologic, cancer control/behavioral, observational, ancillary, correlative, or other biological studies.

Pilot Trial? (displayed if Phase = NA)	Complete and Abbreviated	If the study is a pilot, as defined below, select **Yes**. Otherwise, select **No**.
Purpose	Complete and Abbreviated	Select a purpose from the drop-down list. • **Treatment** - Protocol designed to evaluate one or more interventions for treating a disease, syndrome or condition. • **Prevention** - Protocol designed to assess one or more interventions aimed at preventing the development of a specific disease or health condition. • **Supportive Care** - Protocol designed to evaluate one or more interventions where the primary intent is to maximize comfort, minimize side effects or mitigate against a decline in the subject's health or function. In general, supportive care interventions are not intended to cure a disease. • **Screening** - Protocol designed to assess or examine methods of identifying a condition (or risk factors for a condition) in people who are not yet known to have the condition (or risk factor). • **Diagnostic** - Protocol designed to evaluate one or more interventions aimed at identifying a disease or health condition. • **Health Services Research** - Protocol designed to evaluate the delivery, processes, management, organization or financing of health care. • **Basic Science** - Protocol designed to examine the basic mechanism of action (e.g., physiology, biomechanics) of an intervention. • **Other** - Any purpose not included in this list.
Pilot Trial? (displayed if Phase = NA)		

If Primary Purpose is "Other", describe: (displayed if Purpose = Other)	Complete and Abbreviated	If the primary purpose is **Other**, describe the purpose of the trial. You do not need to provide a Purpose Comment for trials with any other Purpose designation.
Site Principal Investigator	Abbreviated	Click **Look Up Person** and search for the principal investigator. See [Looking Up Registered Persons](#).

null

Recording Lead Organizations and Principal Investigators

Recording Lead Organizations and Principal Investigators

The Lead Organization is the institution that is the principal administrative organization responsible for the study. In multi-site trials that do not have a single assigned coordination center, every participating organization can be named as lead organization.

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.

Add Trial Page – Lead Organization/Principal Investigator Section

How to Complete the Lead Organization/Principal Investigator Section

1. Next to the **Lead Organization** field, click **Look Up**, and search for the organization as per the instructions in [Looking up Registered Organizations](#).
   a. If your trial's lead organization is not listed, you can register it in the system at this point. To register an organization, follow the instructions in [Adding Organizations to CTRP](#).
2. 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 CTRP](#).

Recording Sponsors and Responsible Parties

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 if you indicated that you do not require an XML document.

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

- Sponsor of the clinical trial (as defined in 21 CFR 50.3 or successor regulation)
  - or -
- Principal investigator of such clinical trial if so designated by a sponsor, grantee, contractor, or awardee, so long as the principal investigator is responsible for conducting the trial, has access to and control over the data from the clinical trial, has the right to publish the results of the trial, and has the ability to meet all of the requirements for the submission of clinical trial information.

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

Add Trial Page – Sponsor/Responsible Party Section

If the Responsible Party is the Sponsor, this section expands to display the Responsible Party Personal Contact and Responsible Party Generic Contact fields.

Add Trial Page – Sponsor/Responsible Party Section, Expanded

How to Complete the Sponsor/Responsible Party Section

Select or enter the appropriate information in the text fields and drop-down lists. Fields are described in the following table. Fields marked with an asterisk (*) are required.

Instructions for recording Sponsors/Responsible Parties

Field Label	Description/Instructions
Sponsor*	Click **Look Up Sponsor** and search for the sponsor as per the instructions in <u>Looking Up Registered Persons</u>.
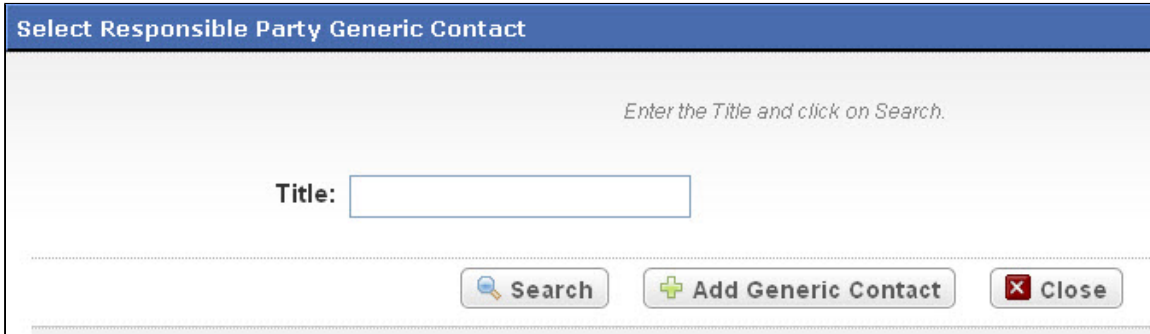
Responsible Party*	Indicate the party who is responsible for the trial. Select one of the following options: • **PI** (principal investigator). Primary medical researcher in charge of carrying out a clinical trial's protocol. **-or-** • **Sponsor**. Name of primary organization that oversees implementation of study and is responsible for data analysis. For applicable clinical trials, sponsor is defined in 21 CFR 50.3. For further elaboration on the definition of Sponsor with respect to responsible party, see http://prsinfo.clinicaltrials.gov/ElaborationsOnDefinitions.pdf. ⚠ Selecting the **Sponsor** option expands this section and displays the **Responsible Party** (a particular person) and **Responsible Party Generic Contact** (a role associated with the Responsible Party) fields.
Responsible Party Personal Contact	If the sponsor is a particular person rather than a role (a generic contact), click **Look Up Person**, and search for the sponsor as per the instructions in Looking Up Registered Persons to record the responsible party's name.
Responsible Party Generic Contact	If the Responsible Contact is a role in the organization, click **Look Up Generic Contact** and follow the instructions in Looking Up Generic Contacts to record the responsible party's name. The **Responsible Party Email Address** and *Responsible Party Phone Number fields are populated automatically.
Responsible Party Email Address*	Enter the responsible party's contact email address. If you selected a Generic Contact, these fields are populated automatically. ℹ Each title or role must be unique. You can not create one role with many email addresses and/or phone numbers.
Responsible Party Phone Number*	Type the responsible party's phone number. See Entering Phone and Fax Numbers

Looking Up Generic Contacts

Generic contacts are names associated with a role in an organization.

How to Look Up Generic Contacts

1. In the **Sponsor** field click **Look Up Sponsor**, and select the appropriate organization.
2. Next to the **Responsible Party Generic Contact** field, click **Look Up Generic Contact**.
   The Select Responsible Party Generic Contact window appears.

Select Responsible Party Generic Contact Window

3. In the **Title** field, type the contact's title or part of the title, and then click **Search**.
   The Select Responsible Party Generic Contact window appears.

Select Generic Contact Window

4. In the contact record you searched for, select the contact's email address and phone number from the drop-down lists, and then click **Select**.
   The title appears in the Generic Contact field, and the contact's email address and phone number appear in their respective fields below the title.
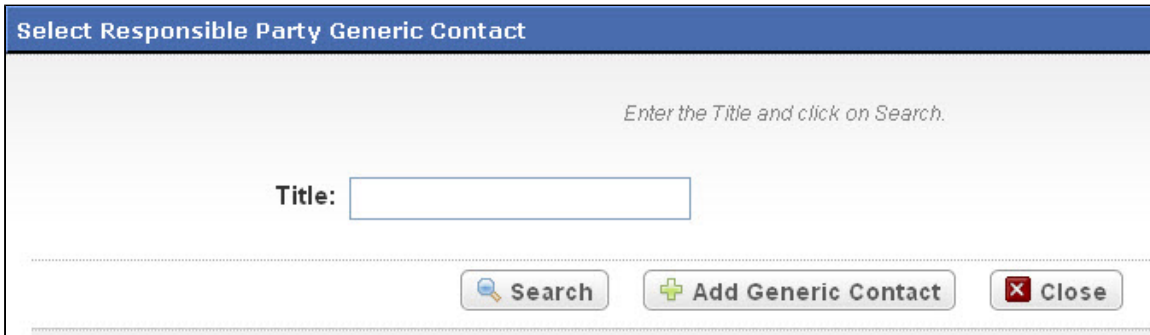
> ⚠ **Correct role or title errors**
>
> If the contact role or title you searched for contains an incorrect email address and/or phone number, do not select an address/number from the drop down list before you click . Instead, type the correct email address/phone number on the Register Trial page, then email the CTRO to request a change to the contact role record.

Adding Generic Contacts

If the generic contact is not listed in your search results, you can add the generic contact information.
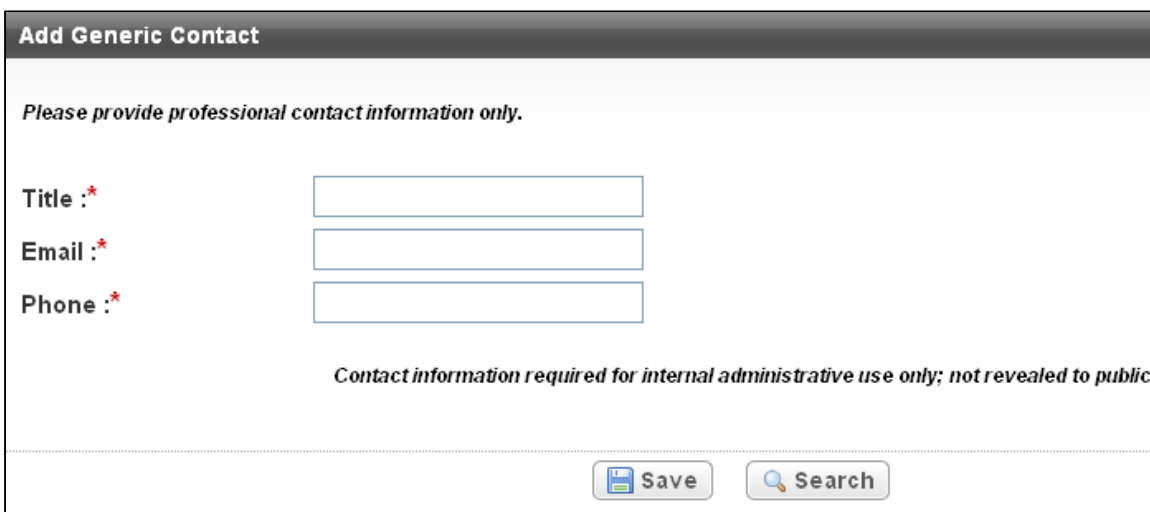
How to Add Generic Contacts

1. In the **Sponsor** field click **Look Up Sponsor**, and select the appropriate organization.
2. Next to the **Responsible Party Generic Contact** field, click **Look Up Generic Contact**.
   The Select Responsible Party Generic Contact window appears.

Select Responsible Party Generic Contact Window

3. Click **Add Generic Contact**.
   The Add Generic Contact window appears.

Add Generic Contact Window

4. Type the contact's title or role, and contact information in the fields provided, and then click **Save**.
   The record you created appears in the results table at the bottom of the window.

Add Generic Contact Window – Contact Record

5. In the contact record you created, select the contact's email address and phone number from the drop-down lists, and then click **Select**.
   The title appears in the field, and the contact's email address and phone number appear in their respective fields below the title.

> ⚠ **Correct role or title errors**
>
> If the contact role or title you searched for contains an incorrect email address and/or phone number, do not select an address/number from the drop down list before you click. Instead, type the correct email address/phone number on the Register Trial page, then email the CTRO to request a change to the contact role record.

Recording Summary 4 Information

Recording Summary 4 Information

To register complete trials only, the lead organization or at least one participating site must be an NCI-designated cancer center. Complete all fields in the Summary 4 Information section. The Trial Submission Category or Summary 4 Funding Sponsor Type fields are pre-populated with the sponsor type (for complete trials) or trial submission category (for abbreviated trials) you chose at the beginning of the Register Trial process. See I - Clinical Trial Summary 4 Categories.

Add Trial Page – Summary 4 Information Section for Complete Trials

Add Trial Page – Summary 4 Information Section for Abbreviated Trials

How to Complete the Summary 4 Information Section

1. Click **Look up Sponsor**, and select the name of the external sponsor or funding source as defined by the Summary 4 report. See the instructions in <u>Looking Up Registered Organizations</u>.
   a. If your trial's funding sponsor is not listed, you can register it in the system at this point. To register an organization, follow the instructions in <u>Adding Organizations to CTRP</u>.
2. In the **Program Code** field (for complete trials) or the **Site Specific Program Code** field (for abbreviated trials), type the code that includes the study.

Recording NIH Grant Information

Recording NIH Grant Information

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.

An NIH grant identification number consists of several parts, each having a distinct meaning.

For example: `1R01CA009999-08A1S2`

where,

- `1` is the single-digit code identifying the type of application received and processed
- `R01` (position 2 - 4) is the three-digit code identifying a specific category of extramural activity. It corresponds to Funding Mechanism element in the NIH grant information section.
- `CA` (position 5 - 6)is the two-letter code identifying the assignment or funding NIH Institute or Center. It corresponds to Institute Code element in the NIH grant information section.
- `009999` (position 7 - the dash) is the five- or six-digit number generally assigned sequentially to a series within an Institute, Center, or Division. It corresponds to the Serial Number element in the NIH grant information section.
- `-` (dash) separates the serial number from the grant year
- `08` is the two-digit number indicating the actual segment or budget period of a project The grant year is preceded by a dash to separate it from the serial number.
- `A1` is the letter code for a resubmitted application, (commonly referred to as an Amendment) and related number that identifies a particular amendment record
- `S2` is the letter code for Revision (for Supplemental funding) and related number identifying a particular supplemental record.

> ℹ️ The Grant Identification Number is also commonly referred to as assignment number, as grant identification Assignment Number, application number, as grant identification Application Number, or the award identification number, as grant identification Award Identification Number, depending upon its processing status.

For a complete guide to NIH grant information, see the following web pages:

- http://ocga.ucsd.edu/Proposals/NIH/Grants/Proposal_Preparation.htm 🔗
- http://grants.nih.gov/grants/funding/funding_program.htm

NIH Grant Information (for NIH funded Trials)				
To record grant information, provide values for all fields, and then click the **Add Grant** button.				
Funding Mechanism	**Institute Code**	**Serial Number**	**NCI Division/Program Code**	
--Select--	--Select--		--Select--	Add Grant
Funding Mechanism	**NIH Institute Code**	**Serial Number**	**NCI Division/Program Code**	**Action**
G07	CK	123456	RRP	Delete

Add Trial Page – NIH Grant Information Section

How to Complete the NIH Grant Information Section

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

Field Label	Description/Instructions
Funding Mechanism	Type the initial letter(s) and or number(s) in the Funding Mechanism field and then select the NIH unique identifier from the drop-down list. The funding mechanism is a 3-character code used to identify areas of extramural research activity applied to funding mechanisms. ✅ **Tip** Click the down arrow in the field, and then use the up and down arrow keys on your keyboard to scroll up and down the drop-down list. When you arrive at the appropriate code, press the **ENTER** key. For a list of NIH grant 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, contract, or inter-agency agreement. The support may be financial or administrative. For a list of valid codes, see [Institute Codes](#).
Serial Number	Type the five- or six-digit number generally assigned sequentially to a series within an Institute, Center, or Division, for example, 009999.
NCI Division/Program Code	Type the initial letter(s) of the division or program code, and then select the code for the organizational unit that provides funding for the study, from the drop-down list. For a list of Division and Program codes, see [NCI Division and Program Codes](#).

2. Click **Add Grant**.

> ℹ️ The **Add** button is operable only after you have provided the grant information in all fields.

The grant is displayed and added to the trial, and the Grant fields are reset.

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

Recording Trial Statuses and Dates

Recording Trial Statuses and Dates

This section pertains to complete trials. 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.

It includes the following topics:

- [Recording Trial Statuses and Dates](#)
  - [Trial Status Transitions](#)
  - [Status Rules for Start and Primary Completion Dates](#)

How to Complete the Status/Dates Section

Select or enter the appropriate information in the text fields and drop-down lists. Fields are described in the following table. Items with an asterisk are required fields.

Field Label	Description/Instructions

Current 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 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.
Current Trial Status Date*	Enter the date on which the current trial status became effective. See Selecting and Entering Dates and Rules for Status/Dates relationships.
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.

Trial Start Date*	Enter the date on which the trial started, or is expected to start. Indicate whether the start date is the one on which the trial is expected to start, or the date on which it actually started by selecting **Anticipated** or **Actual**. See [Rules for Status/Dates Relationships](#).
Primary Completion Date*	Select the date on which the trial ended, or is expected to end. Indicate whether the start date is the one on which the trial is expected to be primarily completed, or the date on which it actually was primarily completed, by selecting **Anticipated** or **Actual**. See [Rules for Status/Dates relationships](#).
Completion Date*	Select the date on which the trial was completed, or is expected to be complete. Indicate whether the start date is the one on which the trial is expected to be completed, or the date on which it actually was completed, by selecting **Anticipated** or **Actual**. See [Rules for Status/Dates relationships](#)

> ☑ **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**.

Valid trials used in CTRP are mapped to ClinicalTrials.gov-defined recruitment values as listed in the table below. ClinicalTrials.gov status definitions are provided in [Recording Site Recruitment Statuses and Dates](#).

Trial Status Transitions

The table and diagram below illustrate the relationships between statuses. Statuses are recorded in the order indicated by the arrows.

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
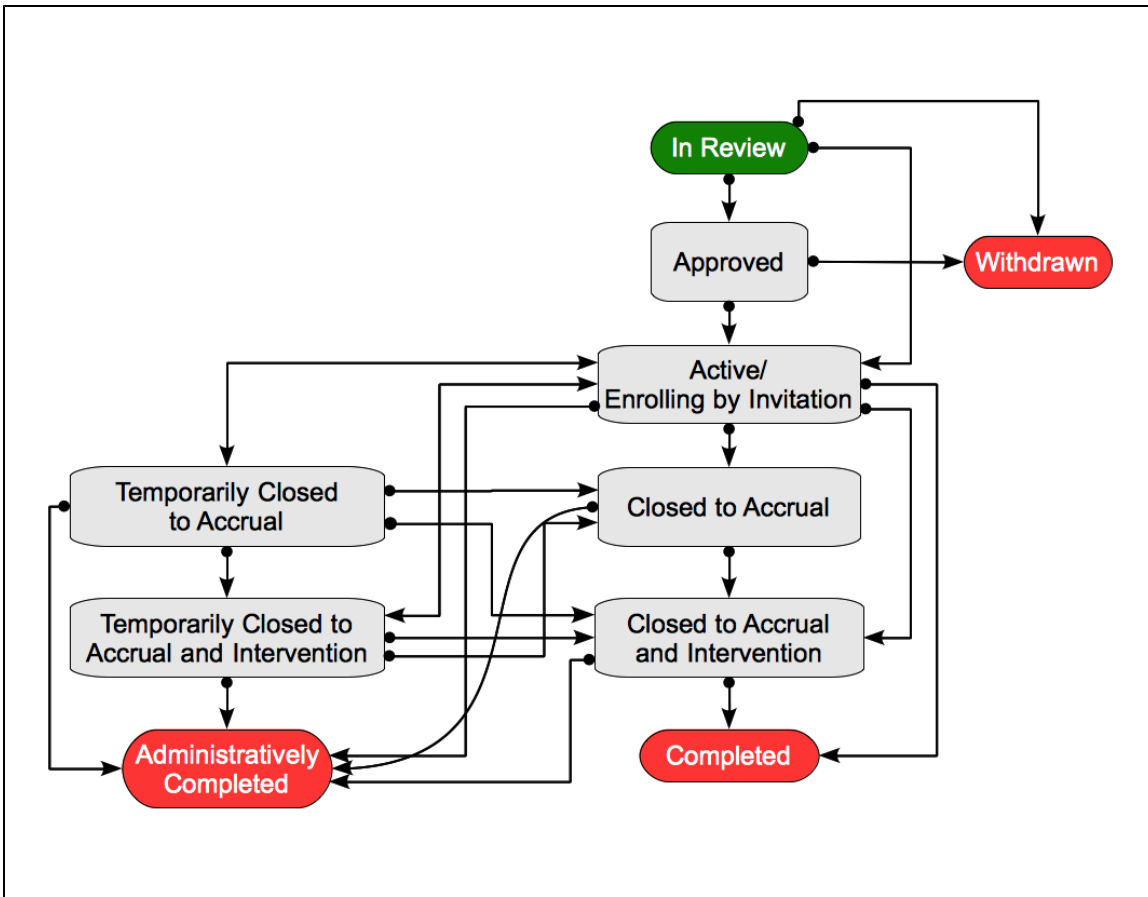
Relationships Between Trial Statuses

Status Rules for Start and Primary Completion Dates

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 at the bottom of the diagram represent the date rules, relative to the statuses, for trial Start Dates compared with Primary Completion Dates and Completion Dates.

Status Rules diagram:

Status phases (top):
- In Review
- Approved or Withdrawn
- Active/Enrolling by Invitation
- Temporarily Closed to Accrual
- Temporarily Closed to Accrual and Intervention
- Closed to Accrual
- Closed to Accrual and Intervention
- Complete or Admin. Complete

Time Line — Primary Completion Date — Study Completion Date — Start Date

	Approved or Withdrawn / In Review	Active/Enrolling, Temporarily Closed, Closed to Accrual	Closed to Accrual and Intervention	Complete or Admin. Complete
Start Date Type	Actual/Anticipated*	Actual*	Actual*	Actual*
Primary Completion Date Type	Actual/Anticipated	Actual/Anticipated	Actual/Anticipated	Actual
Study Completion Date Type	Anticipated	Anticipated	Anticipated	Actual

* In CTRP only; not in XML

Status Rules for Start and Primary Completion Dates

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 equal to or greater than the Trial Start Date
- The Completion Date is always equal to or greater than the Primary Completion Date

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
Current Trial Status is Approved or In Review	Trial Start Date could be Actual or Anticipated
Current Trial Status is Complete	All date types must be actual

Recording Site Recruitment Statuses and Dates

Recording Site Recruitment Statuses and Dates

This section pertains to abbreviated trials. Trial status refers to the current stage or state of participant/patient enrollment at the participating site level.
Valid trial statuses are listed in the table below.

Current trial status definitions

Trial Status in the CTRP Registration Site	Trial Status in ClinicalTrials.gov	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 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.

Status/Dates (site specific)

Site Recruitment Status*   --Select--

Site Recruitment Status Date*   [____] (mm/dd/yyyy)

Date Opened for Accrual: [____] (mm/dd/yyyy)

Date Closed for Accrual: [____] (mm/dd/yyyy) *Opened for Accrual Date is mandatory if Closed for Accrual Date is provided.*

Add Trial Page – Status/Dates Section, Abbreviated Trial

How to Complete the Status/Dates Section

- Select or enter the appropriate information in the text fields and drop-down lists. Fields are described in the following table. Items with an asterisk are required fields.

Instructions for recording Site Recruitment Statuses/Dates

Field Label	Description/Instructions
Site Recruitment Status*	Select the current stage or state of the trial or study.
Site Recruitment Status Date*	Enter the date on which the current trial status became effective. See Trial Status Rules for Start and Primary Completion Dates.
Date Opened for Accrual	If appropriate, enter the date on which the trial was opened for accrual.

Date Closed for Accrual	If appropriate, enter the date on which the trial was closed for accrual.

Trial Status Rules for Start and Primary Completion Dates

Trial Status Rules for Start and Primary Completion Dates

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 at the bottom of the diagram represent the date rules, relative to the statuses, for trial Start Dates compared with Primary Completion Dates and Completion Dates.

Status Rules for Start and Primary Completion Dates

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 equal to or greater than the Trial Start Date
- The Completion Date is always equal to or greater than the Primary Completion Date

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
Current Trial Status is Approved or In Review	Trial Start Date could be Actual or Anticipated
Current Trial Status is Complete	All date types must be actual

Recording IND and IDE Information

Recording IND and IDE Information

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

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

Add Trial Page – IND/IDE Section

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:
	
	• For IND trials:
	  • Center for Drug Evaluation and Research
	  • Center for Biologics Evaluation and Research
	• For IDE trials:
	  • Center for Devices and Radiological Health
	  • Center for Biologics Evaluation and Research

IND/IDE Holder Type*	Select one of the following typesholder types: • Investigator • Organization • Industry • NIH • NCI
NIH Institution, NCI Division/Program Code* (required if the holder type is NIH or NCI)	Select a code from the drop-down list. See [Institute Codes](#) and [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 statuses: • **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 trial is associated with the U.S. FDA and does not require IRB 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

Recording Regulatory Information

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

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

Regulatory Information Section

How to Complete the Regulatory Information Section

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

table. Items with an asterisk are required fields. 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*	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, you are required to complete the **Delayed Posting** field.
Delayed Posting Indicator*	Indicate whether the release of trial information on ClinicalTrials.gov is being delayed until after an interventional device has been approved or cleared by selecting **Yes** or **No**. Select **No** if the trial does not include a device.

Data Monitoring Committee Appointed Indicator	Optionally, indicate whether a data monitoring committee has been appointed for this trial by selecting **Yes** or **No**.
	ℹ️ 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

Recording Trial-Related Documents

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

- For complete trials
    - Complete protocol document
    - Participating sites (if not included in the protocol document). Multi-site trials require a list of participating sites and contact information.
    - Informed Consent (complete trials only, if not included in the protocol document)

    > ℹ️ If the Informed Consent and/or Participating Sites are not included as part of the protocol document, upload them separately as "Trial-Related Documents."

- For abbreviated trials
    - Abbreviated Trial Template (if you do not provide an NCT number)

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. Please see the information about creating PDFs in Converting Documents to PDFs .

Add Trial Page – Trial Related Documents for Complete Trials

Add Trial Page – Trial Related Documents for Abbreviated Trials

> ℹ️ The procedure for uploading documents is the same for all document types.

How to Submit Trial Related Documents

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

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

3. Repeat these steps above for each type of document.

> ✅ **Adding Multiple "Other" Documents**
>
> You can upload more than one (1) "Other" document. After you have uploaded the first of your "Other" documents, click the **Add More** link. A new **Other** document field is displayed.

Converting Documents to PDFs

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

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

> ⚠️ **Abstractors are not able to copy and paste text from _scanned_ document pages**
>
> PDFs of scanned documents can not be edited, copied, or read with OCR (optical character recognition) applications, and should therefore be avoided.

Converting Text-Based Files to PDFs in Windows OS

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".

Converting Text-Based Files to PDFs in Mac OSX

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 location, rename your PDF file, and then click **Save**.

Related Topics

- [Using CTRP Registration Templates and Resources](#)
- [Using the Complete Trial Participating Sites Template](#)

Editing Trial Details

Editing Trial Details

You can edit trial details after you have reviewed them at any time before you submit the trial to the CTRP. If you want to edit a trial that you 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**.

Related Topics

- [Registering Multiple Trials in a Batch](#)
- [Amending Trials](#)
- [Updating Trials](#)

Printing Trial Information

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**.

Completing and Deleting Saved Drafts

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.

> 🚫 **The systems deletes drafts after 30 days**
>
> If you do not complete the registration, the system will automatically delete the draft 30 days after you have saved it.

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 in the Saved Draft Search Results table.

Saved Draft Search Results					
One item found. 1					
Temp Trial Identifier	**Title**	**Lead Organization**	**Lead Org Trial Identifier**	**Action**	**Action**
74326653	Saved Draft Test	Example Organization	123456	Complete	Delete
Export options: CSV	Excel					

Saved Draft Record

2. Do one of the following in the appropriate columns on the right side of the table:
   - To delete the record, click **Delete**. The draft record is deleted from the system permanently.
     - or -
   - 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 Main Steps for Registering Trials.

Related Topics

- Printing Trial Information
- Amending Trials
- Reviewing and Submitting Trial Amendments

Registering Multiple Trials

Registering Multiple Trials

You can submit multiple trials for registration by recording trial data in batch templates, preformatted Excel spreadsheets. There are separate templates for complete and abbreviated trials. Additionally, the way in which you submit the data differs between the two types of trials.

This section includes the following topics:

-
-

Registering Multiple Complete Trials in Batch Files

Registering Multiple Complete Trials in Batch Files

This section includes the following topics:

As an authorized CTRP submitter you can use the CTRP Registration Site's 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 Registration Site's batch upload feature. CTRO staff use the information you provide in these documents to register your trials.

> ℹ️ **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:

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

Main Steps for Uploading Your Complete Trial Data
1. Prepare the trial data file. See [Preparing Trial 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 application batch upload web page at https://trials.nci.nih.gov/registry/admin/batchUpload.action. See [Submitting Complete Trial Registration Batch Files](#).

Preparing Trial 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 and Resources](#).

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

How to Prepare Trial Data Files

1. Download the batch upload template (Excel spreadsheet) containing the mandatory and optional data for the trial(s) from http://www.cancer.gov/clinicaltrials/conducting/ncictrp/resources.
2. Enter the trial data elements as specified in the template.

> ⓘ The .xls file that contains the trial data you want to register via the CTRP Registration Site's batch upload feature, and the trial-related documents associated with it, must meet certain 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	• Complete • Interventional only
Summary 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

Data Specification 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	• Contact • Generic Contact
Number of "Other" Trial Identifiers	Multiple
Data Submission Options	• XML file is required for trial submission to ClinicalTrials.gov • XML file is not required for trial submission to ClinicalTrials.gov
Person and Organization Information Options	• PO-ID for the person or organization • 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 nci ctro@mail.nih.gov. Or, you can use the search organization/person feature in the CTRP Trial Registration application to ascertain PO-IDs.

Template Requirements

You *must* adhere to the following requirements:

- List trial elements required for registration in the order specified in the Batch Upload Data Element Spec tab in the batch upload template.
- 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".
- 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.
- Identify each trial uniquely. For example, append your cancer center unique trial identifier to the file name.

> ℹ️ You can enter dates in the following formats:
>
> - MM/dd/yyyy
> - MM-dd-yyyy
> - yyyy/MM/dd
> - yyyy-mm-dd

Study Type	- Complete - Interventional only
Summary 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

Data Specification 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	- Contact - Generic Contact
Number of "Other" Trial Identifiers	Multiple
Data Submission Options	- XML file is required for trial submission to ClinicalTrials.gov - XML file is not required for trial submission to ClinicalTrials.gov

Person and Organization Information Options	• PO-ID for the person or organization
	• 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 the CTRP Trial Registration application to ascertain PO-IDs.

Template Requirements

You must adhere to the following requirements:

- List trial elements required for registration in the order specified in the Batch Upload Data Element Spec tab in the batch upload template.
- 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.
- 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.
- Identify each trial uniquely. For example, append your cancer center unique trial identifier to the file name.

Preparing Complete 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.

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.[1]

> ⛔ The trial document Zip file that you intend to upload **MUST NOT** include folders or other Zip files.

Trial-Related Document Requirements

Basic criteria for trial-related documents include the following:

File Types	• Microsoft Word (.doc) • Adobe PDF[1]

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

null

Submitting Trial Registration Batch Files

> ℹ 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. For details, see Trial-Related Document Requirements.

How to Upload Trial Registration Batch Files

1. Navigate to the batch upload URL that you received from the CTRO.
   The Batch Upload page appears. All fields are required.

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 the trial data.

> ✅ **Use the most current batch upload template**
>
> To ensure that you use the version of the batch upload template that is valid for the version of the CTRP Registration Site you are using, click the **here** link, which directs you to the [CTRP web site](#).

4. Next to the **Documents Zip** field, click **Browse** and navigate to the `.zip` file that contains all the trial-related documents.
5. Click **Upload Trials**.
   The Batch Trial Upload Confirmation window appears.

Batch Trial Upload Confirmation

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

Please click here to submit another file.

Batch Trial Upload Confirmation Window

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.

Related Topics

- [Registering Multiple Abbreviated Trials in Batch Files](#)
- [Recording Trial-Related Documents](#)
- [Searching for Persons](#)
- [Searching for Organizations](#)

Registering Multiple Abbreviated Trials in Batch Files

Registering Multiple Abbreviated Trials in Batch Files

This section includes the following topics:

- [Registering Multiple Abbreviated Trials in Batch Files](#)
    - [Main Steps for Submitting Your Abbreviated Trial Data](#)
    - [Preparing Abbreviated Trial Data Files](#)
        - [Trial Requirements](#)
        - [Data Specification Requirements](#)
        - [Template Requirements](#)
    - [Submitting Abbreviated Trial Registration Batch Files](#)

As an authorized CTRP submitter, you can use the CTRP Registration Site's abbreviated batch template to register multiple new trials that were conducted at a given site, and to update them as necessary. The abbreviated batch template, a predefined Excel spreadsheet, provides the structure for recording your trial data. Once you have recorded the trial data, email the spreadsheet to the CTRO. CTRO staff use the information you provide in these documents to register your trials.

> **ℹ Before You Begin**
>
> Contact the CTRO at ncictro@mail.nih.gov to request approval for sending batch files to CTRP. Include your login name, first and last names, and email address stored in your CTRP profile. Once you have received approval, you do not have to request approval for subsequent batches.

Main Steps for Submitting Your Abbreviated Trial Data

1. Prepare the trial data file. See Preparing Abbreviated Trial Data Files.
2. Email the file to the CTRO at ncictro@mail.nih.gov as an attachment.

Preparing Abbreviated Trial Data Files

The CTRP web site provides a batch template, valid data values, data definitions, examples, and rules for registering batches of abbreviated trials.

How to Prepare Trial Data Files for Abbreviated Trials

1. Download the abbreviated trial batch template (Excel spreadsheet) containing the mandatory and optional data for the trial(s) from http://www.cancer.gov/clinicaltrials/conducting/ncictrp/resources.
2. 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. Refer to the specifications below.

Trial Requirements

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

Study Type	Abbreviated Interventional
Trial Submission Category	Industrial
Processing Statuses for Trial Updates	Accepted and beyond

Data Specification Requirements

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

Number of Trials per File	100 maximum

Person and Organization Data	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 lookup features in the CTRP Trial Registration application to search for PO-IDs.
Primary purpose, Phase, Disease and Intervention Data	If you provide an NCT number, the primary purpose, phase, disease and intervention data are optional.

Template Requirements

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, 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.
- 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.
- Identify each trial uniquely. For example, append your cancer center unique trial identifier to the file name.
- If more than one disease or intervention is included, list them on additional lines, one per line.

Submitting Abbreviated Trial Registration Batch Files

The CTRP website provides an abbreviated trial batch template, valid data values, data definitions, examples, and rules for registering batches of abbreviated trials.

How to Submit Abbreviated Trial Batch Files

1. In Microsoft Excel, list the trial elements required for registration in the order specified in the Registry_Abbreviated_Trial_Template.xls file. To access the `Registry_Abbreviated_Trial_Template.xls` file, see Downloading Trial Registration Templates.
2. Email the file to CTRO at ncictro@mail.nih.gov as an attachment.
   CTRO staff process your file and register your trials.

> ℹ️ **Trial Ownership**
>
> Make sure to clearly indicate, using the appropriate fields in the batch file, which user from your institution you want assigned as trial owner for each of the trials you are submitting.

> **ℹ Duplicate Trial Management**
>
> If the CTRO identifies a trial as a duplicate to an existing trial, you can request that they add your organization information to the existing trial as a participating site instead of creating a duplicate. You can send a request to the CTRO to add your organization information to the existing trial as a participating site using the same template, or, you can create a separate request using the [Abbreviated Participating Sites Template](#).

Related Topics

- [Registering Multiple Complete Trials in a Batch](#)
- [Recording Trial-Related Documents](#)

4 - Updating Trials

4 - Updating Trials

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

This section contains the following topics:

- [About Trial Updates](#)
- [Updating Trials](#)
- [Reviewing and Submitting Trial Updates](#)
- [Editing Updated Details](#)
- [Printing Updated Trial Information](#)
- [Changing Trial Status Information](#)

About Trial Updates

View Source

About Trial Updates

The CTRP Registration Site 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 [Updating Trial Statuses](#) for instructions.

> **ℹ** 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.

> **☑ Tip**
>
> You can also update trials in batches. See [Registering Multiple Complete Trials in Batch Files](#).

Updating Trials

å

Updating Trials

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

- Other trial identifier
- 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 NIH Trial Statuses/Dates](#), their definitions in the CTRP Registration Site, and equivalents in ClinicalTrials.gov.
- 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.

> ✅ **Updating trial statuses from the Search Results table**
>
> 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](#).

How to Update Trials

1. On the navigation pane on the left side of the page, click **Search 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](#).
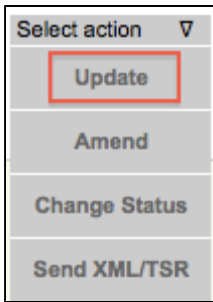
"Available Actions" Column - Select Action List

3. In the **Available Actions** column, click **Select action > Update**.
   The Update Trial page displays the data currently registered with CTRP.
4. Make changes to the fields as necessary. Instructions for recording each of the fields are provided in [Register ing New Trials](#).
5. 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).
6. To review the information you provided, click **Review Trial**.
   The system checks the updated information for errors, and displays the results at the top of the Update Trial page.
7. If necessary, correct any errors, and click **Review Trial**. Repeat this cycle until your update is error-free.
8. Submit the trial update.
   The system sends you an update notification — with the details of what has changed — whenever you update accepted trials.

Reviewing and Submitting Trial Updates

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.

> ℹ 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.

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**.

Changing Trial Status Information

Changing Trial Status Information

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

> ℹ️ **Processing Requirements**
>
> You can change the accrual status of trials that have reached the processing status Accepted or beyond. Refer to Recording Site Recruitment Statuses and Dates for status definitions.

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.
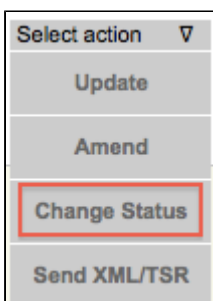
   "Available Actions" Column - Select Action List

2. In the **Select action** drop-down list, click the **Change Status** link.
   The Update Status window appears.

Update Status Window

3. Make changes to the status information as necessary. If you changed the status to Administratively Complete, Withdrawn, or Temporarily Closed, enter the reason for status change.

4. Click **Save**. See Recording Trial Statuses and Dates for detailed instructions.

Related Topics

- Rules for Trial Status Start and Primary Completion Dates
- Recording Trial Statuses and Dates

5 - Amending Trials

5 - Amending Trials

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

This section includes the following topics:

- About Trial Amendments
- Amendment Process Life Cycle
- Amending Trials
- Reviewing and Submitting Trial Amendments
- Editing Amended Details
- Printing Amended Trial Information

About Trial Amendments

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 status. (See the trial processing diagram.) 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.

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

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

> ℹ️ You can also amend trials in batches. See Preparing the Trial Data File for Complete Trials.

Related Topics

- Amendment Process Life Cycle
- Amending Trials
- Reviewing and Submitting Trial Amendments

Amendment Process Life Cycle

Amendment Process Life Cycle

The CTRP processes submissions in much the same way as it processes original trial data. You may need to submit an amendment more than once during the course of your study, and the process is repeated each time you submit an amendment.

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

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

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

Related Topics

- [Amending Trials](#)
- [Reviewing and Submitting Trial Amendments](#)

Amending Trials

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[1]

  - Change Memo[1] – Contains a summary of changes to the original, or last amended, trial submission

  - Protocol Highlighted Document
  - IRB Approval for the amended protocol

null

How to Amend Trials

1. On the navigation pane on the left side of the page, click **Search 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](#).
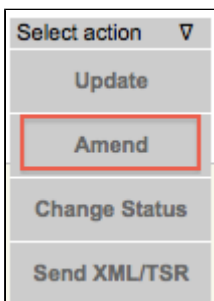
"Available Actions" Column - Select Action List
3. In the **Available Actions** column, click **Select action > Amend**.
   The Amendment Trial page displays the data currently registered with the CTRP.
4. Select or enter the appropriate information in the text fields and drop-down lists, following the instructions

provided in [Registering New Trials](#).

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

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.

Related Topics

- [About Trial Amendments](#)
- [Updating Trials](#)

Reviewing and Submitting Trial Amendments

Reviewing and Submitting Trial Amendments

After you have finished amending the trial information, review the information for errors and edit any details that do not match the changes in your change memo, amended protocol document, or other source. You can print a copy of the Amendment Trial and 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 Details](#).
4. Click **Submit**.

Related Topics

- [Amending Trials](#)
- [Editing Amended Details](#)
- [Printing Amended Trial Information](#)

Editing Amended Details

Editing Amended Details

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.

Related Topics

- [Amending Trials](#)
- [Printing Amended Trial Information](#)

Printing Amended Trial Information

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**.

Related Topics

- [Amending Trials](#)
- [Editing Amended Details](#)

6 - Adding Your Site to Abbreviated Trials

6 - Adding Your Site to Abbreviated Trials

This section provides instructions for adding your site as a participating site to abbreviated trials. You can add your organization as a participating site to any Industrial[1] (abbreviated) trial, excluding RSS trials, that has the processing status Accepted or beyond. Once added, you can update your site's record at any time. See [Updating Participating Site Organization Records](#) .

Information that you can update includes the following:

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

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This section includes the following topics:

Main Steps for Adding Your Organization as a Participating Site

How to Add Your Organization as a Participating Site

1. Search for the trial that your site is participating in by following the instructions in [Searching for Trials](#). The **Available Actions** column in the search results table displays actions currently available for the trial.
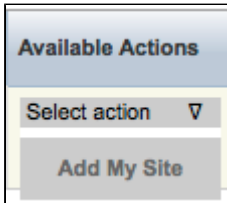
Available Actions - Add My Site

2. In the search results table's **Available Actions** column, click **Select action > Change Status**. The Add Your Participating Site dialog box appears. The organization associated with your Registration account appears in the Organization Name field by default.

Add Your Participating Site

3. Select or enter the appropriate information in the text fields and drop-down lists. Fields are described in the following table. Items with an asterisk are required fields.

Field	Description/Instructions
Organization Name*	Name of organization added as a participating site. The organization associated with your Registration account appears in the Organization Name field by default.
Local Trial Identifier*	Enter the identifier used at the participating site.

Site Principal Investigator*	Look up the site principal investigator by following the instructions in Looking Up Registered Persons.
Site Specific Program Code	Optionally, enter the program code used at the participating site.
Site Recruitment Status*	Select the current stage or state of the trial or study. Refer to Recording Site Recruitment Statuses and Dates.
Site Recruitment Status Date*	Enter the date on which the current trial status became effective. See Trial Status Rules for Start and Primary Completion Dates.
Date Opened for Accrual	If appropriate, enter the date on which the trial was opened for accrual.
Date Closed for Accrual	If appropriate, enter the date on which the trial was closed for accrual.

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

Participating Site Added to a Trial Record

Updating Participating Site Organization Records

Appointed participating site record owner(s) and the trial's owner(s) can update information about their respective organizations in the same trial record. For information about appointed participating site records, see 7 - Managing Participating Site Record 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 search results table's **Actions** column, select **Update My Site**

The Update Your Participating Site dialog box appears. The organization associated with your Registration account appears in the Organization Name field by default.

Update Your Participating Site

3. Enter the new information in the fields as appropriate, following the instructions in Adding Organizations as Participating Sites.
4. Click **Save**. Your information is updated.

Related Topics

- Using CTRP Registration Templates and Resources
- Searching for Persons
- Adding Persons to CTRP

7 - Managing Participating Site Record Ownership

7 - Managing Participating Site Record Ownership

> ℹ️ Site Record ownership applies to Industrial (abbreviated) trials only.

This section provides instructions for assigning and un-assigning participating site record ownership to other registered CTRP users from your organization for abbreviated trials in which your organization is a participant. This assignment is for your site *only* on any given trial.

Participating site record 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.

Information that you can update includes the following:

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

As a Site Administrator, you can assign/unassign participating site record[1] ownership to other registered CTRP users who are affiliated with your organization. You can assign ownership rights to multiple users and multiple trials at the same time. For example, you can grant ownership to three users within your organization in a single step. Or, you can grant one user ownership participating sites on three trial records in a single step.

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> ℹ️ Users must have a CTRP Registration Site account, complete with organizational affiliation, in order for you to grant them participating site trial record ownership.

How to Manage Participating Site Record Ownership

1. On the navigation pane on the left side of the page, click **Manage Site Record Ownership**.
   The Manage Participating Site Record Ownership page displays the names of registered CTRP users on the left side, and the trials in which your site is a participant on the right.

2. In the **Organization Members** table, select one or more of your organization's members.
3. Select the trials to which you want to assign or unassign participating site record ownership.
4. Click **Assign Ownership** or **Unassign Ownership**.

Related Topics

- Adding Organizations as Participating Sites to Registered Industrial Trials
- Managing Trial Ownership
- Granting and Revoking Administrative Authority

8 - Managing Site Administration Within Your Organization

8 - Managing Site Administration Within Your Organization

This section introduces you to site administration management and provides instructions for granting and revoking administrative authority.

Each organization registered in the CTRP system can have more than one site administrator 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. 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. See [Creating CTRP Registration Site Accounts](#). Otherwise, request administration authority from the current site administrator.

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

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

  > ℹ️ 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. See [Managing Trial Ownership](#) .

- A site administrator can do the following:
  - Assign and remove trial ownership
  - Grant and revoke administrative rights to other users in the organization
  - Revoke own administrative rights

  > ℹ️ Site administrators can view and manage trials only for a site playing the lead organization role.

> ⚠️ **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.

This section includes the following topic:

- [Granting and Revoking Administrative Authority](#)

Granting and Revoking Administrative Authority

Granting and Revoking Administrative Authority

As a site site administrator, you can grant and revoke administrative rights to other users[1] in your organization. Site administrators are the only CTRP Registration Site users who have access to the Site Administration menus on the navigation pane. No other user will see these menus.

How to Grant and Revoke Site Administrator Rights

1. On the navigation pane on the left side of the page, click **Site Administration**.
   If applicable, the Site Administration page displays the current administrators that you previously have granted administrator rights to.

Site Administration Page

2. To search for a CTRP Registration Site user you want to promote to site administrator, search for the user by first name, last name, or email address, and then click **Search**.
   The user's name appears in the Search Results list.
3. To promote the user to site administrator, select the check box in the **Allow 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.

4. To revoke administrative access, locate the user in the Search Results section, and clear the check box under the **Allow Site Admin** column.
5. Click **Save**.

Related Topics

- [Managing Site Administration Within Your Organization](#)
- [Displaying Trial Ownership](#)
- [Managing Trial Ownership](#)

9 - Displaying Trial Ownership

9 - Displaying Trial Ownership

As a site administrator, you can display trial ownership for any trial owned by your site for which your organization is the lead organization. Trial ownership allows a user to view trial details, update trials, and amend trials. Additionally, you can indicate whether a user would like to receive system notifications, including TSRs and XML files, on a
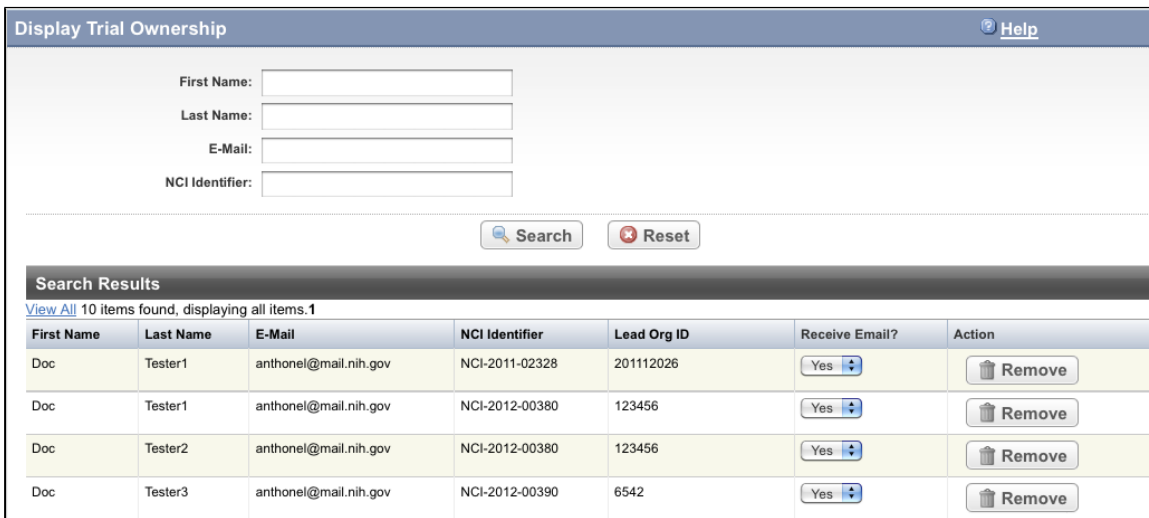
trial-by-trial basis.

> ℹ️ **TSR and XML distribution**
>
> TSR and XML documents are sent to all trial owners.

How to Display Trial Ownerhip

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

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 Trial Identifier in the field provided, and then click **Search**.
   All owners of the selected trial are listed in the Search Results list.
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**.
5. To revoke ownership of a trial, locate the user/trial in the **Search Results** list, and then click **Remove**.

Related Topics

- Granting and Revoking Administrative Authority
- Managing Site Administration Within Your Organization
- Managing Organizational Access Through Trial Ownership

8

10 - Managing Trial Ownership

10 - Managing Trial Ownership

This section provides instructions for managing trial ownership.

As a Site Administrator, you can grant and remove trial ownership rights to multiple users[1] and multiple trials[1] at the same time. For example, you can grant ownership of one trial to three CTRP Registration Site users within your organization. Or, you can grant one user ownership of three trials.
Trial ownership of abbreviated trials is limited to the original submitter or another CTRO-appointed person upon request from the organization.

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

null

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

How to Manage Trial Ownership

1. On the navigation pane on the left side of the page, click **Manage Trial Ownership**.
   The Manage Trial Ownership page displays the names of your organization's CTRP Registration Site users on the left side, and your organization's owned trials on the right.

Manage Trial Ownership Page

2. To assign ownership, select the check box in the **Allow as Owner?** column for each user you want to assign to a trial(s).
3. On the right side of the page, select the check box in the **Select?** column for each trial to which you want to assign ownership.

4. To enable the user to receive email notifications about the trial, select the check box in the **Email Notifications?** column.

5. Click **Assign Ownership**.

> ☑ **Granting Ownership to All Trials**
>
> To assign a user(s) ownership to all listed trials, click **Check All**, and then click **Assign Ownership**. You can use the same process to unassign ownership to all trials.

6. To revoke ownership, clear the check box in the **Allow as Owner?** column for each user you want to unassign as an owner.

> ℹ️ Do not revoke trial ownership from the original trial submitter.

7. On the right side of the page, select the trial(s) to which you want to unassign ownership, and then click **Unassign Ownership**.

> ☑ **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 Trial Status Definitions.) 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.

Related Topics

- Granting and Revoking Administrative Authority
- Displaying Trial Ownership
- Managing Site Administration Within Your Organization

11 - Managing Access to Subject Accruals

11 - Managing Access to Subject Accruals

This section provides instructions for assigning and un-assigning access to the Subject Accruals application on a trial-by-trial basis, and for reviewing current assignments and trial details.

This section includes the following topics:

- Assigning and Un-Assigning Subject Accrual Access
- Viewing Accrual Assignment History
- Viewing Accrual Assignment History by Trial

> ⚠️ You can assign accrual access only to trials that have been abstracted and verified.

Assigning and Un-Assigning Subject Accrual Access

Assigning and Un-Assigning Subject Accrual Access

You can authorize a user to submit subject accrual data for trials that have been fully abstracted and verified.
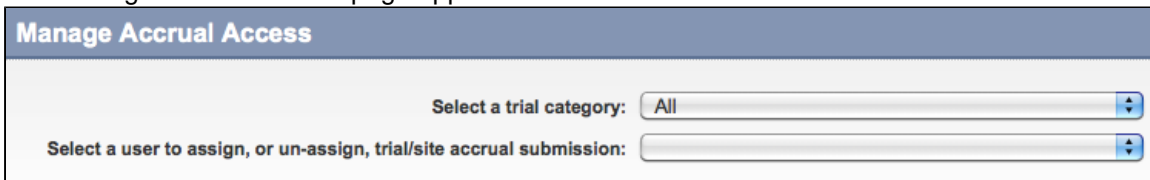
The table below outlines the access and trial assignment rules for Non-Industrial (Institutional and Externally Peer-Reviewed) and Industrial trials.

Access/Assignment	Non-Industrial Trial	Industrial Trial
Access Grantor (Who can grant access?)	A registered user logged in as the Lead Organization's site administrator	A registered user logged in as the site administrator
Grantee (Who can be granted access?)	Any registered user affiliated with the grantor's organization (including the site administrator)	Any registered user affiliated with the grantor's organization (including the site administrator)
Accessible Trial Types (What trials can be assigned?)	Non-industrial trials for which the grantor's organization is the lead organization	Industrial trials for which the grantor's organization is the lead organization or participating site
Access Assignment (How is access assigned?)	On a per-trial basis; not at the participating site level	On a per-trial basis; not at the participating site level
Accrual Submission (Who can submit accrual data)	Any assigned user, for any participating site trials for which the grantor's organization is the lead organization	Any assigned user affiliated with the participating site

Assigning Users Accrual Submission Access

How to Assign Subject Accrual Access

1. On the navigation pane, click **Assign & Un-Assign Access**.
   The Manage Accrual Access page appears.

   Manage Accrual Access

   Select a trial category: All
   Select a user to assign, or un-assign, trial/site accrual submission:

2. Select the category of trial you want to assign, either **Industrial**, **Non-Industrial**, or **All**.
3. Select the user to whom you want to grant access.
   The list of trials available for accrual submission for the user you selected is displayed on 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.

> ℹ️ 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 you want the user to submit accrual data, and then click the single arrow (**>**) under **Assign**.
   A comment box appears.

> ✅ **You can select multiple trials**
>
> To select multiple trials, click one trial, then press and hold the CTRL key and click one or more others. Then click the single arrow (**>**) under **Assign**.
>
> To assign all trials, click the double arrow (**>>**) under **Assign.**

5. In the **Comment** box, enter a comment about this assignment, and then click **Save**.
   The trials you selected are moved to the Assigned list. The user will have access to them when logged in to the Subject Accruals application.

Un-Assigning Users Accrual Submission Access

How to Assign Subject Accrual Access

1. On the navigation pane, click **Assign & Un-Assign Access**.
   The Manage Accrual Access page appears.

2. Select the category of trial you want to assign, either **Industrial**, **Non-Industrial**, or **All**.
3. Select the user to whom you want to grant access.
   The list of trials available for accrual submission for the user you selected is displayed on the Not Assigned list on the left side of the page, and trials to which access had previously been granted appear in the Assigned list on the right.

4. From the **Assigned** trial list, select the trial to which you want to un-assign access, and then click the single arrow (**<**) under **Un-assign**.
   A comment box appears.

> ✅ **You can select multiple trials**
>
> To select multiple trials, click one trial, then press and hold the CTRL key and click one or more others. Then click the single arrow (**<**) under **Un-Assign**.
>
> To assign all trials, click the double arrow (**<<**) under **Un-Assign.**

5. In the **Comment** box, enter a comment regarding the un-assignment, and then click **Save**.
   The trials you selected are moved to the Not Assigned list, and the user will no longer have access to them.

Related Topics

- Viewing Accrual Assignment History
- Viewing Accrual Assignment History by Trial
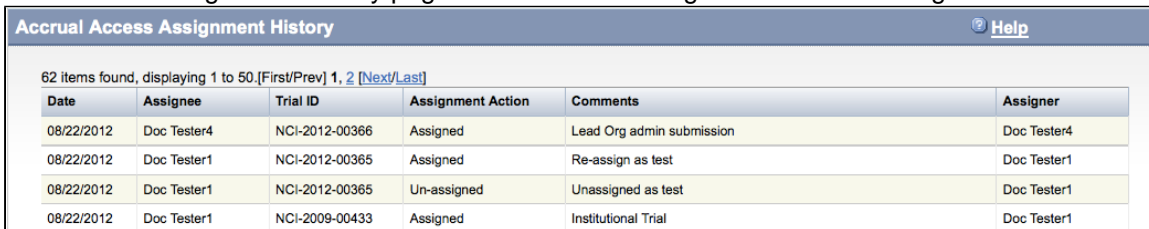
Viewing Accrual Assignment History

Viewing Accrual Assignment History

As a site administrator, you can view a history of your organization's trials to which users have been granted and revoked user access.

How to View Accrual Assignment History

1. On the navigation pane, click **Assignment History**.
   The Accrual Assignment History page lists all access assignments and un-assigments.

2. To sort the list, click any of the column headers.
   An arrow appears to the right of the column header. Click the arrow to change the sort order.

Related Topics

- Assigning and Un-Assigning Subject Accrual Access
- Viewing Accrual Assignment History by Trial

Viewing Accrual Assignment History by Trial

Viewing Accrual Assignment History by Trial

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

How to View Accrual Assignment History by Trial

1. On the navigation pane, click **Assignment by Trial**.
   The Accrual Access Assignment by Trial page lists all access assignments and un-assigments grouped by trial type.

2. To sort the lists, click any of the column headers.
   An arrow appears to the right of the column header. Click the arrow to change the sort order.

Related Topics

- Assigning and Un-Assigning Subject Accrual Access
- Viewing Accrual Assignment History

12 - Managing Your Account

12 - Managing Your Account

This section provides instructions for modifying your CTRP Registration Site account.

This section includes the following topics:

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

Resetting Your NCI Password

Resetting Your NCI Password

You can reset your NCI password from the NCI Password Station directly, or from the CTRP Registration application login page.

How to Reset Your NCI Password

- Navigate to the NCI Password Station at http://password.nci.nih.gov, or visit NCICB Application Support at http://ncicb.nci.nih.gov/support. Once you have logged in to the NCI Password Station, use the **Change Password** feature to create a new password.
  - or -
- On the CTRP 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.

Related Topics

- Creating CTRP Registration Site Accounts
- Logging In to the CTRP Registration Site
- Retrieving Your Username

Retrieving Your Username

Retrieving Your Username

You can retrieve your username from the CTRP Registration Login page.

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.

Managing Your User Account Profile

Managing Your User Account Profile

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

How to Edit Your Account Information

1. On the navigation pane on the left side of the page, click **My Account**.
   The My Account page appears, populated with the information you previously supplied for your account.
2. In the **Your Account Profile** section, make any changes as necessary.

> ⚠️ **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.

3. Click **Submit** to save your changes.

Related Topics

- [Creating CTRP Registration Site Accounts](#)
- [Logging in to the CTRP Registration Site](#)

13 - Using CTRP Registration Templates and Resources

13 - Using CTRP Registration Templates and Resources

The CTRP provides templates and other resources on their website that you can use to facilitate trial information gathering and registration. You can also use the templates to update and amend complete trials, and update abbreviated trials, that you have registered previously. CTRO staff use the information you provide in these documents to abstract your trials.

This section provides instructions for submitting participating site information for complete and abbreviated trials; and disease/condition and intervention information for abbreviated trials.

Additionally, batch upload templates guide you through the process of registering multiple trials at one time using the CTRP Registration Site's batch upload feature. See [Registering Multiple Trials](#).

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

This section contains the following topics:

- [Downloading Trial Registration Templates](#)
- [Using the Complete Trial Participating Sites Template](#)
- [Using the Abbreviated Trial Participating Sites Template](#)
- [Using the Abbreviated Trial Template](#)

Downloading Trial Registration Templates

Downloading Trial Registration Templates

You can download the following templates (MS Excel files) from the [CTRP website](#):

- Complete trial templates:
    - CTRP Registry 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 Registry 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.

    > ⓘ For information about trial updates and amendments, see About Trial Amendments and About Trial Updates.

- Abbreviated trial templates:
    - CTRP Registry Abbreviated Batch Upload Template. Use this template as a guide to record trial data required for registering multiple interventional abbreviated trials. See Registering Multiple Abbreviated Trials in Batch Files.
    - CTRP Registry Abbreviated Participating Sites Template. Use this template to record interventional abbreviated trial participating site data.
    - CTRP Registry Abbreviated Trial Template. Use this template to submit disease and intervention information for an interventional abbreviated trial that does not have an NCT number (and therefore has not been published in ClinicalTrials.gov). See Using the Abbreviated Trial Template.

How to Download CTRP Templates

1. On the navigation pane, click **Useful Templates and Documentation**.
   The NCI CTRP website Resources page appears in a new browser window.
2. Click the link for the document you want to download.
3. Save the file to your local hard drive.

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

Using the Complete Trial Participating Sites Template

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.

This section includes the following topics:

- Main Steps for Submitting Your Complete Trial Participating Sites Data
- Preparing Complete Trial Participating Sites Data Files
    - Trial Requirements
    - Data Specification Requirements

- Submitting Complete Trial Participating Sites Files

Main Steps for Submitting Your Complete Trial Participating Sites Data

1. Prepare the trial data file. See Preparing Complete Trial Participating Sites Data Files.
2. Upload the file via the trial-related document feature in the Registration application. See Submitting Complete Trial Participating Sites Files.

> ℹ️ 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.

Preparing Complete Trial Participating Sites Data Files

The CTRP web site provides a template that 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) from the CTRP web site at http://www.cancer.gov/clinicaltrials/conducting/ncictrp/resources. See Downloading Trial Registration Templates.
2. Enter the trial data elements as specified in the template.

> ℹ️ 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.

Trial Requirements

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

Study Type	• Complete • Interventional only
Summary 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

Data Specification Requirements

You must adhere to the following requirements:

- List trial elements required for registration in the order specified in the template. Collaborator information is optional.
- Do not change the spelling of data elements, valid values, or the order of the columns in the spreadsheet.
- Conform to the valid values guidelines when entering trial data. Valid values for each of the trial elements, where applicable, are listed in the template.
- Identify each trial uniquely. For example, append your cancer center unique trial identifier to the file name.
- Participating site information must include the following data elements:
    - Organization name and address
    - At least one study site investigator's name and role in the trial
    - 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.

> ℹ️ 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/contacts 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 lookup features in the CTRP Trial Registration application to search for PO-IDs.

Submitting Complete Trial Participating Sites Files

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

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 CTRP_Registry_Complete_Trial_Participating_Sites_Template.xls file. 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 the Registration application. For upload instructions, see Recording Trial-Related Documents.

Related Topics

- Recording Trial-Related Documents
- Downloading Trial Registration Templates
- Using the Abbreviated Trial Participating Sites Template

Using the Abbreviated Trial Participating Sites Template

Using the Abbreviated Trial Participating Sites Template

As an authorized CTRP submitter, you can use the CTRP Registry Abbreviated Trial Participating Sites Template to submit participating site information for industry-lead trials that do not have NCT numbers (and therefore have not been published in ClinicalTrials.gov). The template, a predefined Excel spreadsheet, provides the structure for recording your trial data.

This section includes the following topics:

Main Steps for Submitting Your Abbreviated Trial Participating Sites Data

1. Prepare the trial data file. See [Preparing Abbreviated Trial Participating Sites Data Files](#).
2. Upload the file via the trial-related document feature in the Registration application or email it the CTRO at ncictro@mail.nih.gov. See [Submitting Abbreviated Trial Participating Sites Files](#).

> 🛈 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 abbreviated interventional trials only.

Preparing Abbreviated Trial Participating Sites Data Files

The [CTRP web site](#) provides a template that includes data element requirements, valid values, and rules for registering abbreviated trial participating sites information.

How to Prepare Abbreviated Trial Participating Sites Data Files

1. Download the Abbreviated Trial Participating Sites Template (Excel spreadsheet) from the [CTRP web site](#) at http://www.cancer.gov/clinicaltrials/conducting/ncictrp/resources. 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.

Trial Requirements

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

Study Type	Abbreviated Interventional
Summary 4 Trial Submission Category	Industrial
Processing Statuses for Trial Updates	Accepted and beyond

Data Specification Requirements

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.

> ℹ️ 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 lookup features in the CTRP Trial Registration application to search for PO-IDs.

Submitting Abbreviated Trial Participating Sites Files

You can submit the data file when you register your trial via the [Registration application](). Or, email the file to the CTRO.

How to Submit Abbreviated Trial Participating Sites Files

1. In Microsoft Excel, list the trial elements required for registration in the order specified in the CTRP_Registry_Abbreviated_Trial_Participating_Sites_Template.xls file. To access the template, see [Downloading Trial Registration Templates]().
2. Once you have completed the template, do one of the following:
    - Upload it via the **Trial Related Documents** section on the **Register Trial** page in the [Registration application](). For upload instructions, see [Recording Trial-Related Documents]().
      - **or** -
    - Email the file to the [CTRO]() as an attachment.

Related Topics

- [Recording Trial-Related Documents]()
- [Downloading Trial Registration Templates]()
- [Using the Complete Trial Participating Sites Template]()

Using the Abbreviated Trial Template

Using the Abbreviated Trial Template

As an authorized CTRP submitter, you can use the CTRP Registration Site's abbreviated trial template to submit disease and intervention information for industry-lead trials that do not have NCT numbers (and therefore have not been published in ClinicalTrials.gov). The abbreviated trial template, a predefined Excel spreadsheet, provides the structure for recording your trial data. Once you have completed the template, upload it via the trial-related document feature in the Registration application. The CTRO requires this information for trial validation.

This section includes the following topics:

- Main Steps for Submitting Your Abbreviated Trial Data
- Preparing Abbreviated Trial Template Files
    - Data Specification Requirements
    - Template Requirements
- Submitting Abbreviated Trial Template Files

Main Steps for Submitting Your Abbreviated Trial Data

1. Prepare the trial template file. See Preparing Abbreviated Trial Template Files.
2. Upload the file via the trial-related document feature in the Registration application.

Preparing Abbreviated Trial Template Files

The CTRP web site provides a template that includes data element requirements, valid values, and examples and rules for registering abbreviated trial disease and intervention information.

How to Prepare Abbreviated Trial Templates

1. Download the abbreviated trial template (Excel spreadsheet) from http://www.cancer.gov/clinicaltrials/conducting/ncictrp/resources.
2. Enter the trial data elements as specified in the template.

> ℹ️ 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 abbreviated interventional trials only.

Data Specification Requirements

Ensure that the template file conforms to the following criteria:

Number of Trials per File	1
Number of Diseases and Interventions per File	At least one disease/condition *and* one intervention

Template Requirements

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, 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.
- Conform to the valid values guidelines in the template when entering trial data.
- Identify each trial uniquely. For example, append a unique trial identifier to the file name.

- If more than one disease or intervention is included, list each of them on a separate line.

Submitting Abbreviated Trial Template Files

You can submit the template file when you register your trial via the [Registration application](#).

How to Submit Abbreviated Trial Template Files

1. In Microsoft Excel, list the trial elements required for registration in the order specified in the CTRP_Registry_Abbreviated_Trial_Template.xls file. To access the file, 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 the [Registration application](#). For upload instructions, see [Recording Trial-Related Documents](#).

Related Topics

- [Recording Trial-Related Documents](#)
- [Downloading Trial Registration Templates](#)
- [Using the Abbreviated Trial Participating Sites Template](#)

A - Working With Persons and Organizations

A - Working With Persons and Organizations

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

This appendix includes the following topics:

- [Looking Up Registered Persons](#)
- [Adding Persons to CTRP](#)
- [Looking Up Registered Organizations](#)
- [Adding Organizations to CTRP](#)

Looking Up Registered Persons

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.

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

How to Look Up Registered Persons

1. Next to the **Principal Investigator** field, click **Look Up Person**. The Search Persons window appears.

Search Persons Window

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.

> ✅ **Using wildcard characters (%)**
>
> You can type a series of characters in any of the search fields 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 (%) between characters of the string as necessary.

> ⚠ **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.

> ℹ **Note**
>
> You must enter search criteria in at least one field.

3. Click **Search**. The Select Persons window displays the results of your search.

Search Persons Window-Results

> ☑ **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.

Adding Persons to CTRP

Adding Persons to CTRP

If you are unable to find the person you searched for, you can request that a person be added to the system.

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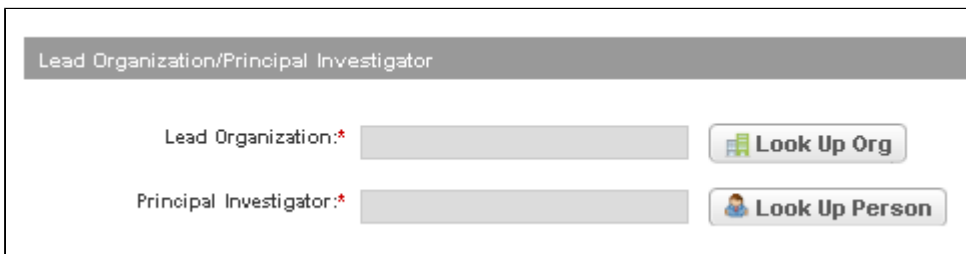
When you register a person, the CTRO staff curate the person's record, then add it to the list of registered persons in CTRP.

> ℹ 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. On the Register Trial page, navigate to the **Lead Organization/Principal Investigator** section.

Lead Organization/Principal Investigator Section

2. Next to the **Principal Investigator** field, click **Look Up Person**. The Search Persons window appears.

Search Persons Window

3. Click **Add Persons**. The Add Person window appears.

Add Person Window

4. Enter the person information in the fields provided. Fields marked with an asterisk are required. 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.

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

5. 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, 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.

Looking Up Registered Organizations

Looking Up Registered Organizations

The procedure for searching for an organization registered in the Clinical Trials Reporting Program is the same throughout the application, whether you are searching for a

lead organization, funding source, or other role. To link an organization to a role, you select the organization's record from a list of search results.

> ℹ The procedure below uses the lead organization role on the Register Trial page as an example.

How to Look Up Registered Organizations

1. Next to the **Lead Organization** field, click **Look Up**.
   The Select Lead Organization window appears.

Search Organizations Window

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

> ✅ **Using wildcard characters (%)**
>
> You can type 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.

> ⚠ **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 Lead Organization window displays the results of your search.

PO-ID	CTEP ID	Organization Name	Family Name	City	State	Country	Zip	Action
23863935		Example		Boston	MA	United States	320159	✓ Select

Search Organizations Window – Search Results

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

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

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

5. To link an organization to the trial, scroll through the results list until you locate the correct organization record, and then click **Select**.
   The organization's name you selected appears in the Lead Organization field.

Adding Organizations to CTRP

Adding Organizations to CTRP

If you are unable to find the organization you searched for, you can request that an organization be added to the system.

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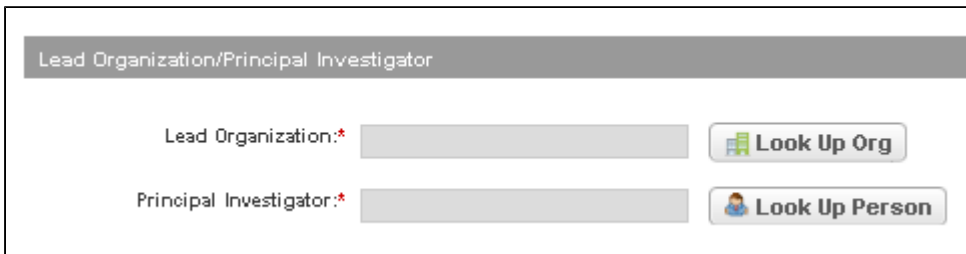
When you register an organization, the CTRO staff curate the organization's record, then add it to the list of registered organizations in CTRP.

> ℹ️ The procedure below uses the Lead Organization on the Register Trial page as an example. The same fields may not appear in all Add Organization windows however.

How to Add Organizations to CRTP

1. On the navigation pane, click **Register Trial**, and then scroll down to the Lead Organization/Principal Investigator section.

Lead Organization/Principal Investigator Section

2. Next to the **Lead Organization** field, click **Look Up Org**.
   The Select Lead Organization window appears.

Select Lead Organization Page

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

Add Organization Window

4. In the **Organization Name** field, type the full name of your organization.
5. Provide information in the fields provided. Fields marked with an asterisk are required.
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.

B - Common Tasks and Data Element Formats

B - Common Tasks and Data Element Formats

This appendix provides detailed instructions for tasks that are common to many of the procedures for registering trials in the Clinical Trials Reporting Program (CTRP). It includes a key to the icons used throughout the site, and valid formats for entering such data as dates and phone numbers.

This appendix includes the following topics:

- Navigating Search Results Lists
- Requesting Trial Summary Reports and XML Documents
- Selecting and Entering Dates
- Entering Phone and Fax Numbers

Navigating Search Results Lists

Navigating Search Results Lists

The system lists records satisfying search criteria in Search Results tables. You can navigate through the search results in several ways, as detailed in the following table.

Methods for Viewing Search Results and Trial Details

To do this...	Do this...	Additional Notes
Sort your results by column	Click the column heading once to sort the records in ascending order. Click the column heading again to reverse the sort order.	-
Move to the next page of results	Click **Next** or click the next page number above or below the list of results.	The **Next** link is not active on the last page of results.
Move to the previous page of results	Click **Prev** or click the preceding page number above or below the list of results.	The **Prev** link is not active on the first page of results.
Move to a specific page of results	Click the specific page number above or below the list of results.	-
Move to the first page of results	Click **First** above or below the list of results.	The **First** link is not active on the first page of results.
Move to the last page of results	Click **Last** above or below the list of results.	The **Last** link is not active on the last page of results.

Requesting Trial Summary Reports and XML Documents

Requesting Trial Summary Reports and XML Documents

You can request a copy of a Trial Summary Report (TSR) or the XML document for a trial you own if it meets the following criteria:

- The trial is complete
- Requires submission to ClinicalTrials.gov (for XML documents)
- Has a processing status Abstraction Verified or subsequent status

How to Request TSR and XML Documents

1. On the navigation pane on the left side of the page, click **Search Trials** to locate the trial for which you want to request a TSR or XML document.
   The trial you searched for appears in the Submitted Clinical Trials Search Results table. Available actions are listed (if any) for each record.
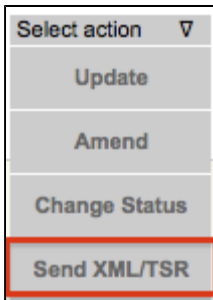
Search Results Table Action Column –Send XML/TSR

2. In the **Available Actions** column, click **Select action > Send XML/Send TSR**.
   The system sends the document you requested to the trial's owner(s) and site administrator(s).

Selecting and Entering Dates

Selecting and Entering Dates

You can enter a date in the field directly, or select a date from the calendar.

How to Select Dates From a Calendar

1. Click the **Calendar** icon.
   The calendar pop-up window appears.

Calendar Pop-up Window

2. Use the carets (**>** for month, and **>>** for year) at the top of the calendar to move forward and backward to the next/previous month or year.
3. Click the date from the calendar.
4. Click **Close**.

> ℹ️ Selecting a date from the calendar records a date/time stamp.

Entering Phone and Fax Numbers

Entering Phone and Fax Numbers

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.

C - Funding Mechanism Codes

C - Funding Mechanism Codes

This appendix provides the values for funding mechanism codes, the NCI codes used to identify areas of extramural research activity applied to various funding mechanisms.

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
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

D - Institute Codes

D - Institute Codes

This appendix provides the values for codes used to identify NIH, NCI, and funding mechanisms.

Institute Codes

Code	Organization
AA	National Institute on Alcohol Abuse and Alcoholism (NAAA)
AE	Office of 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 & Kidney Diseases
AO	Niaid Research Support
AR	National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)

AT	National Center For Complementary and Alternative Medicine (NCCAM)
BC	Division of Basic Sciences (NCI)
BX	Biomedical Laboratory Research & Development
CA	National Cancer Institute (NCI)
CB	Division of Cancer Biology and Diagnosis (NCI)
CD	Office of The Director, Centers For Disease Control & 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 & Development
DA	National Institute on Drug Abuse (NIDA)
DC	National Institute on Deafness and Other Communication Disorders (NICDC)

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 Prev and Health Promo
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 (NIEH)
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 (NIAMS)
GW	Genome Association Studies (GAS)
HB	Division of Blood Diseases and Resources (NHLBI)
HC	Ivision of Epidemiology & Clinical Applications (NHLBI)
HD	National Institute of Child Health & Human Development (NICHD)
HG	National Human Genome Research Institute (NHARI)
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 & 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 Center on Minority Health and Health Disparities (NCMHD)
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, STDS and TB Prevention
RD	Office of Research & Development
RX	Rehabilitation Research & 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
TS	Agency For Toxic Substances and Disease Registry

WH	Women's Health Initiative (WHI, OD)
RC	Center For Cancer Research (CCR)
RG	Center For Scientific Review (CSR)
RM	Nih Roadmap Initiative, Office of The Director (RMOD)
RR	National Center For Research Resources (NCRR)
TW	Fogarty International Center (FIC)
WT	Worker Education Training Program (WETP)
VA	Veterans Affairs
WC	Office of Workforce and Career Development

E - NCI Division and Program Codes

E - NCI Division and Program Codes

This appendix provides the values for NCI Division codes, the codes used to identify the name of the NCI Division responsible for a grant.

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

F - Trial Processing Statuses

F - Trial Processing Statuses

This appendix provides the definitions of each of the statuses that occur during the course of the trial processing workflow. It also illustrates the workflow so that you can see the relationships between the trial statuses.

Trial statuses are listed and illustrated below.

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
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.[1] These trials are displayed in PA but not in trial search results in the Registration application.

null

Trial Processing Workflow

The following procedure describes how a trial submission is processed and verified.

1. Trial submitter submits the trial; the status is **Submitted**.
2. Document Specialist validates the submission:
   - If the submission is not valid, the trial status is **Rejected**.
   - If the submission is validated by the Document Specialist, the trial status is **Accepted**.
   - If there is insufficient information to validate the submission, or the trial has been delayed, the trial can be placed **On Hold**.
3. Document Specialist starts trial abstraction:
   - Administrative processing is started and completed.
   - Scientific processing is started and completed.
4. Document Specialist completes the abstraction, and starts the QC.
5. Document Specialist completes QC, and the status changes to **Abstracted**.
6. Document Specialist sends Trial Summary Report (TSR) to the Principal Investigator, and the status changes to **Verification pending**.
7. Submitter Principal Investigator receives the TSR and returns feedback to the Document Specialist.
8. Document Specialist receives the feedback, and the status changes to **Abstraction Verified-Response**.
   - If the abstraction is not correct, the Document Specialist performs administrative and scientific processing again.
   - If the abstraction is correct, the verification is complete.

The following graphic illustrates the flow of a trial submission.
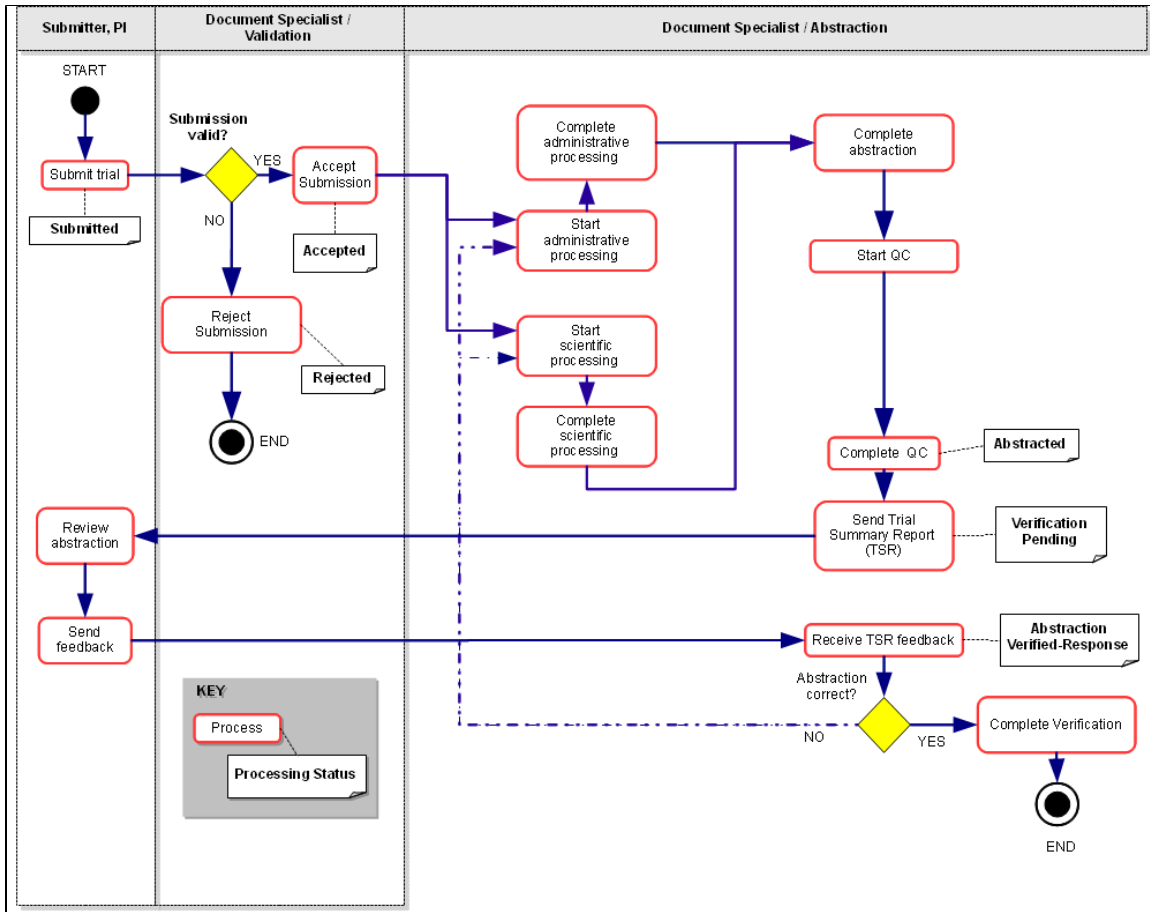
Trial Processing Life Cycle

G - Trial Phase Value Definitions

G - Trial Phase Value Definitions

- **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/11** - 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) - For epidemiologic, cancer control/behavioral, observational, ancillary, correlative, or other biological studies.

H - Trial Summary Reports and XML Files

H - Trial Summary Reports and XML Files

The CTRP system generates two types of trial documents that contain abstracted data as follows:

- **Trial Summary Report (TSR)** – Report that presents all abstracted data in an easy-to-read format. The report is sent as an attachment in an email to the trial submitter 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 highlights the differences between the original and amended versions.

- **XML File** – File that contains abstracted data in the format suitable for submission to ClinicalTrials.gov. This document is sent only to trial submitters who indicated that an XML file is required for submission to ClinicalTrials.gov when they registered the trial.

The following is an example of the first two pages of a TSR:

Trial Summary Report

Date: 08/23/2012
Record Verification Date: 05/29/2012

Trial Identification

Trial Category	Complete
NCI Trial Identifier	NCI-2012-00366
Lead Organization Trial Identifier	PreventionTest123
Other Trial Identifiers	• Test123 • Test456 • NCT454test • OtherID123
NCT Number	NCT454
DCP Trial Identifier	Test DCPID123
CTEP Trial Identifier	TestCTEPID123

General Trial Details

Official Title	Test trial test
Brief Title	This is a brief title
Acronym	TEST
Brief Summary	
This is a brief summary	
Detailed Description	
This is detailed description. This is detailed description. This is detailed description. This is detailed description. This is detailed description. This is detailed description. This is detailed description. This is detailed description. 3049 3434)(&* "hello"	
Keywords	Testkeyword1
Reporting Dataset Method	Abbreviated
Sponsor	Test Responsible Party Sponsor
Lead Organization	Test Lead Organization
Principal Investigator	TestHarlast, TestHar affiliated with Test Lead Organization
Responsible Party	Name/Official Title: TestHarlast, TestHar, Organization: Test Lead Organization, email: test@example.com, phone: 555-555-5555
Overall Official	TestHarlast, TestHar affiliated with Test Lead Organization in the role of Principal Investigator

Status/Dates

Current Trial Status	Active as of 04/25/2012
Trial Start Date	04/01/2012-Actual
Primary Completion Date	04/25/2015-Anticipated

Regulatory Information

Oversight Authorities	United States: Food and Drug Administration
FDA Regulated Intervention?	Yes
Section 801?	Yes
Delayed Posting Indicator?	No
DMC Appointed?	Yes
IND/IDE Study?	Yes

Human Subject Safety

Board Approval Status	Submitted, approved
Board Approval Number	12345
Board	Test IRB, 1 Lansing Road, Lansing, MI, 34567 USA, email: irb@example.com
Affiliation	Affiliation is abc

IND/IDE

Type	Grantor	Number	Holder Type	Holder	Expanded Access	Expanded Access Status	Exempt Indicator
IND	CDER	55555	NCI	DCP	No		No
IDE	CBER	45612	NCI	CTEP	No		No

NIH Grants

Funding Mechanism	NIH Institution Code	Serial Number	NCI Division/Program Code
B01	AA	55558	DCP
P30	AM	12345	DCP

Summary 4 Information

Funding Category	Institutional

The following is an example of part of an XML file. It contains all abstracted data in code format that can be submitted to CT.gov for registration.

```xml
<?xml version="1.0" encoding="UTF-8" ?>
- <clinical_study>
  - <id_info>
      <org_study_id>PreventionTest123</org_study_id>
    - <secondary_id>
        <id>NCI-2012-00366</id>
        <id_type>Registry Identifier</id_type>
        <id_domain>CTRP (Clinical Trial Reporting Program)</id_domain>
      </secondary_id>
    - <secondary_id>
        <id>B01AA55558</id>
        <id_type>NIH Grant Number</id_type>
      </secondary_id>
    - <secondary_id>
        <id>P30AM12345</id>
        <id_type>NIH Grant Number</id_type>
      </secondary_id>
      <org_name>replace with PRS Organization Name you log in with</org_name>
    </id_info>
    <is_fda_regulated>Yes</is_fda_regulated>
    <is_section_801>Yes</is_section_801>
    <delayed_posting>No</delayed_posting>
    <is_ind_study>Yes</is_ind_study>
  - <ind_info>
      <ind_grantor>CDER</ind_grantor>
      <ind_number>55555</ind_number>
      <has_expanded_access>No</has_expanded_access>
    </ind_info>
    <brief_title>This is a brief title</brief_title>
    <acronym>TEST</acronym>
    <official_title>Test trial test trial test trial test trial %dlfk #lkj</official_title>
  - <sponsors>
    - <lead_sponsor>
        <agency>Test Responsible Party Sponsor</agency>
      </lead_sponsor>
    - <resp_party>
        <resp_party_type>Principal Investigator</resp_party_type>
        <investigator_title>Principal Investigator</investigator_title>
        <investigator_affiliation>Test Lead Organization</investigator_affiliation>
```

I - Clinical Trial Summary 4 Categories

I - Clinical Trial Summary 4 Categories

This appendix provides definitions of CTRP trial categories.

Clinical trials in the CTRP are categorized as follows:

- **Complete**. Trials in this category include the following types of interventional trials:
    - **NationalCooperative Group**.
        - American College of Radiology Imaging Network

- American College of Surgeons Oncology Group
- Cancer and Leukemia Group B
- Children's Oncology Group
- Eastern Cooperative Oncology Group
- European Organization for Research and Treatment of Cancer
- Gynecologic Oncology Group
- National Cancer Institute of Canada, Clinical Trials Group
- National Surgical Adjuvant Breast and Bowel Project
- North Central Cancer Treatment Group
- Radiation Therapy Oncology Group
- Southwest Oncology Group

- **Externally Peer-Reviewed**. **Externally Peer-Reviewed**. R01s and P01s or other trial mechanisms funded by NIH or supported by other peer-reviewed funding organizations.
- **Institutional.**In-house trials authored or co-authored by cancer center investigators and undergoing scientific peer-review solely by the Protocol Review and Monitoring System of the Center. The center investigator should have primary responsibility for conceptualizing, designing and implementing the trial and reporting results. It is acceptable for industry and other entities to provide some support (e.g., drug, devices, other funding) but the trial should clearly be the intellectual product of the center investigator.
- **Abbreviated**. **Abbreviated**. Trials in this category are Industrial trials. The design and implementation of these studies is controlled by the pharmaceutical company.

CTRP Registration Credits

CTRP Registration Credits

The following technical and domain experts contributed to the development of this document.

> 🛈 This section lists the current members of the CTRP Project Team.

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