NCI CTRP Accrual User's Guide v4.3

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- CTRP Website
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- PRS and U.S. Public Law 110-85 (http://prsinfo.clinicaltrials.gov/fdaaa.html)
- Dictionary of cancer terms
- Terminology resources

You can print and export wiki pages
You can send this page to a printer or convert it to a PDF, HTML, or Word document. See Printing and Exporting Wiki Pages.

Application Support

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

About this Guide

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

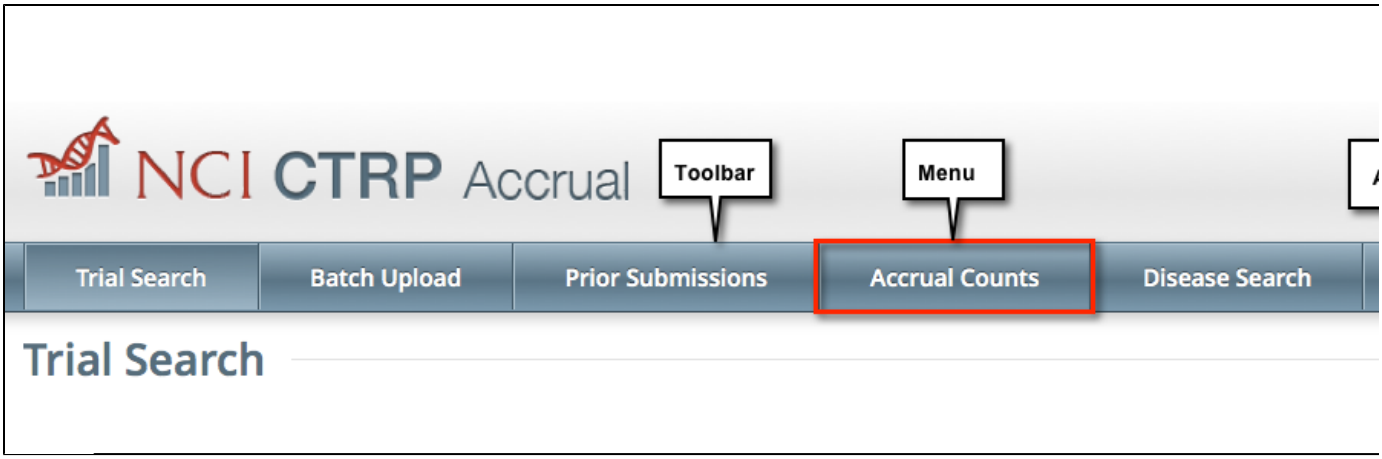
Audience

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

Navigating Accrual

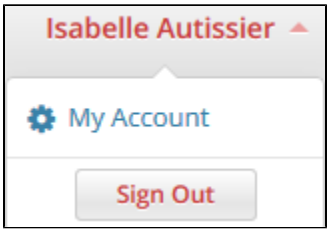
Using the Toolbar

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



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

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



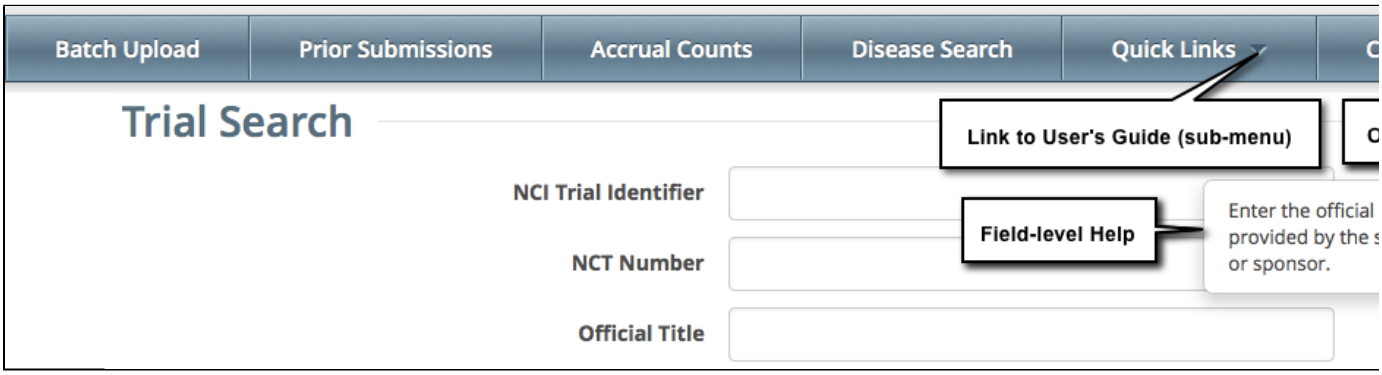
Getting Help

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

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

How to Display Instructions/Information for a Field

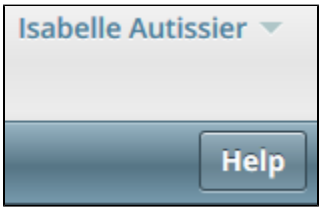
Hover your cursor over the Help icon next to it.



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

How to Launch Online Help

On the right side of the toolbar, click **Help**.



How to access the User's Guide

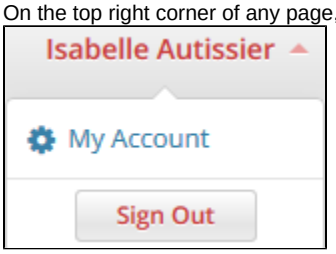
On the toolbar, click **Quick Links > Accrual User's Guide**.

Changing the Color Scheme

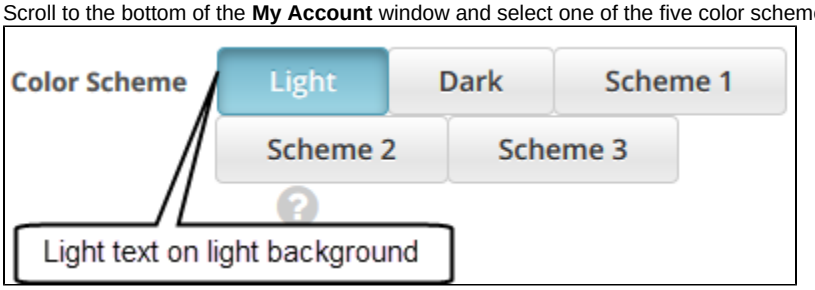
You can choose a site-wide color scheme to suit your preferences.

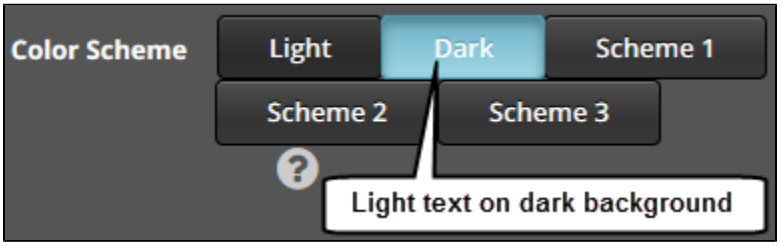
How to Change the Color Scheme

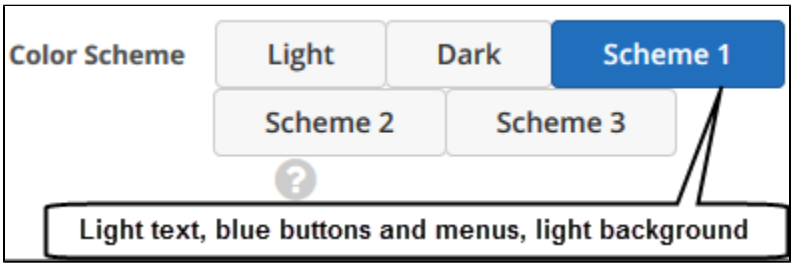
1. On the top right corner of any page, click **(User Name) > My Account**.

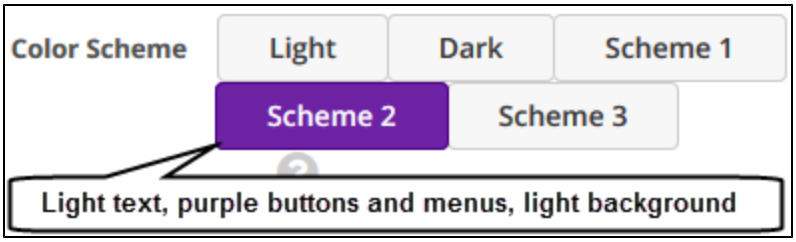


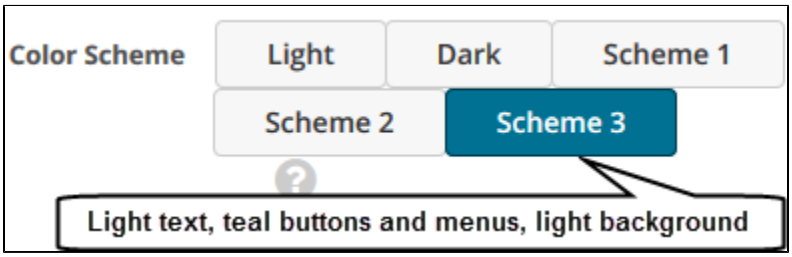
2. Scroll to the bottom of the **My Account** window and select one of the five color schemes.











Application Support

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

When submitting support requests, please include:

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

Contacting the Clinical Trials Reporting Office

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

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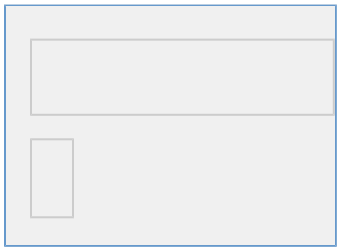

Opening Linked Pages

- To open the top

ic in this tab, click the relevant topic link.
-or-

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

Getting Started with Accrual v4.3

Getting Started with Accrual v4.3

Topic Links

Tested Browsers

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

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

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

About Accrual

Accrual provides authorized members of the cancer research community with access to cancer clinical trials registered with the CTRP for the purpose of reporting accrual data for clinical studies. It 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) as well as those that have been approved or withdrawn. These trials are categorized as follows:

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

What's New in this Release of Accrual

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

Issue Type	Development #	Documentation #	Description	Link to Content in this User Guide	Comments

Task	NA	PO-9352	Add information to Accrual User Guide to cover ICD10 codes for Disease not specified and Healthy Volunteer	Searching for Diseases and Sites	NA
Bug	PO-9213	NA	Issues with RESTful fine-grained accrual service not applying rule that lets SuAbstractors submit accruals for CTEP and DCP trials	NA	NA
Improvement	PO-9114	PO-9131	Accrual REST Service needs to support CDUS batch file submission for asynchronous processing.	NA	NA
Task	PO-9097	NA	Run script to remove accruals for specified OHSU Knight Cancer Center trials	NA	NA
Improvement	PO-9095	PO-9131	Allow use of DCP ID with REST Accrual service	NA	NA
Task	PO-9010	NA	Create a report showing subject records submitted by users with incorrect accrual submission privileges	NA	NA
Bug	PO-9002	NA	Major: CTRO #41179: Accrual Issue - NCI-2011-03659	NA	NA
Task	NA	PO-8989	Add a checklist in Accrual Users Guide showing preconditions for submitting accruals to trials	Prerequisites	NA
Bug	PO-8980	NA	Accrual: If Disease code is not Valid for a given Disease code System it shall give a proper message	NA	NA
New Feature	NA	PO-8951	CTRP 4.3 Documentation	(Refer to other links in this column.)	NA
Bug	PO-8939	NA	Accrual REST Service is producing a confusing error message when study subject's disease coding system does not match that of trial	NA	NA
Bug	PO-7153	NA	Accruals - check the COUNTRY table for country instead of regulatory authority for UI and Batch	NA	NA

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Prerequisites

Before you can submit accrual data to a given trial in CTRP, the system requires the following:

- The trial must be registered in CTRP. For information and instructions, refer to Getting Started with Registration v4.3 in the NCI CTRP Registration User's Guide.
- Once the trial has been registered, it must be fully abstracted. This work is done by the CTRO. Trial owners can help by responding to their requests for information in a timely manner.
- 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 account creation feature. For instructions, refer to Creating New CTRP Accounts via Email in the NCI CTRP Registration User's Guide.
  - **Via your NCI credentials**. If you are a new user and you *have* an NCI account, create a CTRP account via your NCI credentials using the CTRP account feature. For instructions, refer to Creating New CTRP Accounts Using NIH or NCI Credentials in the NCI CTRP Registration User's Guide.
- Once you have obtained a CTRP User Account, request authorization to access your trials. For instructions, refer to Requesting Permission to Submit Accrual Data, below.

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Requesting Permission to Submit Accrual Data

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

> If you do not have a CTRP account, register for one via the CTRP account feature. For instructions, see Creating NCI CTRP User Accounts.

Your administrator can grant you permission to submit accrual data by assigning you one of the following roles:

- **Trial submitter.** Submits accrual data on a trial-by-trial basis. (Only Super Abstractors can submit accrual data for CTEP and DCP trials.)

- **Site Accrual submitter**. Submits accrual data for all eligible trials (institutional and externally peer-reviewed) in the submitter's organization that are currently registered in the CTRP, and for trials that will be registered in the CTRP in the future.

  ⚠ The Site Accrual Submitter's affiliated organization must be a lead or participating site.

- **Organization Family Accrual Submitter**. Submits accrual data for all eligible trials that are currently registered in the CTRP, and for trials that will be registered in the CTRP in the future.

  ⚠ The Organization Family Accrual Submitter's affiliated organization or any of the organization's family members must be a lead or participating site.

How to Request Access to Your Studies

Contact your organization's site administrator to request accrual access for your studies. Site Administrators manage Accrual access via the Registration application. Instructions for Site Administrators are in Assigning and Unassigning Access to Accrual in the NCI CTRP Registration User's Guide.

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Searching for and Selecting Your Trials v4.3

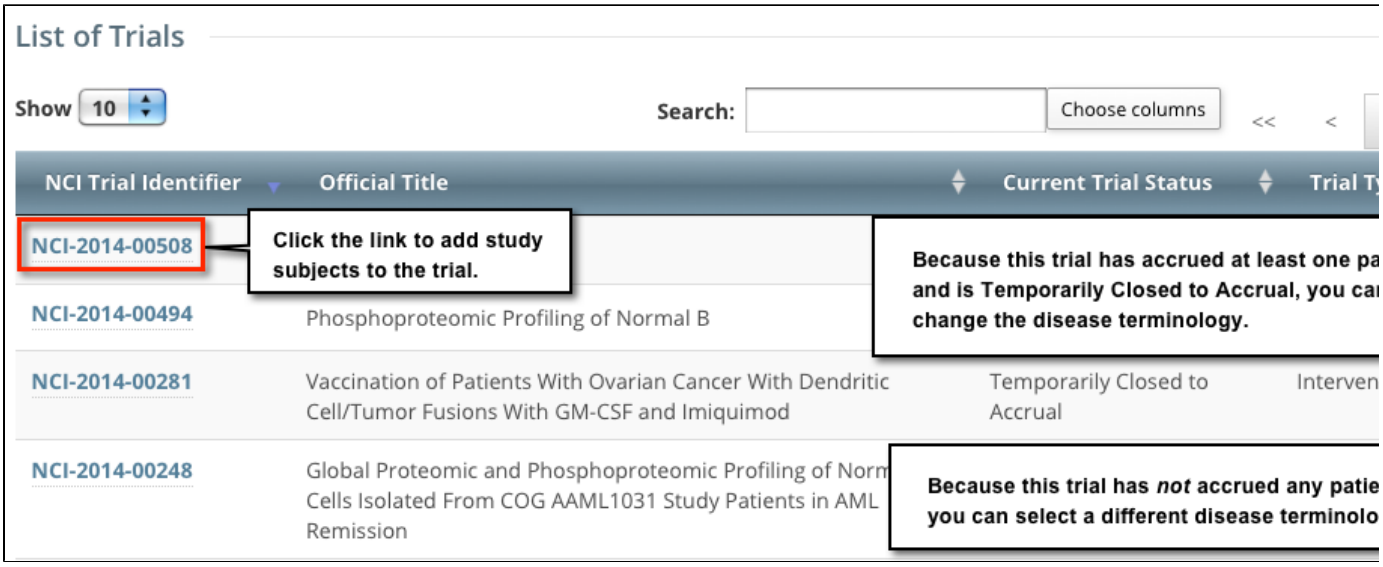
Searching for and Selecting Your Trials v4.3

Topic Links

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

Searching for Trials in Accrual

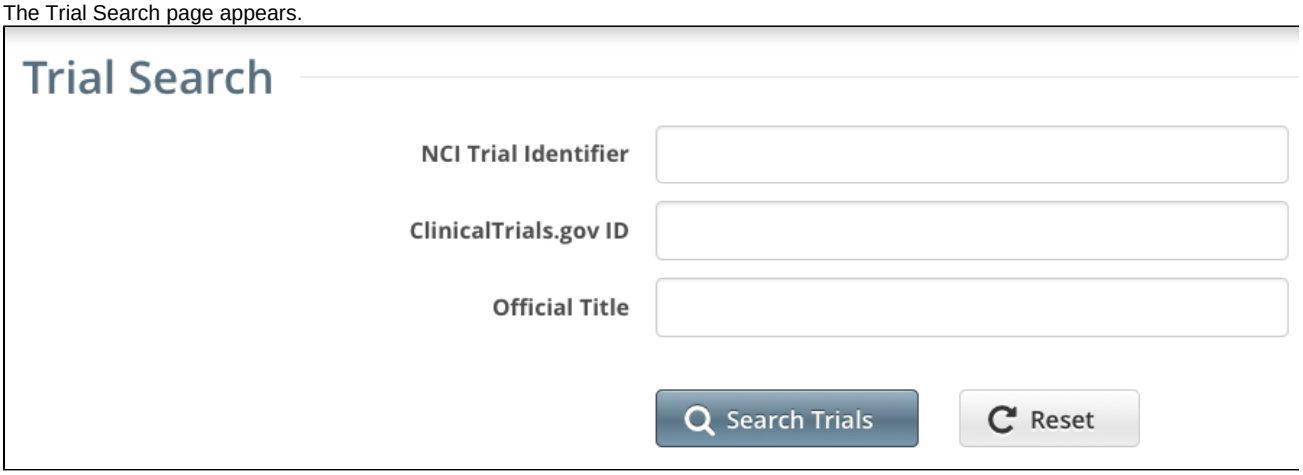
The list of trials to which you have been granted access is displayed automatically when you log in to Accrual. For information on navigating and working with lists of trials, see Working with Accrual Tables and Search Results .



ⓘ **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 Permission to Submit Accrual Data .

How to Search For Trials

1. On the toolbar, click **Trial Search**.
   The Trial Search page appears.

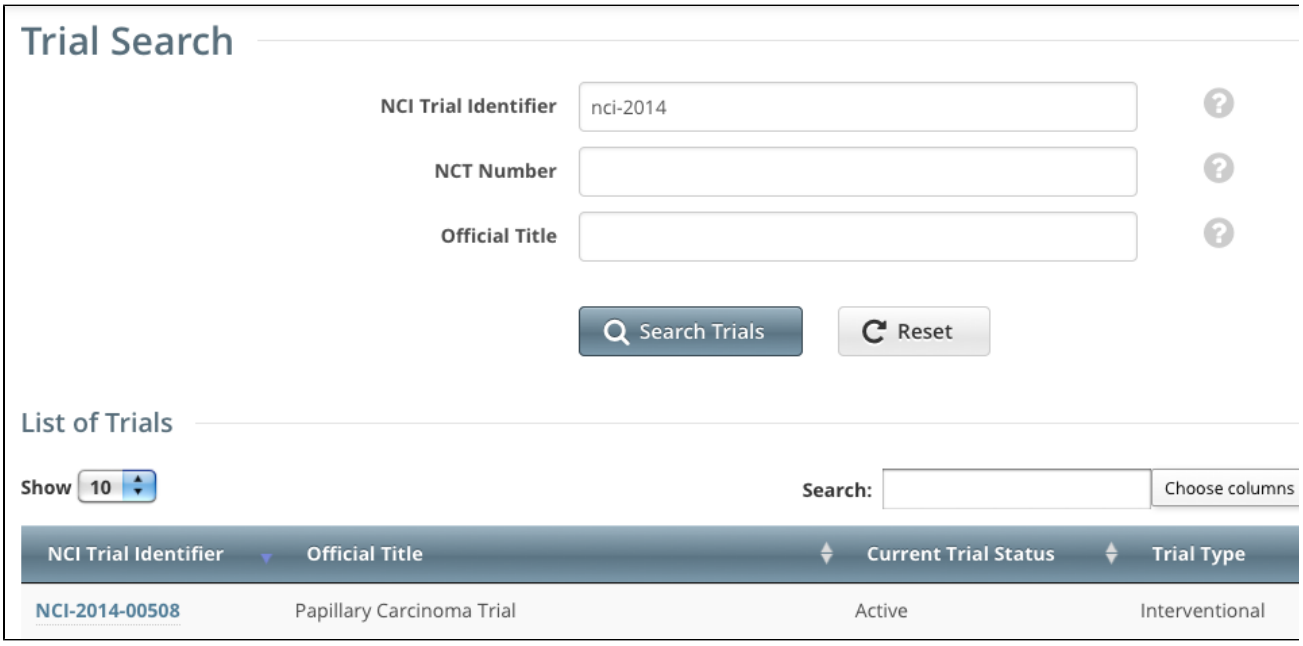


2. Enter the **NCI Trial Number**, **ClinicalTrials.gov Identifier**, or **Official Title** in the fields provided.
3. Press **ENTER** or click **Search Trials**.

> 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.

> **DCP and CTEP Trials are restricted**
> DCP and CTEP trials are listed among the results for users affiliated with the trial's lead organization and Super Abstractors only. However, only Super Abstractors can edit the accrual records.



Each trial is listed by NCI trial identifier, official title, current trial status, trial type, and Accrual disease terminology. 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 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.

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Viewing Trial Details in Accrual

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

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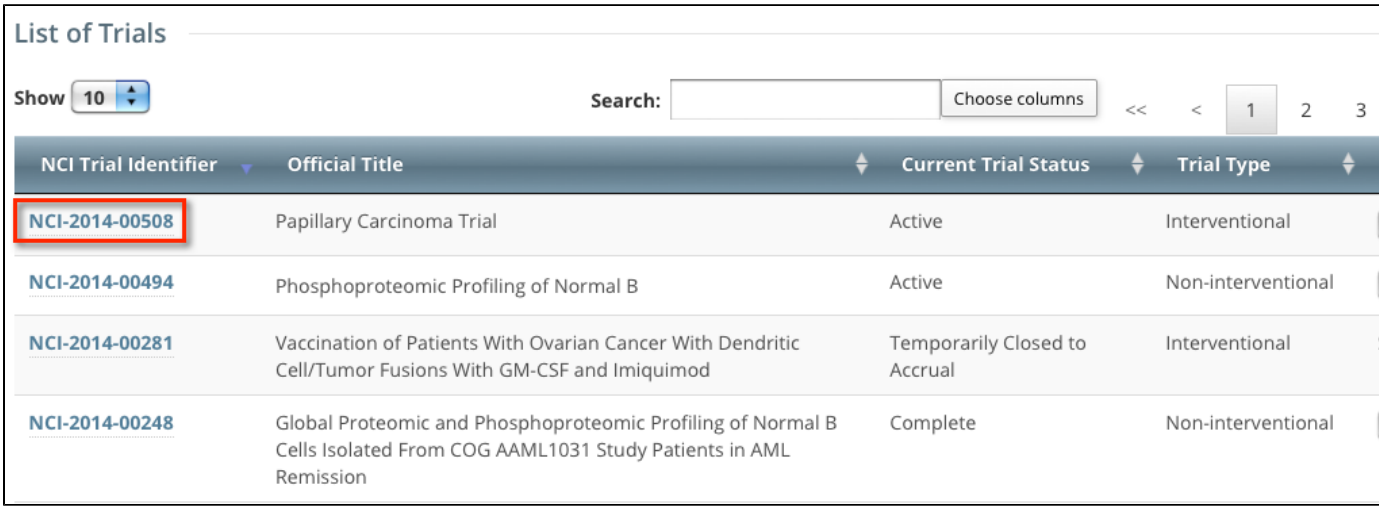
Selecting Listed Trials in Accrual

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 Working with Accrual Tables and Search Results .
2. To view a given trial, click its corresponding **NCI Trial Identifier** link.



Accrual displays the Trial Search (top) and the List of Trials (bottom) sections on the first page automatically after you have logged in. The List of Trials contains the trials to which you have been granted access.

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Working with Complete Trial Accruals v4.3

Working with Complete Trial Accruals v4.3

Topic Links

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

When working with study subject records, use either ICD-9, ICD-O-3, ICD-10, or SDC code terminology, regardless of your submission method (via the web application or batch upload); do not use different codes for the same record.

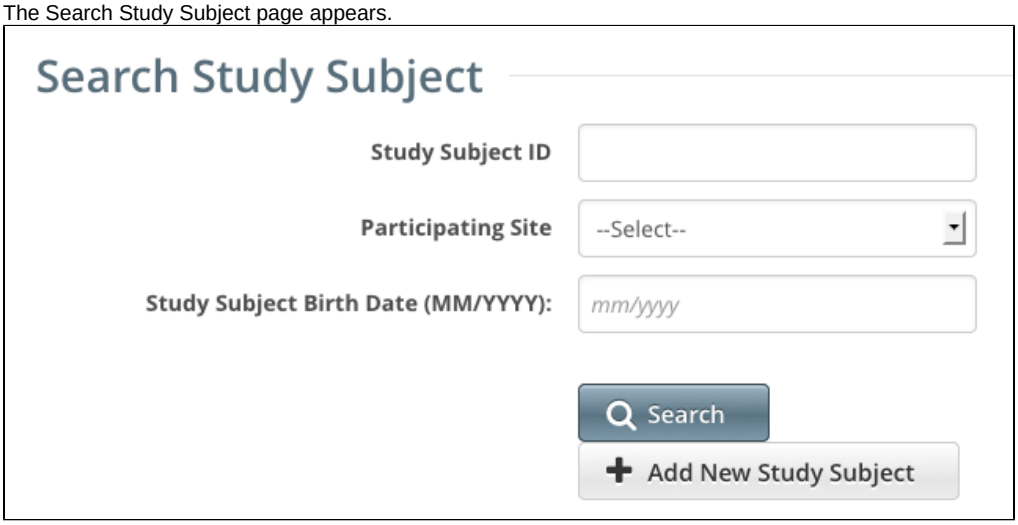
Adding Study Subjects

You can add one or more study subject accrual records for any trial to which you have been granted access.

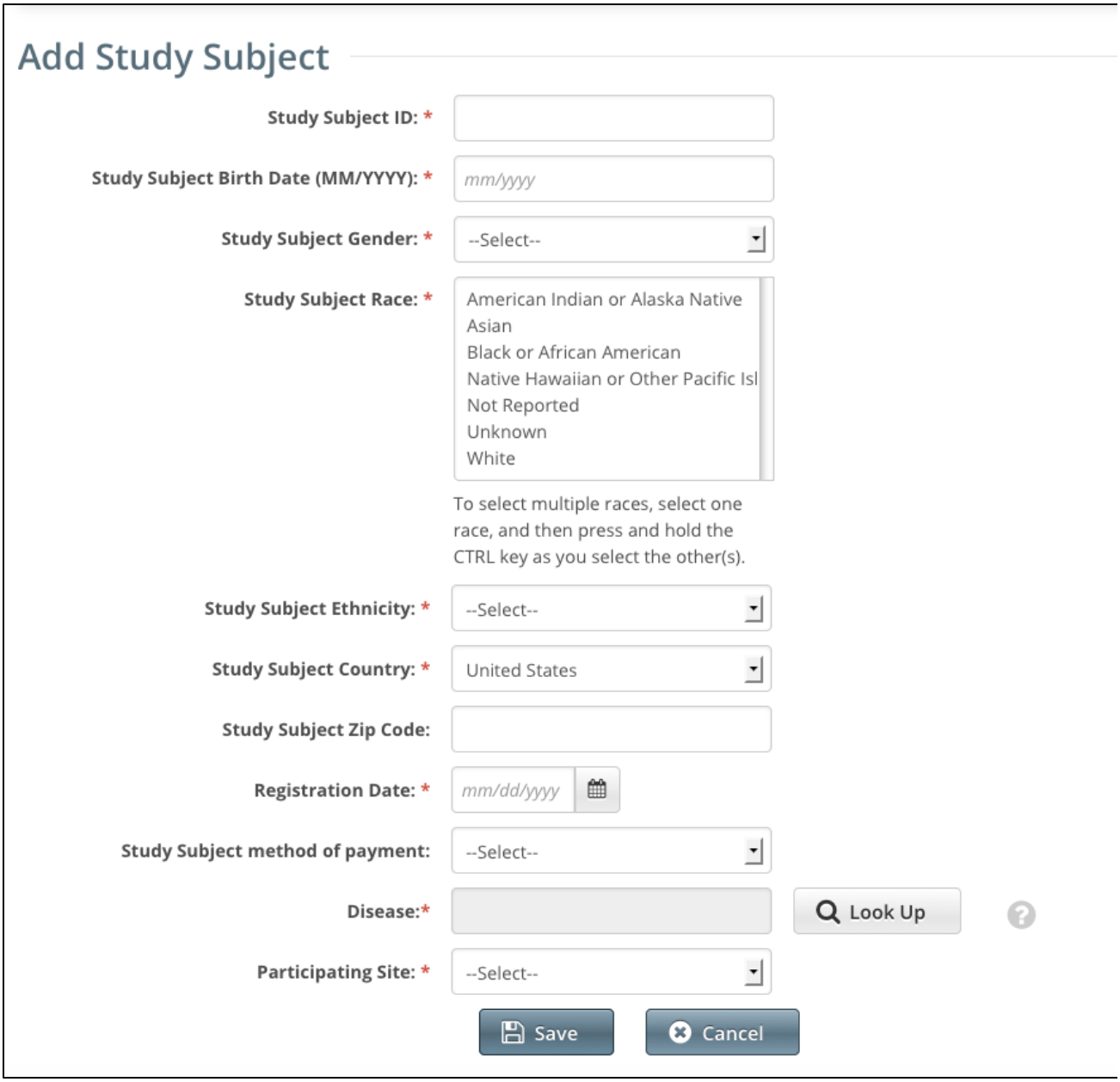
See Requesting Permission to Submit Accrual Data .
Study subject records include demographic data as well as the disease name.

How to Add Study Subject Records

1. Select the trial you want to work with by following instructions in Selecting Listed Trials in Accrual or Searching for Trials in Accrual , and clicking the corresponding NCI Trial Identifier link.
   The Search Study Subject page appears.



2. Click **Add New Study Subject**.
   The Add Study Subject page appears.



3. Enter the appropriate demographic information in the text fields and drop-down lists. The following table describes the fields. An asterisk (*) indicates a required field. For a list of valid values and formats for each field, see Accrual Data Elements for Complete Trials .

Descriptions and instructions for study subject demographic data fields

Study Subject Information	Instruction/Description
Study Subject ID*	Enter the unique Patient ID as per the lead organization or the study site where the subject is registered.
Study Subject Birth Date*	Enter 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**/**CMD** 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	Enter 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.
Study Subject Method of Payment	For United States study subjects only, select the appropriate payment method.
Site*	Click **Look Up**, and follow the instructions in Selecting Sites for Study Subject Records Using ICD-O-3 Codes. Mandatory for ICD-O-3 trials unless you record a CD-O-3 Disease Code. Optionally, record both Site and Disease codes. Site codes are available at http://training.seer.cancer.gov/head-neck/abstract-code-stage/codes.html.
Disease*	Click **Look Up**, and follow the instructions in Selecting Diseases for Study Subject Records. Mandatory for ICD-9 and SDC trials; and for ICD-O-3 trials unless you record a CD-O-3 Site Code. Use Histology codes when C codes are not available (for example, for Multiple Myeloma, NHL, Leukemia).
Participating Site*	Select the appropriate site from the drop-down list.

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

You can submit accrual data to the NCI CTEP's Clinical Data Update 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.

If your organization currently submits subject accrual information for studies to CTEP or DCP via the CDUS system, continue to report subject accrual information via CDUS. The NCI will manage the transfer of subject accrual data for CDUS trials internally. Otherwise, submit your organization's subject accrual data to CTRP.

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Searching for Diseases and Sites

You can search for diseases directly from the toolbar or while adding or entering study subject records. Refer to the instructions below.

- Searching for Diseases from the Toolbar
- Selecting Diseases for Study Subject Records
- Selecting Sites for Study Subject Records Using ICD-O-3 Codes

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Searching for Diseases from the Toolbar

You can search for diseases by name or code directly from the toolbar. For instructions for selecting diseases, for example, when you add or edit a study subject record, see Selecting Diseases for Study Subject Records.

How to Search for Diseases from the Toolbar

1. On the toolbar, click **Disease Search**.
   The Search Diseases window appears.

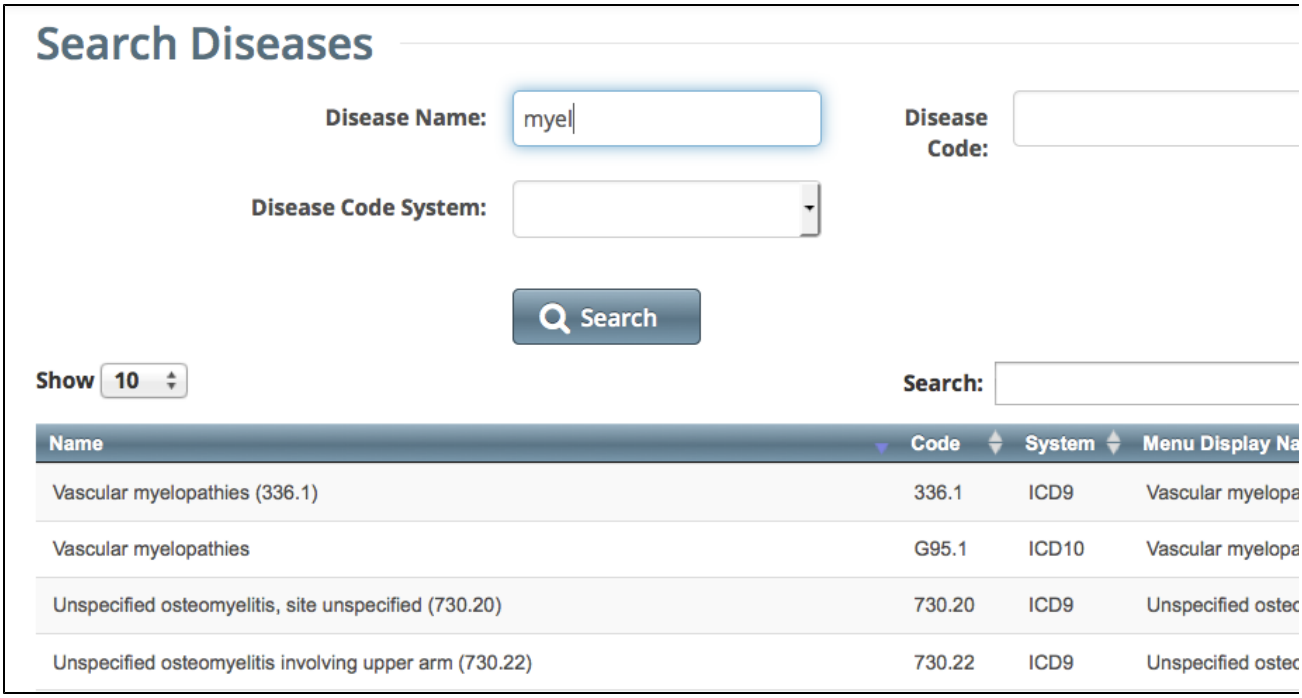
2. In the **Disease Name** field, type part or all of the disease/condition or site being studied, or, in the **Disease Code** field, enter part or all of the disease or site code.

> **Search tips**
> Enter 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.

The following table lists codes for disease not specified, healthy volunteer, and donors:

Category	ICD-10	SDC	ICD9
Disease not specified	Z1000	80000001	V100
Healthy volunteer	Z76.3	80000000	V99
Donors	Z52.9	(NA)	(NA)

3. From the **Disease Code System** drop-down list, select either **ICD-9** (International Classification of Diseases, 9th Revision), **ICD-10** (International Classification of Diseases, 10th Revision) **ICD-O-3** (International Classification of Diseases for Oncology, 3rd Edition) or **SDC** (CTEP's Simplified Disease Classification).
4. Press **Enter**, or click **Search**.
   The system searches for the disease/condition or site in the database, and returns a list of results.



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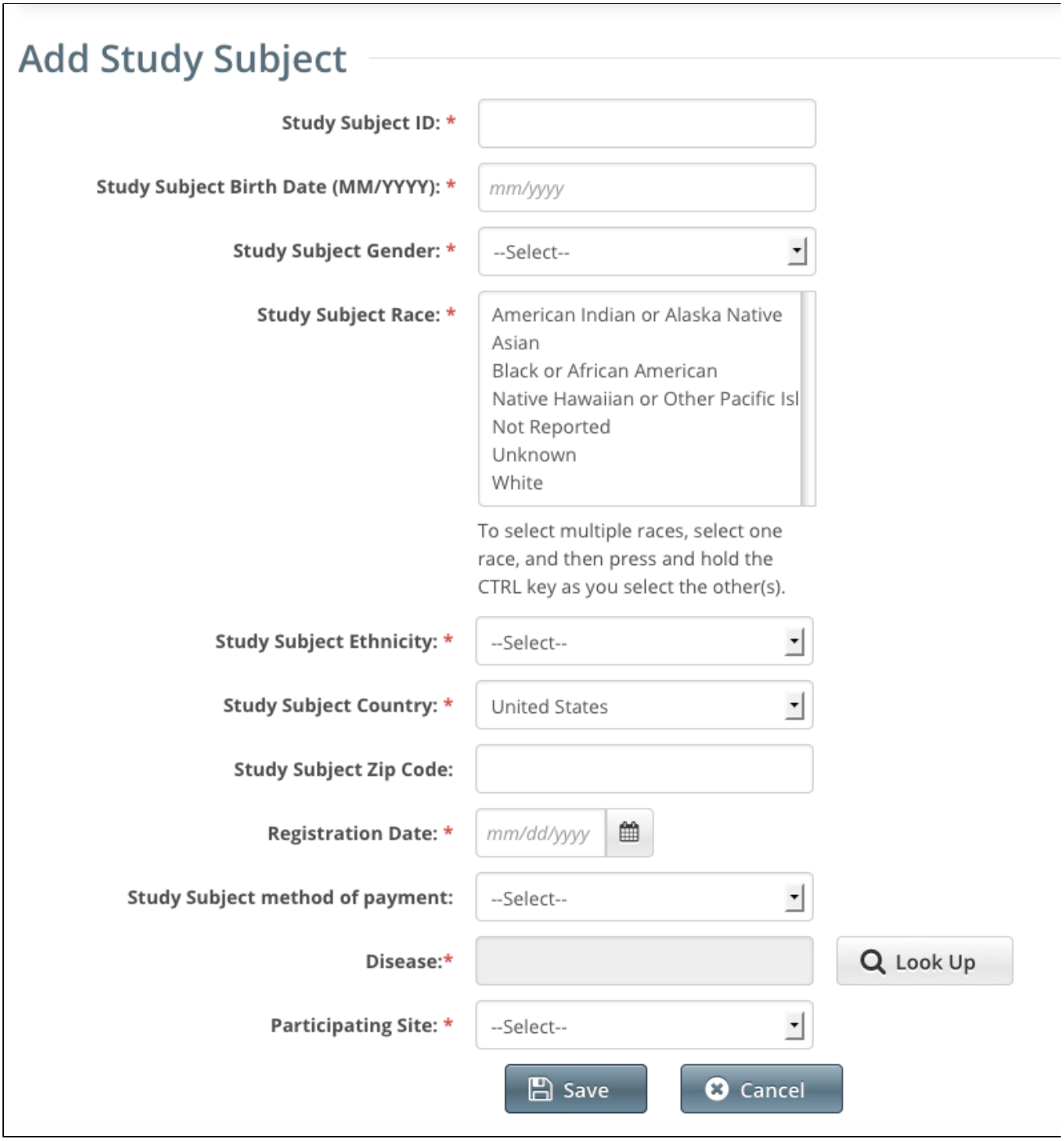
Selecting Diseases for Study Subject Records

The procedure for searching for diseases while adding or entering study subject records is the same as that for searching for them using the Disease Search menu. The difference is that in addition to searching for diseases, you can select them for association with the study subject record.

How to Search for and Select Diseases

1. Select the trial you want to work with by following instructions in Selecting Listed Trials in Accrual or Searching for Trials in Accrual , and clicking 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.

4. In the **Disease Name** field, type part or all of the disease/condition or site being studied, or, in the **Disease Code** field, enter part or all of the disease or site code.

> **Search tips**
> Type as many letters of the disease/condition or site 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.

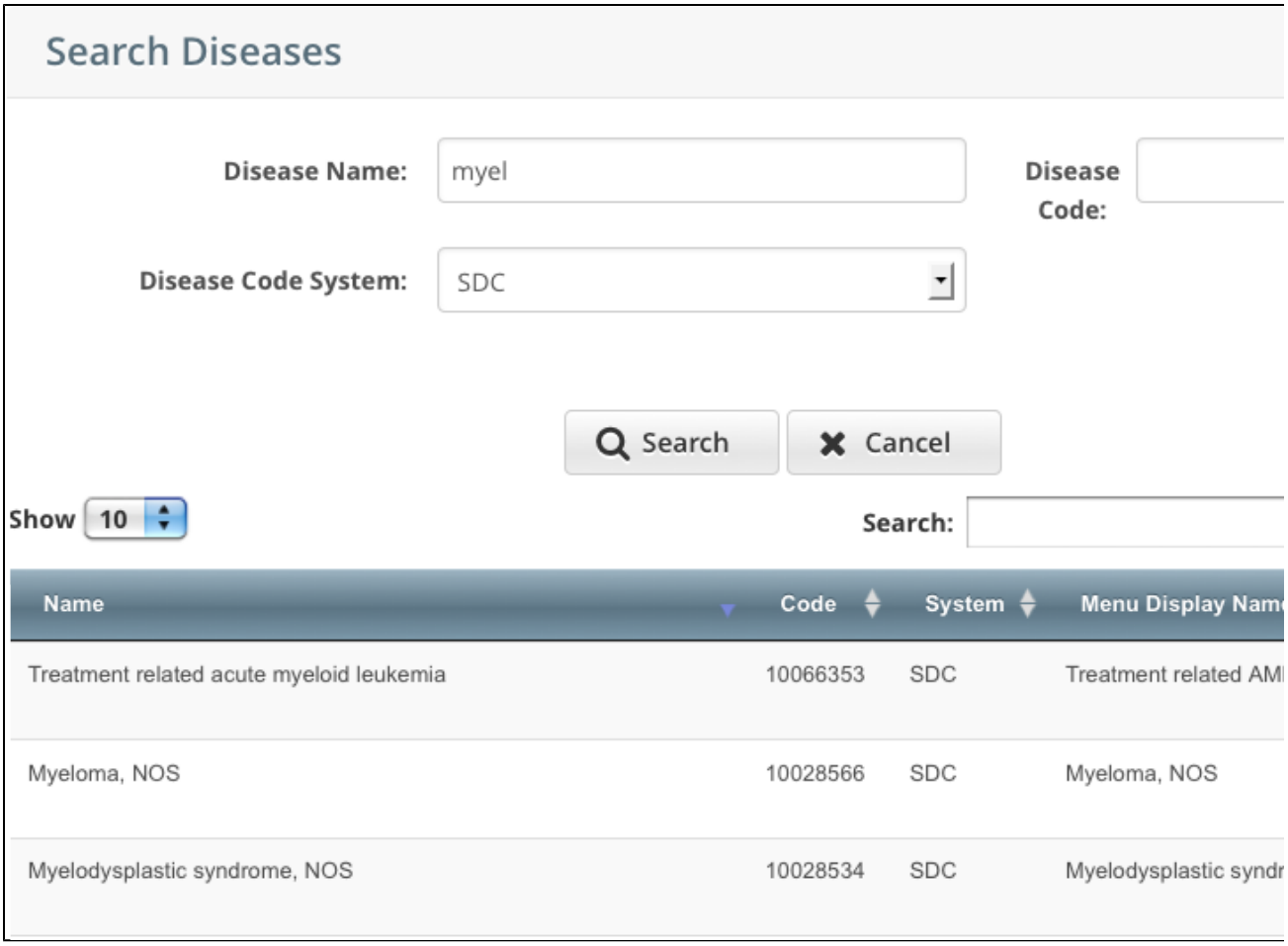
The following table lists codes for disease not specified, healthy volunteer, and donors:

Category	ICD-10	SDC	ICD9
Disease not specified	Z1000	80000001	V100
Healthy volunteer	Z76.3	80000000	V99
Donors	Z52.9	(NA)	(NA)

5. From the **Disease Code System** drop-down list, select either **ICD-9** (International Classification of Diseases, 9th Revision), **ICD-10** (International Classification of Diseases, 10th Revision) **ICD-O-3** (International Classification of Diseases for Oncology, 3rd Edition) or **SDC** (CTEP's Simplified Disease Classification).

> If the trial has at least one existing study subject record, the Disease Code System displays only the code system associated with the existing record(s). This ensures that all subjects in the study share the same terminology.

6. Press **Enter**, or click **Search**.
The system searches for the disease/condition in the database, and returns a list of results.



7. Navigate to the disease/condition being studied, and click **Select**. See Working With Accrual Tables and Search Results .
   The system populates the Disease field for you.

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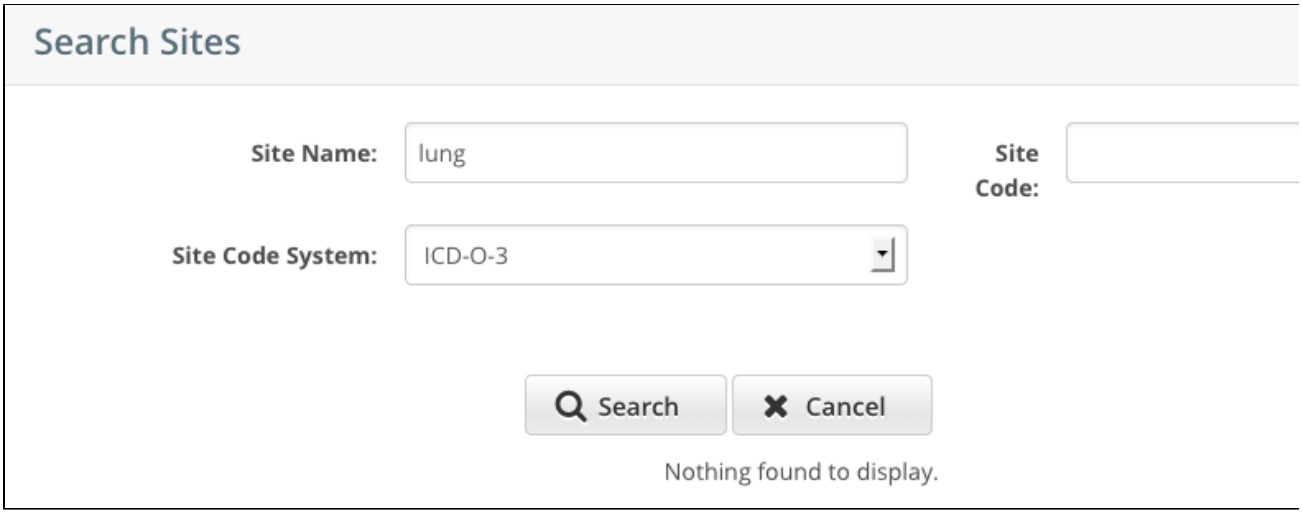
Selecting Sites for Study Subject Records Using ICD-O-3 Codes

For trials that use ICD-O-3 trials, select a site to associate with a study subject. The site code is optional if you associate(ed) a disease code with the subject.

How to Search for Sites

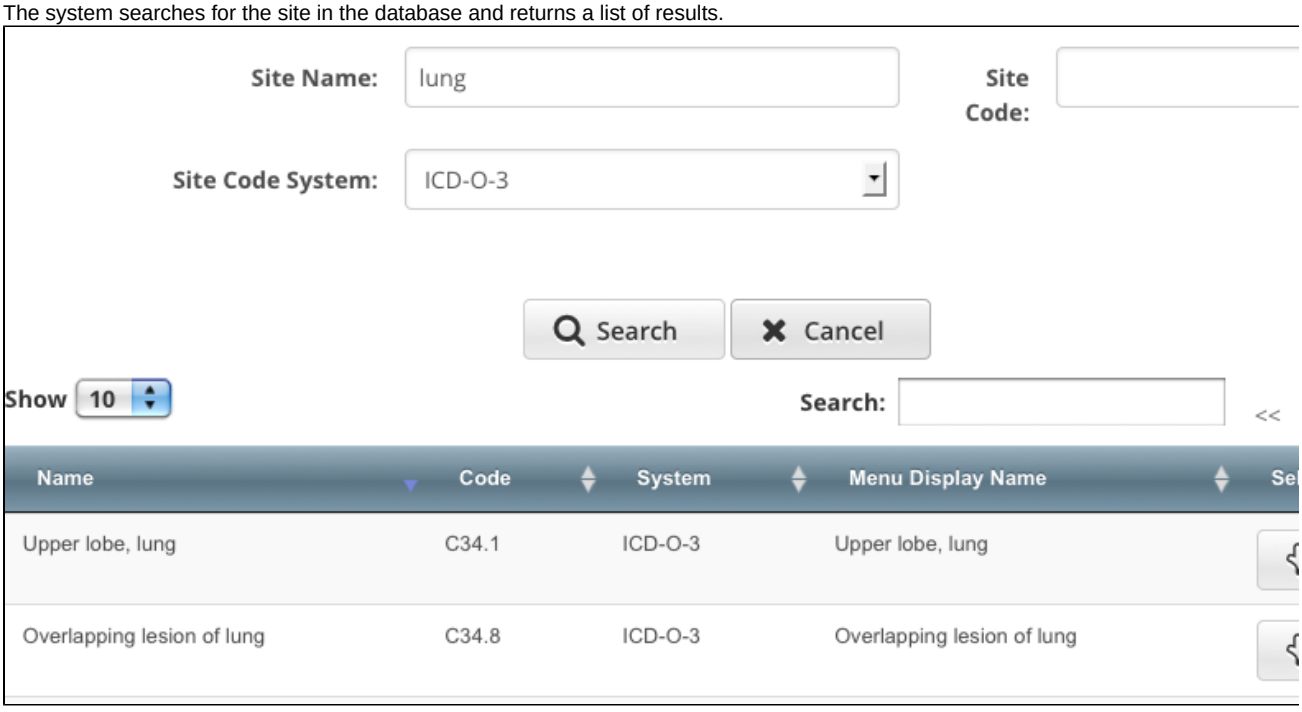
1. Select the trial you want to work with by following instructions in Selecting Listed Trials in Accrual or Searching for Trials in Accrual , and clicking the corresponding NCI Trial Identifier link.
2. At the bottom of the **Search Study Subject** section, click **Add New Study Subject**.
   The Add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



4. In the **Site Name** field, type part or all of the site being studied. The Site Code System, **ICD-O-3** (International Classification of Diseases for Oncology, 3rd Edition) is preselected for you.

> **Search tips**
> Type as many letters of the site 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. Press **Enter**, or click **Search**.
The system searches for the site in the database and returns a list of results.



6. Navigate to the site being studied, and click **Select**. See Working with Accrual Tables and Search Results .
The system populates the Site field for you.

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Searching for Study Subjects

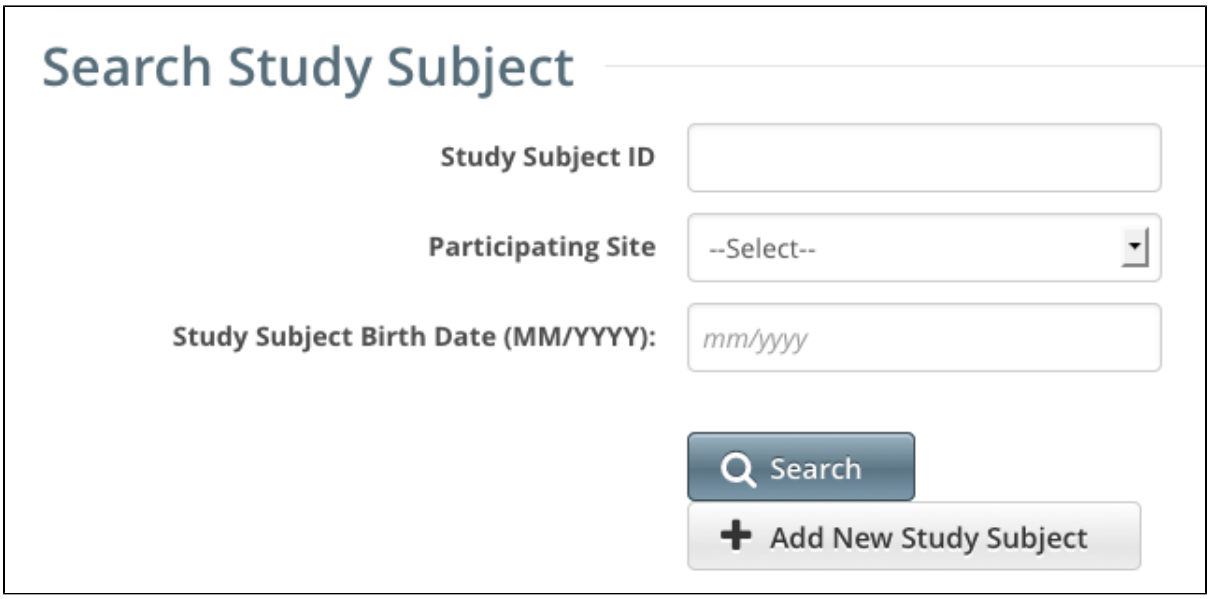
You can search for a particular study subject record using any combination of the following three criteria:

- 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. Select the trial you want to work with by following instructions in Selecting Listed Trials in Accrual or Searching for Trials in Accrual , and clicking the corresponding NCI Trial Identifier link.
   The Search Study Subject page appears.



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 when this record was updated in CTRP

4. To delete a study subject record, click the **Delete** icon (trash can).
5. To edit a study subject record, click the **Edit** icon (pencil), and follow the instructions in Adding Study Subjects .

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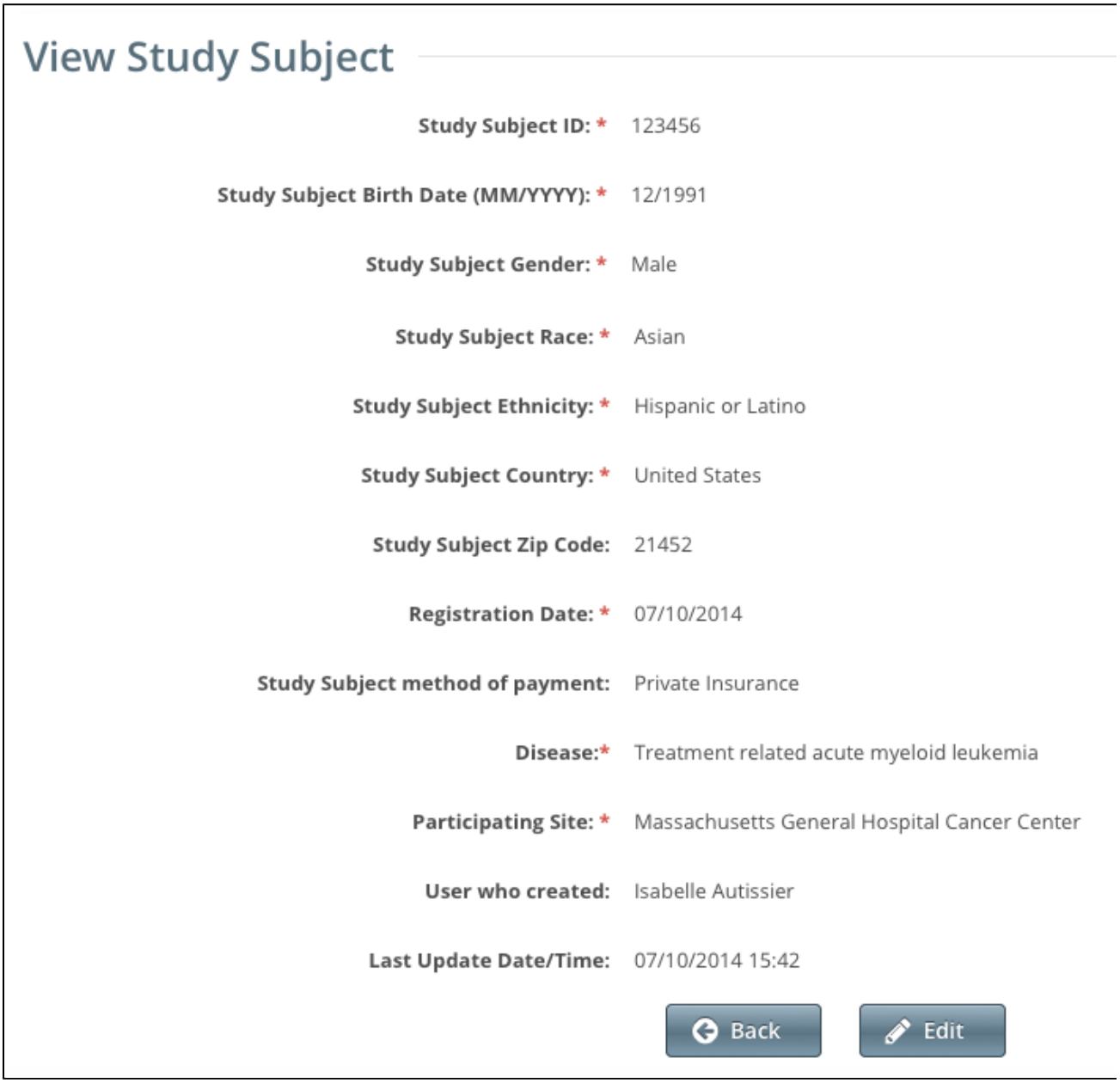
Reviewing Study Subject Records

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. Select the trial you want to work with by following instructions in Selecting Listed Trials in Accrual or Searching for Trials in Accrual , and clicking the corresponding NCI Trial Identifier link.
   The Accrual Submissions page displays any accrual records that may have been submitted previously.

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.



3. To return to the accrual record, click **Back**.
4. To change the study subject record, click **Edit**, and follow the instructions in Adding Study Subjects .

Return to top of page

Working with Abbreviated and Other Trial Accruals v4.3

Working with Abbreviated and Other Trial Accruals v4.3

This section describes how to record, update, and delete the total number of accruals (accrual count) associated with *Abbreviated* and *Other* clinical trials. 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* trial must enter its own accrual count into CTRP. For *Abbreviated* trials, the lead organization is the pharmaceutical company running the trial.

Study subject demographic data
Abbreviated and *Other* study records include the total number (count) of study subjects accrued per site on a given trial; full patient demographic data is not recorded.

When working with study subject records, use either ICD-9, ICD-10, ICD-O-3, or SDC code terminology, regardless of your submission method (via the web application or batch upload); do not use different codes for the same record.

Recording Participating Site Accrual Counts

You can record, update, or delete the number of patients that your site accrued to date per *Abbreviated* or *Other* trial.

You can record/update/delete accrual counts only if you are a registered member of one or more of the Participating Sites or you are affiliated with the site for a given trial.

The CTRP system records each **COUNT** you submit as the **total** (cumulative) number of subjects accrued to date, no matter how frequently you submit them. That is, the system does not add the count you enter here (or by the batch submission process) to previously-recorded counts.

For example, if you submit an initial 10 subjects in December, the CTRP system records the counts you submit the following March per the table below.

If the Number of Subjects You Submit in December is This...	...and the Number of Subjects You Submit the following March is This...	...Then the number of Subjects CTRP Records is This:	Explanation
10	10	10	CTRP records the most recent total COUNT.
10	15	15	CTRP records the most recent total COUNT. It does not add your latest submission to your previous count. If you had intended to record a count of 25 (10 + 15), you would have had to submit a count of 25 in March.
10	0	0	CTRP records the most recent total COUNT. It does not add/subtract your latest submission from your previous count. If you had intended to record a count of 10 (10 + 0), you would have had to submit a count of 10 in March.

This holds true whether you submit your counts by day, quarter, or year. The count includes the numbers of subjects you submit by the batch file process.

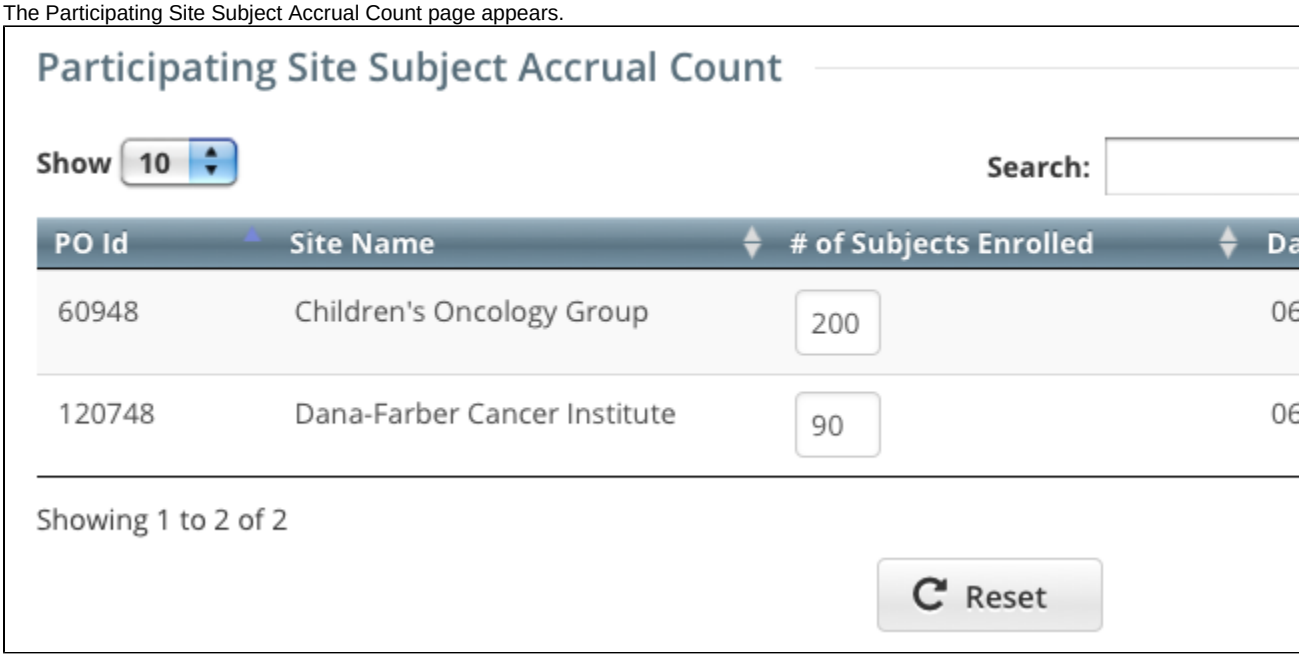
For example,

If You Submit Your Count on This Date...	And the Number of Subjects You Submit is This...	...Then the number of Subjects CTRP Records is This:	Explanation
March 30	10	10	CTRP records the most recent total COUNT.
March 31	15	15	CTRP records the most recent total COUNT. It does not add your latest submission to your previous count. If you had intended to record a count of 25 (10 + 15), you would have had to submit a count of 25.
March 31	• 15 via the user interface • 15 via the batch file process	15	CTRP records the most recent total COUNT. It does not add the number of subjects you submit in the user interface to the number you submit via the batch process. If you had intended to record a count of 30 (15 + 15), you would have had to submit a count of 30 either in the batch file or the user interface.

Do not submit a count that is less than the previously submitted count unless the previous submission was an error
If you submit a new count that is less than the CTRP system previously recorded, the CTRP system considers your previous submission an error. Do not submit a lesser value unless you are intentionally correcting/deleting accruals. For example, if the CTRP system previously recorded 100 subjects, and you submit 85, the CTRP system records 85.

How to Record and Update Site Subject Accrual Counts

1. Select the trial you want to work with by following instructions in Selecting Listed Trials in Accrual or Searching for Trials in Accrual , and clicking the corresponding NCI Trial Identifier link.
   The Participating Site Subject Accrual Count page appears.



2. In the **Number (#) of Subjects Enrolled** field, enter the number of subjects currently enrolled in studies at your site.
3. In the **Actions** column of the record you want to update, click the **Save** icon.
   A message at the top of the table indicates that the record has been updated successfully.

How to Delete Site Subject Accrual Counts

1. In the **Actions** column of the record you want to delete, click the **Delete** icon (trash can).
2. Click **OK** on the pop-up message to confirm that you want to delete the accrual count(s).

All the accrual counts for the site(s) you selected are deleted.

Working with Non-Interventional Trial Accruals v4.3

Working with Non-Interventional Trial Accruals v4.3

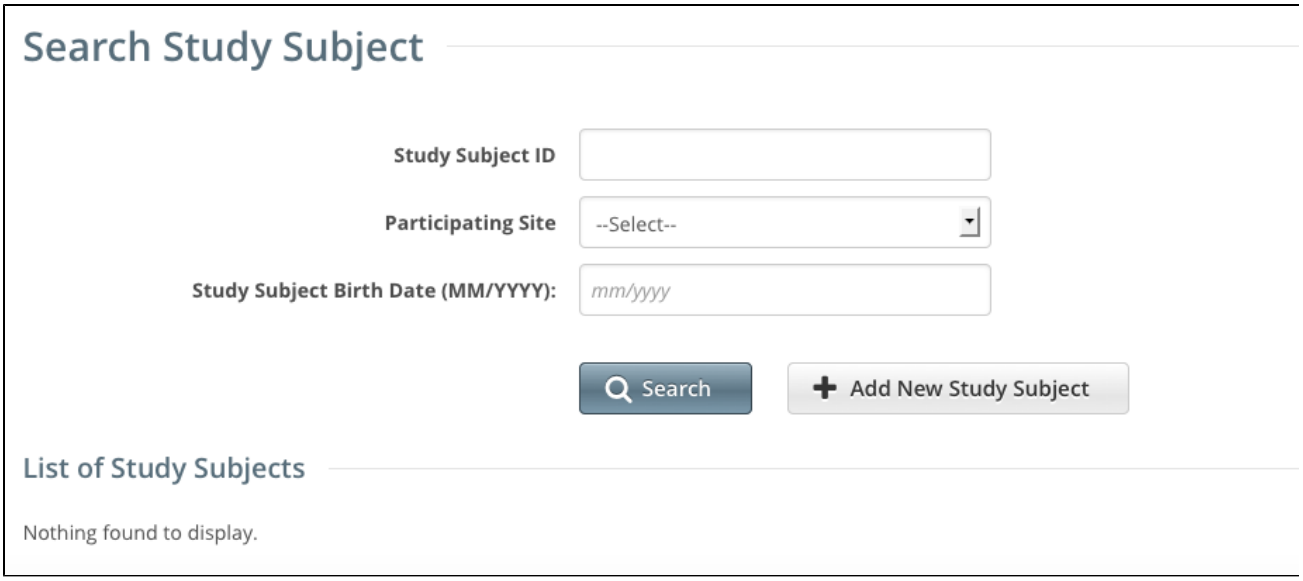
Topic Links

This section describes how to submit and update accruals for non-interventional trials. Participating sites enter accrual data at the summary level by default. The summary level consists of the accrual count per site only. However, if there are no accrual records for your trial in CTRP currently, you can enter demographic accrual information at the study subject, or patient level. Once a participating site has recorded accruals, you can no longer choose which level to use; you must enter subsequent accrual data at the same level.

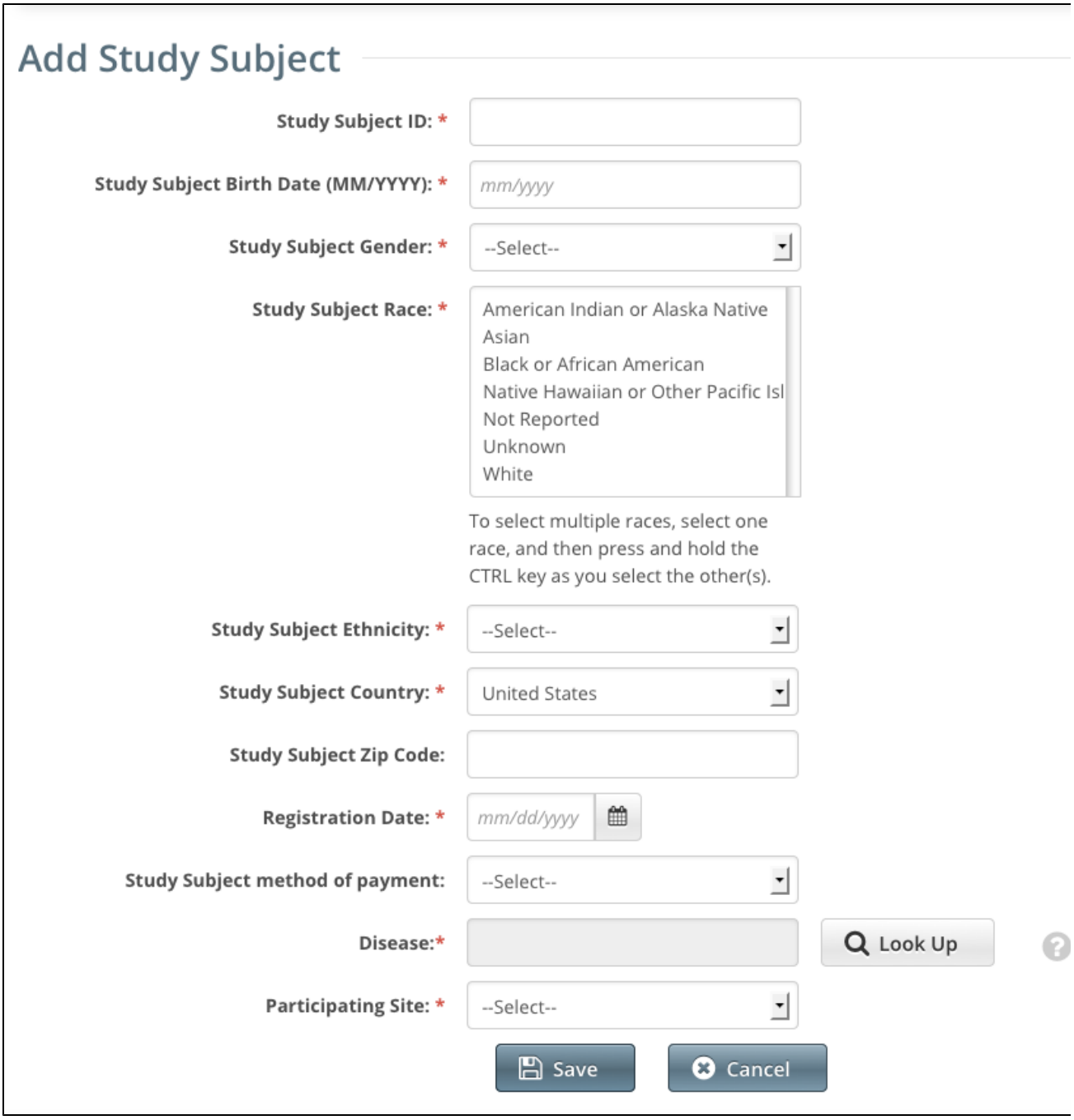
Submitting Accruals at the Subject Level for Non-Interventional Trials

How to Submit Accruals at the Subject Level for Non-Interventional Trials

1. Select the trial you want to work with by following instructions in Selecting Listed Trials in Accrual or Searching for Trials in Accrual .
   The Search Study Subject/List of Study Subjects page appears. If no accrual counts have been recorded for this trial previously, you can elect to submit your accrual data at the summary level instead of the subject level.



2. Optionally, to record accrual counts at the summary level, click **Switch to Summary Level Accrual**, and follow the instructions in Submitting Accruals at the Summary Level . Otherwise, continue with the next steps.
3. Click **Add New Study Subject**.
   The Add Study Subject page appears.



4. Enter the appropriate demographic information in the text fields and select items from drop-down lists. The following table describes the fields. An asterisk (*) indicates a required field. For a list of valid values and formats for each field, see Accrual Data Elements for Complete Trials .

Descriptions and instructions for study subject demographic data fields

Study Subject Information	Instruction/Description
Study Subject ID*	Enter the unique Patient ID as per the lead organization or the study site where the subject is registered.
Study Subject Birth Date*	Enter 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/CMD** 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	Enter 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.
Study Subject Method of Payment	For United States study subjects only, select the appropriate payment method.
Site*	Click **Look Up**, and follow the instructions in Selecting Sites for Study Subject Records Using ICD-O-3 Codes. Mandatory for ICD-O-3 trials unless you record a CD-O-3 Disease Code. Optionally, record both Site and Disease codes. Site codes are available at http://training.seer.cancer.gov/head-neck/abstract-code-stage/codes.html.
Disease*	Click **Look Up**, and follow the instructions in Selecting Diseases for Study Subject Records. Mandatory for ICD-9 and SDC trials; and for ICD-O-3 trials unless you record a CD-O-3 Site Code. Use Histology codes when C codes are not available (for example, for Multiple Myeloma, NHL, Leukemia).
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.

You can submit accrual data to the NCI CTEP's Clinical Data Update 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.

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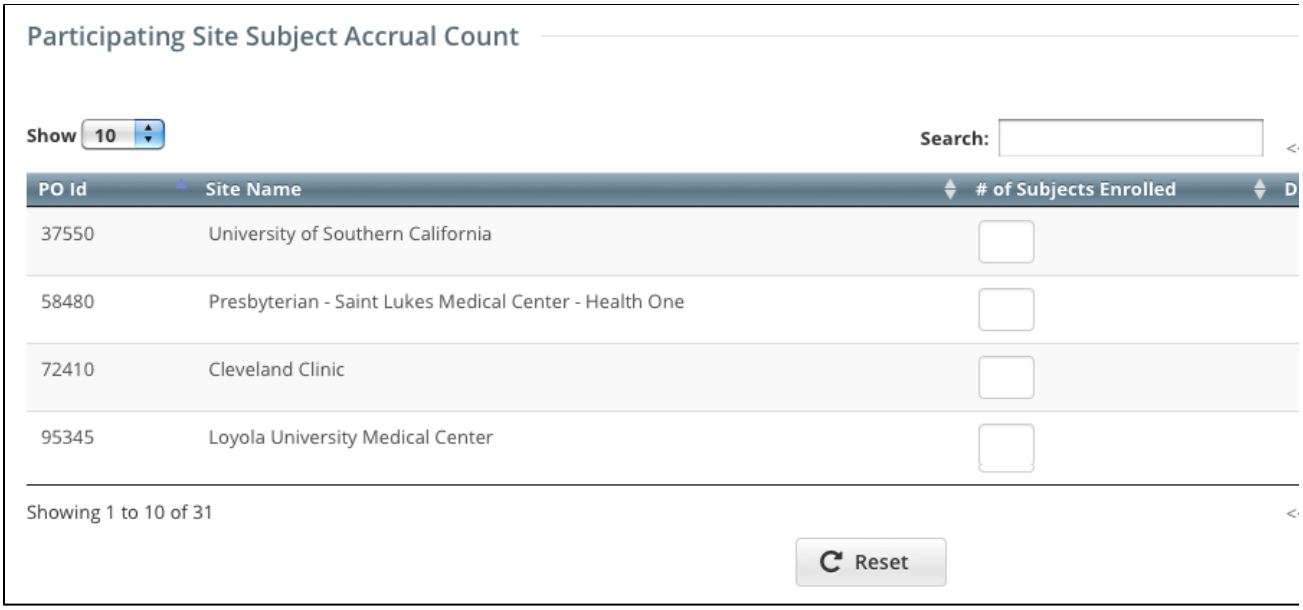
Submitting Accruals at the Summary Level for Non-Interventional Trials

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

How to Submit Accruals at the Summary Level for Non-Interventional Trials

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. If no accrual counts have been recorded for this trial previously, you can elect to submit your accrual data at the subject level instead of the summary level.



3. Optionally, to record accrual counts at the subject level, click **Switch to Subject Level Accrual**, and follow the instructions in Submitting Accruals at the Subject Level for Non-Interventional Trials . Otherwise, continue with the next steps.
4. In the **Number of Subjects Enrolled** field(s), enter the number of subjects currently enrolled in this study at your site.
5. To clear all the entries, click **Reset**. Otherwise, be sure to c lick the **Save** icon for each site.
   A message at the top of the table indicates that the record has been updated successfully. Because you submitted accrual counts at the summary level, you must continue to record accruals at this level in the future.

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Working with Prior Accrual Submission Records v4.3

Working with Prior Accrual Submission Records v4.3

Topic Links

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. Those methods include the Accrual user interface (UI), single submissions and batch uploads, and 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
- Download accrual batch upload Zip files

Only the user who submitted the batch file can download the Zip files.

Accessing Trials with Prior Accruals Records

The system displays accrual records according to your affiliation with organizations and the role organizations play in any given trial. The following tables show the relationships between you, your affiliated organization, and the records available to you.

***Complete* Trials Category:**

User Access to Accruals by Trial	Affiliated Organization Role	Submissions View
Access to trial for own site	Participating Site	Submissions for own site only
Access to trial for own site and other sites that are members of the organization family of user's affiliated organization	Participating Site	Site submissions and accruals submitted by organization family member sites
Access to trial for own site and other sites that are *not* members of the organization family of user's affiliated organization	Participating Site	Submissions for own site only
Access to a given trial	Lead Organization	All accrual submissions for the trial by any and all participating sites

***Abbreviated* Trials Category:**

User Access to Accruals by Trial	Affiliated Organization Role	Submissions View
Access to trial for own site	Participating Site	Submissions for that trial only
Access to trial for own site and other sites that are members of the organization family of user's affiliated organization	Participating Site	Site submissions and accruals submitted by organization family member sites
Access to trial for own site and other sites that are *not* members of the organization family of user's affiliated organization	Participating Site	Submissions for that trial only

All trials to which you have been granted access, per the rules described in the tables above, are listed automatically when you open the Prior Submissions page . Optionally, you can limit the list of prior submissions that are displayed to a given date or range of dates.

The system displays the following information for each trial:

- **Trial ID**. Trial identification given to the trial when it was registered with the CTRP
- **Files/Subject**. Links to the following accrual details:
  - Batch file (when applicable)
  - Trial subjects
  - Trial counts
- **Submission Method**. Mechanism used to submit accrual data, i.e., via Accrual (web application), batch uploads, or the Accrual service
- **Submission Date/Time**. Date the accrual record was either added or modified in CTRP
- **Submitted by**. Name of the registered CTRP user who submitted the accrual information
- **Submission Accepted?**. Indicates whether or not the submission was processed successfully (Yes), or there were errors in the submission (No). Immediately after submitting new or updated accrual data, the system sends you an email message that indicates whether the submission passed or failed. If the processing failed, the email message explains the nature of the errors.

Export Options
You can export historical accrual submission records as listed to Excel spreadsheets and/or CSV (comma-separated values) files.

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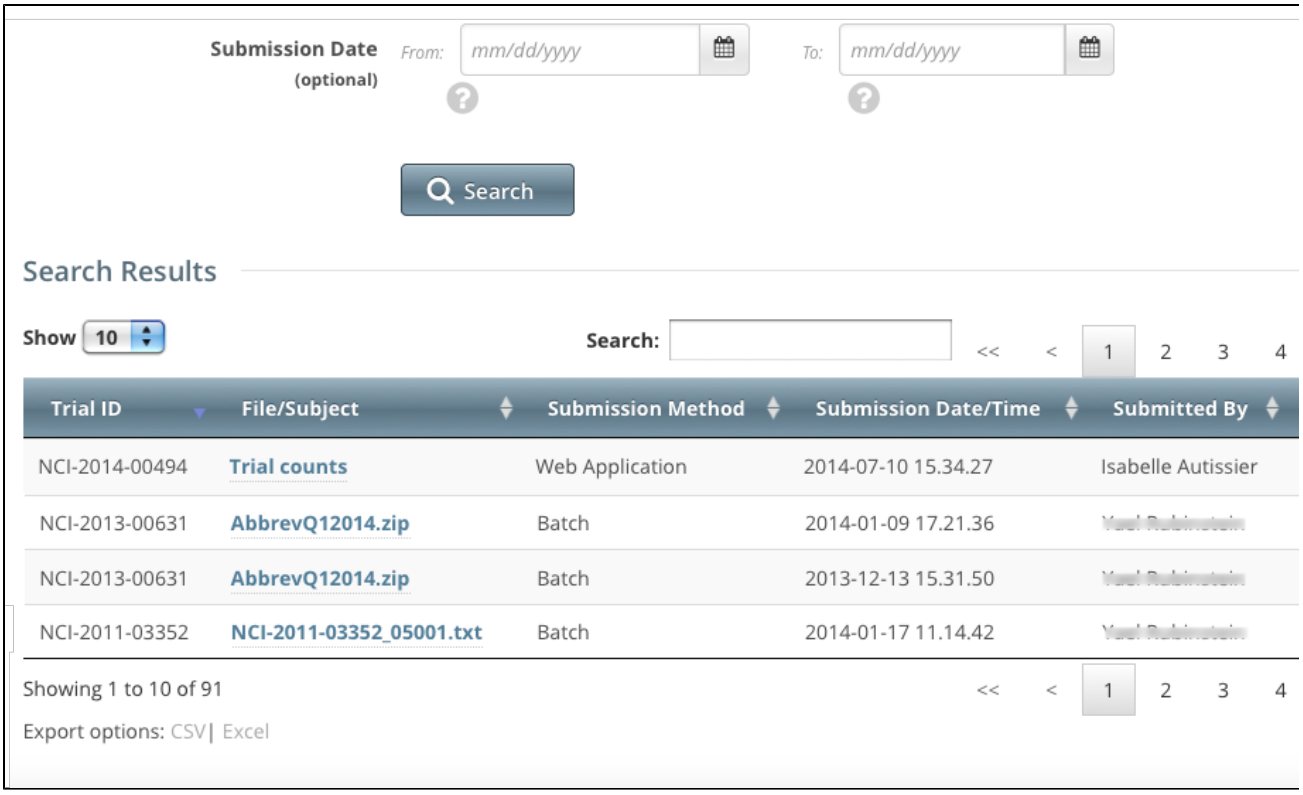
Reviewing and Updating Prior Accrual Submissions

For *Complete* trials, the system displays all subject records that have been previously submitted, whether a subject record was added, modified, or deleted. Each study subject is listed with its associated trial record individually.

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

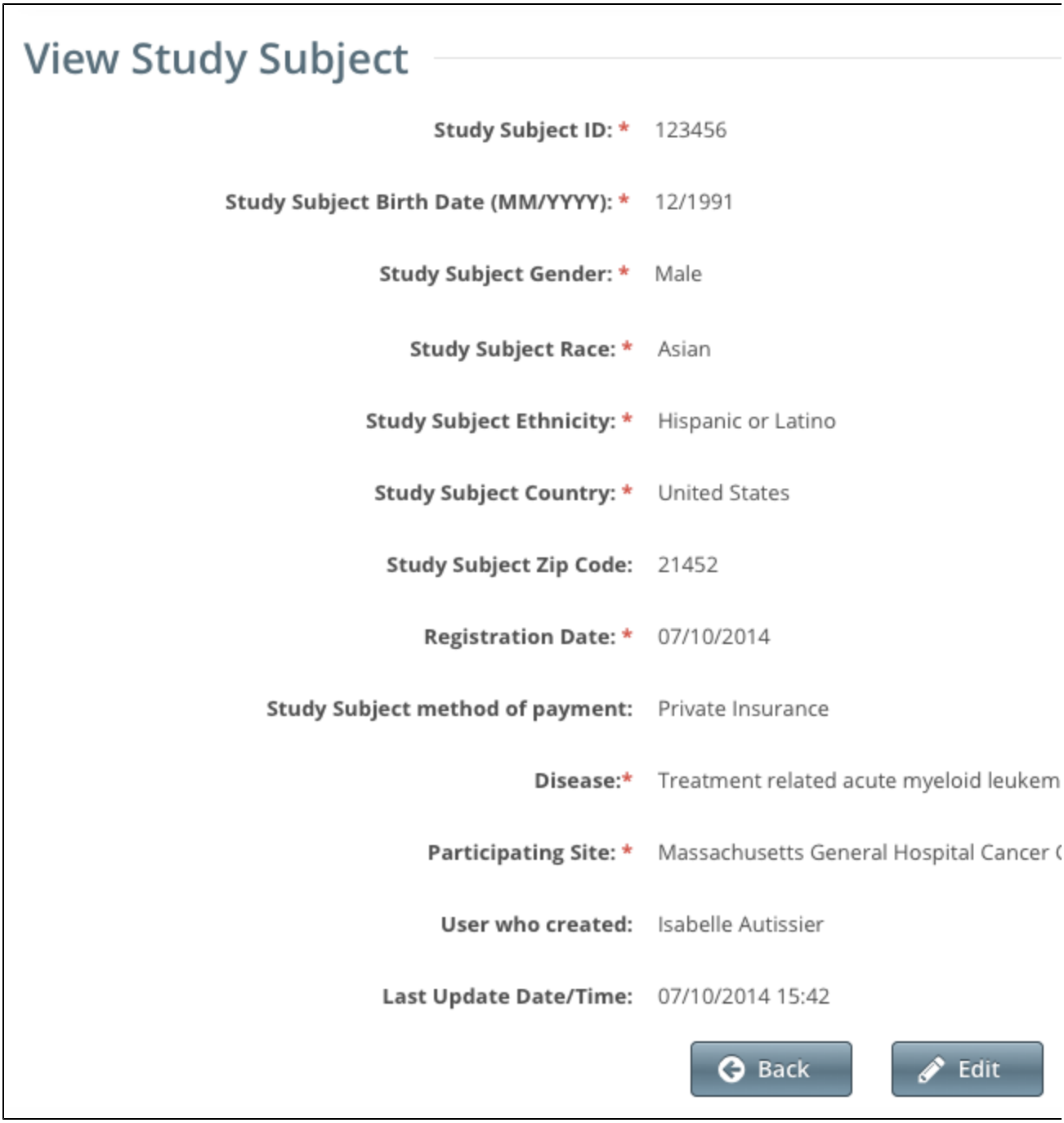
1. On the toolbar, click **Prior Submissions**.
   All of your organization's prior accrual submission records to which you have been granted Accrual access are listed automatically.



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**.

> **You can sort and filter Submission Records**
> To filter and sort the list of prior submissions, see Working with Accrual Tables and Search Results.

3. Optionally, to export the historical accrual submission records, scroll to the bottom of the list of records, click **CSV** to download the records as a comma-separated-value text file, or **Excel** to download the records as an Excel spreadsheet. Follow your browser/operating system instructions to view or save the document.
4. To view a subject's demographic and submission data, in the **File/Subject** column, select the **Study Subject ID** link**.**
The View Study Subject page displays all the data recorded to date.



5. To update a subject's demographic data, click the **Edit** icon (pencil).

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Downloading Accrual Batch Data Files

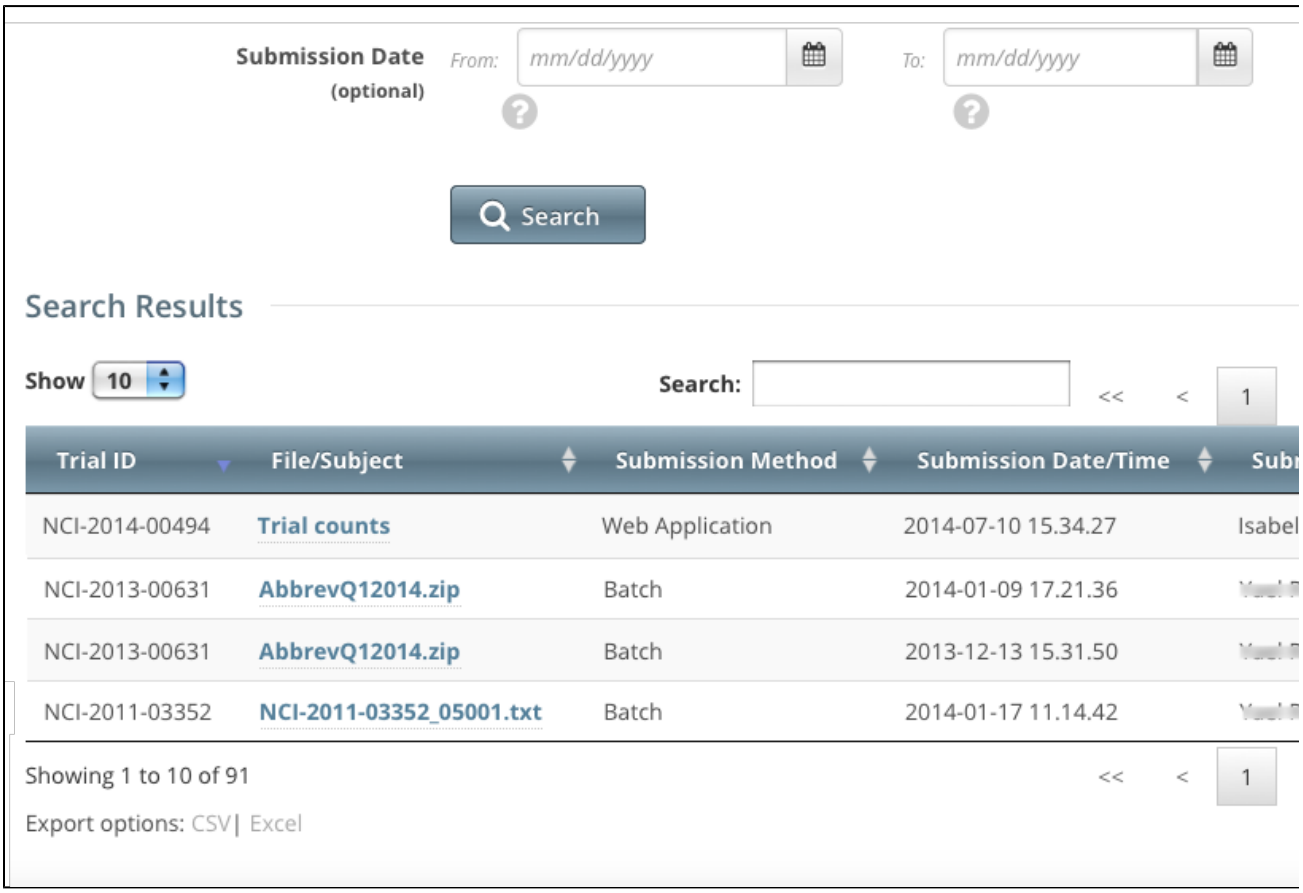
Only the ZIP file submitter and Super Abstractors can download ZIP files from the Prior Submissions page.

From the Prior Submissions page, you can download previously submitted accrual files (.txt or .zip) that were uploaded via the Batch Upload feature.

All trials to which you have been granted access, per the rules described in Accessing Trials with Prior Accruals Records , are listed automatically when you open the Prior Submissions page . Optionally, you can limit the list of prior submissions that are displayed to a given date or range of dates.

How to Download Submitted Subject Accrual Files

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



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/Subject** column for the non-industrial trial of interest, click the link to the file.
   Follow your browser/operating system instructions to view or save the document.

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Submitting Accrual Data Batch Files v4.3

Submitting Accrual Data Batch Files v4.3

Topic Links

This section provides instructions for uploading batch files via the Accrual user interface. 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.

> Once you have been granted permission to submit accrual data, 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 Accrual Batch Files for detailed instructions.

Only Super Abstractors can upload accrual data batch files for CTEP and DCP trials. For these trials, the system assigns default patient disease codes if the disease code was not included in the batch file. The following table maps disease code systems to their default codes.

Disease Code System	Default Code Assigned
ICD-O-3	C998 (site code) 7001 (histology code)

ICD-9	V100
ICD-10	Z1000
SDC	8000001

If a trial currently has no existing study subjects, and if all study subjects are missing the disease code in the CDUS file being submitted, the system assigns the CTEP SDC "disease not specified code, i.e., " 80000001, by default. The system cannot process files in which invalid study subject disease codes are provided.

Preparing CTRP Accrual Batch Files

When a trial has accrued many subjects, rather than entering the data subject-by-subject via the user interface (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 an 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 CTRP Accrual Batch File Tool 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 Accrual Batch Data Files .

Key Facts about CTRP Accrual Batch Files

- The 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. Comparison of CTRP and CDUS Accrual Data Elements 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. The text file can be UTF-8 or ANSI-encoded.
- 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.
- Only Super Abstractors can upload accruals for CTEP and DCP trials in the CTRP.

Do not include the following items in Zip files that you intend to upload:

- Folders or other Zip files
- Path names. Some ZIP/compression tools provide an option to include the entire file path name when compressing a file. Path names describe the location of the file.

- Each batch submission uploaded into CTRP is treated as an *update* to existing records or as an addition of new ones.
- Upload accruals for CTEP and DCP trials via CTEP CDUS batch accrual files only.

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 trial. 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 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 place 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` (f or a single file) or `.zip` for compressed .txt files.

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Accrual Batch File Data for Complete Trials

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 are ignored, but the place holders (commas) must still be present in the data file, whether empty or filled.

Before you begin

CTRP considers each accrual submitted as the total (cumulative) count to date. Be sure to read the information about accrual counts in Recording Participating Site Subject Accrual Counts.

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 Comparison of CTRP and CDUS Accrual Data Elements for a list of all the CDUS fields for these tables.

Complete Trial Data Elements 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.

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>,<Birt
h_Date>,<Gender>,<Ethnicity>,<Payment_Method>,<Subject_Registration_Date>,<Registering
_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,,,,,,,,,238
.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
```

ICD-O-3 Trial Format for Disease and Site Codes
For trials using ICD-O-3 codes, use the Subject Disease Code position for ICD-O-3 Site and/or Histology codes. If you use both Site and Histology codes, separate them by a semi-colon as per the example below.
Format: site code; histology code
Code: `C64.9;8000`
Examples:
SDC Disease Code:
`PATIENTS,NCI-2011-03861,8732228,84124,,196311,1,9,1,20060809,CALGB,149280,,,,,,,,,`**`238.7`**`,,`
ICD-O-3 Site and Histology Codes:
`PATIENTS,NCI-2011-03861,8732228,84124,,196311,1,9,1,20060809,CALGB,149280,,,,,,,,,`**`C64.9;8000`**`,,`
ICD-O-3 Site Code only:
`PATIENTS,NCI-2011-03861,8732228,84124,,196311,1,9,1,20060809,CALGB,149280,,,,,,,,,`**`C64.9`**`;,,`
ICD-O-3 Histology Code only:
`PATIENTS,NCI-2011-03861,8732228,84124,,196311,1,9,1,20060809,CALGB,149280,,,,,,,,,  ;`**`8000`**`,,`

Complete Trial Record Data Field Requirements

The tables in this section contain 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.

Accrual Data Elements Table with CTRP-Accepted Values

Accrual Data Elements table with CTRP-Accepted values for Complete trials

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-rep form, questionnaire, interview, etc. Genders in batch files do not have to correspo as a trial eligibility criterion.

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	Payment Method Codes in batch files are not
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 CT 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 • ICD-O-3 codes • ICD-10	For SDC Disease Code: StudySubject / diease_identifier For ICD-9 Disease Code: StudySubject / icd9diease_identifier	Disease code is mandatory for all trials excep PIO. Cancer specific ICD-9-CM disease codes in th Information about these disease codes is avai a.com For trials using ICD-O-3 terminology, use this Histology Codes. When using both Site and H them by a semicolon (;). Site codes are avail cancer.gov/head-neck/abstract-code-stage/co Use Histology codes when C codes are not av Multiple Myeloma, NHL, Leukemia). For uploading CDUS batch files, see the note
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	Multiple races in batch files are permissible ev "Unknown" is indicated.
Change Code	O	Additions or changes since the last report	• 1 • 2 • NULL	AccrualCollections / changeCode	1 or NULL = changes in the file; the CTRP sy the submission 2 = If the trial's current accrual is 0, the CTRP as a Code 1 change. If the trial's current accru system saves the file but does not process it.

For Super Abstractors uploading CDUS Accrual batch files
Use the following default disease codes when uploading a CDUS accrual batch file:

- For patients missing the disease code
  - ICD-9: V100
  - SDC: 80000001
  - ICD-O-3
    - Site code: C998
    - Histology code: 7001
  - ICD-10: Z1000

Use the CTEP SDC "disease not specified code" 80000001 by default if the trial currently has NO existing patients, and all disease codes in the CDUS file are missing.

Accrual Data Elements Table with CDUS-Accepted Values

Accrual Data Elements table with CDUS-Accepted values for Complete trials

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 ICD-9-CM disease codes in the range 140 to 239. Information about these disease codes is available at http://www.icd9data.com
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

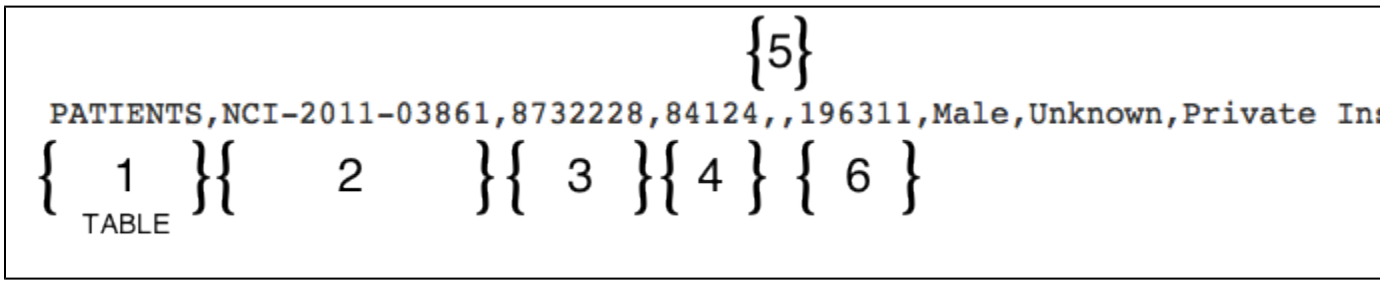
The following table lists the data fields by the table in which they are recorded. It also provides the field number (field position in a row); and the format and character limits for each field.

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) [1]	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 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.

---

[1] For trials using ICD-O-3 terminology, use this position for Site and/or Histology Codes. When using both Site and Histology codes, separate them by a semicolon (;).

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Accrual Batch File Data for Abbreviated Trials

Abbreviated Studies in CTRP are those with the Data Table 4 trial submission category of Industrial. The CTRP requires 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.

Before you begin
The CTRP considers each accrual submitted as the total (cumulative) count to date. Be sure to read the information about accrual counts in Recording Participating Site Subject Accrual Counts.

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-2012-00225","Site 1","10"
"ACCRUAL_COUNT","NCI-2012-00225","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.

Accrual Data Elements with CTRP-Accepted Values

Accrual Data Elements table with CTRP accepted values

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 / assignedIdentfier
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

Accrual Data Elements with CDUS-Accepted Values

Accrual Data Elements table with CDUS-Accepted values

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.

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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 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 ncicbiit@mail.nih.gov.

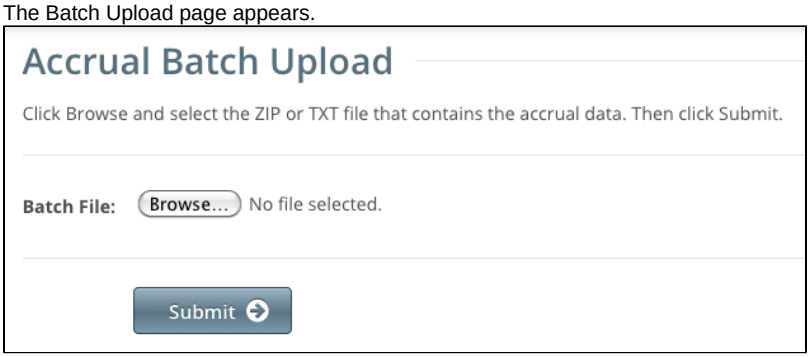
Once you have created your Accrual Batch Upload file, upload it via the CTRP Accrual web interface. Existing accrual data for the study will be updated and any new data you submit will be added.

The batch upload template currently does NOT provide a way to enter accrual disease code terminology; instead, the default value of SDC is used.

The batch files you submit do not delete previously accrued patients/patient data. Use the Accrual application user interface to delete accrued subjects as necessary.

How to Upload Accrual Batch Files

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



2. Click **Browse** and select the .txt or .zip file that contains your accrual data.
3. 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 information listed below. The system will also notify you if it is unable to process your Zip file.

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

The system checks your submissions to ensure there are no duplicates. The system does not process a study subject record if it detects that a participating site in the same trial has registered a subject with the same Study Subject ID. The system includes details about which Study Subject IDs are affected in an error message.

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

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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.

If the batch (.zip) file contains both valid (error-free) and invalid files, the system processes the valid files and notifies you about the files that it could not process.

If the CTRP system was unable to identify an organization that you submitted in your batch file, it determines if the organization was nullified and merged with another organization. If so, the system includes the new organization name in the error message.

For Super Abstractors
If a CDUS batch file contains accruals for sites that have not been added yet to the trial in the CTRP, the system processes the valid sites and then emails you a list of participating sites from your file that are missing in the CTRP. You can correct this type of error by adding the site(s) to the trial and resubmitting the accrual batch file.

How to Resolve Accrual Batch File Upload Errors

1. Go through 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.

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Downloading Accrual Count Reports v4.3

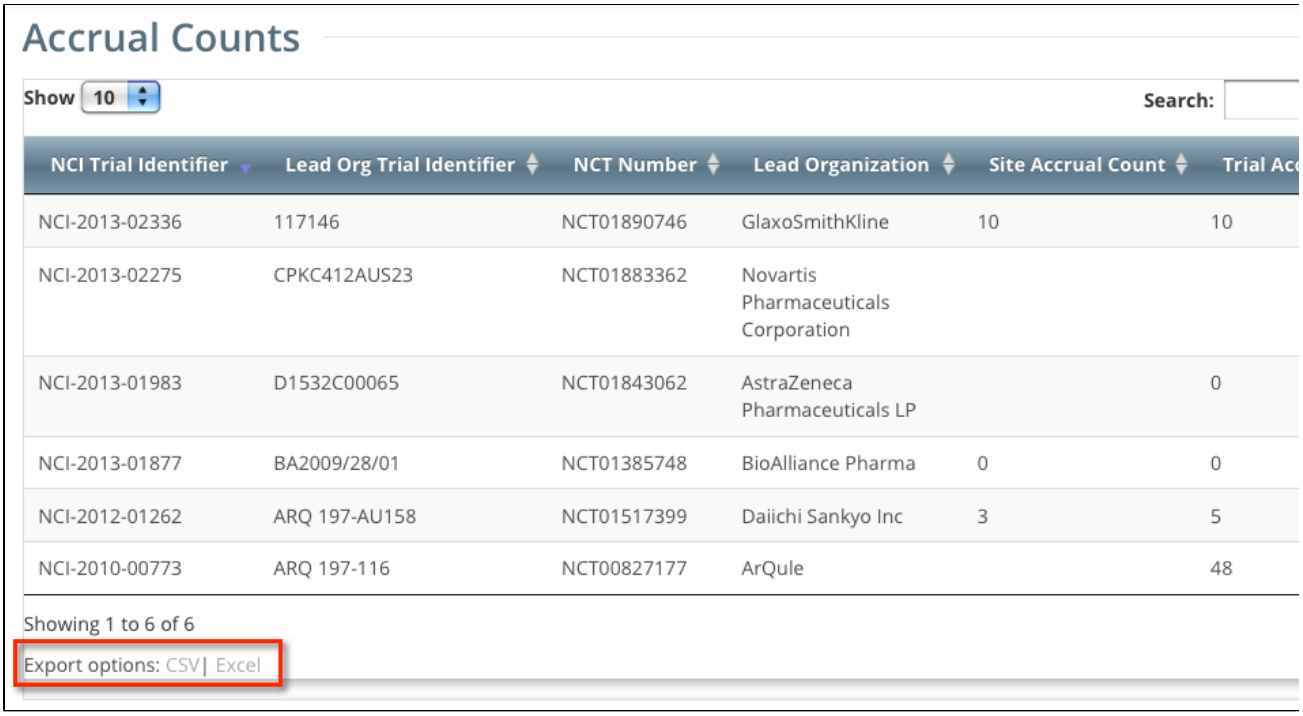
Downloading Accrual Count Reports v4.3

This section provides instructions for downloading a report that lists site accrual counts. For *Complete* trials, the report includes accrual counts for the lead organization. For *Abbreviated* trials, the report includes accrual counts from participating sites.

The Accrual Count report includes accrual information for your affiliated organization or participating site only. You must have Accrual access to use this feature.

How to Download Accrual Account Reports

1. On the toolbar, click **Accrual Counts**.
   The Accrual Count page displays trials to which you have access.



2. At the bottom of the list of trials, click **CSV** to download the report as a comma-separated-value text file, or **Excel** to download the report as an Excel spreadsheet.

Managing Your CTRP Account v4.3

Managing Your CTRP Account v4.3

Topic Links
• Resetting Your Password • Retrieving Your Username • Managing Your User Account Profile

This section provides instructions for modifying your CTRP account.

Resetting Your Password

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

How to Reset Your NCI Password

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

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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.

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Managing Your User Account Profile

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

> **Changing your Organizational Affiliation results in loss of privileges**
> If you change your organizational affiliation, the system revokes your existing Site Admin and Accrual Submission privileges.

How to Edit Your Account Information

1. On the top right corner of any page, click **Your Username > My Account.**
   The My Account page appears, populated with the information you previously supplied for your account.
2. In the **Your Account Profile** section, make any changes as necessary, and then click **Save**.

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

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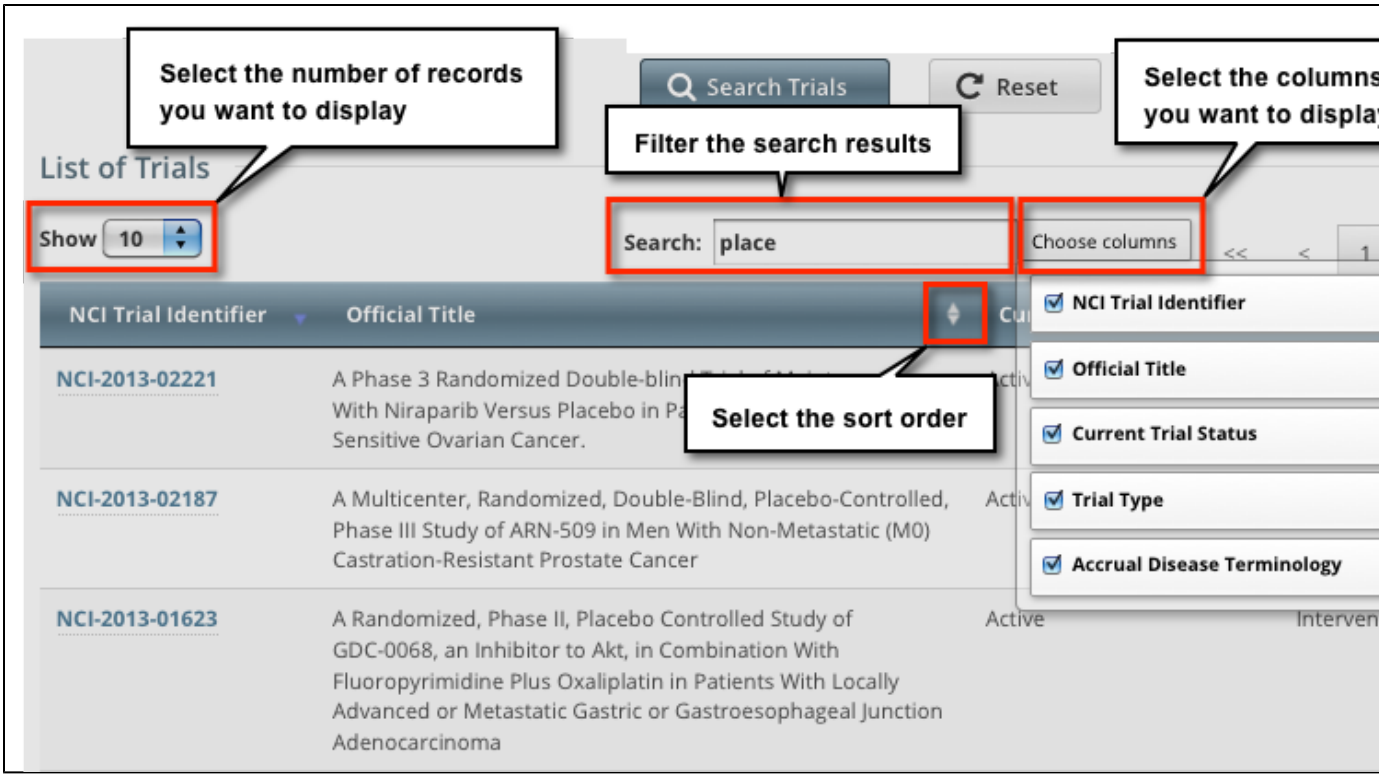
Working with Accrual Tables and Search Results v4.3

Working with Accrual Tables and Search Results v4.3

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

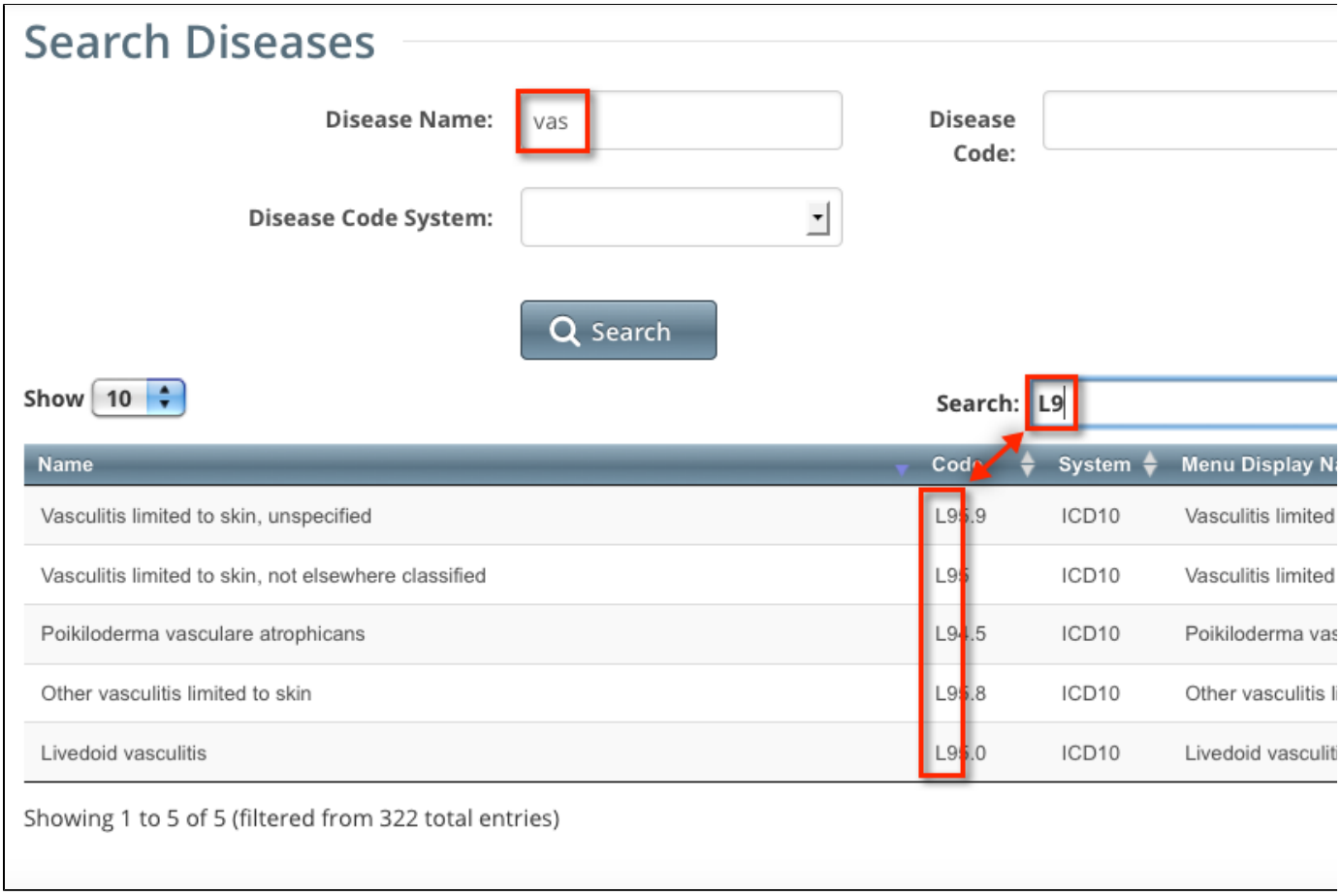
To do this...	Do this...
Move horizontally across the page	Press the Left arrow (**<–**) or Right arrow (**–>**) on your keyboard.
Sort your results by column	Click the **Sort** icons (up arrow for ascending order; down arrow for descending order).
Move to the first page of results	Click **<<**.
Move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



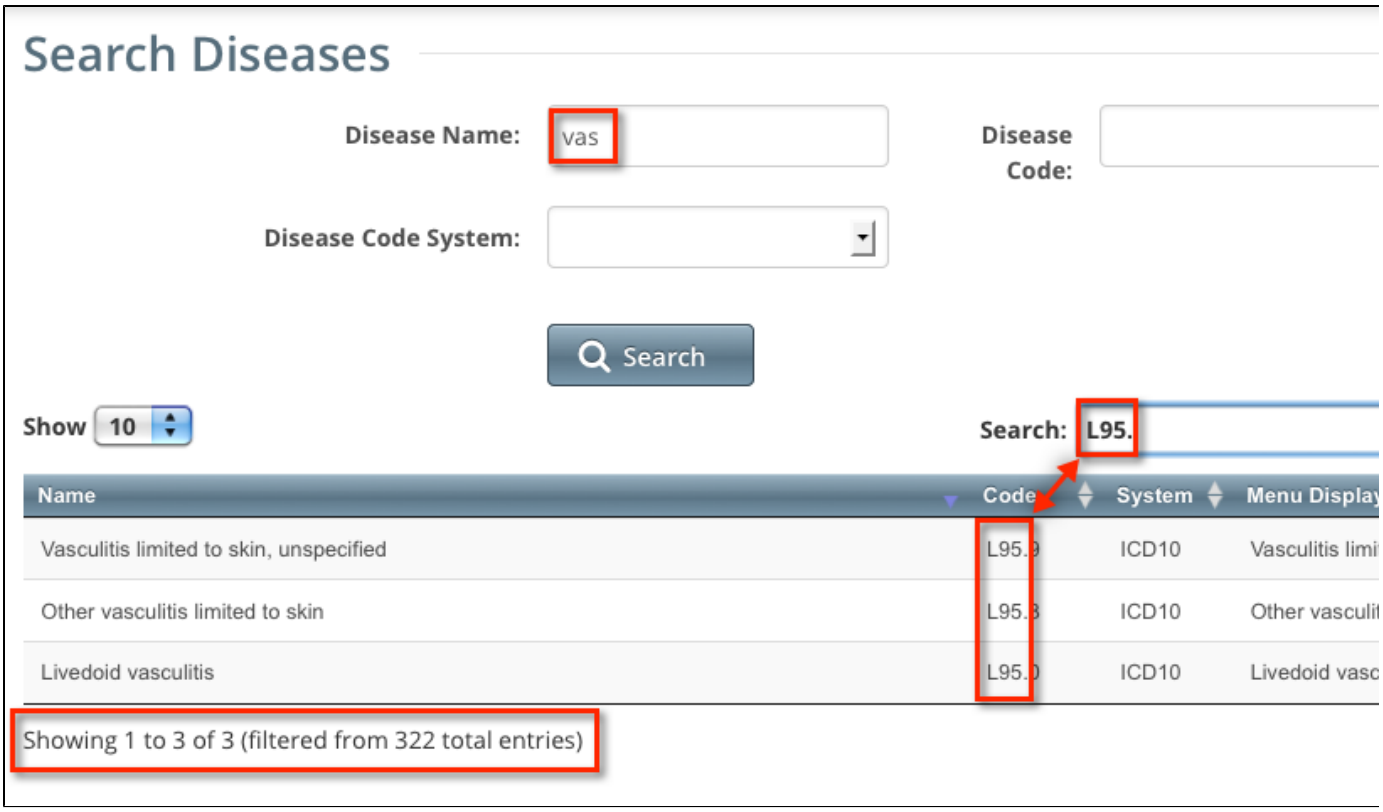
Filtering Search Results

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

For example, in the figure below, the results list has been filtered to display only diseases that contain "L9" in the Disease Code.



Adding one more character, "." as shown below, filtered out the remaining diseases because the decimal point (".") was not included in the Disease Code.



Accrual Data Elements for Complete Trials v4.3

Topic Links

The tables in this section 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.

Accrual Data Elements Table with CTRP Accepted Values

Accrual Data Elements table with CTRP-Accepted values for Complete trials

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-rep form, questionnaire, interview, etc. Genders in batch files do not have to correspo as a trial eligibility criterion.
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	Payment Method Codes in batch files are not
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 CT 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 • ICD-O-3 codes • ICD-10	For SDC Disease Code: StudySubject / diease_identifier For ICD-9 Disease Code: StudySubject / icd9diease_identifier	Disease code is mandatory for all trials excep PIO. Cancer specific ICD-9-CM disease codes in th Information about these disease codes is avai a.com For trials using ICD-O-3 terminology, use this Histology Codes. When using both Site and H them by a semicolon (;). Site codes are avail cancer.gov/head-neck/abstract-code-stage/co Use Histology codes when C codes are not av Multiple Myeloma, NHL, Leukemia). For uploading CDUS batch files, see the note

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	Multiple races in batch files are permissible ev "Unknown" is indicated.
Change Code	O	Additions or changes since the last report	• 1 • 2 • NULL	AccrualCollections / changeCode	1 or NULL = changes in the file; the CTRP sy the submission 2 = If the trial's current accrual is 0, the CTRP as a Code 1 change. If the trial's current accru system saves the file but does not process it.

For Super Abstractors uploading CDUS Accrual batch files
Use the following default disease codes when uploading a CDUS accrual batch file:

- For patients missing the disease code
  - ICD-9: V100
  - SDC: 80000001
  - ICD-O-3
    - Site code: C998
    - Histology code: 7001
  - ICD-10: Z1000

Use the CTEP SDC "disease not specified code" 80000001 by default if the trial currently has NO existing patients, and all disease codes in the CDUS file are missing.

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Accrual Data Elements Table with CDUS Accepted Values

Accrual Data Elements table with CDUS-Accepted values for Complete trials

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 ICD-9-CM disease codes in the range 140 to 239. Information about these disease codes is available at http://www.icd9data.com
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	--	--

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Accrual Data Elements for Abbreviated Trials v4.3

Accrual Data Elements for Abbreviated Trials v4.3

Topic Links

The tables in this section 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.

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.

Accrual Data Elements Table with CTRP Accepted Values for Abbreviated Trials

Accrual Data Elements table with CTRP accepted values

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 / assignedIdentfier
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

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Accrual Data Elements Table with CDUS Accepted Values for Abbreviated Trials

Accrual Data Elements table with CDUS-Accepted values

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	--

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Comparison of CTRP and CDUS Accrual Data Elements v4.3

Comparison of CTRP and CDUS Accrual Data Elements v4.3

Topic Links

This section provides the full list of CDUS (*Clinical Data Update System*) data elements for Complete trials, and indicates which of the elements are captured in CTRP. Accrual Data Elements for Complete Trials lists each data element and indicates which are mandatory, conditional, or optional.

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 TABLE

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