NCI Clinical Trials Reporting Program Subject Accrual 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 instructions for using the NCI Clinical Trials Reporting Program Accrual site to report accrual data for clinical studies registered with the CTRP (Clinical Trials Reporting Program).

Audience

This guide is designed for authorized users who want to view or submit accrual data for specific studies and sites.

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.

- 1 - Getting Started with Accrual introduces you to the NCI Clinical Trials Reporting Program Accrual (CTRP Accrual) site, and provides instructions for creating an account and logging in to the system.
- 2 - Searching for, and Selecting Your Trials describes how to use the CTRP Accrual site to search for and select the trials in the CTRP for which you want to provide new or updated accrual data.
- 3 - Working with Complete Trial Accruals provides instructions for searching for, adding, updating, and deleting study subject records associated with complete clinical trials.
- 4 - Working with Abbreviated Trial Accruals provides instructions for submitting and updating the total number of accruals associated with abbreviated clinical trials.
- 5 - Submitting Accrual Data Batch Files describes how to create and upload accrual data files singly as .TXT files or in multiple files that have been compressed into a Zip file.
- 6 - Working with Prior Accrual Submission Records provides instructions for accessing, updating, and downloading existing accruals.
- 7 - Managing Your CTRP User Account provides instructions for modifying your NCI CTRP Accrual Site account.
- 8 - Common Tasks and Data Element Formats provides detailed instructions for tasks that are common to many of the procedures included in this guide.
- Appendix A - Accrual Data Elements for Complete Trials contains detailed information about each of the data elements included in the Batch Upload file for Complete trials, including the CDUS Accepted Values.
- Appendix B - Accrual Data Elements for Abbreviated Trials contains detailed information about each of the data elements included in the Batch Upload file for Abbreviated trials, including the CDUS Accepted Values.
- Appendix C - Comparison of CTRP and CDUS Accrual Data Elements lists CDUS data elements and indicates which of them are captured in CTRP.

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 with Accrual

1 - Getting Started with Accrual

This section introduces you to the NCI Clinical Trials Reporting Program Accrual (CTRP Accrual) site, and provides instructions for creating an account and logging in to the system.

This section includes the following topics:

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 CTRP Subject Accrual

About CTRP Subject Accrual

The CTRP Subject Accrual site provides authorized members of the cancer research community with access to cancer clinical trials registered with the CTRP (Clinical Trials Reporting Program) for the purpose of reporting accrual data for clinical studies. This release of the application enables users to enter patient (study subject) demographic data for Complete trials and patient accrual counts for Abbreviated trials that have been abstracted (i.e., have reached the Abstracted status). These trials are categorized as follows:

- **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.

Who Should Submit Accrual Data?

Patient accrual data should be submitted for interventional studies registered in CTRP. A summary of the type of data and the organization responsible for submitting the data to CTRP is provided below.

For National Studies

For national studies, CTRP collects patient demographic data for each patient accrued to that particular study. (See Patient Accrual Data Elements for more information.) The coordinating center is typically responsible for submitting patient accrual data for all participating sites in the study. Please contact the CTRO if you have questions about who should be submitting accrual data to CTRP for National studies.

> ⚠ CTEP/DCP PIOs transfer most, if not all, accrual data for National trials to CTRP. Center accrual submitters who want to submit accrual data for a National trial should contact the CTRO first at ncictro@mail.nih.gov to verify that the accrual should be reported by the Center, and not by CTEP or DCP.

For Institutional and Externally Peer-Reviewed Studies

For institutional and peer-reviewed studies, CTRP collects patient demographic data for each patient accrued to that particular study. (See Patient Accrual Data Elements for more information.) The lead organization assigned to a study is typically responsible for submitting patient accrual data for all participating sites in the study.

For Abbreviated Studies

For industrial studies, only a total count of patients accrued per participating site is required. The organizations responsible for submitting this data are the participating sites associated with the particular study in CTRP. Each participating site will submit their own patient accrual data, which will consist of only the total number of patients accrued at that particular site for that particular study.

Subject Accrual Reporting Methods

CTRP provides three methods for reporting accrual data:

1. **CTRP Application User Interface – Manual data entry**. The user can log into the CTRP system using a web browser and enter accrual data for studies to which the user has access. For Abbreviated studies, the user can enter accrual count of the participating site they are affiliated with by entering the total number of subjects accrued to date. For Complete studies, the user can enter each patient, including the relevant demographic data, via the user interface.
2. **CTRP Application User Interface – Batch file**. This method allows the user to submit patient accrual data in the form of text files that contain all the relevant accrual information for a particular study. The user can log into the CTRP accrual application using a web browser, select the batch file that contains the accrual data, and upload it for processing by the CTRP application.
3. **CTRP Trial Registration Service – System-to-System Integration**. This method enables vendors, cancer centers, and other stakeholders to report accrual data using the CTRP Subject Accrual web service. Refer to the Subject Accrual Service Documentation for further information.

This User's Guide primarily covers methods 1 and 2.

How Often Should Patient Accrual Data be Submitted?

Patient accrual data should be submitted to CTRP on a quarterly basis once accrual has started for a particular study. CTRP will follow the same schedule that most centers are already using for submission of accrual data to the NCI CTEP's Clinical Update Data System (CDUS).

Cutoff Dates for Data Collection:

- September 30
- December 31
- March 31
- June 30

Deadlines for Reporting to CTRP:

Submission of accrual data to CTRP should be completed each quarter as soon after the data collection cutoff date as possible, but no later than 30 days after the cutoff date.

Related Topics

- Requesting an Accrual Site Account
- Logging In to the CTRP Accrual Site

What's New in this Release of CTRP Subject Accrual

What's New in this Release of CTRP Subject Accrual

This version of the CTRP Subject Accrual application has the following new features and improvements:

- **Batch Submissions**
  - Batch file submissions no longer replace existing subject accrual records. Instead, each subsequent submission is now treated as an update to existing data or as an addition of new subjects to the study.
  - Processing capability improvements. The system now is able to process batch files with up to 50,000 records.
  - During processing, CTRP now considers two additional fields (Change Code and Registering Group Code) in a batch file. Providing values for these two fields remains optional.
- **Getting Help**
  - Now you can hover your cursor over fields in the application to see instructions related to it.
  - The online Help for the application now directs you to the instructions that apply to the page you are on.
- **Deleting Study Subject Records**
  - You can delete an existing patient in CTRP *only* from the Subject Accrual application's Search Study Subject page.
- **Viewing Prior Submissions**
  - You now have the option to view all prior accrual submissions via the Subject Accrual application.
  - The prior submissions list displays the date of submission, name of submitter, link to the batch file, and the mechanism used for submission (i.e., the Subject Accrual web application's graphical user interface (GUI), batch upload, or the Accrual service).
- **Managing User Access to the Subject Accrual Application**

- Organization's site administrators can now assign or un-assign their registered users access to the Subject Accrual application via a new feature in the NCI CTRP Registration site.

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Obtaining a CTRP User Account

Obtaining a CTRP User Account

In order to use the CTRP Accrual application, you must have a CTRP User Account. There are two ways to register for a CTRP account, as follows:

- Via your email address. If you are a new user and you *do not have* an NCI account, you can request one via your email address using the CTRP Registration account creation feature.
- Via your NCI credentials. If you are a new user and you *have* an NCI account, create a CTRP account via your NCI credential using the CTRP Registration account feature.

Once you have obtained a CTRP User Account, request authorization to access your trials. See Requesting Access to Your Trials for instructions.

Requesting Access to Your Trials

Requesting Access to Your Trials

In order to view and submit accrual data for your trials, you must be a registered CTRP user. Additionally, you must request access to your trials.

> If you do not have a CTRP user account, register for a CTRP account via the CTRP Registration account feature. For instructions, see Obtaining a CTRP User Account.

How to Request Access to Your Trials

Contact your organization's site administrator to request accrual access for your studies. For instructions on how a Site Administrator can manage access to studies in Accruals, see the section on Managing Access to Subject Accruals in the CTRP Registration Site User's Guide.

Logging In to the CTRP Accrual Site

Logging In to the CTRP Accrual Site

Once you have created a CTRP user account, and have been granted accrual access to at least one study, you can log in to the CTRP Accrual Site and search for clinical trials to submit accrual data.

Gather all the protocol data you need before you begin

The system locks you out if it detects 90 minutes of in-activity. The system also locks you out after three unsuccessful attempts to log in within 24 hours. In the event that you cannot remember your password, or have been locked out of your account, contact Application Support.

How to Log In to the CTRP Accrual Site

1. Navigate to the NCI CTRP Accruals home page at http://trials.nci.nih.gov/accrual.
2. On the Home page, click the **Log In** button on the right side of the banner.
   The Login page appears.
3. Enter your NIH/NCI username and password in the fields provided. If you do not have a registered username and password, see Obtaining a CTRP User Account.
   If you have forgotten your password, see the instructions in Changing Your CTRP User Password.
4. Click **Log In**.
5. After you have read the public reporting burden notice, click **Accept**.

Related Topics

- Managing Your User Account Profile
- Obtaining a CTRP User Account

2 - Searching for, and Selecting Your Trials

2 - Searching for, and Selecting Your Trials

This section describes how to use the CTRP Accrual site to search for and select the trials for which you want to provide new or updated accrual data.

This section includes the following topics:

Searching for Trials in Accrual

Searching for Trials in Accrual

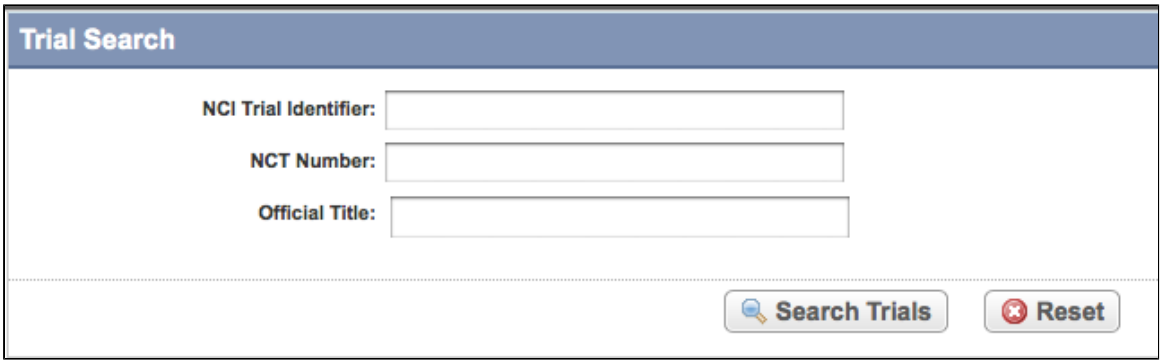
The list of trials to which you have been granted access is displayed automatically when you log in to the CTRP Accrual site. For information on navigating and working with lists of trials, see Navigating Search Results Lists.

Accessing your trials

If you do not see any studies listed when you log in, you may not have been granted access to submit accrual data for any trials yet. Be sure to request access from your organization's administrator as explained in Requesting Access to Your Trials.

How to Search For Trials

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

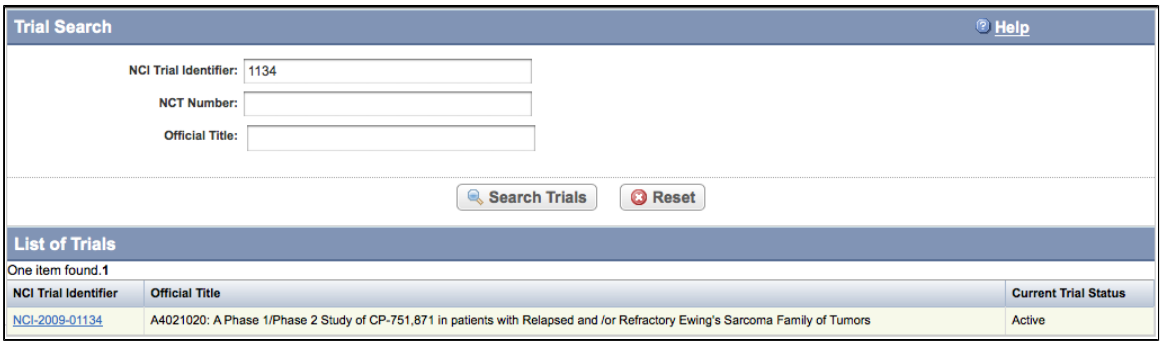


Search Page-Trial Search Section

2. On the **Trial Search** page, type the **NCI Trial Number**, **NCT Number**, or **Official Title** in the fields provided, then click **Search**.

> You can search for a trial by one or more criteria, or you can list all trials to which you have been granted access by leaving all of the search criteria fields blank. If you search by the **Official Title**, use keywords and wildcards rather than phrases or the entire title. Doing so minimizes the potential for excluding any titles with misspellings or slightly different phrasing from the search results . For example a *Phase II trial* may have been recorded as a *Phase 2 trial*.

   The Search Trials page refreshes and displays the trial(s) you searched for.



Trial Search Page

Each trial is listed by NCI trial identifier, official title and current trial status. Trial statuses are defined in the table below.

- **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.

3. To view a given trial, click its corresponding **NCI Trial Identifier** link.

   For Abbreviated trials, the page displays the number of study subjects currently enrolled for each of the participating sites, and the navigation menu changes to **Record Accrual Account**. See Working with Abbreviated Trial Accruals.

   For Complete trials, the page displays a list of study subjects currently enrolled, and the navigation menu changes to **Study Subject Search**. See Working with Complete Trial Accruals.

Viewing Trial Details

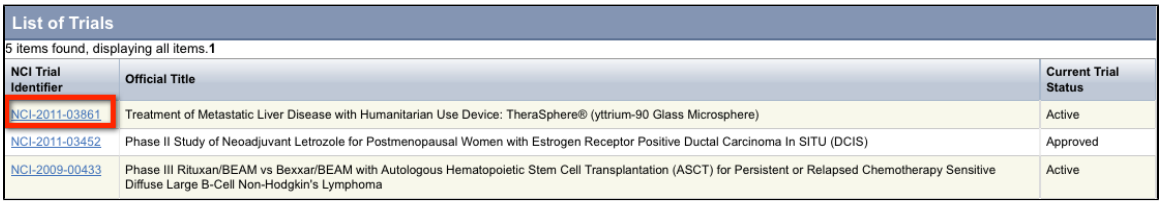
To view details for a given clinical trial record, click its associated **NCI Trial Identifier** link. See Selecting Listed Trials in Accrual.

Selecting Listed Trials in Accrual

Selecting Listed Trials in Accrual

The CTRP Accrual site displays the Trial Search (top) and the List of Trials (bottom) sections on the first page automatically after you have logged in and accepted the notification regarding public reporting burden.

The List of Trials page displays the trials to which you have been granted access.



List of Trials

5 items found, displaying all items.1

NCI Trial Identifier	Official Title	Current Trial Status
NCI-2011-03861	Treatment of Metastatic Liver Disease with Humanitarian Use Device: TheraSphere® (yttrium-90 Glass Microsphere)	Active
NCI-2011-03452	Phase II Study of Neoadjuvant Letrozole for Postmenopausal Women with Estrogen Receptor Positive Ductal Carcinoma In SITU (DCIS)	Approved
NCI-2009-00433	Phase III Rituxan/BEAM vs Bexxar/BEAM with Autologous Hematopoietic Stem Cell Transplantation (ASCT) for Persistent or Relapsed Chemotherapy Sensitive Diffuse Large B-Cell Non-Hodgkin's Lymphoma	Active

List of Accessible Trials

> ✅ You can sort the list of trials by clicking a column heading. To reverse the sort order, click the column heading again.

How to Select Trials on the List of Trials Page

1. Navigate to the trial you want to work with by following the instructions in Navigating Trial Lists.
2. To view a given trial, click its corresponding **NCI Trial Identifier** link.

Related Topics

3 - Working with Complete Trial Accruals

3 - Working with Complete Trial Accruals

This section describes how to search for, add, update, and delete study subjects associated with Complete clinical trials. For information about Industrial trials, see Working With Abbreviated Trial Accruals.

This section includes the following topics:

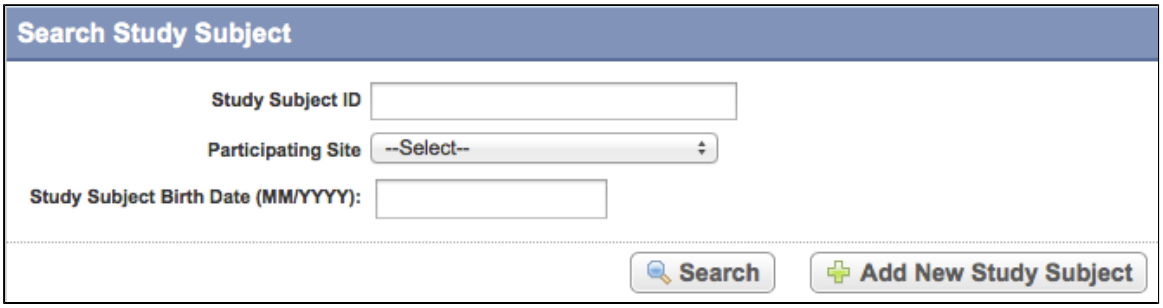
Adding Study Subjects

Adding Study Subjects

You can add one or more study subject accrual records for any trial to which you have been granted access[1]. See Requesting Access to Your Trials.
Study subject records include demographic data as well as the disease name. You are required to complete all fields marked with an asterisk (*).

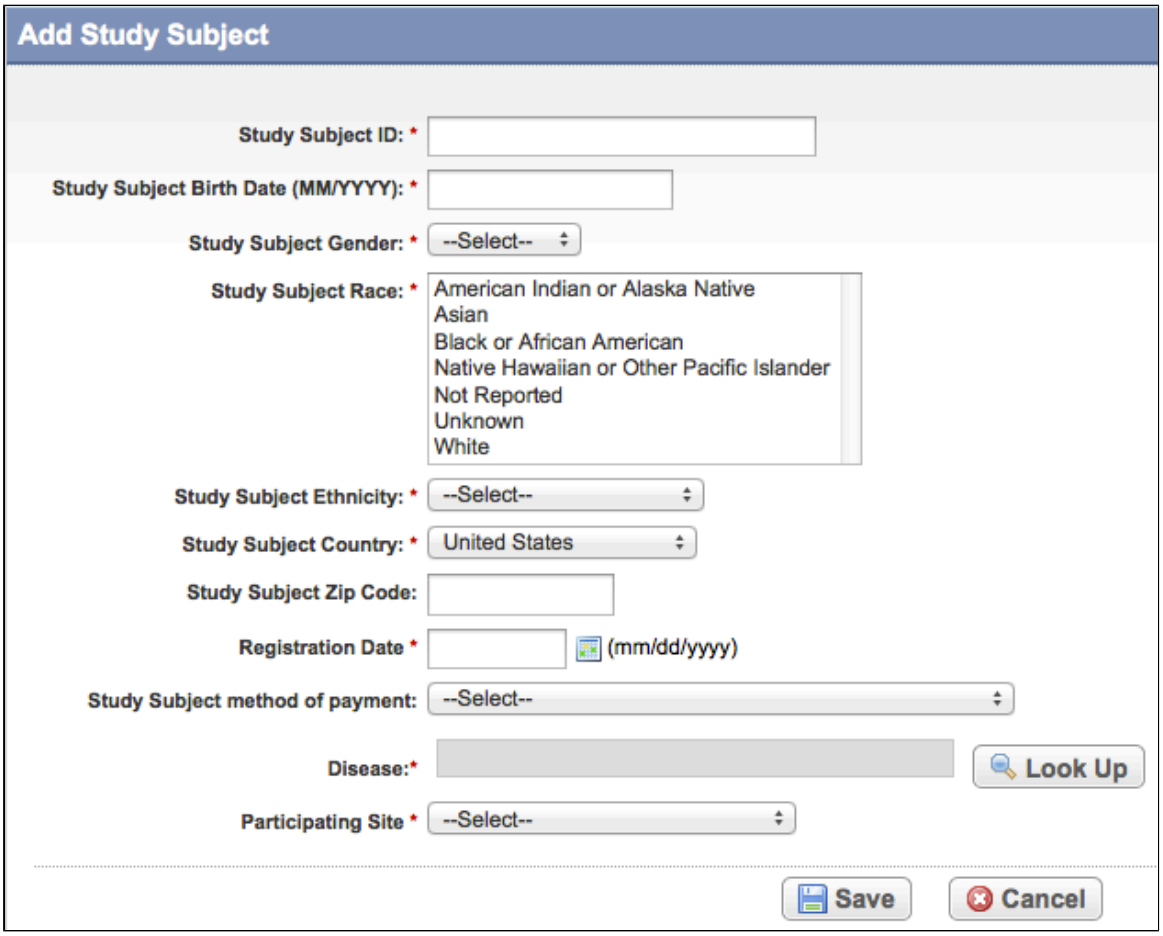
How to Add Study Subject Records

1. Select the trial you want to work with by following instructions in Selecting Listed Trials or Searching for Trials in Accrual, by clicking the corresponding NCI Trial Identifier link.
2. If the **Search Study Subject/List of Study Subjects** page is not already displayed, on the navigation pane, click **Study Subject Search**.
   The **Search Study Subject/List of Study Subjects** is displayed.



Search Study Subject/List of Study Subjects

3. At the bottom of the **Search Study Subject** section, click **Add New Study Subject**.
   The Add Study Subject page appears.



Add Study Subject page

4. Enter the appropriate demographic information in the text fields and Select from drop-down lists. Fields are described in the following table. Fields marked with an asterisk are required.

   Descriptions and instructions for study subject demographic data fields

Study Subject Information	Instruction/Description
Study Subject ID*	Type the unique Patient ID as per the lead organization or the study site where the subject is registered.
Study Subject Birth Date*	Type the subject's month and year of birth in the format `MM/YYYY`.
Study Subject Gender*	Select the subject's gender. If gender information is not available, select **Unknown**.

Study Subject Race*	Select one or more values for race. To select multiple races, select one race, and then press and hold the **CTRL** key as you select the other(s).
Study Subject Ethnicity*	Select a value for ethnicity.
Study Subject Country*	Select the subject's country of origin.
Study Subject Zip Code	Type the subject's Zip Code if known. This field is mandatory if the country of origin is United States.
Registration Date*	Enter the date that the subject was registered for the trial. See Selecting and Entering Dates
Study Subject Method of Payment	For United States study subjects only, select the appropriate payment method.
Disease*	Click **Look Up**, and follow the instructions in Searching for Diseases.
Participating Site*	Select the appropriate site from the drop-down list.

5. Click **Save**.
   The study subject record appears in the List of Study Subjects.

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You can submit accrual data to the NCI CTEP's Clinical Update Data System (CDUS) on a quarterly basis (i.e., December 31, March 31, June 30) up to 30 days following the end of the quarter.

For complete trials, lead organizations report all subjects accrued for the trial (both in the lead organization and in all participating sites). For abbreviated trials, each participating site reports the number of its own accruals (accrual count) only.

Related Topics

- Uploading Accrual Data Files
- Searching for Diseases
- Searching for Study Subjects
- Updating Study Subject Records
- Deleting Study Subject Records

Searching for Diseases

Searching for Diseases

How to Search for Diseases

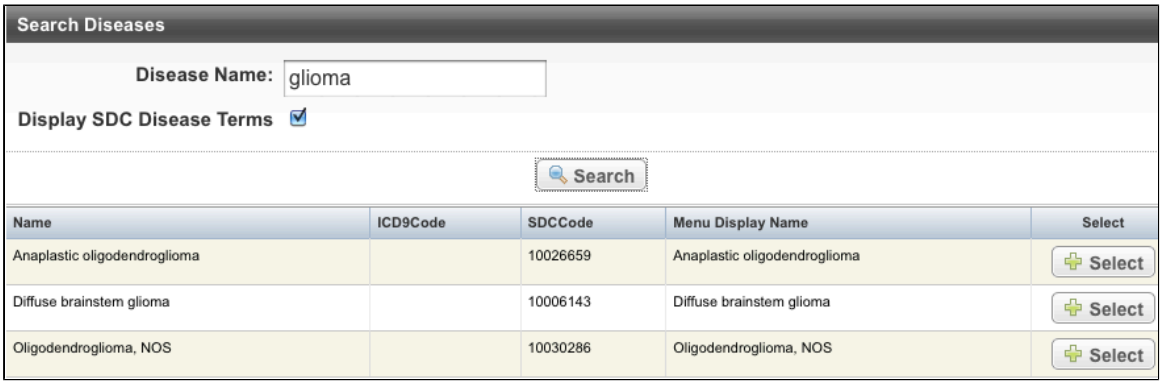
1. Navigate to the trial you want to work with by following the instructions in Selecting Listed Trials or Searching for Trials in Accrual, and then click the corresponding NCI Trial Identifier link.
2. At the bottom of the **Search Study Subject** section, click **Add New Study Subject**.
   The Add Study Subject page appears.
3. To assign a disease to the study subject, next to the **Disease** field, click **Look Up**.
   The Search Diseases window appears.

Search Diseases Window

4. In the **Disease Name** field, type part or all of the disease/condition being studied. To include SDC (CTEP's Simplified Disease Classification) disease names in your search, select the **Display SDC Disease Terms** ch eck box.

> **Search tips**
>
> Type as many letters of the disease/condition name as possible to reduce the number of 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.

5. Click **Search**.
   The system searches for the disease/condition in the database, and returns a list of results.



Search Disease Window

6. Scroll through the list (if necessary) to locate the disease/condition being studied, and click **Select**.
   The system populates the Disease field for you.

Related Topics

Searching for Study Subjects

Searching for Study Subjects

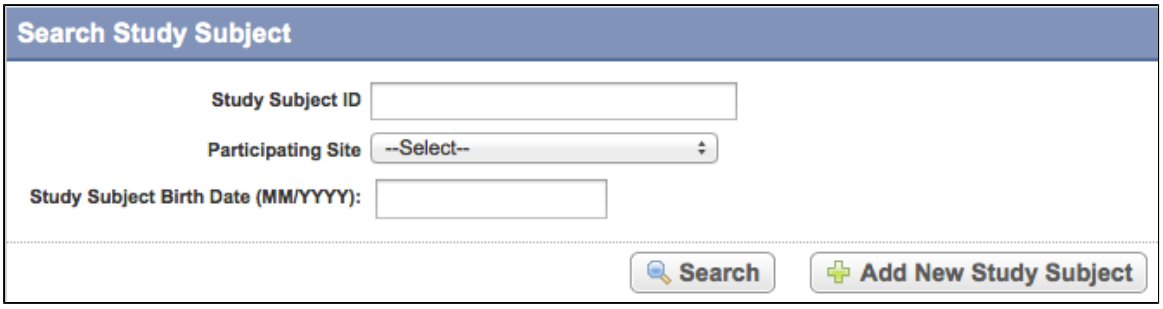
You can search for a particular study subject record using any combination of the following three criteria:

- Study Subject ID
- Participating Site
- Birth Date

> You must select a trial before you can search for study subjects. For instructions, see Searching for, and Selecting Your Trials.

How to Search for Study Subjects

1. If the **Search Study Subject/List of Study Subjects** page is not already displayed, on the navigation pane, click **Study Subject Search**.
   The Search Study Subject page appears.

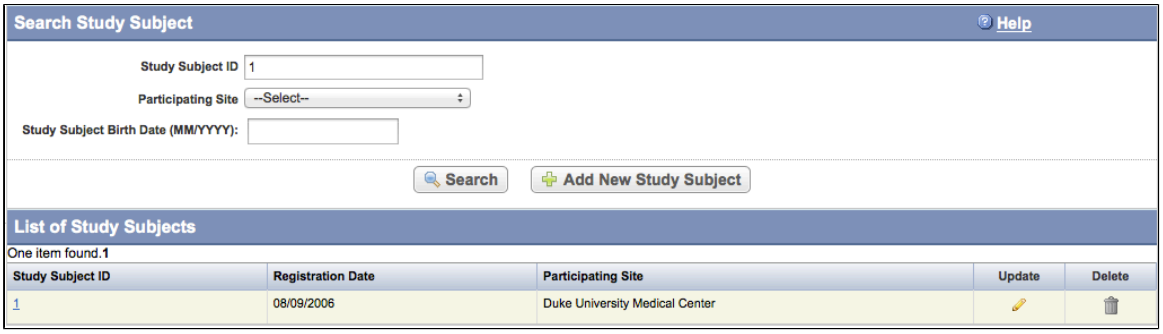


Search Study Subject Page

2. Type or select your search criteria from one or more of the fields provided.

> **You can list all study subjects**
>
> You can search for a trial by one or more criteria, or you can list all subjects associated with trials to which you have been granted access by leaving all of the search criteria fields blank.

3. Click**Search**.
   Your search results are displayed in the List of Study Subjects section of the page. The list is sorted by Study Subject ID, and includes the following information:
   - Study Subject ID
   - Date on which the subject was registered at a given participating site
   - The Participating Site where this subject is registered
   - Date/Time of when this record was updated in CTRP



Search Study Subject Page - Search Result

Related Topics

- Reviewing Study Subject Records
- Adding Study Subjects
- Updating Study Subject Records
- Deleting Study Subject Records

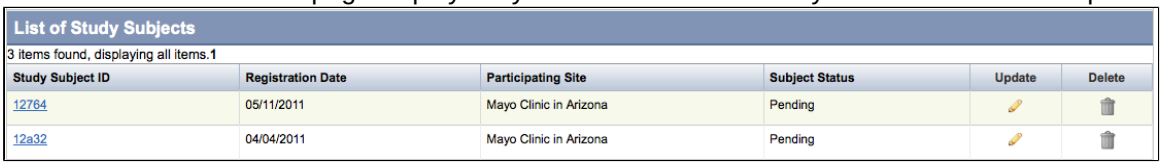
Reviewing Study Subject Records

Reviewing Study Subject Records

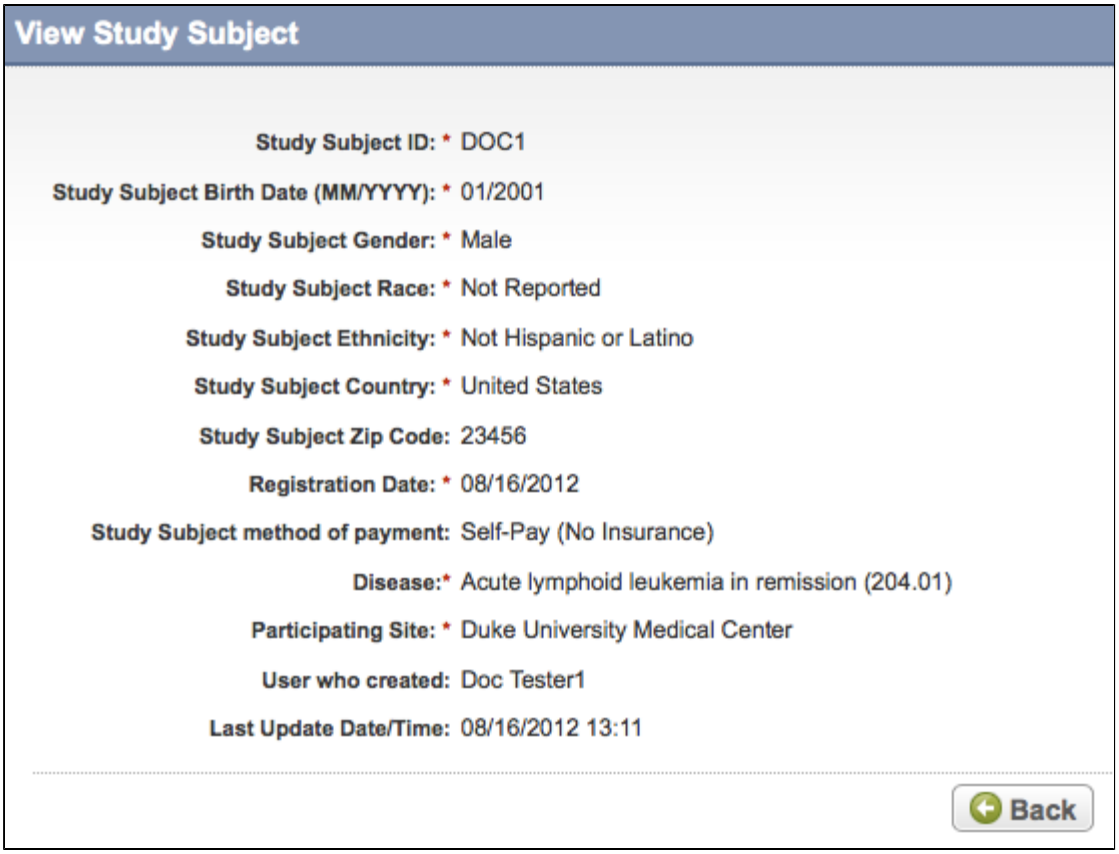
CTRP Accrual site enables you to review the collection of non PII (Personally Identifiable Information) study subject data associated with a particular non-industrial trial registered with the CTRP.

How to Review Study Subject Records

1. Navigate to the appropriate trial and click the **NCI Trial Identifier**. For instructions on locating a particular trial, see Searching for Trials in Accrual.
   The Accrual Submissions page displays any accrual records that may have been submitted previously.



   List of Study Subject Records
2. Click the **Study Subject ID** of interest.
   The Study Subject page displays the study subject's demographic details recorded to date as well as information about the record itself.



Study Subject Page

3. To return to the accrual record, click **Back**.

Related Topics

- Searching for Study Subjects
- Adding Study Subjects
- Updating Study Subject Records
- Deleting Study Subject Records

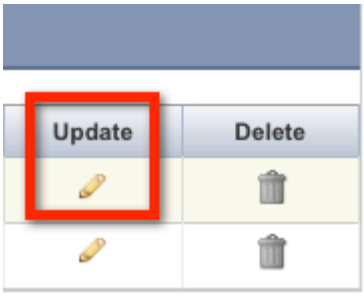
Updating Study Subject Records

Updating Study Subject Records

You can update study subject records for Complete trials as necessary.

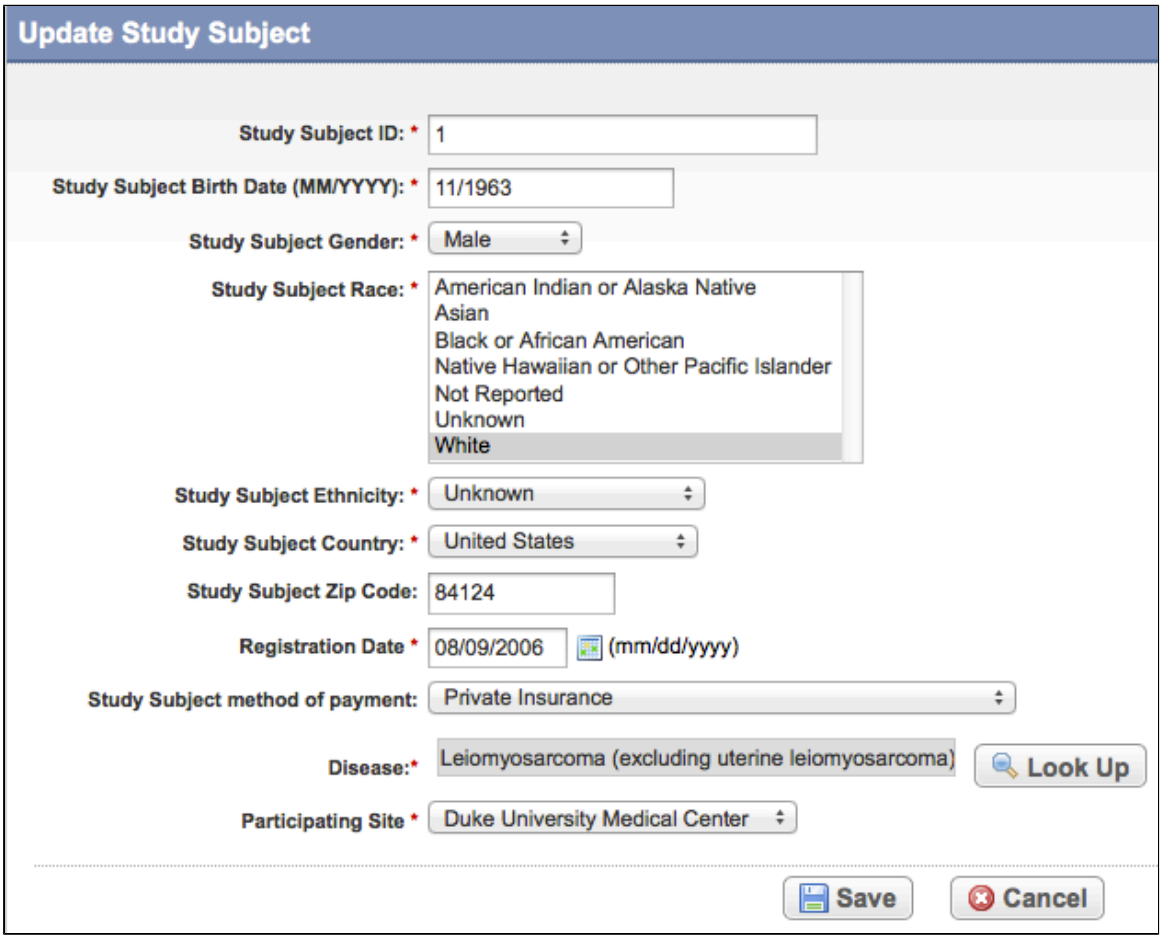
How to Update Study Subject Records

1. Navigate to the trial you want to work with by following the instructions in Selecting Listed Trials in Accrual or Searching for Trials in Accrual, and then click the corresponding **NCI Trial Identifier** link.
2. If the **Search Study Subject/List of Study Subjects** page is not already displayed, on the navigation pane, click **Study Subject Search**.
   The **Search Study Subject/List of Study Subjects** is displayed.



Study Subject Records - Update Icon

3. In the list of study subjects, click the **Update** icon.
   The Update Study Subject page displays the study subject's current information.



Update Study Page

4. Make any changes as appropriate, and then click **Save**.

Related Topics

- Reviewing Study Subject Records
- Searching for Study Subjects
- Deleting Study Subject Records

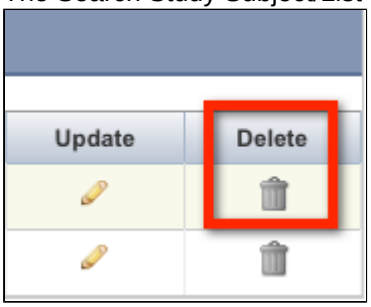
Deleting Study Subject Records

Deleting Study Subject Records

If a subject has been enrolled to an incorrect study or added due to an administrative error, you have the option to delete the subject from that study.

How to Delete Subject Records

1. Navigate to the trial you want to work with by following the instructions in Selecting Listed Trials or Searching for Trials, and then click the corresponding **NCI Trial Identifier** link.
2. If the **Search Study Subject/List of Study Subjects** page is not already displayed, on the navigation pane, click **Study Subject Search**.
   The Search Study Subject/List of Study Subjects is displayed.



Study Subject Records - Delete Icon

3. In the list of study subjects, click the **Delete** icon.

> Be sure to select the **Delete** icon for the proper record. Once you have deleted a study subject record, there is no way to retrieve it. However, you can add it back to the trial later

   The Subject Delete Reason window appears.

Subject Delete Reason

4. Select the reason for deleting this subject, either **Enrolled in Incorrect Study** or **Other Administrative Error** , and then click **OK**.

> **You can cancel the deletion process**
>
> If you decide not to delete the subject record, click **Cancel**.

Related Topics

- Reviewing Study Subject Records
- Searching for Study Subjects
- Updating Study Subject Records
- Adding Study Subjects

4 - Working with Abbreviated Trial Accruals

4 - Working with Abbreviated Trial Accruals

This section describes how to submit and update the total number of accruals (accrual count) associated with an Abbreviated clinical trial. For instructions for submitting accrual data for Complete trials, see Working with Complete Trial Accruals.

Because pharmaceutical companies do not enter their data into CTRP, each participating site on an Abbreviated study must enter its own accrual count into CTRP. For Abbreviated studies, the lead organization is the pharmaceutical company running the trial.

> **Patient demographic data.**
>
> Abbreviated study records include the total number (count) of patients accrued per site on a given trial; full patient demographic data is not recorded.

Submitting Participating Site Subject Accrual Counts

Each participating site can submit/update the number of patients accrued to date per study.

How to Submit Participating Site Subject Accrual Counts

1. Locate the trial of interest by following the instructions in Selecting Listed Trials in Accrual or Searching for Trials in Accrual.
2. Click the trial's **NCI Trial Identifier**.
   The Participating Site Subject Accrual Count page appears, and the navigation pane displays the Record Accrual Information menu.

Site Subject Accrual Count Page

3. In the **Number of Subjects Enrolled** field, enter the number of subjects currently enrolled in studies at your site.
4. In the **Save** column, select the check box for the record you want to update, and then click **Save**.
   A message at the top of the table indicates that the record has been updated successfully.

5 - Submitting Accrual Data Batch Files

5 - Submitting Accrual Data Batch Files

This section provides instructions for uploading batch files via the CTRP Accrual application. It also provides instructions for resolving any errors that may have occurred during the import process.

The batch upload feature enables you to submit accrual data for multiple subjects and one or more trials at a time rather than having to enter data for each subject/study individually via the CTRP Accrual web application.

> You can upload accrual data files singly as plain text files or in multiple text files that have been compressed into a Zip file. See Preparing CTRP Subject Accrual Batch Files for detailed instructions.

This section contains the following topics:

Related Topic

Subject Accrual Service Documentation

Preparing CTRP Subject Accrual Batch Files

Preparing CTRP Subject Accrual Batch Files

When a trial has accrued many subjects, rather than entering the data subject-by-subject via UI, you can upload all study subject data into CTRP using a batch file upload. The information that follows provides all the details you need to create a CTRP Accruals Batch file.

> **Use the Batch File Utility as a guide**
>
> If you are new to the batch file creation process, you can use the Batch File Utility at https://ncisvn.nci.nih.gov/svn/coppa/trunk/documents/user_guides/accrual_application_guide/Accrual%20Batch%20File%20Tool.xlsm to get you started. With it you can produce properly-formatted batch files that you can upload in the Accrual application.

> When you create a batch file, ensure that each data element conforms to the requirements.
>
> - List each data element in its appropriate position in a given row
> - Use the correct character cases (CAPITAL vs. lower case letters)
> - Use the correct character lengths (number of characters allowed in a single field)

After you have prepared a batch file, you can upload it to CTRP. For instructions on submitting batch files, see Uploading CTRP Subject Accrual Batch Data Files.

Key Facts about CTRP Accrual Batch Files

This section provides a summary of key facts about preparing CTRP Accrual batch files.

- The CTRP Accrual Batch File format is based on the CTEP Clinical Data Update System (CDUS) file format. You can obtain a copy of the *CDUS Instructions and Guidelines*, which explains the CDUS file format in great detail, at the CTEP web site at http://ctep.cancer.gov/protocolDevelopment/electronic_applications/cdus.htm.
- Although the CTRP accrual batch file format is CDUS-compatible, CTRP captures a subset of all the CDUS

required data elements. Appendix C provides a list of all the CDUS fields with a note next to each field indicating whether CTRP captures it.

- Different data elements are required and expected when submitting accrual data to CTRP for Complete trials (National, Externally Peer Reviewed, and Institutional) than for Abbreviated Trials (Industrial). Instructions are provided below for preparing batch files for both Complete and Abbreviated Trials.
- A CTRP accrual batch file is a TXT (.txt) file with fields delimited (separated) by commas.
- Each CTRP batch text file contains accrual data for a *single* trial.
- You can compress one or more CTRP accrual batch text files into a single Zip file and then upload this Zip file into CTRP. CTRP will unzip the file and process each TXT file. Your Zip file can include batch files for both Complete and Abbreviated Trials.
- Each batch submission uploaded into CTRP is treated as an update to existing records or as an addition of new ones.

> ⚠ If you upload data to a trial that already has accrual data, the batch file is considered an **update**. The system compares your new data to existing data using identifiers. When the identifiers match, existing data in CTRP is updated. When there are no matching identifiers, data is added to the existing study. For Abbreviated trials, the system updates the accrual counts.

An Introduction to Batch Files

> ⚠ This section provides general background information about batch file structure. Subsequent sections provide specific details about the CTRP Subject Accrual Batch file structure.

Each line of text in a batch file corresponds to one record that consists of various required or optional data elements. Each data element is separated by a comma.

Traditional Table Structure

Column 1	Column 2	Column 3	Column 4
Row 1-Field 1	Row 1-Field 2	Row 1-Field 3	Row 1-Field 4
Row 2-Field 1	Row 2-Field 2	Row 2-Field 3	Row 2-Field 4

Corresponding Comma-Delimited Structure

Comma-Delimited Structure

```
Field 1,Field 2,Field 3,Field 4
Field 1,Field 2,Field 3,Field 4
```

The number of fields in a row is dictated by the number of fields required in a CTRP or CDUS record. The Complete Trial Table and Abbreviated Trial Table indicate how many fields are required in each CDUS record, and how many are required in a CTRP record. The batch file must contain values or palce holders (commas) equal to the number of required fields corresponding to the CDUS format. Leave fields that are not required by CTRP blank, but keep the commas to indicate the "missing" field values.

For example, if a CDUS record requires six fields, as shown below, and the CTRP record requires only three, use commas to indicate the "missing" values.

Fields Required for CDUS Records

```
CDUS Field 1,CDUS Field 2,CDUS Field 3,CDUS Field 4,CDUS Field 5,CDUS Field 6
```

Fields Required for CTRP Batch File

```
CTRP Field 1,CTRP Field 2,,,,CTRP Field 6
```

In a traditional table grid structure, the column headings indicate the order in which the field values occur. In CTRP batch files, the column heading is implicit, and the field order is sequential from left to right, beginning at Field 1.

Traditional Table Structure

Column 1	Column 2	Column 3	Column 4
Row 1-Field 1	Row 1-Field 2	Row 1-Field 3	Row 1-Field 4

Comma-Delimited Structure

```
Field #1,Field #2,Field #3,Field #4
```

The first field in each record is reserved for the table name, which is always in CAPITAL letters. The exact field number for each data element is provided in the Complete Trial Record Data Field Requirements and Abbreviated Trial Record Data Field Requirements tables.

Example - Using Automobiles Instead of Patients

Suppose CDUS stores information about cars (rather than accrued patients) in its database in a table called AUTOMOBILES.

In this example, CDUS records each of the following six data elements:

- Table Name
- VIN (Vehicle Identification Number)
- Make
- Model
- Color
- Year

These data elements are arranged in the following sequence:

Table Name	VIN	Make	Model	Color	Year

The corresponding comma-delimited sequence is as follows:

Comma-Delimited Data Elements

```
<AUTOMOBILE>,<vin>,<make>,<model>,<color>,<year>
```

A traditional table structure for these CDUS data elements and their values are shown below.

Table Name	VIN	Make	Model	Color	Year
AUTOMOBILE	ABC-123456	Ford	Mustang	Black	1965

The corresponding comma-delimited structure is as follows:

Comma-Delimited Data Values

```
AUTOMOBILE,ABC-123456,Ford,Mustang,Black,1965
```

And, to extend this example, suppose that CTRP does not capture the Model nor Color of the car. In this case, the final record in the CTRP batch file would be as follows:

Comma-Delimited CTRP Data Values

```
AUTOMOBILE,ABC-123456,Ford,,,1965
```

File Naming Conventions

The CTRP Accrual Batch File is a TEXT file with fields delimited (separated) by commas. The file can have any name. However, we recommend using the following file naming conventions:
`NCI Protocol Number_date.txt` (with the date format: YYYYMMDD)

Example File Name

```
NCI-2012-00XXX_20090430.txt
```

The total number of characters in the file name including the file path must be less than or equal to 260. Use the file extensions `.txt` (for a single file) or `.zip` for compressed .txt files.

Batch File Data for Complete Trials

Complete Trials in CTRP are those with the Summary 4 trial submission categories of National, Externally Peer Reviewed, or Institutional.

The CTRP Accrual Batch File conforms to the CDUS file specification, but it only uses a limited number of fields from that file. Data in the rest of the fields is ignored, but the place holders (commas) must still be present in the data file, whether empty or filled.

Complete Trial Tables

Tables identify the record type for each record. The CTRP uses the following tables for complete trials.

Table Name	Number of CDUS Fields (Excluding the Table Name)	Number of Fields Used by CTRP (Excluding the Table Name)	Purpose
COLLECTIONS	10	2	Identifies the study for this data file
PATIENTS	23	12	Subject-specific accrual data
PATIENT_RACES	3	3	Subject's Race

See Appendix C for a list of all the CDUS fields for these tables.

Complete Trial Data Element and Field Formats

Each row in a batch file is associated with a single record in the database. The first field in each line identifies the name of the table that a record belongs to. Subsequent fields contain different data element values for the same table. The number of fields required in each record, and the values they must contain, are provided in the Complete Trial Record Data Field Requirements table. Because many more elements are required in CDUS records than in CTRP records, many fields in your batch file will be null (contain no field values at all). In these cases, use a comma to indicate a field for which there is no datum.

> ⚠ If a comma is part of the value, enclose the fields in double quotes. Otherwise the use of double quotes is optional.

Examples of Valid Data Formats

```
"COLLECTIONS","NCI-2009-012345",,,,,,,,"1"

-OR-

COLLECTIONS,"NCI-2009-012345",,,,,,,,1

-OR-

COLLECTIONS,NCI-2009-012345,,,,,,,,1
```

Complete Trial Data Record Formats

Each line of the data file contains one record, is prefixed by the table name, and is comma delimited.

Important!

Use blank fields for those fields that are included in the CDUS standard but not used by the CTRP.

Valid Record Formats and Field Sequence

```
COLLECTIONS,<Study_Identifier>,,,,,,,,<Change_Code>
PATIENTS,<Study_Identifier>,<Study_Subject_Identifier>,<Zip_Code>,<Country_Code>,<Bi
rth_Date>,<Gender>,<Ethnicity>,<Payment_Method>,<Subject_Registration_Date>,<Registe
ring_Group_Identifier>,<Study_Site_Identifier>,,,,,,,,,<Subject_Disease_Code>,,
PATIENT_RACES,<Study_Identifier>,<Study_Subject_Identifier>,<Race>
```

The following is an example batch file for a study that has three study subjects, and one race per subject using CTRP accepted valid values. In the example below "Male", for example, is used instead of a CDUS accepted numeric value of "1".

Example Batch File

```
COLLECTIONS,NCI-2011-03861,,,,,,,,1
PATIENTS,NCI-2011-03861,873222899999999,84124,,196311,Male,Unknown,Private
Insurance,20060809,CALGB,149280,,,,,,,,,238.7,,
PATIENTS,NCI-2011-03861,8732228,84124,,196311,Male,Unknown,Private
Insurance,20060809,CALGB,149280,,,,,,,,,238.7,,
PATIENTS,NCI-2011-03861,1,84124,,196311,Male,Unknown,Private
Insurance,20060809,CALGB,149280,,,,,,,,,185.0,,
PATIENT_RACES,NCI-2011-03861,8732228,White
PATIENT_RACES, NCI-2011-03861,873222899999999,Asian
PATIENT_RACES,NCI-2011-03861,1,White
```

The following is another example batch file, accepted by CTRP, for the same study but using CDUS accepted numeric codes instead of the text values used in the example above .

Example Batch File

```
COLLECTIONS,NCI-2011-03861,,,,,,,,1
PATIENTS,NCI-2011-03861,873222899999999,84124,,196311,1,9,1,20060809,CALGB,149280,,,
,,,,,,,238.7,,
PATIENTS,NCI-2011-03861,8732228,84124,,196311,1,9,1,20060809,CALGB,149280,,,,,,,,,2
38.7,,
PATIENTS,NCI-2011-03861,1,84124,,196311,1,9,1,20060809,CALGB,149280,,,,,,,,,185.0,,
PATIENT_RACES,NCI-2011-03861,8732228,01
PATIENT_RACES, NCI-2011-03861,873222899999999,05
PATIENT_RACES,NCI-2011-03861,1,01
```

Complete Trial Record Data Field Requirements

The following table contains detailed information about each of the data elements included in the Batch Upload file.

The CDUS Accepted Values are provided to show differences in case your system is already producing the CDUS file. In most cases, both CTRP and CDUS values are accepted.

Subject Accrual Data Elements table with CTRP-accepted values

Subject Accrual Data Element Name	**Mandatory=M; Optional=O Conditional = C**	**Definition**	**CTRP Accepted Values**	**Information Model Class / Diagram Mapping**	**Comments/Conditions**
Study Identifier	M	Unique identifier assigned to the study	NCI, CTEP, or DCP Identifier	Study Protocol / assignedIdentfier	--
Study Subject Identifier	M	Unique identifier (numeric or alphanumeric) assigned to subjects in a study	Any numeric or alphanumeric value assigned to a study subject	Study Subject / identifier	--
ZIP Code	C	String of characters used to identify the five-digit Zone Improvement Plan (ZIP) code that represents the geographic segment that is a subunit of the ZIP code, assigned by the U.S. Postal Service to a geographic location to facilitate mail delivery.	5 digit numeric ZIP code	Patient / postalAddress	Mandatory if U.S.

Country of Residence	C	Name of a country from which a person or their biological family had previous residence or past ancestors.	2-letter ISO Country Codes	Patient / postalAddress	Mandatory if not U.S.
Patient's Date of Birth	M	The month and year on which the person was born	YYYYMM	Patient / birthDate	Year and Month are mandatory
Gender of a Person	M	Text designations that identify gender. Gender is described as the assemblage of properties that distinguish people on the basis of their societal roles	• Male • Female • Unspecified • Unknown	Patient / sexCode	Identification of gender is based upon self-report and may come from a form, questionnaire, interview, etc.
Ethnicity	M	Text for reporting information about ethnicity based on the Office of Management and Budget (OMB) categories	• Hispanic or Latino • Not Hispanic or Latino • Not Reported • Unknown	Patient / ethnicGroupCode	--

Payment Method	O	Term for an entity, organization, government, corporation, health plan sponsor, or any other financial agent who pays a healthcare provider for the healthcare service rendered to a person or reimburses the cost of the healthcare service	• Private Insurance • Medicare • Medicare and Private Insurance • Medicaid • Medicaid and Medicare • Military or Veterans Sponsored, NOS • Military Sponsored (Including CHAMPUS & TRICARE) • Veterans Sponsored • Self-Pay (No Insurance) • No Means of Payment (No Insurance) • Managed Care • State Supplemental Health Insurance • Other • Unknown	StudySubject / paymentMethodCode	--
Subject Registration Date	M	Date the subject was registered to the study	YYYYMMDD	PerformedSubjectMilestone / registrationDate	--
Registering Group Code	O	Unique CTEP Group code assigned to the group that originally registered the patient for the study	--	StudySubject / registrationGroupId	For trials with Group participation, provide CTEP Group Code, if available

Study Site Identifier	M	Unique identifier (PO ID) assigned to the institution accruing the patient to the study	CTRP Person/Organization ID (PO ID)	Study Site / identifier	--
Subject Disease Code	M	Code that identifies a disease	• CTEP Simplified Disease Code (SDC) terms • ICD 9 CM codes	For SDC Disease Code: StudySubject / diease_identifier For ICD9 Disease Code: StudySubject / icd9diease_identifier	Disease code is mandatory for all trials except those managed by DCP PIO. Cancer specific ICD9 CM disease codes in the range 140 to 239. Information about these disease codes is available at http://www.icd9data.com/2012/Volume1/140-239/default.htm

Race	M	Text for reporting information about race based on the Office of Management and Budget (OMB) categories	• American Indian or Alaska Native • Asian • Black or African American • Native Hawaiian or Other Pacific Islander • Not Reported • Unknown • White	Patient / raceCode	--
Change Code	O	Additions or changes since the last report	• 1 • 2 • NULL	AccrualCollections / changeCode	1 or NULL = changes in the file; CTRP will process and save the submission 2 = no changes in the file: CTRP will not process the file, but will save the submission

Subject Accrual Data Elements table with CDUS-accepted values

Subject Accrual Data Element Name	**Mandatory=M; Optional=O Conditional = C**	**Definition**	**CDUS Accepted Values**	**Comments/Conditions**
Study Identifier	M	Unique identifier assigned to the study	CTEP Identifier	--
Study Subject Identifier	M	Unique identifier (numeric or alphanumeric) assigned to subjects in a study	Any numeric or alphanumeric value assigned to a study subject	--

ZIP Code	C	String of characters used to identify the five-digit Zone Improvement Plan (ZIP) code that represents the geographic segment that is a subunit of the ZIP code, assigned by the U.S. Postal Service to a geographic location to facilitate mail delivery.	5 digit numeric ZIP code	Mandatory if U.S.
Country of Residence	C	Name of a country from which a person or their biological family had previous residence or past ancestors.	2-letter ISO Country Codes	Mandatory if not U.S.
Patient's Date of Birth	M	The month and year on which the person was born	YYYYMM	Year and Month are mandatory
Gender of a Person	M	Text designations that identify gender. Gender is described as the assemblage of properties that distinguish people on the basis of their societal roles	• 1 = Male • 2 = Female • 9 = Unknown	Identification of gender is based upon self-report and may come from a form, questionnaire, interview, etc.
Ethnicity	M	Text for reporting information about ethnicity based on the Office of Management and Budget (OMB) categories	• 1 = Hispanic or Latino • 2 = Not Hispanic or Latino • 8 = Not Reported • 9 = Unknown	--

Payment Method	O	Term for an entity, organization, government, corporation, health plan sponsor, or any other financial agent who pays a healthcare provider for the healthcare service rendered to a person or reimburses the cost of the healthcare service	• 1 = Private Insurance • 2 = Medicare • 3 = Medicare and Private Insurance • 4 = Medicaid • 5 = Medicaid and Medicare • 6 = Military or Veterans Sponsored, Not Otherwise Specified (NOS) • 6A = Military Sponsored (including CHAMPUS or TRICARE) • 6B = Veterans Sponsored • 7 = Self pay (no insurance) • 8 = No means of payment (no insurance) • 98 = Other • 99 = Unknown	--
Subject Registration Date	M	Date the subject was registered to the study	YYYYMMDD	--
Registering Group Code	O	Unique CTEP Group code assigned to the group that originally registered the patient for the study	--	--
Study Site Identifier	M	Unique identifier (PO ID) assigned to the institution accruing the patient to the study	CTEP Site ID	--

Subject Disease Code	M	Code that identifies a disease	• CTEP Simplified Disease Code (SDC) terms • ICD 9 CM codes	Disease code is mandatory for all trials except those managed by DCP PIO. Cancer specific ICD9 CM disease codes in the range 140 to 239. Information about these disease codes is available at http://www.icd9data.com/2012/Volume1/140-239/default.htm
Race	M	Text for reporting information about race based on the Office of Management and Budget (OMB) categories	• 01 = White • 03 = Black or African American • 04 = Native Hawaiian or Other Pacific Islander • 05 = Asian • 06 = American Indian or Alaska Native • 98 = Not Reported • 99 = Unknown	--
Change Code	O	Additions or changes since the last report	--	--

Complete Trial Record Data Field Formats

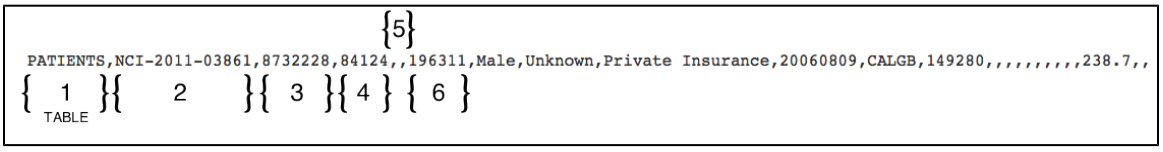
The following table lists the data fields by the table in which they are recorded. It also provides the field number (field position in a row); and the format and character limits for each field.**Tables**

	Field (Field Position in a Row)	**Format (Maximum Number of Characters)**
COLLECTIONS	Study Identifier (2)	Text (35)

COLLECTIONS	Change Code (11)	Number (1)
PATIENTS	Study Identifier (2)	Text (35)
PATIENTS	Study Subject Identifier (3)	Text (20)
PATIENTS	ZIP Code (4)	Text (10)
PATIENTS	Country of Residence (5)	Text (2)
PATIENTS	Patient's Date of Birth (6)	Date (YYYYMM)
PATIENTS	Gender of a Person (7)	Text (10)
PATIENTS	Ethnicity (8)	Text (25)
PATIENTS	Payment Method (9)	Text (50)
PATIENTS	Subject Registration Date (10)	Date (YYYYMMDD)
PATIENTS	Registering Group Identifier (11)	Text (25)
PATIENTS	Study Site Identifier (12)	Text (25)
PATIENTS	Subject Disease Code (22)	Number (10)
PATIENT_RACES	Study Identifier (2)	Text (35)
PATIENT_RACES	Study Subject Identifier (3)	Text (20)
PATIENT_RACES	Race (4)	Text (45)

The relation between COLLECTIONS, PATIENTS, and PATIENT_RACES is that a COLLECTIONS can have multiple PATIENTS, and PATIENTS can have multiple PATIENT_RACES. These relations are maintained through the use of consistent Study Identifier and Study Subject Identifier fields.

Using the format table, you can determine that you must enter the **Patient's Date of Birth** in the **sixth position** in a row in the **PATIENTS** table as **YYYYMM**. The following diagram contains a typical line of text from a batch file. Brackets with numbers indicate the field position number.



In the example above, the fifth field position (5) is null (blank) because it (Country of Residence) is a conditionally required field and in this example is not required.

Batch File Data for Abbreviated Trials

Abbreviated Studies in CTRP are those with the Summary 4 trial submission category of Industrial. The CTRP require users to submit accrual totals only for these trials. Do not submit subject-specific data. The CTRP Accrual Batch File uses the same file format as CDUS, but the fields are unique to CTRP.

Abbreviated Trial Tables

Tables identify the record type for each record. CTRP uses the following tables for abbreviated studies.

Table Name	Number of CDUS Fields (Excluding the Table Name)	Number of Fields Used by CTRP (Excluding the Table Name)	Purpose
COLLECTIONS	10	1	Identifies the study for this data file
ACCRUAL_COUNT	0	3	Aggregate accrual data

Abbreviated Trial Data Record Formats

Each line of the data file contains one record, is prefixed by the table name, and is comma delimited.

> ⚠ Use blank fields for those fields that are included in the CDUS standard but not used by the CTRP.

Valid Record Formats and Field Sequence

```
COLLECTIONS,<Study_Identifier>,,,,,,,,,
ACCRUAL_COUNT,<Study_Identifier>,<Study_Site_Identifier>,< Study_Site_Accrual_Count>
```

The following is an example batch file for one study and two study sites.

Example Batch File

```
COLLECTIONS,NCI-2012-00225,,,,,,,,,
"ACCRUAL_COUNT","NCI-2009-00003","Site 1","10"
"ACCRUAL_COUNT","NCI-2009-00003","Site 2","20"
```

Abbreviated Trial Record Data Field Requirements

The following table contains detailed information about each of the data elements included in the Batch Upload file for Abbreviated Trials. The CDUS Accepted Values are provided to show differences in case your system is already

producing the CDUS file.

Subject Accrual Data Elements table with CTRP-accepted values

Subject Accrual Data Element Name	Mandatory=M; Optional=O Conditional = C	Definition	CTRP Accepted Values	Information Model Class / Diagram Mapping
Study Identifier	M	Unique identifier assigned to the study	NCI, CTEP, or DCP Identifier	Study Protocol / assignedIdentifier
Study Site Identifier	M	Unique identifier (PO ID) assigned to the institution accruing the patient to the study	PO ID	Study Site / identifier
Study Site Accrual Count	M	Numeric count of subjects accrued at a study site to date	Numeric	Study Site / subjectAccrualcount

Subject Accrual Data Elements table with CDUS-accepted values

Subject Accrual Data Element Name	Mandatory=M; Optional=O Conditional = C	Definition	CDUS Accepted Values
Study Identifier	M	Unique identifier assigned to the study	CTEP Identifier
Study Site Identifier	M	Unique identifier (PO ID) assigned to the institution accruing the patient to the study	CTEP Site ID
Study Site Accrual Count	M	N/A	--

Abbreviated Trial Data Field Requirements

Tables	Field (Field Position in a Row)	Format (Maximum Number of Characters)
COLLECTIONS	Study Identifier (2)	Text (35)
ACCRUAL_COUNT	Study Identifier (2)	Text (35)
ACCRUAL_COUNT	Study Site Identifier (3)	Text (25)
ACCRUAL_COUNT	Study Site Accrual Count (4)	Text (10)

> The COLLECTIONS and ACCRUAL_COUNT tables are linked by consistent Study Identifier and Study Site Identifier fields. There is no limit to the number of ACCRUAL_COUNT records.

Uploading CTRP Subject Accrual Batch Data Files

Uploading CTRP Subject Accrual Batch Data Files

Once you have created your Accruals Batch Upload file, it can be uploaded via the CTRP Accrual web interface. Existing accrual data for the study will be updated and any new data you submit will be added.

> The batch files you submit do not delete previously accrued patients. Use the Subject Accruals application user interface to delete accrued subjects as necessary.

This section contains the following topics:

Uploading Accrual Batch Files

Be sure to complete your batch file preparation first

Before you begin, gather all the protocol data you need. See Preparing CTRP Subject Accrual Batch Files for instructions.

The system logs you out if it detects that you have not used the application for 90 minutes. The system also logs you out after three unsuccessful attempts to log in within 24 hours. In the event that you cannot remember your password, contact Application Support at http://ncicb.nci.nih.gov/support.

How to Upload Accrual Batch Files

1. On the navigation pane, click **Batch Upload**
   The Batch Upload page appears.

Accrual Batch Upload Page

2. Click **Browse** and select the .txt or .zip file that contains your accrual data.
   Click **Submit**.
   Your file is uploaded to the system and processed in the background

When processing has been completed, the system sends you an email message to inform you of the status of your file(s). It includes the following information:

- NCI Identifier
- Number of subject accruals that the system imported
- Details of any errors that may have occurred during the import process

Once you have uploaded your batch file, the CTRP system continues to update the record status both by email and the Accrual application. To view the information you uploaded, see Reviewing and Updating Prior Accrual Submissions.

Resolving Accrual Batch File Upload Errors

If the email notice you received after uploading a batch file indicated that errors occurred during the the import process, you can use the following steps to correct them before re-submitting your accruals batch file.

How to Resolve Accrual Batch File Upload Errors

1. Go thru the list of errors described in detail in the status email you received for each line in your text file that caused the error.
2. Correct the errors.
3. Save the file and re-submit.

6 - Working with Prior Accrual Submission Records

6 - Working with Prior Accrual Submission Records

The CTRP system maintains records of all prior accrual submissions on a trial-by-trial basis. Additionally, the system records the method that was used to submit the information to the CTRP: via the Subject Accrual web application's graphical user interface (GUI), including single submissions and batch uploads; or the Accrual service.

The Accruals Historical Submissions Page allows you to do the following:

- List all of your organization's previous accrual submissions
- Limit the list of trials displayed to a particular submission date or a range of dates
- Access the accrual records (trial counts and subject details for a given trial, allowing you to modify existing data and add new accrual records)
- Download accrual batch upload TXT files previously submitted

This section contains the following topics:

Accessing Trials with Prior Accruals Records

Accessing Trials with Prior Accruals Records

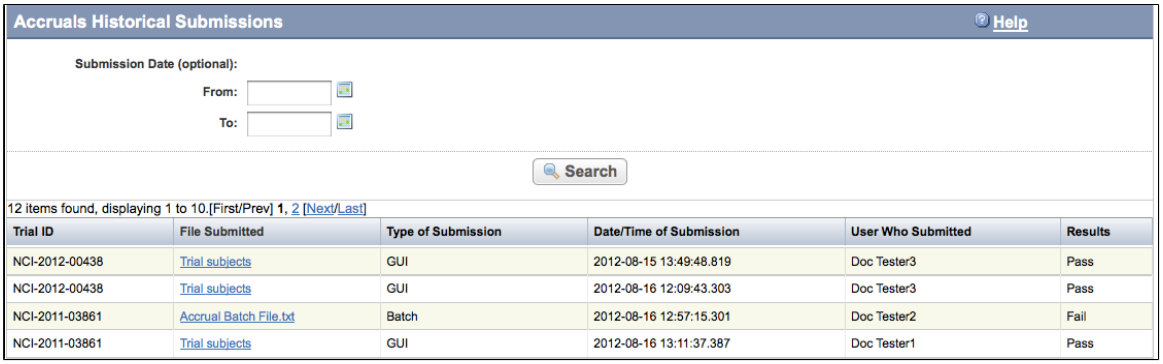
All trials to which you have been granted permission to submit accruals are listed automatically when you log into the Accruals application. Optionally, you can limit the list of trials that are displayed to a given date or range of dates.

The following information for each trial is displayed:

- **Trial ID**. The trial identification given to the trial when it was registered with the CTRP
- **Files Submitted**. Links to the following accrual details
  - Batch file (when applicable)
  - Trial subjects
  - Trial counts
- **Type of Submission**. Mechanism used to submit accrual data i.e. via the Subject Accrual web application's graphical user interface (GUI), batch uploads, or the Accrual service
- **Date and Time of Submission**. Date the accrual record was either added or modified in CTRP
- **User who Submitted**. Name of the Registered CTRP user who submitted the accrual information
- **Results**. Indicates whether or not the submission was processed successfully (Pass), or there were errors in the submission (Fail). Immediately after submitting new or updated accrual data, the system sends you an email message, indicating whether the submission passed or failed. If the processing failed, the email message explains the nature of the errors.

How to Access Trials with Prior Accrual Records

1. On the navigation pane, click **Prior Submissions**
   All of your organization's prior accrual submission records to which you have been granted Accrual access are listed automatically.



List of Prior Submissions by Trial

2. Optionally, to limit the list of submissions to a date, or range of dates, in the **From** field, select or enter the first date of the range or the exact date of the submission you are searching for. In the **To** field, enter the last date of the range. Then click **Search**.

> **Sorting Prior Submission Records**
>
> You can sort the list of prior submissions by column (except for the File Submitted column) by clicking the column header.

Reviewing and Updating Prior Accrual Submissions

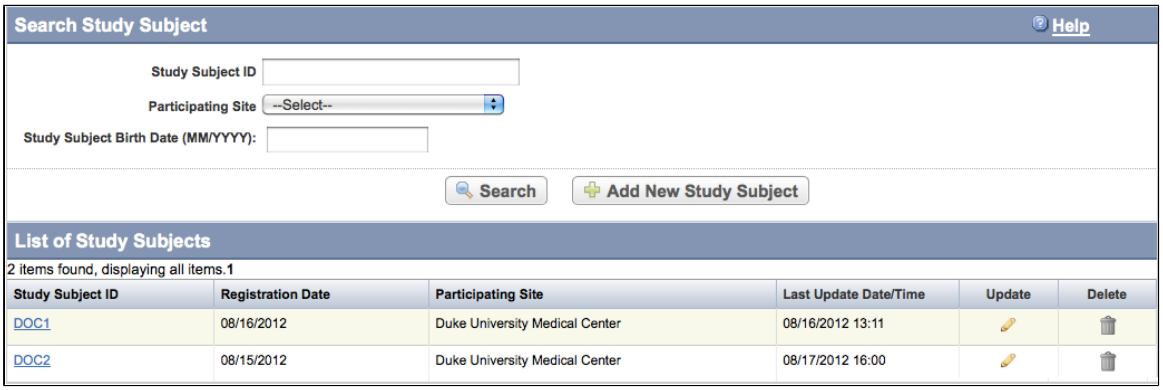
Reviewing and Updating Prior Accrual Submissions

For Complete trials, all subject records that have been previously submitted are displayed, whether a subject record was added, modified, or deleted.

How to Review and Modify Prior *Complete* Trial Accrual Submissions

1. On the navigation pane, click **Prior Submissions**.
2. To access records of all subjects that were submitted for a given trial at a specific date/time, select the **Trial Subjects** link for the trial of interest. See Accessing Trials with Prior Accruals Records.

> **Locating a study subject record**
>
> To locate a particular study subject without having to scroll through a long list of records, use the Search Study Subject feature.



Accrual Study Subject Records

3. To review a subject's demographic and submission data, in the **List of Study Subjects**, select the **Study Subject ID** link**.**
4. To update a subject's demographic data, click the **Update** icon (pencil) and then follow the instructions in Updating Study Subject Records.
5. To delete a subject, click the Delete icon (trash can) and then follow the instructions in Deleting Study Subject Records.

Downloading Submitted Subject Accrual Files

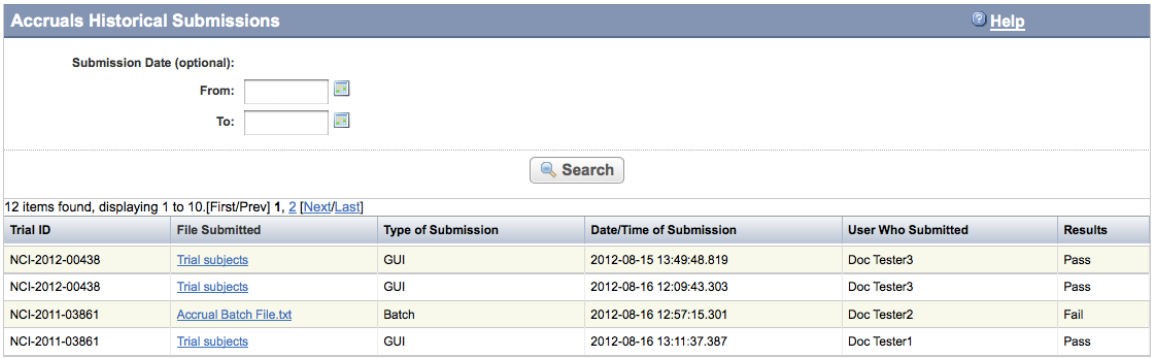
Downloading Submitted Subject Accrual Files

For non-industrial trials, you can download the last accrual submission file (.txt or .zip) that was uploaded via the Batch Upload feature.

How to Download Submitted Subject Accrual Files

All trials to which you have been granted permission to submit accruals are listed automatically when you log in to the Accruals application. Optionally, you can limit the list of trials displayed to a given date or range of dates.

1. On the navigation pane, click **Prior Submissions**
   All trials to which you have been granted Accrual access that have existing subject accrual records are listed automatically.



List of Prior Submissions by Trial

2. Optionally, to limit the list of submissions to a date, or range of dates, in the **From** field, select or enter the first date of the range or the exact date of the submission you are searching for. In the **To** field, enter the last date of the range. Then click **Search**.
3. In the **File Submitted** column for the non-industrial trial of interest, click the link to the file.
   The file is downloaded to your computer, where you can view and/or save it.

7 - Managing Your CTRP User Account

7 - Managing Your CTRP User Account

This section provides instructions for modifying your NCI CTRP User account.

Resetting Your 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.

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

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

8 - Common Tasks and Data Element Formats

8 - Common Tasks and Data Element Formats

This section provides detailed instructions for tasks that are common to many of the procedures included in this guide.

This section includes the following topics:

Navigating Trial 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.

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.

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**.

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

Appendix A - Accrual Data Elements for Complete Trials

Appendix A - Accrual Data Elements for Complete Trials

The following tables contain detailed information on each of the data elements included in the Batch Upload file. The first table provides values that are valid for the Batch Upload file. The CDUS Accepted Values in the second table are provided to show differences in values in case your system is already producing the CDUS file.

Use of CDUS Values

Although you can use CDUS values, they are being phased out in the CTRP. It is best, therefore, to use the CTRP values listed in the table below.

When you create a batch file, ensure that each data element conforms to the requirements.

- List each data element in its appropriate position in a given row
- Use the correct character cases (CAPITAL vs. lower case letters)
- Use the correct character lengths (number of characters allowed in a single field)
- If a comma is part of the value, enclose the field in double quotes. Otherwise the use of double quotes is optional.

Subject Accrual Data Elements table with CTRP-accepted values

Subject Accrual Data Element Name	Mandatory=M; Optional=O Conditional = C	Definition	CTRP Accepted Values	Information Model Class / Diagram Mapping	Comments/Conditions
Study Identifier	M	Unique identifier assigned to the study	NCI, CTEP, or DCP Identifier	Study Protocol / assignedIdentfier	--
Study Subject Identifier	M	Unique identifier (numeric or alphanumeric) assigned to subjects in a study	Any numeric or alphanumeric value assigned to a study subject	Study Subject / identifier	--
ZIP Code	C	String of characters used to identify the five-digit Zone Improvement Plan (ZIP) code that represents the geographic segment that is a subunit of the ZIP code, assigned by the U.S. Postal Service to a geographic location to facilitate mail delivery.	5 digit numeric ZIP code	Patient / postalAddress	Mandatory if U.S.
Country of Residence	C	Name of a country from which a person or their biological family had previous residence or past ancestors.	2-letter ISO Country Codes	Patient / postalAddress	Mandatory if not U.S.

Patient’s Date of Birth	M	The month and year on which the person was born	YYYYMM	Patient / birthDate	Year and Month are mandatory
Gender of a Person	M	Text designations that identify gender. Gender is described as the assemblage of properties that distinguish people on the basis of their societal roles	• Male • Female • Unspecified • Unknown	Patient / sexCode	Identification of gender is based upon self-report and may come from a form, questionnaire, interview, etc.
Ethnicity	M	Text for reporting information about ethnicity based on the Office of Management and Budget (OMB) categories	• Hispanic or Latino • Not Hispanic or Latino • Not Reported • Unknown	Patient / ethnicGroupCode	--

Payment Method	O	Term for an entity, organization, government, corporation, health plan sponsor, or any other financial agent who pays a healthcare provider for the healthcare service rendered to a person or reimburses the cost of the healthcare service	• Private Insurance • Medicare • Medicare and Private Insurance • Medicaid • Medicaid and Medicare • Military or Veterans Sponsored, NOS • Military Sponsored (Including CHAMPUS & TRICARE) • Veterans Sponsored • Self-Pay (No Insurance) • No Means of Payment (No Insurance) • Managed Care • State Supplemental Health Insurance • Other • Unknown	StudySubject / paymentMethodCode	--
Subject Registration Date	M	Date the subject was registered to the study	YYYYMMDD	PerformedSubjectMilestone / registrationDate	--
Registering Group Code	O	Unique CTEP Group code assigned to the group that originally registered the patient for the study	--	StudySubject / registrationGroupId	For trials with Group participation, provide CTEP Group Code, if available

Study Site Identifier	M	Unique identifier (PO ID) assigned to the institution accruing the patient to the study	CTRP Person/Organization ID (PO ID)	Study Site / identifier	--
Subject Disease Code	M	Code that identifies a disease	• CTEP Simplified Disease Code (SDC) terms • ICD 9 CM codes	For SDC Disease Code: StudySubject / diease_identifier For ICD9 Disease Code: StudySubject / icd9diease_identifier	Disease code is mandatory for all trials except those managed by DCP PIO. Cancer specific ICD9 CM disease codes in the range 140 to 239. Information about these disease codes is available at http://www.icd9data.com/2012/Volume1/140-239/default.htm

Race	M	Text for reporting information about race based on the Office of Management and Budget (OMB) categories	• American Indian or Alaska Native • Asian • Black or African American • Native Hawaiian or Other Pacific Islander • Not Reported • Unknown • White	Patient / raceCode	--
Change Code	O	Additions or changes since the last report	• 1 • 2 • NULL	AccrualCollections / changeCode	1 or NULL = changes in the file; CTRP will process and save the submission 2 = no changes in the file: CTRP will not process the file, but will save the submission

Subject Accrual Data Elements table with CDUS-accepted values

Subject Accrual Data Element Name	**Mandatory=M; Optional=O Conditional = C**	**Definition**	**CDUS Accepted Values**	**Comments/Conditions**
Study Identifier	M	Unique identifier assigned to the study	CTEP Identifier	--
Study Subject Identifier	M	Unique identifier (numeric or alphanumeric) assigned to subjects in a study	Any numeric or alphanumeric value assigned to a study subject	--

ZIP Code	C	String of characters used to identify the five-digit Zone Improvement Plan (ZIP) code that represents the geographic segment that is a subunit of the ZIP code, assigned by the U.S. Postal Service to a geographic location to facilitate mail delivery.	5 digit numeric ZIP code	Mandatory if U.S.
Country of Residence	C	Name of a country from which a person or their biological family had previous residence or past ancestors.	2-letter ISO Country Codes	Mandatory if not U.S.
Patient's Date of Birth	M	The month and year on which the person was born	YYYYMM	Year and Month are mandatory
Gender of a Person	M	Text designations that identify gender. Gender is described as the assemblage of properties that distinguish people on the basis of their societal roles	• 1 = Male • 2 = Female • 9 = Unknown	Identification of gender is based upon self-report and may come from a form, questionnaire, interview, etc.
Ethnicity	M	Text for reporting information about ethnicity based on the Office of Management and Budget (OMB) categories	• 1 = Hispanic or Latino • 2 = Not Hispanic or Latino • 8 = Not Reported • 9 = Unknown	--

Payment Method	O	Term for an entity, organization, government, corporation, health plan sponsor, or any other financial agent who pays a healthcare provider for the healthcare service rendered to a person or reimburses the cost of the healthcare service	• 1 = Private Insurance • 2 = Medicare • 3 = Medicare and Private Insurance • 4 = Medicaid • 5 = Medicaid and Medicare • 6 = Military or Veterans Sponsored, Not Otherwise Specified (NOS) • 6A = Military Sponsored (including CHAMPUS or TRICARE) • 6B = Veterans Sponsored • 7 = Self pay (no insurance) • 8 = No means of payment (no insurance) • 98 = Other • 99 = Unknown	--
Subject Registration Date	M	Date the subject was registered to the study	YYYYMMDD	--
Registering Group Code	O	Unique CTEP Group code assigned to the group that originally registered the patient for the study	--	--
Study Site Identifier	M	Unique identifier (PO ID) assigned to the institution accruing the patient to the study	CTEP Site ID	--

Subject Disease Code	M	Code that identifies a disease	• CTEP Simplified Disease Code (SDC) terms • ICD 9 CM codes	Disease code is mandatory for all trials except those managed by DCP PIO. Cancer specific ICD9 CM disease codes in the range 140 to 239. Information about these disease codes is available at http://www.icd9data.com/2012/Volume1/140-239/default.htm
Race	M	Text for reporting information about race based on the Office of Management and Budget (OMB) categories	• 01 = White • 03 = Black or African American • 04 = Native Hawaiian or Other Pacific Islander • 05 = Asian • 06 = American Indian or Alaska Native • 98 = Not Reported • 99 = Unknown	--
Change Code	O	Additions or changes since the last report	--	--

Appendix B - Accrual Data Elements for Abbreviated Trials

Appendix B - Accrual Data Elements for Abbreviated Trials

The following tables contain detailed information on each of the data elements included in the Batch Upload file. The first table provides values that are valid for the Batch Upload file. The CDUS Accepted Values in the second table are provided to show differences in values in case your system is already producing the CDUS file.

Use of CDUS Values

Although you can use CDUS values, they are being phased out in the CTRP. It is best, therefore, to use the CTRP values listed in the table below.

When you create a batch file, ensure that each data element conforms to the requirements.

- List each data element in its appropriate position in a given row
- Use the correct character cases (CAPITAL vs. lower case letters)
- Use the correct character lengths (number of characters allowed in a single field)
- If a comma is part of the value, enclose the field in double quotes. Otherwise the use of double quotes is optional.

Subject Accrual Data Elements table with CTRP-accepted values

Subject Accrual Data Element Name	Mandatory=M; Optional=O Conditional = C	Definition	CTRP Accepted Values	Information Model Class / Diagram Mapping
Study Identifier	M	Unique identifier assigned to the study	NCI, CTEP, or DCP Identifier	Study Protocol / assignedIdentifier
Study Site Identifier	M	Unique identifier (PO ID) assigned to the institution accruing the patient to the study	PO ID	Study Site / identifier
Study Site Accrual Count	M	Numeric count of subjects accrued at a study site to date	Numeric	Study Site / subjectAccrualcount

Subject Accrual Data Elements table with CDUS-accepted values

Subject Accrual Data Element Name	Mandatory=M; Optional=O Conditional = C	Definition	CDUS Accepted Values

Study Identifier	M	Unique identifier assigned to the study	CTEP Identifier
Study Site Identifier	M	Unique identifier (PO ID) assigned to the institution accruing the patient to the study	CTEP Site ID
Study Site Accrual Count	M	N/A	--

Appendix C - Comparison of CTRP and CDUS Accrual Data Elements

Appendix C - Comparison of CTRP and CDUS Accrual Data Elements

This appendix lists CDUS (*Clinical Data Update System*) data elements for Complete trials, and indicates which of them are captured in CTRP.

COLLECTIONS TABLE

CDUS Fields	Fields Used by CTRP?
Protocol_ID	Yes
Subm_Date	No
CutOff_Date	No
Current_Trial_Status_Code	No
Current_Trial_Status_Date	No
Completer_Name	No
Completer_Phone	No
Completer_FAX	No
Completer_Email	No
Change_Code	Yes

PATIENTS TABLE

CDUS Fields	Fields Used by CTRP?

Protocol_ID	Yes
Patient_ID	Yes
Zip_Code	Yes
Country_Code	Yes
Birth_Date	Yes
Gender_Code	Yes
Ethnicity_Flag	Yes
Method_Of_Payment	Yes
Date_Of_Entry	Yes
Reg_Group_ID	Yes
Reg_Inst_ID	Yes
TX_On_Study	No
Off_TX_Reason	No
Last_TX_Date	No
Off_Study_Reason	No
Off_Study_Date	No
Subgroup_Code	No
Ineligibility_Status	No
Baseline_PS_Code	No
Prior_Chemo_Regs	No
Disease_Code	Yes
Resp_Eval_Status	No
Baseline_Abnormalities_Flag	No

PATIENT_RACES

CDUS Fields	Fields Used by CTRP?
Protocol_ID	Yes
Patient_ID	Yes
Race_Code	Yes

CTRP Subject Accrual Credits

CTRP Subject Accrual 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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