


1. NCI CTRP Accrual User Guide	2
1.1 CTRP Accrual Tasks	3
1.1.1 Getting Started with Accrual	4
1.1.1.1 About Accrual	5
1.1.1.2 Accrual Prerequisites	6
1.1.1.2.1 Requesting Permission to Submit Accrual Data	7
1.1.1.2.2 Preparing a Trial Record to Receive Accrual Data	8
1.1.1.3 Using the Navigation Panel in Accrual	9
1.1.1.4 Getting Help in Accrual	11
1.1.2 Searching for and Selecting Your Trials	12
1.1.2.1 Searching for Trials in Accrual	13
1.1.2.2 Viewing Trial Details in Accrual	14
1.1.3 Working with Complete Trial Accruals	15
1.1.3.1 Adding Study Subjects	16
1.1.3.2 Searching for Diseases and Sites	19
1.1.3.2.1 Searching for Diseases from the Navigation Panel	20
1.1.3.2.2 Selecting Diseases for Study Subject Records	22
1.1.3.2.3 Selecting Sites for Study Subject Records Using ICD-O-3 Codes	25
1.1.3.3 Searching for Study Subjects	28
1.1.3.4 Reviewing Study Subject Records	30
1.1.3.5 Deleting Study Subjects	31
1.1.4 Working with Abbreviated Trials	32
1.1.4.1 About Participating Site Accrual Counts	33
1.1.4.2 Deleting Participating Site Accrual Counts	34
1.1.4.3 Recording and Updating Participating Site Accrual Counts	35
1.1.5 Working with Non-Interventional Trial Accruals	38
1.1.5.1 Submitting Accruals at the Subject Level for Non-Interventional Trials	39
1.1.5.2 Submitting Accruals at the Summary Level for Non-Interventional Trials	40
1.1.6 Working with Prior Accrual Submission Records	42
1.1.6.1 About Accessing Trials with Prior Accruals	43
1.1.6.2 Reviewing and Updating Prior Accrual Submissions	44
1.1.6.3 Downloading Accrual Batch Data Files	45
1.1.7 Submitting Accrual Data Batch Files	47
1.1.7.1 Preparing CTRP Accrual Batch Files Introduction	48
1.1.7.2 Key Facts about CTRP Accrual Batch Files	49
1.1.7.2.1 An Introduction to Batch Files	52
1.1.7.2.2 File Naming Conventions	54
1.1.7.3 Accrual Batch File Data for Complete Trials	55
1.1.7.3.1 Complete Trial Tables	56
1.1.7.3.2 Complete Trial Data Elements and Field Formats	57
1.1.7.3.3 Complete Trial Data Record Formats	58
1.1.7.3.4 Complete Trial Record Data Field Requirements	60
1.1.7.3.5 Complete Trial Record Data Field Formats	61
1.1.7.4 Accrual Batch File Data for Abbreviated Trials	63
1.1.7.4.1 Abbreviated Trial Tables	64
1.1.7.4.2 Abbreviated Trial Data Record Formats	65
1.1.7.4.3 Abbreviated Trial Record Data Field Requirements	66
1.1.7.4.4 Abbreviated Trial Data Field Requirements	67
1.1.7.5 Uploading Accrual Batch Files	68
1.1.7.6 Resolving Accrual Batch File Upload Errors	70
1.1.8 Downloading Accrual Count Reports	71
1.1.9 Managing Your CTRP Account	73
1.1.10 Working with Accrual Tables and Search Results	74
1.1.10.1 Filtering Accrual Search Results	76
1.2 CTRP Accrual Reference	78
1.2.1 Accrual Data Elements for Complete Trials	79
1.2.1.1 Accrual Data Elements with CTRP-Accepted Values for Complete Trials	80
1.2.2 Accrual Data Elements for Abbreviated Trials	82
1.2.2.1 Accrual Data Elements with CTRP-Accepted Values for Abbreviated Trials	83
1.2.3 PATIENT_RACES TABLE	84
1.2.4 PATIENTS TABLE	85
1.2.5 COLLECTIONS TABLE	86

NCI CTRP Accrual User Guide

Contents of this Page




- [About this Guide](#)
- [Audience](#)

Accrual Links

- [NCI CTRP Accrual](#)
- [Accrual Batch File Tool \(Excel\)](#)

CTRP Resources

- [CTRP Website](#)
- [ClinicalTrials.gov \(http://clinicaltrials.gov\)](http://clinicaltrials.gov)
- [PRS and U.S. Public Law 110-85 \(http://prsinfo.clinicaltrials.gov/fdaaa.html\)](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. Refer to [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 [Application Support](#).

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.


In the following panel, you can search within or browse the page tree for this guide:

Audience

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

CTRP Accrual Tasks

This page tree provides instructions on performing tasks in CTRP Accrual. In the following panel, you can search within or browse the page tree:

 **Opening Linked Pages**

- To open the topic in this tab, click the relevant topic link.
-
- 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

This page tree introduces you to NCI Clinical Trials Reporting Program (CTRP) Accrual:

For browser information, refer to [Browser Support](#).

About Accrual

Accrual is the total number of patients either currently enrolled or anticipated to be enrolled on the clinical study. Enrolled means a participant's, or their legally authorized representative's, agreement to participate in a clinical study following completion of the informed consent process. Potential participants who are screened for the purpose of determining eligibility for the study, but do not participate in the study, are not considered enrolled, unless otherwise specified by the protocol. For more information, refer to <https://prsinfo.clinicaltrials.gov/definitions.html#IntEnrollment>.

The CTRP Accrual application provides authorized members of the cancer research community with access to their clinical study registered in CTRP for the purpose of reporting accrual. It enables users to enter accrual based on the study category: *Complete* or *Abbreviated/Imported*. Only one type of accrual reporting is permitted per study. For information on these types, refer to [CTRP Trial Categories](#), [Study Sources](#) or <https://cancercenters.cancer.gov/GrantsFunding/eData#dt4>.

The CTRP Accrual application, REST Services and Batch Upload allows users to report the following types of accrual data:

Study Type	Default Accrual Reporting Type
Complete Interventional	Subject
Complete Non-Interventional	Subject
Abbreviated/Imported Interventional	Summary
Abbreviated/Imported Non-Interventional	Summary

- Subject: Study subject level reporting of demographic data.
 - Subject accrual is expected to be reported for Complete studies, both Interventional and Non-Interventional, and is the default accrual reporting type.
- Partial Subject: Requires the reporting of Study Subject ID, Registration Date and Participating Site data only. The other accrual data elements are optional.
 - Partial Subject accrual was implemented for unique instances when full Subject/patient-level accrual reporting is not feasible.
 - The reporting of Partial Subject accrual on a Complete Interventional trial requires an approval request submitted to the CTRO (NCICTRO@mail.nih.gov).
 - Centers can change the default accrual reporting type on Complete Non-Interventional studies to Partial Subject within the Accrual application, as long as accrual has not been reported. If accrual has been reported, then the following actions are required:
 - Any previously reported accrual will need to be nullified prior to the change in accrual reporting type.
 - An approval request will need to be submitted to the CTRO (NCICTRO@mail.nih.gov) to change the accrual reporting type to Partial Subject.
- Summary: Total number (count) of study subjects accrued per site on a given study.
 - Summary accrual is expected to be reported for Abbreviated/Imported studies, and is the default accrual reporting type.
 - Centers can change the default accrual reporting type on Complete Non-Interventional studies to Summary within the Accrual application as long as accrual has not been reported. If accrual has been reported, then the following actions are required:
 - Any previously reported accrual will need to be nullified prior to the change in accrual reporting type.
 - An approval request will need to be submitted to the CTRO (NCICTRO@mail.nih.gov) to change the accrual reporting type to Summary.
 - The reporting of Summary accrual on a Complete Interventional trial requires an approval request submitted to the CTRO (NCICTRO@mail.nih.gov).
 - The reporting of Subject or Partial Subject accrual on an Abbreviated/Imported study requires an approval request submitted to the CTRO (NCICTRO@mail.nih.gov).



Refer to the following for required and optional accrual data elements: [Accrual Data Elements with CTRP-Accepted Values for Complete Trials](#)

Accrual Prerequisites

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

- You must have a CTRP user account with authorization to submit accrual to your trials.
- The trial (*Externally Peer-Reviewed, Institutional, or Industrial*) must be registered in CTRP and accepted. If a trial has been rejected or terminated in CTRP, you will not be able to submit accrual on the trial record. Rejected and submission terminated trials will not display for your center in CTRP Accrual.

For instructions on each of these, refer to the following pages:

Requesting Permission to Submit Accrual Data

To view and submit accrual data for your trials:

1. Create a CTRP account. For instructions, refer to [Creating a CTRP Account](#).
2. Request permission to submit accrual data for your trials. 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 Accrual Access](#) in the NCI CTRP Registration User's Guide.

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.
- **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 the lead organization on the trial to submit accrual.

- **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 the lead organization on the trial to submit accrual.

Preparing a Trial Record to Receive Accrual Data

To prepare a study record:

1. Register the study in CTRP. For information and instructions, refer to [Getting Started with Registration](#) in the NCI CTRP Registration User Guide.
2. Once a submission is deemed valid, CTRO will accept the submission in CTRP. The study must be accepted before accrual can be submitted to CTRP. If the CTRO requests more information about the study once the study is registered, respond in a timely manner to facilitate the abstraction process.
3. For Complete/Protocol studies, the overall trial status history must include an open/recruiting status.
4. A Participating site's status history must include an open/recruiting study status before initial accrual can be loaded. Open/recruiting statuses include the following:
 - Active
 - Available
 - Enrolling by Invitation
 - Temporarily Closed to Accrual
 - Temporarily Closed to Accrual and Intervention
 - Temporarily Not Available

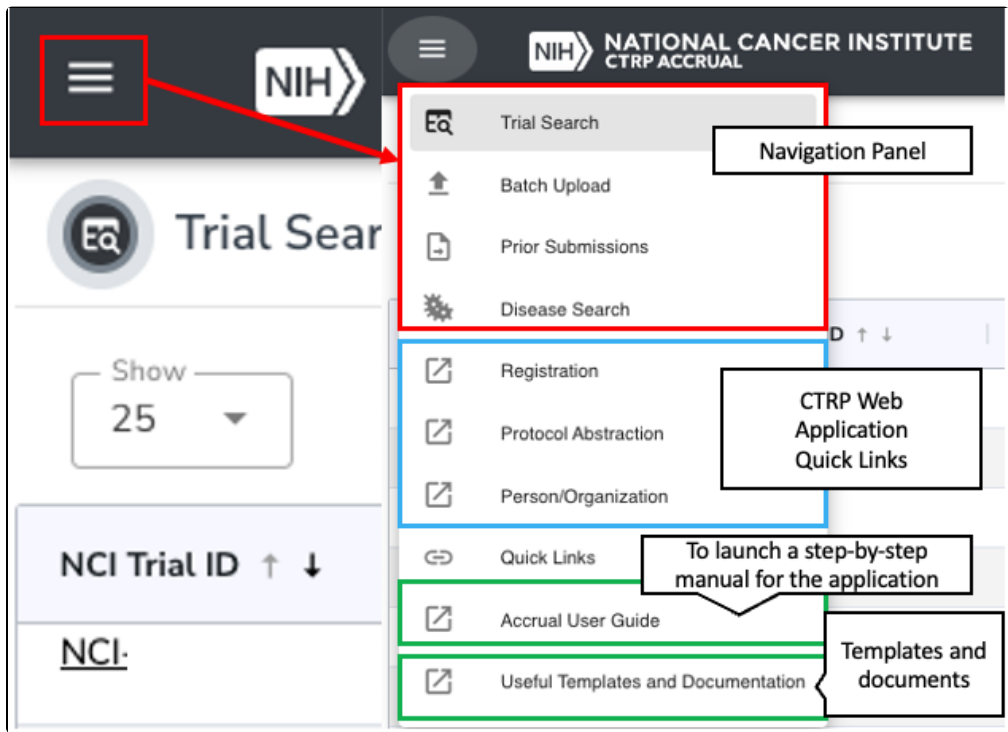
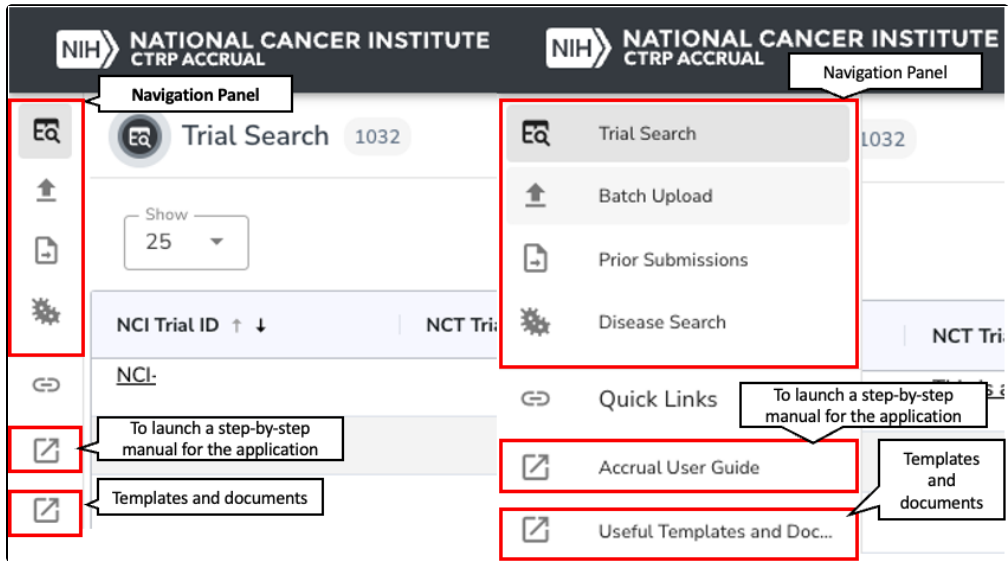


When reporting accrual via Batch Upload and REST Services, ensure the accrual reporting type is properly set on the study(ies) in the CTRP Accrual application. Accrual records reported with a different accrual reporting type than what is on the study record will be rejected. To update the accrual reporting type for all studies other than Complete Non-Interventional, a request must be submitted to the CTRO (NCICTRO@mail.nih.gov) for approval. Centers can change the default accrual reporting type on Complete Non-Interventional studies within the Accrual application, as long as accrual has not been reported. Once accrual has been reported, a request will need to be submitted to the CTRO to change the accrual reporting type to Partial Subject or Summary accrual.

Using the Navigation Panel in Accrual

1. Visit the CTRP Accrual home page at <https://trials.nci.nih.gov>.
2. Log in using your CTRP account and navigate to the CTRP Accrual application.

The navigation panel runs across the left-hand side of each page and remains in place even if you scroll down the page. Hovering the mouse to the navigation panel will expose the hidden menu, displaying the full navigation panel.



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.

NIH NATIONAL CANCER INSTITUTE
CTRP ACCRUAL

Accrual Registration Protocol Abstraction Person/Organization

Access to My Account AT

Trial Search 1032

Navigation Panel

25

Show/Hide Export Search All... Filter Options ?

Accrual Help Topics

NCI Trial ID ↑ ↓	Trial Type ↑ ↓	Trial Category ↑ ↓	Accrual Type ↑ ↓	Accrual Disease Terminology ↑ ↓	Total Trial Accrual ↑ ↓	Last Accrual Update	Action
NCI	Interventional	Complete	Subject	ICD9	1	06/18/2024 17:45	
NCI	Non-interventional	Abbreviated	Summary	SDC	250	07/08/2024 20:31	
NCI	Interventional	Abbreviated	Summary	SDC	10	09/26/2024 16:40	
NCI	Interventional	Abbreviated	Summary	ICD9	153	10/02/2024 21:38	
NCI	Non-interventional	Complete	Partial Subject	ICD10	1	07/02/2024 18:15	
NCI	Interventional	Abbreviated	Summary	ICD-O-3	14	10/07/2019 14:16	
NCI	Interventional	Abbreviated	Summary	ICD-O-3	33	08/07/2023 20:06	
NCI	Interventional	Abbreviated	Summary	SDC	3	10/12/2023 15:27	
NCI	Interventional	Complete	Subject	ICD10	0		
NCI	Non-interventional	Complete	Partial Subject	SDC	1	07/08/2024 21:12	

NIH NATIONAL CANCER INSTITUTE
CTRP ACCRUAL

Access to My Account AT

Trial Search 1032

Navigation Panel

25

Show/Hide Export

Profile Access to My Account

Logoff Log out of New Accrual

Quick Links

- Clinical Trials Reporting Program (CTRP)
- National Cancer Institute (NCI)
- NCI Center for Biomedical Informatics and Information Technology (CBIT)

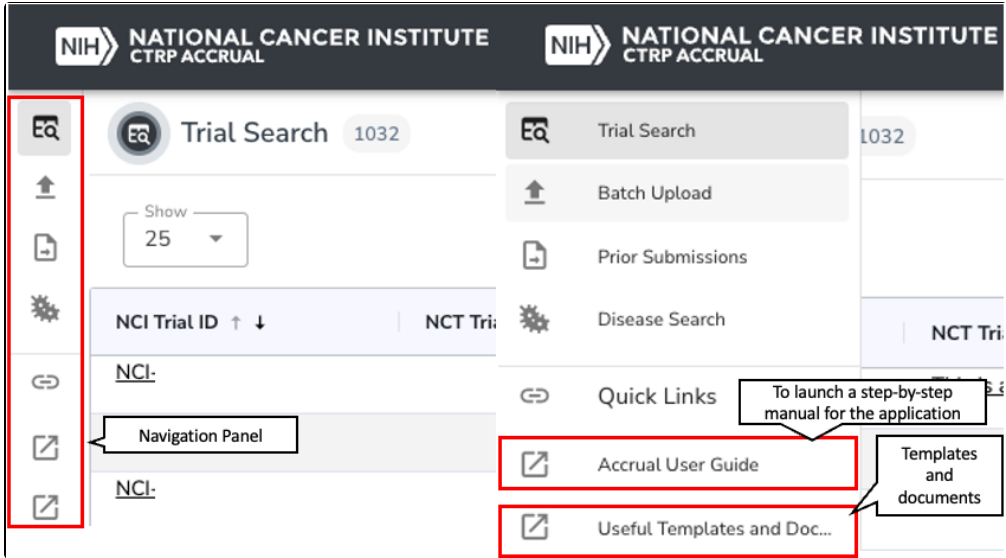
NCI Trial ID ↑ ↓	Trial Type ↑ ↓	Trial Category ↑ ↓	Accrual Type ↑ ↓	Accrual Disease Terminology ↑ ↓
NCI	Interventional	Complete	Subject	ICD9
NCI	Non-interventional	Abbreviated	Summary	SDC
NCI	Interventional	Abbreviated	Summary	SDC


Getting Help in Accrual

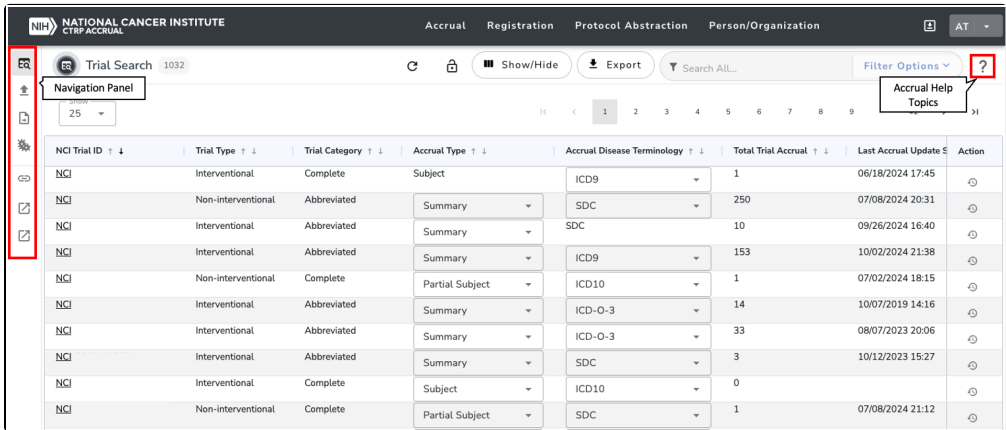
To access the user guides, you can log into CTRP Accrual at <https://trials.nci.nih.gov> and click on the links described below or go directly to [NCI CTRP Accrual User Guide](#). Help is available on each page of the CTRP Accrual web application.

How to Launch Online Help

On the left-hand side navigation panel, click **Accrual User Guide** to launch a comprehensive, step-by-step manual of the application.

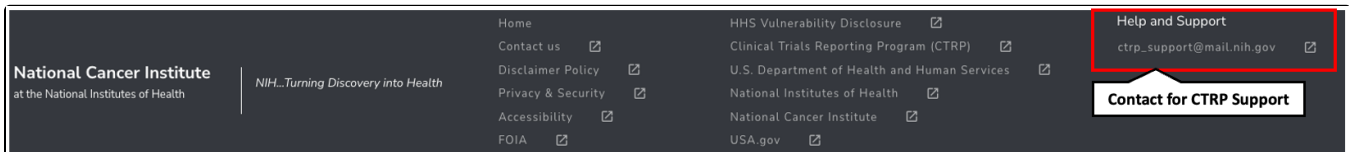


On the right-hand side, click the  icon to launch **Accrual Help Topics**. This is an abridged version of the user guide to assist with specific, accrual reporting tasks.



How to Contact CTRP Support

On the global footer, click ctrp_support@mail.nih.gov to launch a new email message.



Searching for and Selecting Your Trials

This page tree 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

NIH NATIONAL CANCER INSTITUTE CTRP ACCRUAL | Accrual | Registration | Protocol Abstraction | Person/Organization | AT

Trial Search 1032 | Refresh | Lock | Show/Hide | Export | Search All... | Filter Options

Callouts:

- Users can Refresh the table for updated trial information.
- The Trial Search page in CTRP Accrual automatically displays a list of trials to which a user has been granted access to submit accrual against upon login.
- Users can Lock header columns while scrolling.
- Show/Hide allows users to define data elements to display for their list of trials.
- Users can search the auto populated list of trials by entering keyword criteria and/or applying filters.

NCI Trial ID	Trial Type	Trial Category	Accrual Type	Accrual Disease Terminology	Total Trial Accrual	Last Accrual Update	Action
NCI	Interventional	Complete	Subject	ICD9	1	06/18/2024 17:45	
NCI	Non-interventional	Abbreviated	Summary	SDC	250	07/08/2024 20:31	
NCI	Interventional	Abbreviated	Summary	SDC	10	09/26/2024 16:40	
NCI	Interventional	Abbreviated	Summary	ICD9	153	10/02/2024 21:38	
NCI	Non-interventional	Complete	Partial Subject	ICD10	1	07/02/2024 18:15	
NCI	Interventional	Abbreviated	Summary	ICD-O-3	14	10/07/2019 14:16	
NCI	Interventional	Abbreviated	Summary	ICD-O-3	33	08/07/2023 20:06	
NCI	Interventional	Abbreviated	Summary	SDC	3	10/12/2023 15:27	
NCI	Interventional	Complete	Subject	ICD10	0		
NCI	Non-interventional	Complete	Partial Subject	SDC	1	07/08/2024 21:12	

If you do not see any studies listed when you log in, consider the following points:

- Your CTRP user account must have authorization to report accrual data to your studies.
- Studies appear in the list after they have been registered and accepted in CTRP.
- For Complete/Protocol studies:
 - The overall trial status history should include one of the open statuses.
 - Once they have reached an open/recruiting status, they will be available for accrual reporting.
- The Participating Site (PS) on the study record must include one of the open/recruiting statuses before accrual can be reported.

For instructions on each of these, refer to [Accrual Prerequisites](#).

For information on study statuses, refer to [Trial Status Values in the CTRP and ClinicalTrials.gov](#).

i You can search for a study by one or more criteria, or you can list all studies 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 for 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 study may have been reported as a Phase 2 study.

NIH NATIONAL CANCER INSTITUTE CTRP ACCRUAL | Accrual | Registration | Protocol Abstraction | Person/Organization | AT

Trial Search 1032 | Refresh | Lock | Show/Hide | Export | Search All... | Filter Options

Callouts:

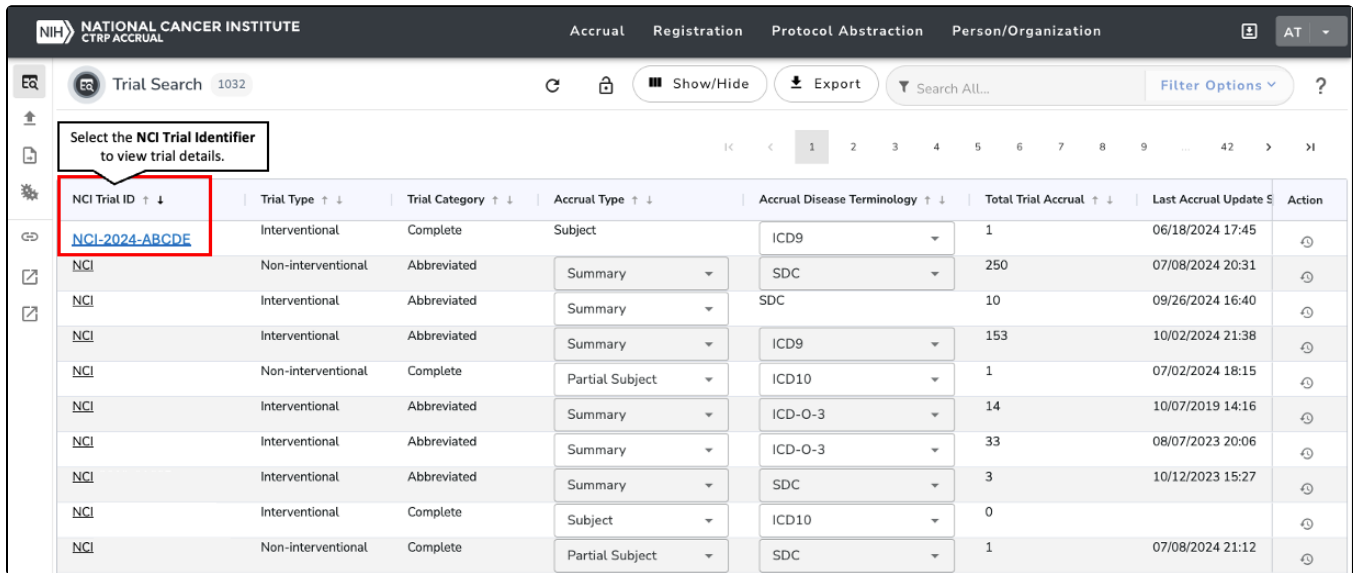
- Select the NCI Trial Identifier to add or edit study subjects to the trial.
- Accrual Disease Terminology can be modified regardless if there are existing accrual records or not.
- Modifying the accrual type on Abbreviated trials (regardless if Interventional or Non-Interventional) requires a user to contact CTRO at ncictro@mail.nih.gov.
- Modifying the accrual type for Non-Interventional, Complete trials does not require a user to contact CTRO.

NCI Trial ID	Trial Type	Trial Category	Accrual Type	Accrual Disease Terminology	Total Trial Accrual	Last Accrual Update	Action
NCI-2024-ABCDE	Interventional	Complete	Subject			06/18/2024 17:45	
NCI	Non-interventional	Abbreviated	Summary			07/08/2024 20:31	
NCI	Interventional	Abbreviated	Summary	SDC	10	09/26/2024 16:40	
NCI	Interventional	Abbreviated	Summary	ICD9	153	10/02/2024 21:38	
NCI	Non-interventional	Complete	Partial Subject	ICD10	1	07/02/2024 18:15	
NCI	Interventional	Abbreviated	Summary	ICD-O-3	14	10/07/2019 14:16	
NCI	Interventional	Abbreviated	Summary	ICD-O-3	33	08/07/2023 20:06	
NCI	Interventional	Abbreviated	Summary	SDC	3	10/12/2023 15:27	
NCI	Interventional	Complete	Subject	ICD10	0		
NCI	Non-interventional	Complete	Partial Subject	SDC	1	07/08/2024 21:12	

Viewing Trial Details 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.



NIH NATIONAL CANCER INSTITUTE CTRP ACCRUAL

Accrual Registration Protocol Abstraction Person/Organization AT

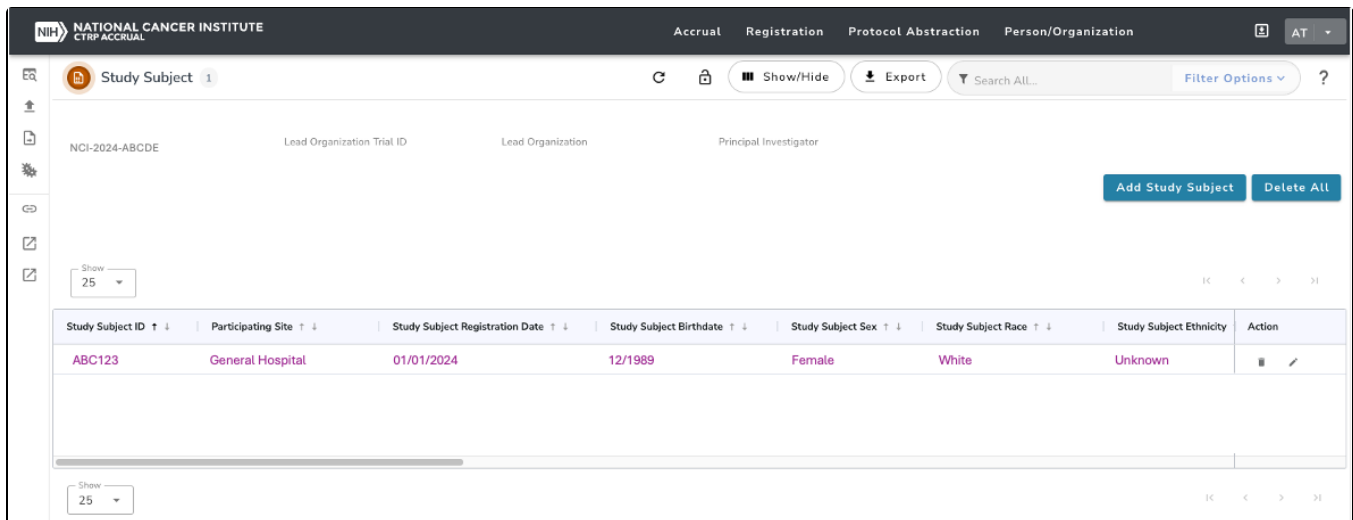
Trial Search 1032

Show/Hide Export Search All... Filter Options ?

Select the NCI Trial Identifier to view trial details.

NCI Trial ID	Trial Type	Trial Category	Accrual Type	Accrual Disease Terminology	Total Trial Accrual	Last Accrual Update	Action
NCI-2024-ABCDE	Interventional	Complete	Subject	ICD9	1	06/18/2024 17:45	
NCI	Non-interventional	Abbreviated	Summary	SDC	250	07/08/2024 20:31	
NCI	Interventional	Abbreviated	Summary	SDC	10	09/26/2024 16:40	
NCI	Interventional	Abbreviated	Summary	ICD9	153	10/02/2024 21:38	
NCI	Non-interventional	Complete	Partial Subject	ICD10	1	07/02/2024 18:15	
NCI	Interventional	Abbreviated	Summary	ICD-O-3	14	10/07/2019 14:16	
NCI	Interventional	Abbreviated	Summary	ICD-O-3	33	08/07/2023 20:06	
NCI	Interventional	Abbreviated	Summary	SDC	3	10/12/2023 15:27	
NCI	Interventional	Complete	Subject	ICD10	0		
NCI	Non-interventional	Complete	Partial Subject	SDC	1	07/08/2024 21:12	

Clicking the NCI Trial Identifier on the Trial Search page will launch the **Study Subject page** to view the accruals of the specified trial.



NIH NATIONAL CANCER INSTITUTE CTRP ACCRUAL

Accrual Registration Protocol Abstraction Person/Organization AT

Study Subject 1

Show/Hide Export Search All... Filter Options ?

NCI-2024-ABCDE Lead Organization Trial ID Lead Organization Principal Investigator

Add Study Subject Delete All

Show 25

Study Subject ID	Participating Site	Study Subject Registration Date	Study Subject Birthdate	Study Subject Sex	Study Subject Race	Study Subject Ethnicity	Action
ABC123	General Hospital	01/01/2024	12/1989	Female	White	Unknown	

Show 25

Working with Complete Trial Accruals

This page tree describes how to search for, add, update, and delete study subjects associated with *Complete* clinical trials.

For information about *Abbreviated* trials, refer to [Working with Abbreviated Trials](#).



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

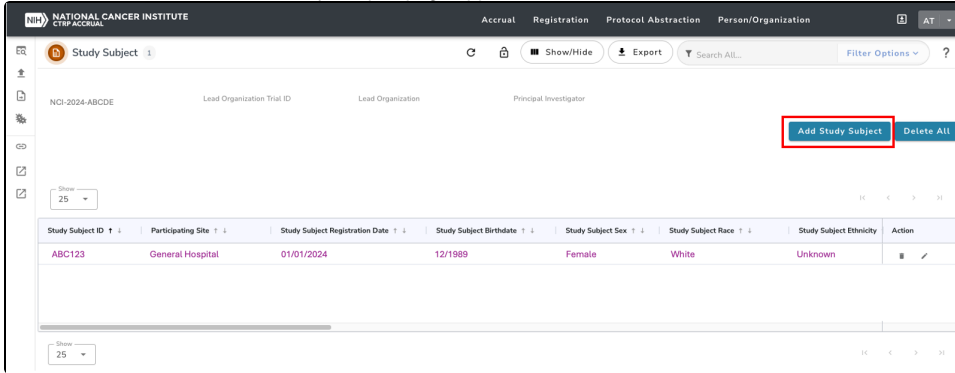
You can add one or more study subject accrual records for any study to which you have been granted access.

If necessary, refer to [Requesting Permission to Submit Accrual Data](#).

Study subject records include demographic data as well as the disease name.

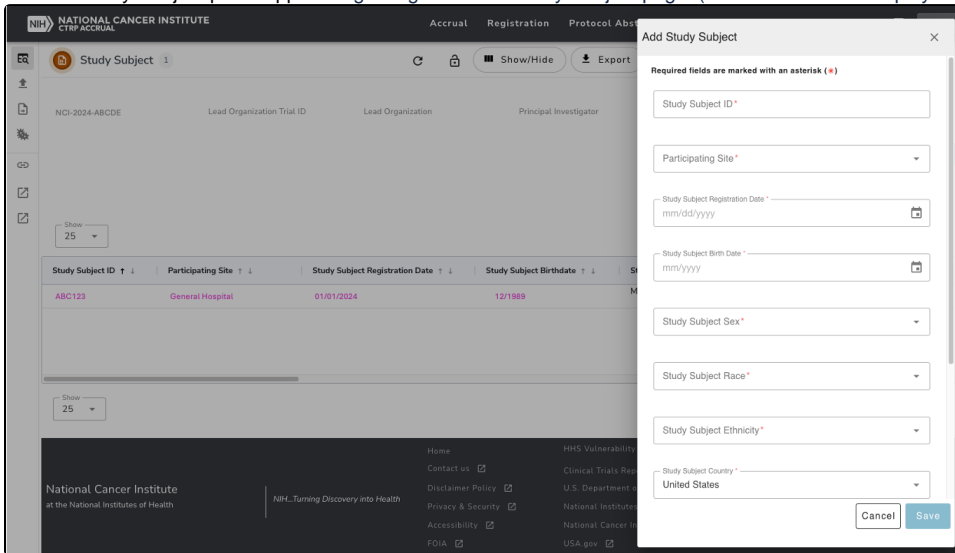
How to Add Study Subject Records

1. Select the study you want to work with by following instructions in [Searching for and Selecting Your Trials](#), and clicking the corresponding NCI Trial Identifier link. The Search Study Subject page appears.



2. Click **Add Study Subject**.


The Add Study Subject panel appears right-aligned to the Study Subject page. (Screenshot below displays Subject accrual)



3. Enter the required demographic information in the text fields and drop-down lists. An asterisk (*) indicates a required field.
4. The following table describes the valid values and formats for each field.

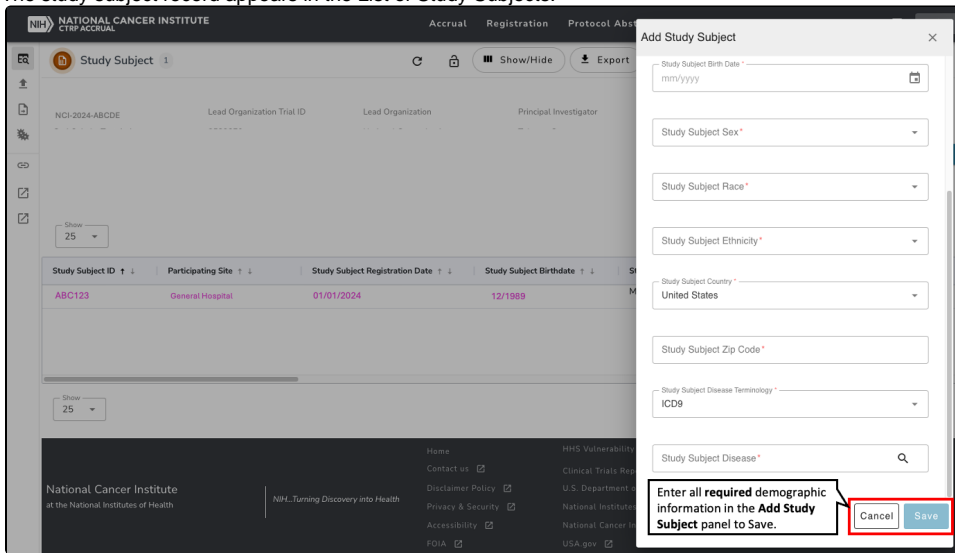
Accrual Data Element	Definition	Required (R) /Conditional (C)		Accepted Values
		Subject	Partial Subject	
Study Subject ID	Enter the unique Patient ID as per the lead organization or the study site where the subject is registered.	R	R	Any numeric or alphanumeric value
Participating Site	Select the appropriate site from the drop-down list.	R	R	
Study Subject Registration Date	Enter the date that the subject was registered on the study.	R	R	<ul style="list-style-type: none"> User Interface format: MM/DD/YYYY REST format: YYYY-MM-DD Batch Upload format: YYYYMMDD

Study Subject Birthdate (MM/YYYY)	<p>Enter the subject's month and year of birth in the format MM/YYYY.</p> <div style="border: 1px solid gray; padding: 5px; margin-bottom: 10px;">  Age is calculated by the difference between the Study Subject Registration Date and Study Subject Birthdate. </div> <div style="border: 2px solid red; padding: 5px;">  The subject's age reported in CTRP cannot be greater than 120 years. </div>	R		<ul style="list-style-type: none"> • Accrual application format: MM/YYYY • REST Services format: YYYY-MM-DD • Batch Upload format: YYYYMM
Study Subject Sex	<p>Sex means a person's classification as male or female based on biological distinctions. Select the subject's biological sex. If biological sex information is not available, select Unknown.</p>	R		<ul style="list-style-type: none"> • Male • Female • Unknown
Study Subject Race	<p>Select one or more values for race.</p> <p>To select multiple races, select one race, and then press and hold the CTRL/CMD key as you select the other(s).</p>	R		<ul style="list-style-type: none"> • American Indian or Alaska Native • Asian • Black or African American • Native Hawaiian or Other Pacific Islander • Not Reported • Unknown • White
Study Subject Ethnicity	<p>Select a value for ethnicity.</p>	R		<ul style="list-style-type: none"> • Hispanic or Latino • Not Hispanic or Latino • Not Reported • Unknown
Study Subject Country	<p>Select the study subject's country of residence.</p>	R		<p>CTRP is using the International Standards Organization country codes:</p> <p>https://www.iso.org/obp/ui/#search</p>
Study Subject Zip Code	<p>Enter the study subject's zip code.</p>	C	C	<p>Required if the Study Subject Country is the US, US territories and outlying islands.</p> <p>Must be in a 5 digit or 9 digit (DDDDD-DDDD) format</p>
Study Subject Disease Terminology	<p>The accrual disease terminology selected at the trial level is inherited. Click the field to select a different disease terminology.</p>	R		<ul style="list-style-type: none"> • SDC • ICD9 • ICD10 • ICD-O-3 • Legacy Codes - CTEP
Study Subject Disease	<p>Click Look Up, and follow the instructions in Selecting Diseases for Study Subject Records.</p> <div style="border: 2px solid red; padding: 5px; margin-top: 10px;">  For ICD-O-3, CTRP uses a hybrid model with the codes from IACR and the codes in NCI SEER that are not available in IACR. </div>	R		<p>Partial Subject:</p> <ul style="list-style-type: none"> • Disease is <u>not</u> required. • ICD-O-3: If Disease is reported, Site is also required. <p>Study Subject:</p> <ul style="list-style-type: none"> • Disease Code is required for all trial types. • ICD-O-3: Disease and Site are required.

<p>Study Subject Disease Site (ICD-O-3)</p>	<p>Click Look Up, and follow the instructions in Selecting Sites for Study Subject Records Using ICD-O-3 Codes.</p> <p>Site Code information is available at: http://www.iacr.com.fr/index.php?option=com_content&view=category&layout=blog&id=100&Itemid=57</p> <div style="border: 1px solid red; padding: 5px; margin-top: 10px;"> <p> CTRP uses a hybrid model with the codes from IACR and the codes in NCI SEER that are not available in IACR.</p> </div>	<p>C</p>	<p>Partial Subject:</p> <ul style="list-style-type: none"> • Site is <u>not</u> required. • ICD-O-3: If Site is reported, Disease is also required. <p>Study Subject:</p> <ul style="list-style-type: none"> • Site is required for all trial types. • ICD-O-3: Site and Disease are required.
--	---	----------	--

5. Click **Save**.

The study subject record appears in the List of Study Subjects.



For Complete studies, lead organizations report all subjects accrued for the study (both in the lead organization and in all participating sites). For Abbreviated studies, each participating site reports the number of its own accruals (accrual count) only.

- If your organization currently reports subject accrual information for studies to CTEP or DCP via the CDUS/OPEN systems, continue to report subject accrual information via CDUS/OPEN. The NCI will manage the transfer of subject accrual data for CDUS/OPEN studies internally. Otherwise, report your organization's subject accrual data to CTRP.

Searching for Diseases and Sites

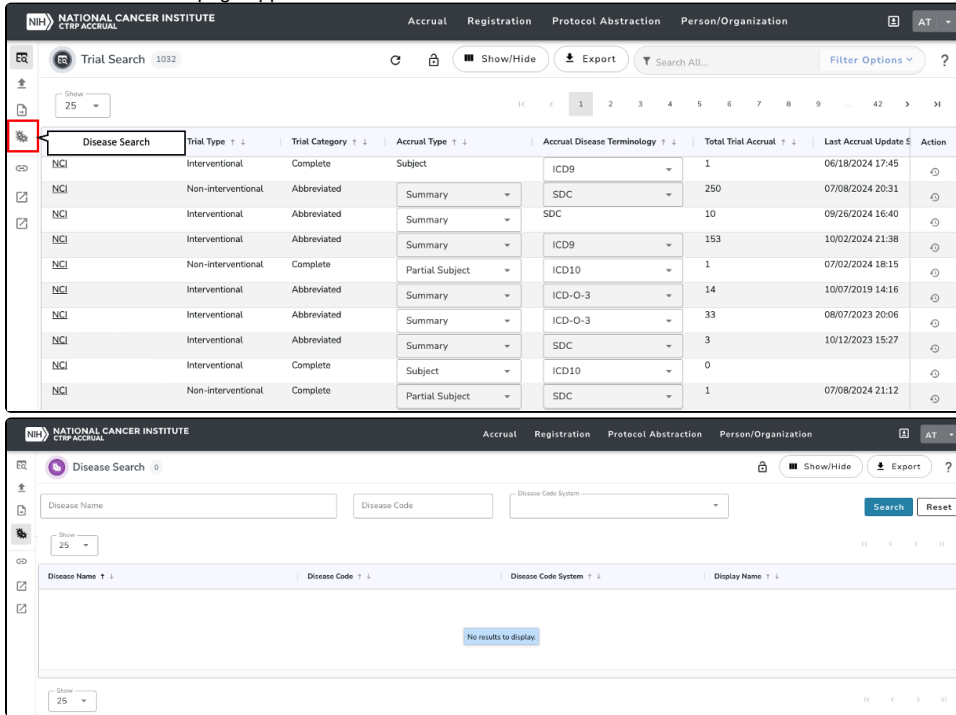
You can search for diseases directly from the toolbar or while adding or entering study subject records. Refer to the instructions below.

Searching for Diseases from the Navigation Panel

You can search for diseases by name or code directly from the navigation panel. For instructions for selecting diseases, for example, when you add or edit a study subject record, refer to [Selecting Diseases for Study Subject Records](#).

How to Search for Diseases from the Navigation Panel

1. On the left-hand navigation panel, click **Disease Search**.
The Search Diseases page 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	ICD-0-3
Disease not specified	Z1000	80000001	V100	7001/1
Healthy volunteer	Z76.3	80000000	V99	7002/0
Donors	Z52.9	(NA)	(NA)	(NA)
Unknown Primary Site	(NA)	(NA)	(NA)	C80.9

3. From the **Disease Code System** drop-down list, select one of the following:
 - **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)
 - **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.

NATIONAL CANCER INSTITUTE
 CTSP ACCESS

Accrual Registration Protocol Abstraction Person/Organization AT

Disease Search

Disease Name: myel Disease Code System: SDC

Show: 25

Disease Name	Disease Code	Disease Code System	Display Name
Acute myeloid leukemia, NOS	10000884	SDC	Acute myeloid leukemia
Acute promyelocytic leukemia	10001019	SDC	Acute promyelocytic leukemia
Chronic idiopathic myelofibrosis	10028537	SDC	Chronic idiopathic myelofibrosis
Chronic myelogenous leukemia, Philadelphia chromosome positive	10009013	SDC	CM, - Philadelphia chromosome
Chronic myelomonocytic leukemia	10009018	SDC	Chronic myelomonocytic leukemia
Juv Chronic myelomonocytic leukemia	10023249	SDC	Juvenile myelomonocytic leukemia
Myelodysplastic syndrome, NOS	10028534	SDC	Myelodysplastic syndrome, NOS
Myeloma, NOS	10028566	SDC	Myeloma, NOS
Treatment related acute myeloid leukemia	10066353	SDC	Treatment related AML

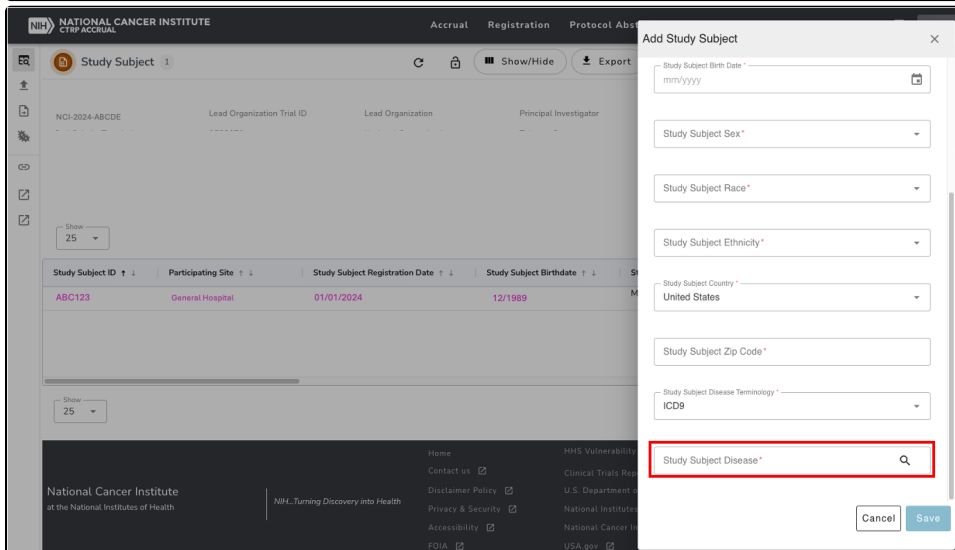
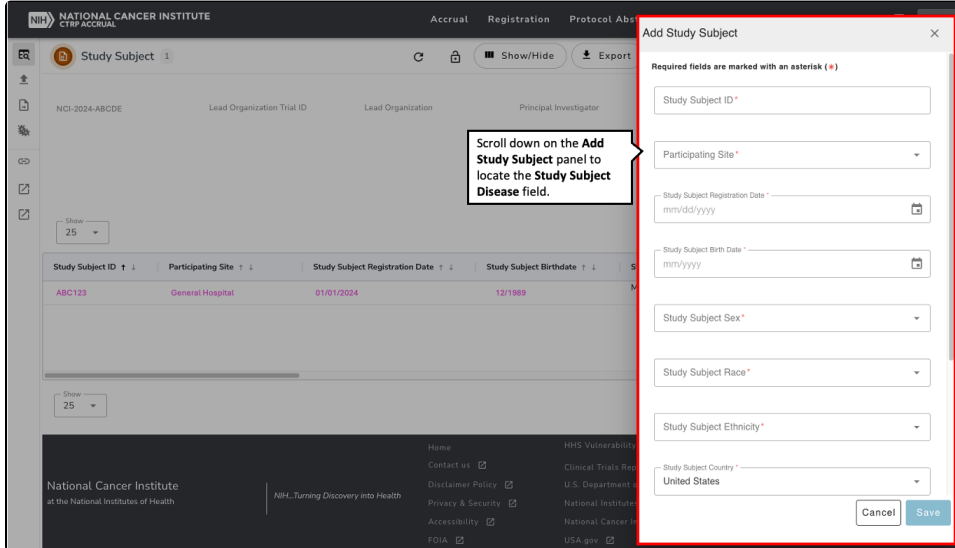
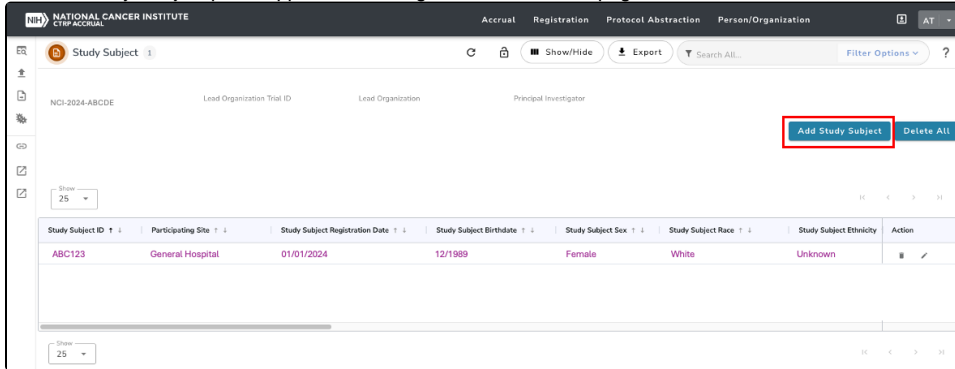
Show: 25

Selecting Diseases for Study Subject Records

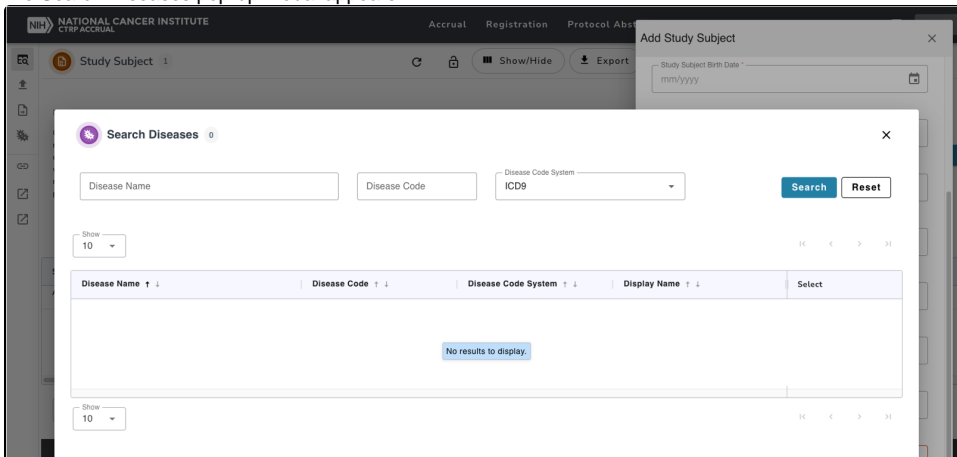
The procedure for searching for diseases while adding or entering study subject records is the same as that for searching for them using the Disease Search menu. The difference is that in addition to searching for diseases, you can select them for association with the study subject record.

How to Search for and Select Diseases

1. Select the trial you want to work with by following instructions in [Searching for and Selecting Your Trials](#), and clicking the corresponding NCI Trial Identifier link.
2. On the **Study Subject** page, click **Add Study Subject**.
The Add Study Subject panel appears on the right-hand side of the page.



- To assign a disease to the study subject, click the spyglass icon in the **Study Subject Disease** field. The Search Diseases pop-up modal appears.



- 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	ICD-O-3
Disease not specified	Z1000	80000001	V100	7001/1
Healthy volunteer	Z76.3	80000000	V99	7002/0
Donors	Z52.9	(NA)	(NA)	(NA)
Unknown Primary Site	(NA)	(NA)	(NA)	C80.9

- From the **Disease Code System** drop-down list, select one of the following:
 - **SDC** (CTEP's Simplified Disease Classification)
 - **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)
 - **Legacy Codes - CTEP**

If the trial has at least one existing study subject record, the **Study Subject Disease Terminology** will display the code system selected at the trial level. You can change the code system when creating or editing an individual study subject record by selecting the drop down in this field. This allows subjects in the same study to have different code systems.

6. Press **Enter**, or click **Search**.

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

Search Diseases 119

Disease Name: lung

Disease Code System: ICD9

Search Reset

Show: 10

Disease Name	Disease Code	Disease Code System	Display Name	Select
Abscess of lung (513.0)	513.0	ICD9	Abscess of lung (513.0)	Select
Acquired absence of lung (V45.76)	V45.76	ICD9	Acquired absence of lung (V45.76)	Select
Acute edema of lung, unspecified (518.4)	518.4	ICD9	Acute edema of lung, unspecified (...)	Select
Agensis, hypoplasia, and dysplasia of lung, con...	748.5	ICD9	Agensis, hypoplasia, and dysplas...	Select
Amebic lung abscess (006.4)	006.4	ICD9	Amebic lung abscess (006.4)	Select
Artificial pneumothorax for collapse of lung (33.32)	33.32	ICD9	Artificial pneumothorax for collaps...	Select
Bacterial smear of specimen from trachea, bronc...	90.41	ICD9	Bacterial smear of specimen from t...	Select
Benign carcinoid tumor of the bronchus and lung...	209.61	ICD9	Benign carcinoid tumor of the bron...	Select
Benign neoplasm of bronchus and lung (212.3)	212.3	ICD9	Benign neoplasm of bronchus and ...	Select
Bilateral lung transplantation (33.52)	33.52	ICD9	Bilateral lung transplantation (33.52)	Select

Show: 10

7. Navigate to the disease/condition being studied, and click **Select**. Refer to [Working with Accrual Tables and Search Results](#). The system populates the **Study Subject Disease** field for you.

NATIONAL CANCER INSTITUTE
CTRF ACCRUAL

Accrual Registration Protocol Abs

Study Subject 1

Study Subject Birth Date: mm/yyyy

Study Subject Sex: *

Study Subject Race: *

Study Subject Ethnicity: *

Study Subject Country: United States

Study Subject Zip Code: *

Study Subject Disease Terminology: ICD9

Study Subject Disease: 513.0: Abscess of lung (513.0)

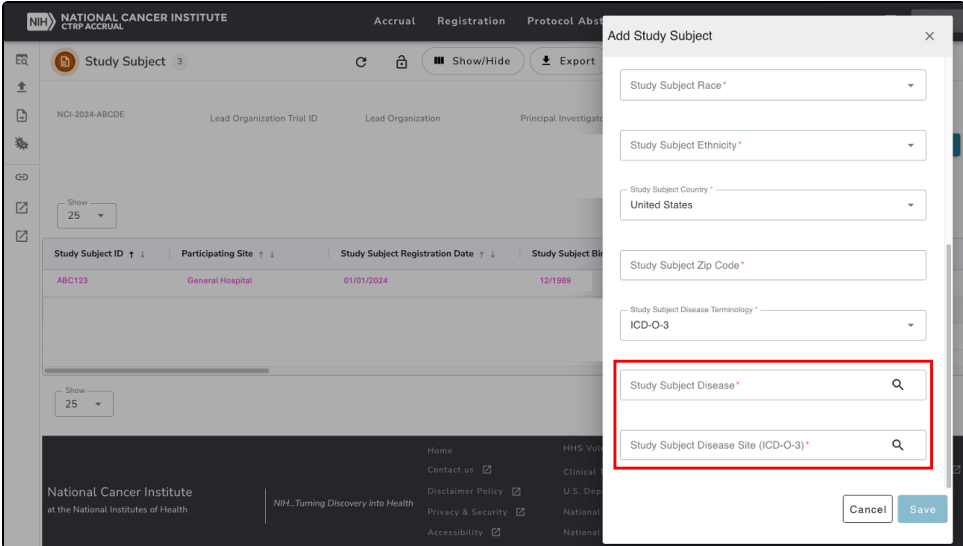
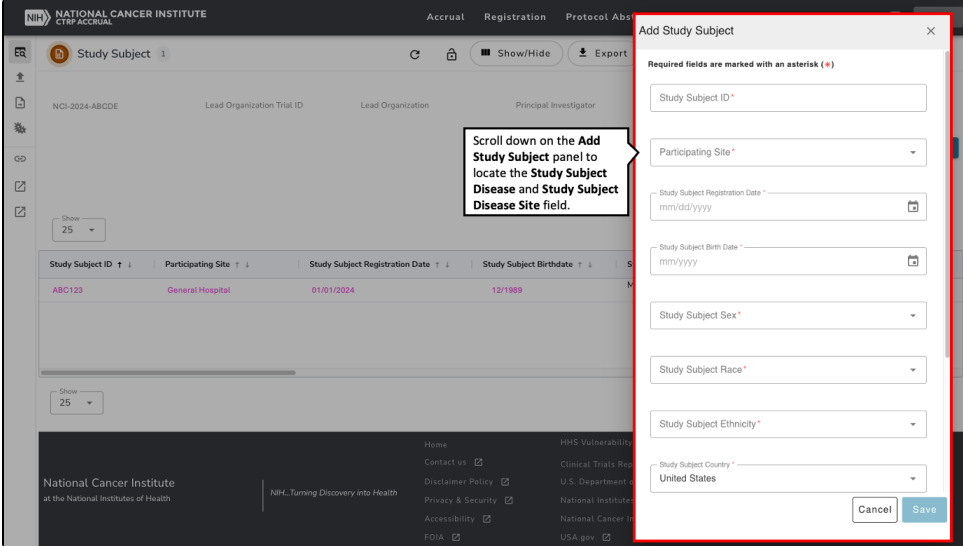
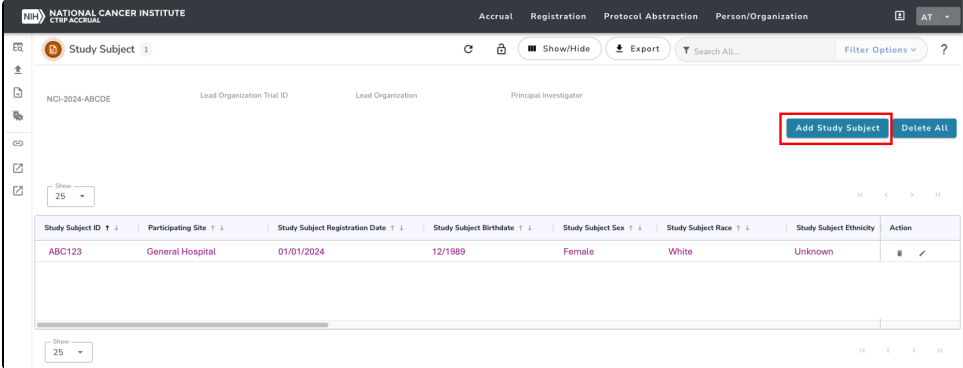
Cancel Save

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

For trials that use ICD-O-3 disease coding, select a site to associate with a study subject.

How to Search for Sites

1. Select the trial you want to work with by following instructions in [Searching for and Selecting Your Trials](#), and clicking the corresponding NCI Trial Identifier link.
2. Click **Add Study Subject**.
The Add Study Subject panel appears on the right-hand side of the page.



- To assign a site to the study subject, click the spyglass icon in the **Study Subject Disease Site** field. The Search Sites window appears.

Search Sites 0

Site Name Site Code Site Code System **ICD-O-3**

Show 10

Site Name ↑ ↓	Site Code ↑ ↓	Site Code System ↑ ↓	Display Name ↑ ↓	Select
No results to display.				

Show 10

- 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.

- Press **Enter**, or click **Search**. The system searches for the site in the database and returns a list of results.

Search Sites 6

Site Name Site Code Site Code System **ICD-O-3**

Show 10

Site Name ↑ ↓	Site Code ↑ ↓	Site Code System ↑ ↓	Display Name ↑ ↓	Select
BRONCHUS AND LUNG	C34	ICD-O-3	BRONCHUS AND LUNG	Select
Lower lobe, lung	C34.3	ICD-O-3	Lower lobe, lung	Select
Lung, NOS	C34.9	ICD-O-3	Lung, NOS	Select
Middle lobe, lung	C34.2	ICD-O-3	Middle lobe, lung	Select
Overlapping lesion of lung	C34.8	ICD-O-3	Overlapping lesion of lung	Select
Upper lobe, lung	C34.1	ICD-O-3	Upper lobe, lung	Select

Show 10

- Navigate to the site being studied, and click **Select**. Refer to [Working with Accrual Tables and Search Results](#). The system populates the Site field for you.

NATIONAL CANCER INSTITUTE
CTRP ACCRUAL

Study Subject 3

Study Subject Race*

Study Subject Ethnicity*

Study Subject Country*

Study Subject Zip Code*

Study Subject Disease Terminology*

Study Subject Disease*

Study Subject Disease Site (ICD-O-3)*



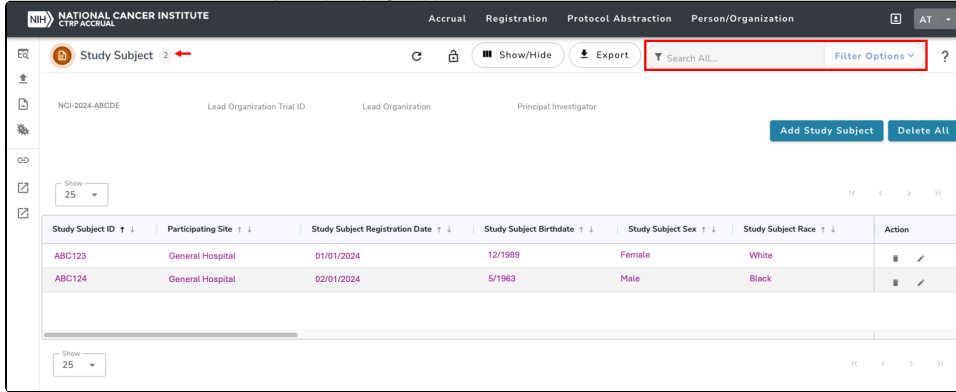
Please note that the ICD-O-3 disease code system requires both the disease code and disease site.

Searching for Study Subjects


You must select a trial before you can search for study subjects. For instructions, refer to [Searching for and Selecting Your Trials](#).

How to Search for Study Subjects

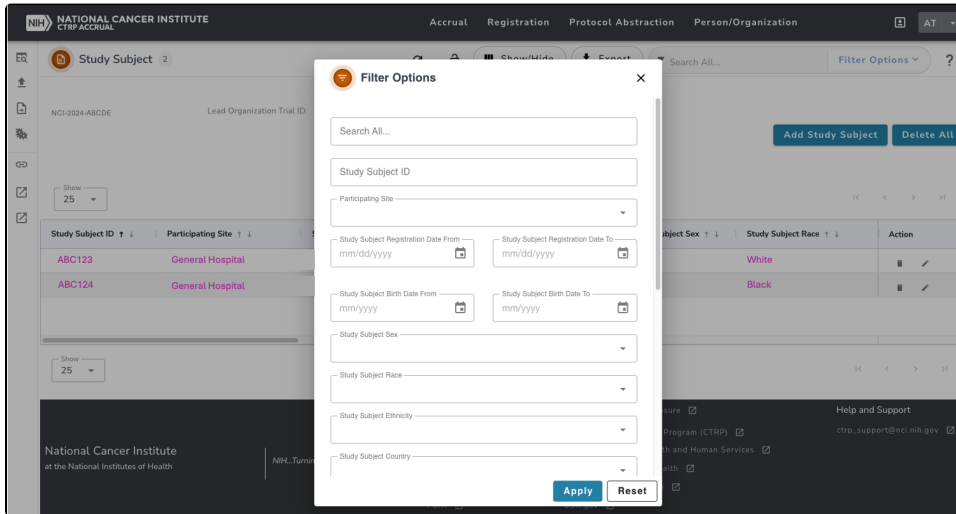
1. Select the trial you want to work with by following instructions in [Searching for and Selecting Your Trials](#), and clicking the corresponding NCI Trial Identifier link. The Search Study Subject page appears.



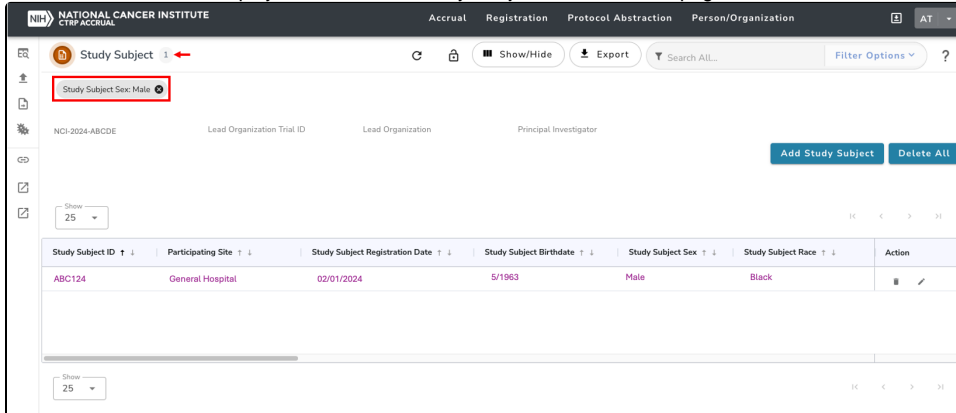
2. Type or select your search criteria from one or more of the fields provided.

 **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 **Apply** in Filter Options or hit **Enter** in the global keyword search box. Your search results are displayed in the List of Study Subjects section of the page.



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](#).

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 [Searching for and Selecting Your Trials](#), and clicking the corresponding NCI Trial Identifier link.
The Accrual Submissions page displays any accrual records that may have been submitted previously.
2. Locate 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 change the study subject record, click the **Edit** icon (pencil) in the Actions column, and follow the instructions in [Adding Study Subjects](#).

Study Subject ID	Participating Site	Study Subject Registration Date	Study Subject Birthdate	Study Subject Sex	Study Subject Race	Action
ABC123	General Hospital	01/01/2024	12/1989	Female	White	
ABC124	General Hospital	02/01/2024	5/1963	Male	Black	



Information about each study subject record can be found by scrolling horizontally within the records table. Demographic details and information regarding the record itself are displayed in each row.

Deleting Study Subjects

Deleting All Subjects From a Study

1. Click **Delete All**
2. Select a value from the **Reason** dialog box
3. Click **Yes, Continue to Delete**

The screenshot shows the 'Study Subject' page in the National Cancer Institute CTRP Accrual system. The page header includes 'NIH NATIONAL CANCER INSTITUTE CTRP ACCRUAL' and navigation tabs for 'Accrual', 'Registration', 'Protocol Abstraction', and 'Person/Organization'. The main content area displays a table with columns for 'Study Subject ID', 'Participating Site', 'Study Subject Registration Date', 'Study Subject Birthdate', 'Study Subject Sex', and 'Study Subject Race'. Two rows are visible: ABC123 (Female, White) and ABC124 (Male, Black). In the top right corner, there are two buttons: 'Add Study Subject' and 'Delete All'. The 'Delete All' button is highlighted with a red rectangular box.

NOTE: Be careful when deleting All Trial Study Subjects. Incorrectly deleted accrual data must be resubmitted by the center.

Deleting Individual Subjects From a Study

1. In the **Actions** column of the record you want to delete, click **Delete** (the trash can icon). A message appears, prompting you to confirm deletion of the study subject record.
2. Click **Yes, Continue to Delete**. The system will delete the study subject record that you selected.

The screenshot shows the 'Study Subject' page in the National Cancer Institute CTRP Accrual system, similar to the previous one. The table displays the same two rows: ABC123 and ABC124. In the 'Action' column for the second row (ABC124), there is a trash can icon. This icon is highlighted with a red rectangular box.

Working with Abbreviated Trials


This section describes how to record, update, and delete the total number of accruals (accrual count) associated with Abbreviated and Other clinical studies, via the web application. For instructions on reporting accrual data for Complete studies, refer to [Working with Complete Trial Accruals](#). For instructions on reporting accrual data via batch upload, refer to [Submitting Accrual Data Batch Files](#).

Pharmaceutical companies are not users of CTRP, therefore each participating site on an Abbreviated study must enter its own accrual count into CTRP. For Abbreviated studies, the lead organization is usually a pharmaceutical company or non-NCI Designated Cancer Center.

For instructions, refer to the following pages:

About Participating Site Accrual Counts

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

 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	<ul style="list-style-type: none"> 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. The user should correct the history so that the counts submitted are cumulative (not decreasing over time).

Deleting Participating Site Accrual Counts

How to Delete Site Subject Accrual Counts

1. Select the study you want to work with by following instructions in [Searching for and Selecting Your Trials](#), and clicking the corresponding NCI Trial Identifier link. The Participating Site Subject Accrual Count page appears.
2. In the **Actions** column of the site count record you want to delete, click **Delete** (the trash can icon).
3. A message will appear, **Subject Accrual Count deleted**, confirming deletion of Subject Accrual Count.

The screenshot shows the NIH National Cancer Institute CTSP Accrual interface. The page title is "Participating Site Subject Accrual Count". Below the title, there are navigation and utility buttons: Show/Hide, Export, Search ALL, and Filter Options. The main content area displays a table with the following columns: PO ID, Site Name, # of Subjects Enrolled, Cut-Off Date, Date Last Updated, and Action. A single record is visible with PO ID 1234567, Site Name Example Site Name, 1 subject enrolled, a cut-off date of 09/30/2017, and a last updated date of 06/21/2018. The Action column for this record contains three icons: a gear, a trash can, and a plus sign. The trash can icon is highlighted with a red box.

NOTE: If only one site has a history of reporting an accrual count on a study, the Delete icon will only delete the most recently reported count. The most recently reported count will display if a site on a study has a history of counts.

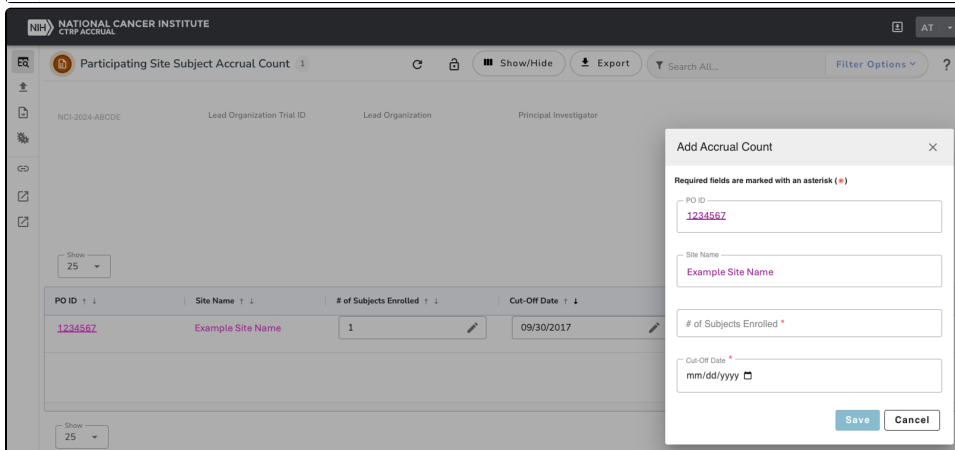
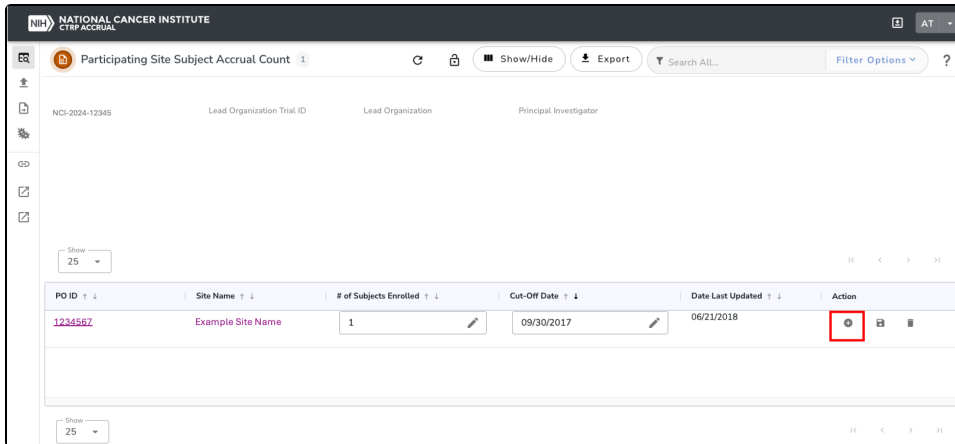
Recording and Updating Participating Site Accrual Counts

How to Record New Site Subject Accrual Counts

Note: The default accrual type for Complete Non-Interventional studies is Subject. However, if no accruals have been reported for this study, the default accrual reporting type can be changed to Summary accrual type. If accrual has been reported, then the following actions are required:

- Any previously reported accrual will need to be nullified prior to the change in accrual reporting type.
- An approval request will need to be submitted to the CTRO (NCICTRO@mail.nih.gov) to change the accrual reporting type to Summary.

1. Select the trial you want to work with by following instructions in [Searching for and Selecting Your Trials](#), and clicking the corresponding NCI Trial Identifier link. Ensure that the trial selected is a Summary accrual type. The Participating Site Subject Accrual Count page appears.



2. To record the accrual information for the first time, in the **Actions** column, click on the **Plus “+”** icon and the **Add Accrual Count** panel should appear.
3. In the **# of Subjects Enrolled** field, enter the number of subjects currently enrolled in studies at your site.
4. In the **Cut-Off Date** field, specify the date from which the cumulative accrual count was calculated. If you do not specify a cut-off date, the system will not allow you to save.
5. Click **Save**. A message "Accrual Count has been added" will appear indicating that the record has been updated successfully.
6. Designated Cancer Center users may view, add, edit or delete an entry. Clicking on the PO ID will allow the user to expand the most recent summary record and view the history of updates made to the accrual count/cutoff history records.

NATIONAL CANCER INSTITUTE
CTSP ACCRUAL

Participating Site Subject Accrual Count

Search All... Filter Options ?

NCI-2024-12345 Lead Organization Trial ID Lead Organization Principal Investigator

Show 25

PO ID	Site Name	# of Subjects Enrolled	Cut-Off Date	Date Last Updated	Action
1234567	Example Site Name	1	09/30/2017	06/21/2018	

Show 25

NATIONAL CANCER INSTITUTE
CTSP ACCRUAL

History

PO ID: 1234567 Site Name: Example Site Name

Show 25

# of Subjects Enrolled	Cut-Off Date	Date Last Updated	Action
1	04/11/2018	06/21/2018	
0	10/26/2017	06/21/2018	
1	10/26/2017	06/21/2018	
0	04/04/2017	06/21/2018	

Show 25

How to Update Site Subject Accrual Counts

1. If updating an existing accrual count record, click on the **Pencil** icon within the field you wish to update.

2. In the **Actions** column of the record you want to update, click **Save** (the floppy disk icon). A message "Accrual Count has been added" will appear indicating that the record has been updated successfully.

Guidelines/Notes on accrual records:

- The accrual should be cumulative and increasing in sequence (e.g., avoiding a scenario of 1, 3, 2).
- Do not enter more than one accrual submission value on the same date (e.g., only one value on one day).
- If you update accrual data in CTRP Accrual, it will not show up on your CTRP [DT4 report](#) until the next day.
- This capability applies to Abbreviated trials, for additional information refer to [Working with Abbreviated and Other Trial Accruals](#).

Working with Non-Interventional Trial Accruals

Abbreviated/Imported trials: Accrual is expected to be reported using the Summary Accrual type (this is the default accrual reporting type). Summary accrual is reported by each participating site. Summary level consists of only a cumulative accrual count per site. Centers can change the default accrual reporting type to Subject (which includes reporting of demographic data) or Partial Subject (which requires the reporting of only Study Subject ID, Registration Date and Participating Site data only) within the CTRP Accrual application as long as there is no accrual recorded for the trial record in CTRP. If accrual has been reported, the accruals will need to be nullified and an approval request will need to be submitted to the CTRO (NCICTRO@mail.nih.gov) to change the accrual reporting type.

Complete/Protocol trials: Accrual is expected to be reported at the Subject level (this is the default accrual reporting type.) Centers can change the default accrual reporting type to Partial Subject or Summary within the CTRP Accrual application, as long as there is no accrual recorded for the trial record in CTRP. If accrual has been reported, the accruals will need to be nullified and an approval request will need to be submitted to the CTRO (NCICTRO@mail.nih.gov) to change the accrual reporting type.

NOTE: Only one type of accrual reporting is allowed per study and only the CTRO can update the accrual type on a study once accrual has been reported.

If you need assistance updating the default accrual type within the CTRP Accrual application or updating the accrual type once accrual has been reported, please contact the CTRO (NCICTRO@mail.nih.gov).

For instructions, refer to the following pages:

Submitting Accruals at the Subject Level for Non-Interventional Trials

How to report accruals at the Subject Level for Non-Interventional Studies

1. Select the study you want to work with by following instructions in [Searching for and Selecting Your Trials](#), and clicking the corresponding NCI Trial Identifier link. The Search Study Subject/List of Study Subjects page appears.
2. The default accrual type for Complete Non-Interventional studies is Subject level. However, if no accruals have been reported for this study, the default accrual reporting type can be changed to the Summary or Partial Subject level. Once accrual has been reported, a request will need to be submitted to the CTRO (NCICTRO@mail.nih.gov) to change the accrual reporting type. To report accrual counts at the Summary level, follow the instructions in [Submitting Accruals at the Summary Level for Non-Interventional Trials](#). Otherwise, follow the instructions in [Adding Study Subjects](#).

Submitting Accruals at the Summary Level for Non-Interventional Trials

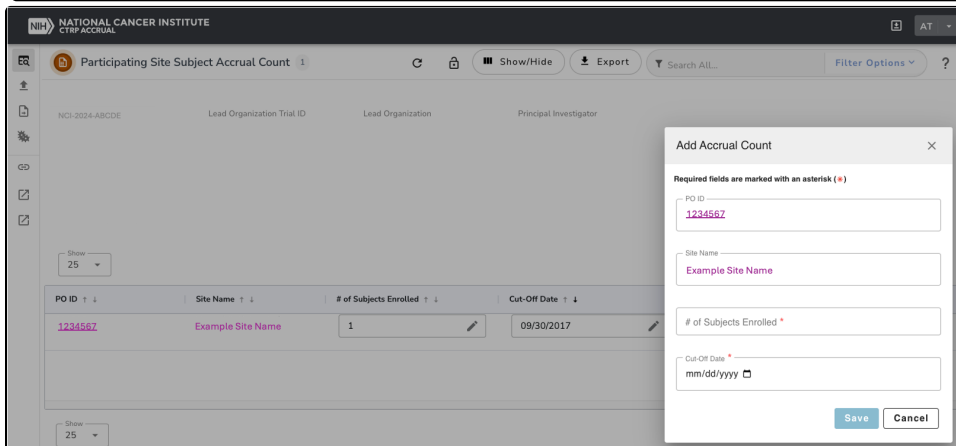
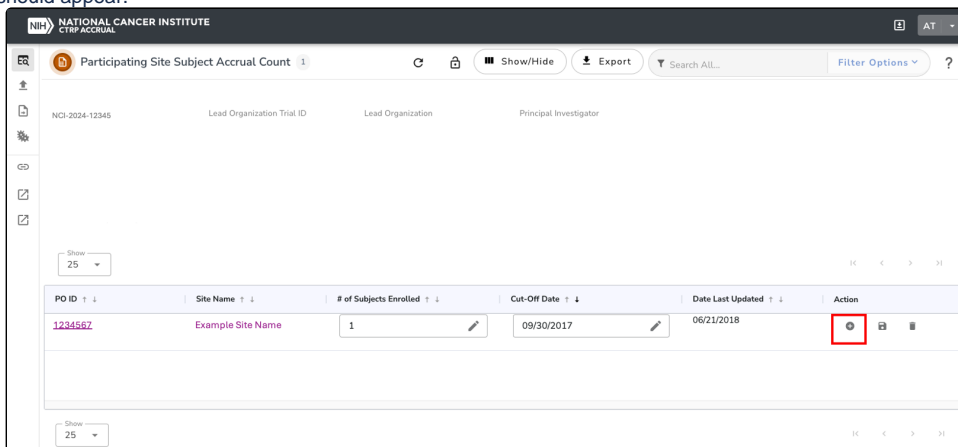
Each participating site can report/update the number of patients accrued to date per trial.

Note: The default accrual type for Complete Non-Interventional studies is Subject. However, if no accruals have been reported for this study, the default accrual reporting type can be changed to Summary accrual type. If accrual has been reported, then the following actions are required:

- Any previously reported accrual will need to be nullified prior to the change in accrual reporting type.
- An approval request will need to be submitted to the CTRO (NCICTRO@mail.nih.gov) to change the accrual reporting type to Summary.

How to Report Accruals at the Summary Level for Non-Interventional Studies

1. Select the study you want to work with by following instructions in [Searching for and Selecting Your Trials](#), and clicking the corresponding NCI Trial Identifier link. The Participating Site Subject Accrual Count page appears.
2. In the **Actions** column of the site you want to add accrual information for, click the **Plus "+"** icon, this will open the **Add Accrual Count** panel should appear.



3. In the **# of Subjects Enrolled** field(s), enter the **total cumulative** number of subjects currently enrolled in this study at your site.
4. In the **Cut-Off Date** field, specify the date from which the cumulative accrual count was calculated. If you do not specify a cut-off date, the system will not allow you to save.

5. Click **Save**. A message "Accrual Count has been added" will appear indicating that the record has been updated successfully.

The screenshot shows the 'Participating Site Subject Accrual Count' interface. At the top, there are navigation options like 'Show/Hide', 'Export', and a search bar. Below this is a table with the following columns: PO ID, Site Name, # of Subjects Enrolled, Cut-Off Date, Date Last Updated, and Action. A single row is visible with the following data: PO ID: 1234567, Site Name: Example Site Name, # of Subjects Enrolled: 1, Cut-Off Date: 09/30/2017, Date Last Updated: 06/21/2018. Three callout boxes are present: one pointing to the '1' in the '# of Subjects Enrolled' column with the text 'Enter the total cumulative number of subjects currently enrolled in this study.'; one pointing to '09/30/2017' in the 'Cut-Off Date' column with the text 'Enter the Cut-Off Date when the cumulative number of subjects was calculated.'; and one pointing to the floppy disk icon in the 'Action' column with the text 'Click the floppy disk icon to save your on screen field values.'

PO ID	Site Name	# of Subjects Enrolled	Cut-Off Date	Date Last Updated	Action
1234567	Example Site Name	1	09/30/2017	06/21/2018	[Floppy Disk Icon]

Working with Prior Accrual Submission Records

The CTRP system maintains records of all prior accrual submissions on a trial-by-trial basis. Additionally, the system records the method that was used to submit the information to the CTRP. 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.

This page tree describes how to perform these tasks:

About Accessing Trials with Prior Accruals

The system displays accrual records according to your organization affiliation within CTRP and whether your organization is the Lead Organization or a Participating Site on any given trial.

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 accruals for your site <i>or</i> any organization affiliation member sites within CTRP	Participating Site	Site submissions and accruals submitted by organization family member sites
Access to trial for own site and other sites that are <i>not</i> 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 accruals for your site <i>or</i> any organization affiliation member sites within CTRP	Participating Site	Site submissions and accruals submitted by organization family member sites
Access to trial for own site and other sites that are <i>not</i> members of the organization family of user's affiliated organization	Participating Site	Submissions for that trial only

Reviewing and Updating Prior Accrual Submissions

Guidelines/Notes on accrual records:

- The accrual should be cumulative and increasing in sequence (e.g., avoiding a scenario of 1, 3, 2).
- Do not enter more than one accrual submission value on the same date (e.g., only one value on one day).
- If you update accrual data in CTRP Accrual, it will not show up on your CTRP [DT4 report](#) until the next day.
- This capability applies to Abbreviated trials, for additional information refer to [Working with Abbreviated and Other Trial Accruals](#).

Downloading Accrual Batch Data Files

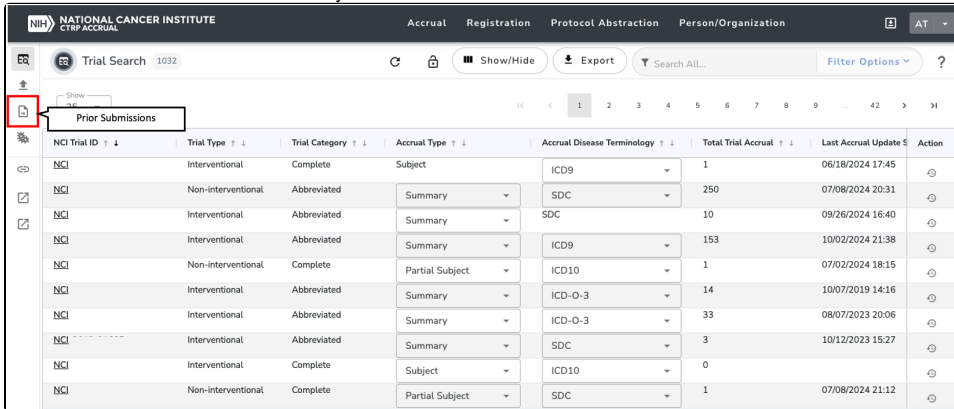
 Only the ZIP file submitter can download ZIP files from the Prior Submissions page.

From the Prior Submissions page, you can download previously submitted accrual files (.txt or .zip) that were uploaded via the Batch Upload feature. For information about this feature, refer to [Submitting Accrual Data Batch Files](#).

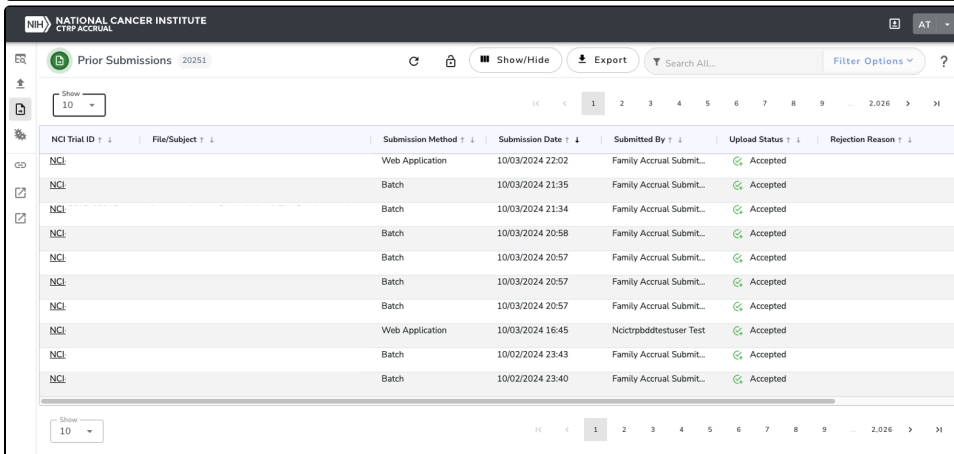
All trials to which you have been granted access, per the rules described in [About Accessing Trials with Prior Accruals](#), are listed automatically when you open the Prior Submissions page. You can limit the list of prior submissions that are displayed to a given date or range of dates.

How to Download Submitted Subject Accrual Files

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

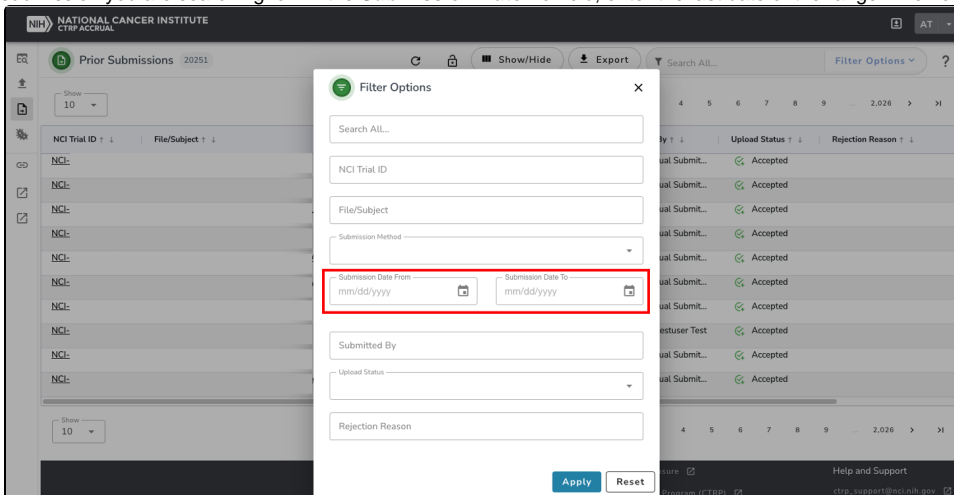


NCI Trial ID	Trial Type	Trial Category	Accrual Type	Accrual Disease Terminology	Total Trial Accrual	Last Accrual Update	Action
NCI	Interventional	Complete	Subject	ICD9	1	06/18/2024 17:45	
NCI	Non-interventional	Abbreviated	Summary	SDC	250	07/08/2024 20:31	
NCI	Interventional	Abbreviated	Summary	SDC	10	09/26/2024 16:40	
NCI	Interventional	Abbreviated	Summary	ICD9	153	10/02/2024 21:38	
NCI	Non-interventional	Complete	Partial Subject	ICD10	1	07/02/2024 18:15	
NCI	Interventional	Abbreviated	Summary	ICD-O-3	14	10/07/2019 14:16	
NCI	Interventional	Abbreviated	Summary	ICD-O-3	33	08/07/2023 20:06	
NCI	Interventional	Abbreviated	Summary	SDC	3	10/12/2023 15:27	
NCI	Interventional	Complete	Subject	ICD10	0		
NCI	Non-interventional	Complete	Partial Subject	SDC	1	07/08/2024 21:12	



NCI Trial ID	File/Subject	Submission Method	Submission Date	Submitted By	Upload Status	Rejection Reason
NCI		Web Application	10/03/2024 22:02	Family Accrual Submit...	Accepted	
NCI		Batch	10/03/2024 21:35	Family Accrual Submit...	Accepted	
NCI		Batch	10/03/2024 21:34	Family Accrual Submit...	Accepted	
NCI		Batch	10/03/2024 20:58	Family Accrual Submit...	Accepted	
NCI		Batch	10/03/2024 20:57	Family Accrual Submit...	Accepted	
NCI		Batch	10/03/2024 20:57	Family Accrual Submit...	Accepted	
NCI		Batch	10/03/2024 20:57	Family Accrual Submit...	Accepted	
NCI		Web Application	10/03/2024 16:45	Ncitrpbdfstester Test	Accepted	
NCI		Batch	10/02/2024 23:43	Family Accrual Submit...	Accepted	
NCI		Batch	10/02/2024 23:40	Family Accrual Submit...	Accepted	

2. To limit the list of submissions to a date, or range of dates, in the **Filter Options** pop-up modal, enter the "to" and "from" date range of the submission you are searching for. In the **Submission Date To** field, enter the last date of the range. Then click **Apply**.



The Filter Options modal is open, showing the following fields:

- Search ALL
- NCI Trial ID
- File/Subject
- Submission Method
- Submission Date From: mm/dd/yyyy
- Submission Date To: mm/dd/yyyy
- Submitted By
- Upload Status
- Rejection Reason

Buttons: Apply, Reset

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




Tip: To download a prior submissions report, follow steps described in [Downloading Accrual Count Reports](#) to export a CSV or Excel file.

Submitting Accrual Data Batch Files

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. For instructions, refer to [Requesting Permission to Submit Accrual Data](#) and [Preparing Accrual Batch Files](#).

For instructions, refer to the following pages:

Preparing CTRP Accrual Batch Files Introduction

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

Instructions are provided below for preparing batch files for both Complete and Abbreviated studies.

- 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* study. 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* Studies.
- Accruals for National studies are reported directly to CTRP from CTEP and/or DCP.



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.



Initial Accrual Batch File Submission:

- The initial accrual batch file reported to CTRP will add accrual records for either Subject, Partial Subject or Summary level accrual based on the default accrual type set on the study.

Subsequent Accrual Batch File Submissions:

- **For Subject or Partial Subject accrual:** Subsequent accrual batch file uploads will update data as appropriate.
 - If there are duplicate records (all fields are the same) within the batch file being reported, the file will not be loaded and a notification will be sent to the user asking for the duplicate record(s) to be removed and the file resubmitted.
 - If an element is changed, for example Study Subject Ethnicity, then the record is considered an update, not a duplicate.
- **For Summary accrual:** Subsequent accrual batch file uploads will replace previously reported/uploaded accrual data. Batch uploads will not append data; cumulative accrual data must be uploaded with each accrual file reported to CTRP.
 - **Please ensure that your CTRP accrual batch file contains all cumulative accrual data for each participating site to date before uploading to CTRP. Failure to include cumulative accrual data will result in erasing your accrual history.**

To download a copy of the of the CTRP Accrual Batch File Tool (includes instructions), go to: [CTRP Accrual Batch File Tool](#)

After you have prepared a batch file, you can upload it to CTRP. For instructions on reporting batch files, see: [Uploading Accrual Batch Files](#)

Complete Study Example Batch File - Subject accrual

```
"COLLECTIONS", "NCI-2018-03045",,,,,,,,,,
"PATIENTS", "NCI-2018-03045", "SU00100", "22201", "US", "199001", "Male", "Hispanic or Latino", "Other", "20190906", ,
7434",,,,,,,,,, "8543/3;C50.4", ,
"PATIENT_RACES", "NCI-2018-03045", "SU00100", "White"
"PATIENT_RACES", "NCI-2018-03045", "SU00100", "Unknown"
```

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

Complete Study Example Batch File - Partial Subject accrual

```
COLLECTIONS, "NCI-2018-03045",,,,,,,,,,
PATIENTS, "NCI-2018-03045", "L1", , , , , "20190101", , "WQ456", , , , ,
PATIENTS, "NCI-2018-03045", "L2", , , , , "20110809", , "WQ456", , , , ,
```

For Summary accrual (typically provided for Abbreviated/Imported - e.g., Industrial study), the following is an example batch file for one study with two participating sites (Sites 1 and 2) supporting monthly accrual updates. Site 1 and 2 in the below example map to "PO ID" (unique to each Participating Site).

Note: Create and report one study per batch load. You can also include individual batch load files in one zip.

Centers have the option to provide quarterly or monthly accrual from studystart date to present. However, centers can provide their accrual with their specified Cut-Off-Date in the batch load file. Note: the Cut-Off Date represents the date when accrual changed (displayed in the example below).

Abbreviated/Imported (e.g., Industrial Studies) Example Batch File - Monthly

```
COLLECTIONS,<Study_Identifier>,,,,,,  
  
"ACCRUAL_COUNT","NCI-2017-00225","Site 1","2","20170630"  
"ACCRUAL_COUNT","NCI-2017-00225","Site 1","2","20170731"  
"ACCRUAL_COUNT","NCI-2017-00225","Site 1","4","20170831"  
"ACCRUAL_COUNT","NCI-2017-00225","Site 1","5","20170930"  
"ACCRUAL_COUNT","NCI-2017-00225","Site 1","6","20171031"  
"ACCRUAL_COUNT","NCI-2017-00225","Site 1","10","20171130"  
"ACCRUAL_COUNT","NCI-2017-00225","Site 1","12","20171231"  
"ACCRUAL_COUNT","NCI-2017-00225","Site 1","15","20180131"  
"ACCRUAL_COUNT","NCI-2017-00225","Site 1","15","20180228"  
"ACCRUAL_COUNT","NCI-2017-00225","Site 1","18","20180331"  
"ACCRUAL_COUNT","NCI-2017-00225","Site 1","18","20180430"  
"ACCRUAL_COUNT","NCI-2017-00225","Site 1","18","20180531"  
"ACCRUAL_COUNT","NCI-2017-00225","Site 1","21","20180630"  
"ACCRUAL_COUNT","NCI-2017-00225","Site 1","21","20180731"  
"ACCRUAL_COUNT","NCI-2017-00225","Site 1","25","20180831"  
  
"ACCRUAL_COUNT","NCI-2017-00225","Site 2","1","20170630"  
"ACCRUAL_COUNT","NCI-2017-00225","Site 2","1","20170731"  
"ACCRUAL_COUNT","NCI-2017-00225","Site 2","5","20170831"  
"ACCRUAL_COUNT","NCI-2017-00225","Site 2","5","20170930"  
"ACCRUAL_COUNT","NCI-2017-00225","Site 2","8","20171031"  
"ACCRUAL_COUNT","NCI-2017-00225","Site 2","9","20171130"  
"ACCRUAL_COUNT","NCI-2017-00225","Site 2","13","20171231"  
"ACCRUAL_COUNT","NCI-2017-00225","Site 2","13","20180131"  
"ACCRUAL_COUNT","NCI-2017-00225","Site 2","14","20180228"  
"ACCRUAL_COUNT","NCI-2017-00225","Site 2","18","20180331"  
"ACCRUAL_COUNT","NCI-2017-00225","Site 2","22","20180430"  
"ACCRUAL_COUNT","NCI-2017-00225","Site 2","30","20180531"  
"ACCRUAL_COUNT","NCI-2017-00225","Site 2","31","20180630"  
"ACCRUAL_COUNT","NCI-2017-00225","Site 2","32","20180731"  
"ACCRUAL_COUNT","NCI-2017-00225","Site 2","33","20180831"
```

Abbreviated/Imported (e.g., Industrial Studies) Example Batch File - Accrual Changes

```
COLLECTIONS,<Study_Identifier>,,,,,,  
  
"ACCRUAL_COUNT","NCI-2016-00225","Site 1","1","20170215"  
"ACCRUAL_COUNT","NCI-2016-00225","Site 1","2","20170820"  
"ACCRUAL_COUNT","NCI-2016-00225","Site 1","4","20180331"  
"ACCRUAL_COUNT","NCI-2016-00225","Site 1","6","20180910"  
"ACCRUAL_COUNT","NCI-2016-00225","Site 1","10","20181202"  
  
"ACCRUAL_COUNT","NCI-2016-00225","Site 2","2","20170128"  
"ACCRUAL_COUNT","NCI-2016-00225","Site 2","4","20170710"  
"ACCRUAL_COUNT","NCI-2016-00225","Site 2","5","20170825"  
"ACCRUAL_COUNT","NCI-2016-00225","Site 2","7","20171031"  
"ACCRUAL_COUNT","NCI-2016-00225","Site 2","9","20171122"  
"ACCRUAL_COUNT","NCI-2016-00225","Site 2","12","20180107"
```

For additional information, refer to the following pages:

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:

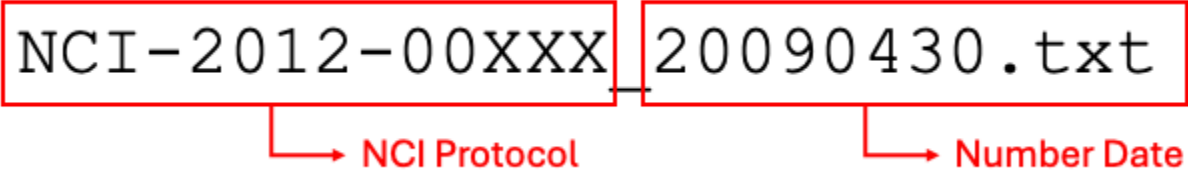
Comma-Delimited CTRP Data Values
AUTOMOBILE , ABC-123456 , Ford , , , 1965

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



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

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](#).

For instructions, refer to the following pages:

Complete Trial Tables

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

Table Name	Number of The Format for CTRP 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

For a list of all The Format for CTRP fields for these tables, refer to Comparison of CTRP and The Format for CTRP Accrual Data Elements.

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>,<Birth_Date>,<Sex>,<Ethnicity>,<Subject_Registration_Date>,<Study_Site_Identifier>,<Subject_Disease_Code>,,
PATIENT_RACES,<Study_Identifier>,<Study_Subject_Identifier>,<Race>
```

Note: For additional information on the Data Elements required for Complete studies, go to [Accrual Data Elements with CTRP-Accepted Values for Complete Trials](#).

The following is an example of a Subject level accrual 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", is used instead of a CDUS/OPEN accepted numeric value of "1".

Example Batch File

```
COLLECTIONS,"NCI-2011-03861",,,,,,1
PATIENTS,"NCI-2011-03861",87322289999999,84124,US,196311,Male,Unknown,,20060809,,149280,,,,,238.7,,
PATIENTS,"NCI-2011-03861",8732228,84124,US,196311,Male,Unknown,,20060809,,149280,,,,,238.7,,
PATIENTS,"NCI-2011-03861",1,84124,US,196311,Male,Unknown,,20060809,,149280,,,,,185.0,,
"PATIENT_RACES","NCI-2011-03861",8732228,White
"PATIENT_RACES","NCI-2011-03861",87322289999999,Asian
"PATIENT_RACES","NCI-2011-03861",1,White
```

The following is another example of a Subject level accrual batch file, accepted by CTRP, for the same study but using CDUS/OPEN 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",87322289999999,84124,US,196311,1,9,,20060809,,149280,,,,,238.7,,
PATIENTS,"NCI-2011-03861",8732228,84124,US,196311,1,9,,20060809,,149280,,,,,238.7,,
PATIENTS,"NCI-2011-03861",1,84124,US,196311,1,9,,20060809,,149280,,,,,185.0,,
"PATIENT_RACES","NCI-2011-03861",8732228,01
"PATIENT_RACES","NCI-2011-03861",87322289999999,05
"PATIENT_RACES","NCI-2011-03861",1,01
```

The following is an example of a Partial level accrual batch file for a study that has two subjects, and only reporting the minimum data fields required for a Partial level accrual batch file (other accrual data fields are optional)

Example Batch File

```
"COLLECTIONS","NCI-2018-03045",,,,,,
"PATIENTS","NCI-2018-03045","L1",,,,,,"20190101",,"WQ456",,,,,,
"PATIENTS","NCI-2018-03045","L2",,,,,,"20110908",,"WQ456",,,,,,
```


Complete Trial Record Data Field Requirements

The table linked in this section contains detailed information about each of the data elements included in the Batch Upload file. The Format for CTRP Accepted Values are provided to show differences in case your system is already producing the Format for CTRP file. In most cases, both CTRP and The Format for CTRP values are accepted.

For field requirements, refer to the following pages:

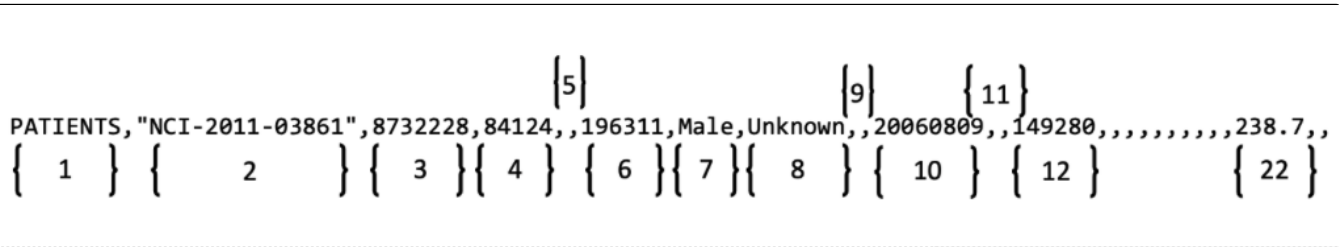
Complete Trial Record Data Field Formats

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	Sex (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)

i 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.



i 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.
- The ninth field position (9) is null (blank) because it (Payment Method) is no longer a field that can be inputted.
- The eleventh field position (11) is null (blank) because it (Registering Group Identifier) is no longer a field that can be inputted.



Footnote for Subject Disease Code (22)

1. For trials using ICD-O-3 terminology, use this position for Site and Histology Codes. The Site and Histology codes should be separated by a semicolon (;). Example given: 8543/3;C50.4

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](#).

Note: The new submission for a trial will completely REPLACE the previous submission (count history) of this trial. In order to maintain the count history, the user will need to attach the previous submissions in the same batch file.

For instructions, refer to the following pages:

Abbreviated Trial Tables

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

Table Name	Number of The Format for CTRP 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	(TBD: 0 or 1)	4	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.

To download a copy of the of the CTRP Accrual Batch File Tool (includes instructions), go to:

[CTRP Accrual Batch File Tool](#)

For Summary Level Accrual (typically provided for Abbreviated/Imported - e.g., Industrial trials), the following is an example batch file for one trial with two participating sites supporting monthly accrual updates. Site 1 and 2 in the below example map to "PO ID" (unique to each Participating Site).

Note: Submit one trial per batch load. You can also include individual batch load files in one zip.

Example Batch File

```
COLLECTIONS,<Study_Identifier>,,,,,,
"ACCRUAL_COUNT","NCI-2017-00225","Site 1","2","20170630"
"ACCRUAL_COUNT","NCI-2017-00225","Site 1","2","20170731"
"ACCRUAL_COUNT","NCI-2017-00225","Site 1","4","20170831"
"ACCRUAL_COUNT","NCI-2017-00225","Site 1","5","20170930"
"ACCRUAL_COUNT","NCI-2017-00225","Site 1","6","20171031"
"ACCRUAL_COUNT","NCI-2017-00225","Site 1","10","20171130"
"ACCRUAL_COUNT","NCI-2017-00225","Site 1","12","20171231"
"ACCRUAL_COUNT","NCI-2017-00225","Site 1","15","20180131"
"ACCRUAL_COUNT","NCI-2017-00225","Site 1","15","20180228"
"ACCRUAL_COUNT","NCI-2017-00225","Site 1","18","20180331"
"ACCRUAL_COUNT","NCI-2017-00225","Site 1","18","20180430"
"ACCRUAL_COUNT","NCI-2017-00225","Site 1","18","20180531"
"ACCRUAL_COUNT","NCI-2017-00225","Site 1","21","20180630"
"ACCRUAL_COUNT","NCI-2017-00225","Site 1","21","20180731"
"ACCRUAL_COUNT","NCI-2017-00225","Site 1","25","20180831"
"ACCRUAL_COUNT","NCI-2017-00225","Site 2","1","20170630"
"ACCRUAL_COUNT","NCI-2017-00225","Site 2","1","20170731"
"ACCRUAL_COUNT","NCI-2017-00225","Site 2","5","20170831"
"ACCRUAL_COUNT","NCI-2017-00225","Site 2","5","20170930"
"ACCRUAL_COUNT","NCI-2017-00225","Site 2","8","20171031"
"ACCRUAL_COUNT","NCI-2017-00225","Site 2","9","20171130"
"ACCRUAL_COUNT","NCI-2017-00225","Site 2","13","20171231"
"ACCRUAL_COUNT","NCI-2017-00225","Site 2","13","20180131"
"ACCRUAL_COUNT","NCI-2017-00225","Site 2","14","20180228"
"ACCRUAL_COUNT","NCI-2017-00225","Site 2","18","20180331"
"ACCRUAL_COUNT","NCI-2017-00225","Site 2","22","20180430"
"ACCRUAL_COUNT","NCI-2017-00225","Site 2","30","20180531"
"ACCRUAL_COUNT","NCI-2017-00225","Site 2","31","20180630"
"ACCRUAL_COUNT","NCI-2017-00225","Site 2","32","20180731"
"ACCRUAL_COUNT","NCI-2017-00225","Site 2","33","20180831"
```



Special Characters

If you include any of the following characters in a value, enclose the field with double quotes:

! " # \$ % & ' () * + , - . / : ; < > = ? @ [] \ ^ _ { } | ~

If you enclose a field with double quotes (as in "NCI-2012-00225"), CTRP interprets the string inside the quote exactly as presented. If the field does not contain any special characters, the quote marks are optional.


Abbreviated Trial Record Data Field Requirements

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

For field requirements, refer to the following pages:

Abbreviated Trial Data Field Requirements

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

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

Uploading Accrual Batch Files

Note: The new submission for a trial will completely REPLACE the previous submission (count history) of this trial. In order to maintain the count history, the user will need to attach the previous submissions in the same batch file.

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 locks you out after three unsuccessful attempts to log in within 24 hours. In the event that you have been locked out of your account, contact us at ctrp_support@nih.gov. If you have forgotten your password, or if you want to reset it for any reason, refer to [Resetting Your Password](#).

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.



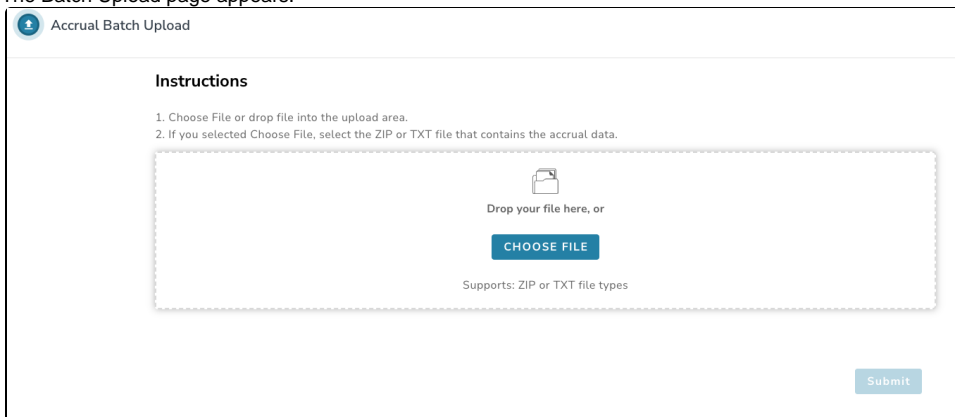
The batch upload template currently does NOT provide a way to enter accrual disease code terminology; instead, the default value of SDC is used.



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 left-hand navigation menu, 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.


A subject is duplicate if


1. There is already an accrual with same subject id on the same PS for a trial.
2. If following attributes (subject id, dob, sex, ethnicity) match for a subject on any other PS on the trial (not including the PS accrual is added to).

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](#).

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 resubmit.

Downloading Accrual Count Reports

This section provides instructions for downloading a report that includes all trials and all accrual reported by the center for those trials. This report can be filtered by Complete trials, Abbreviated trials, or both. For *Complete* trials, the report includes accrual counts reported by the lead organization's cancer center. For *Abbreviated* trials, the report includes accrual counts from participating sites from the cancer center.

i 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. Select the study/studies you want to work with by following instructions in [Searching for and Selecting Your Trials](#).

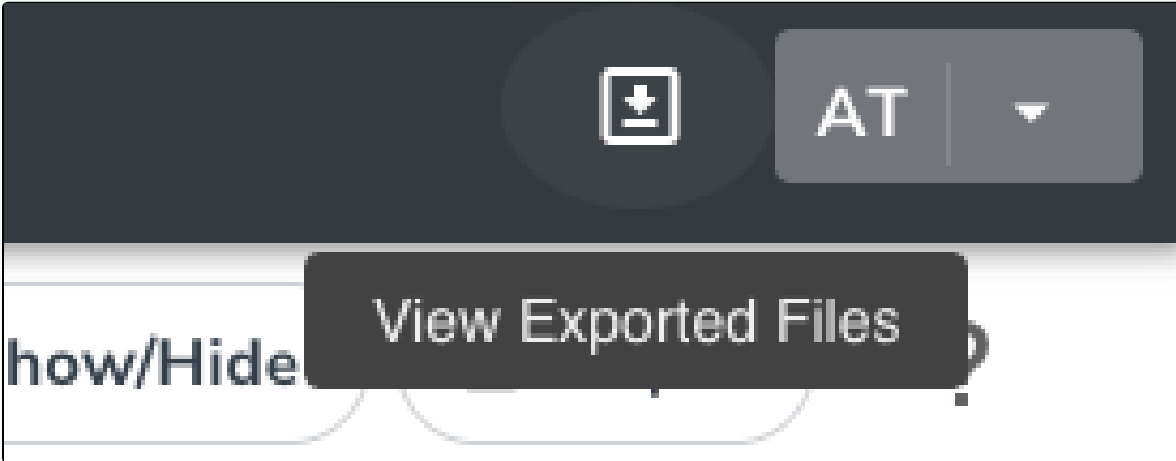
The top screenshot shows the 'National Cancer Institute CTRP ACCRUAL' interface. A table lists trials with columns for NCI Trial ID, Trial Type, Trial Category, Accrual Type, Accrual Disease Terminology, Total Trial Accrual, and Last Accrual Update. An 'Export' button is highlighted with a red box and a callout 'To download a report'. A 'View Exported Files' button is also visible.

The bottom screenshot shows the 'Export Trials' modal. It has a 'File Name' field with a red box and 'Custom file name' text. Under 'File Format', 'Export data in Excel format' is selected. Under 'Column Options', 'Export data from all columns' is selected. A checkbox for 'Apply Download: Yes' is checked and highlighted with a red box. A callout 'To download a file in the background' points to the 'Start Export' button.

2. Click **Export** to launch a pop-up modal.
3. Select **Excel** format to download the report as an Excel spreadsheet. Select **CSV** format to download a comma-separated-value text file.
4. Select **Export data from visible columns** to download the report based on the Show/Hide selection(s). Select **Export data from all columns** to disregard the Show/Hide selection.
5. Click **Start Export** to download report.

✓ Above the **Start Export** button in the pop-up modal, you will see an **Auto Download** toggle.

- If Auto Download is set to "Yes", the file will export immediately in your browser's downloads.
 - This is recommended for smaller data sets.
- If Auto Download is set to "No", the file will export in the background. Once export is complete, the file can be downloaded from the **View Exported Files** icon.
 - This is recommended for larger data sets.



You can download exported files here prior to them expiring. A file will expire *12 hours after* export is initiated.

File Name ↑ ↓	Date Created ↑ ↓	Date Expires ↑ ↓	Action
Test_Export.Csv	12/04/2024 19:14	12/05/2024 07:14	

Annotations in the table:

- File Name entered on Export Trials pop-up modal
- Date and time when the file is exported
- Date and time the file will auto delete
- Delete file

Managing Your CTRP Account

The following pages (in the [NCI CTRP Registration User Guide](#)) provide instructions for modifying your CTRP account.

Working with Accrual Tables and Search Results

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 Show/Hide . 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 All... 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 top of the table, click Export to export the search results to a comma-separated file or Excel to export to a file in Microsoft Excel format.

The screenshot shows the National Cancer Institute (NCI) Accrual Search Results interface. The top navigation bar includes the NCI logo, 'NATIONAL CANCER INSTITUTE CTRP ACCRUAL', and a search bar. Below the search bar, there are several controls: 'Refresh trials', 'Lock/unlock header row', 'Show/Hide', 'Export', and a search field with 'Filter Options'. A 'Show' selector is set to '25'. The main table displays search results with columns for NCI Trial ID, Trial Type, Trial Category, Accrual Type, Accrual Disease Term, and Accrual Count. The table is annotated with callouts: 'Select the number of records you want to display' points to the 'Show' selector; 'Select the sort order' points to a column header; 'Go to a specific page' points to a page number in the pagination; 'Go to the next page' and 'Go to the last page' point to navigation arrows; 'Disease code change indicator' points to a dropdown menu in the 'Accrual Disease Term' column; and 'View a specific trial's prior submissions' points to a circular icon in the rightmost column.



A restricted indicator will display in the NCI Trial ID column on the **Trial Search** page for trials with limited access.

NCI Trial ID ↑ ↓		NCT Trial ID ↑ ↓
<u>NCI-</u>	Restricted	<u>NCT</u>
<u>NCI-</u>	Restricted	<u>NCT</u>
<u>NCI-</u>	Restricted	<u>NCT</u>

Upon clicking the ID to view a trial's accrual on the **Study Subject** page, the restricted indicator will display and all the add, edit, and delete buttons are disabled.

Study Subject 1

Show/Hide
Export
Search ALL...
Filter Options

NCI-	Restricted	Lead Organization Trial ID	Lead Organization	Principal Investigator	
					Add Study Subject Delete

Show 25

Study Subject ID ↑ ↓	Participating Site ↑ ↓	Study Subject Registration Date ↑ ↓	Study Subject Birthdate ↑ ↓	Study Subject Sex ↑ ↓	Study Subject Race ↑ ↓	Action
CTRP123	Test Participating Site	01/01/2020	12/1998	Male	Asian	



For additional instructions, refer to [Filtering Accrual Search Results](#).

Filtering Accrual Search Results

To filter the records or search results, you can either use the **Search All** text box or the **Filters Options** pop-up menu.

The amount of records this user currently has access to *before* searching and filtering.

Users can search by keywords when they click into **Search All** text box or apply **filters**.

NCI Trial ID	Trial Type	Trial Category	Accrual Type	Accrual Disease Terminology	Total Trial Accrual	Last Accrual Update	Action
NCI	Interventional	Complete	Subject	ICD9	1	06/18/2024 17:45	
NCI	Non-interventional	Abbreviated	Summary	SDC	250	07/08/2024 20:31	
NCI	Interventional	Abbreviated	Summary	SDC	10	09/26/2024 16:40	
NCI	Interventional	Abbreviated	Summary	ICD9	153	10/02/2024 21:38	
NCI	Non-interventional	Complete	Partial Subject	ICD10	1	07/02/2024 18:15	
NCI	Interventional	Abbreviated	Summary	ICD-O-3	14	10/07/2019 14:16	
NCI	Interventional	Abbreviated	Summary	ICD-O-3	33	08/07/2023 20:06	
NCI-2019-01685	Interventional	Abbreviated	Summary	SDC	3	10/12/2023 15:27	
NCI-2018-01474	Interventional	Complete	Subject	ICD10	0		
NCI-2017-00612	Non-interventional	Complete	Partial Subject	SDC	1	07/08/2024 21:12	

Type one or more characters contained in any of the fields. The list is filtered as you type subsequent characters. For example, the records table filtered on searching the keyword "Glioblastoma" in the **Search All** text box.

Applying a keyword search displays 30 records referencing "Glioblastoma" in the Official Title.

Global Text: Glioblastoma

NCI Trial ID	Official Title	Trial Type	Trial Category	Accrual Type	Action
NCI	Glioblastoma Therapy	Interventional	Complete	Subject	
NCI	Recurrent Glioblastoma	Interventional	Complete	Subject	
NCI		Interventional	Complete	Subject	
NCI		Non-interventional	Complete	Subject	
NCI		Interventional	Complete	Subject	
NCI		Interventional	Complete	Subject	
NCI		Interventional	Complete	Subject	
NCI		Interventional	Abbreviated	Summary	
NCI		Interventional	Complete	Subject	
NCI		Interventional	Complete	Subject	
NCI		Interventional	Abbreviated	Summary	
NCI	Recurrent Glioblastoma	Interventional	Complete	Subject	

Another example, the records table filtered on various columns (NCT Trial ID and Accrual Type below) via the **Filter Options**.

Applying filter(s) displays 2 records referencing the NCT Trial Identifier and accrual type.

NCI Trial ID: 2020 | Accrual Type: Summary

NCI Trial ID	Trial Type	Trial Category	Accrual Type	Accrual Disease Terminology	Total Trial Accrual	Last Accrual Update Submitted	Action
NCI-2020:	Non-interventional	Complete	Summary	SDC	162	12/11/2024 15:45	
NCI-2020:	Non-interventional	Complete	Summary	ICD10	95	02/01/2021 17:08	

CTRP Accrual Reference


The following pages provide tables and other references relevant to CTRP Accrual:

Accrual Data Elements for Complete Trials

This section contains detailed information on each of the data elements included in the Batch Upload 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 with CTRP-Accepted Values for Complete Trials

Accrual Data Element	Definition	Required (R) /Conditional (C)		Accepted Values
		Subject	Partial Subject	
Study Subject ID	Enter the unique Patient ID as per the lead organization or the study site where the subject is registered.	R	R	Any numeric or alphanumeric value
Study Subject Birthdate	<p>Enter the subject's month and year of birth in the format MM/YYYY.</p> <div style="border: 1px solid #ccc; padding: 5px; margin-bottom: 5px;">  Age is calculated by the difference between the Study Subject Registration Date and Study Subject Birthdate. </div> <div style="border: 2px solid #f00; padding: 5px; margin-bottom: 5px;">  The subject's age reported in CTRP cannot be greater than 120 years. </div>	R		Accrual application format: MM/YYYY REST Services format: YYYY-MM-DD Batch Upload format: YYYYMM
Study Subject Sex	Sex means a person's classification as male or female based on biological distinctions. Select the subject's biological sex. If biological sex information is not available, select Unknown .	R		Male Female Unknown
Study Subject Race	<p>Select one or more values for race.</p> <p>To select multiple races, select one race, and then press and hold the CTRL/CMD key as you select the other(s).</p>	R		American Indian or Alaska Native Asian Black or African American Native Hawaiian or Other Pacific Islander Not Reported Unknown White
Study Subject Ethnicity	Select a value for ethnicity.	R		Hispanic or Latino Not Hispanic or Latino Not Reported Unknown
Study Subject Country	Select the study subject's country of residence.	R		CTRP is using the International Standards Organization country codes: https://www.iso.org/obp/ui/#search
Study Subject Zip Code	Enter the study subject's zip code.	C	C	Required if the Study Subject Country is the US, US territories and outlying islands. Must be in a 5 digit or 9 digit (DDDD- DDDD) format
Registration Date	Enter the date that the subject was registered on the study.	R	R	User Interface format: MM/DD/YYYY REST format: YYYY-MM-DD Batch Upload format: YYYYMMDD
Study Subject Disease	<p>Click Look Up, and follow the instructions in Selecting Diseases for Study Subject Records.</p> <div style="border: 2px solid #f00; padding: 5px; margin-top: 10px;">  For ICD-O-3, CTRP uses a hybrid model with the codes from IACR and the codes in NCI SEER that are not available in IACR. </div>	R		Partial Subject: Disease is not required. ICD-O-3: If Disease is reported, Site is also required. Study Subject: Disease Code is required for all trial types. ICD-O-3: Disease and Site are required.


Study Subject Disease Site (ICD-O-3)	<p>Click Look Up, and follow the instructions in Selecting Sites for Study Subject Records Using ICD-O-3 Codes.</p> <p>Site Code information is available at:</p> <p>http://www.iacr.com.fr/index.php?option=com_content&view=category&layout=blog&id=100&Itemid=577</p> <div style="border: 1px solid red; padding: 5px; margin-top: 10px;">  CTRP uses a hybrid model with the codes from IACR and the codes in NCI SEER that are not available in IACR. </div>	C		<p>Partial Subject:</p> <p>Site is not required.</p> <p>ICD-O-3: If Site is reported, Disease is also required.</p> <p>Study Subject:</p> <p>Site is required for all trial types.</p> <p>ICD-O-3: Site and Disease are required.</p>
Participating Site	Select the appropriate site from the drop-down list.	R	R	

Accrual Data Elements for Abbreviated Trials

This section contains detailed information on each of the data elements included in the Batch Upload 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.

For instructions, refer to the following pages:

Accrual Data Elements 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 / assignedIdentifier
Study Site Identifier	M	Unique identifier (PO ID) assigned to the institution accruing the patient to the study	PO ID	Study Site / identifier
Study Site Accrual Count	M	Numeric count of subjects accrued at a study site to date	Numeric	Study Site / subjectAccrualcount
Cut-Off Date	O	The date from which the cumulative accrual count was calculated.	YYYYMMDD	(TBD)

PATIENT_RACES TABLE

The Format for CTRP Fields	Fields Used by CTRP?
Protocol_ID	Yes
Patient_ID	Yes
Race_Code	Yes

PATIENTS TABLE

Format for CTRP Fields	Fields Used by CTRP?
Protocol_ID	Yes
Patient_ID	Yes
Zip_Code	Yes
Country_Code	Yes
Birth_Date	Yes
Sex_Code	Yes
Ethnicity_Flag	Yes
Method_Of_Payment	No
Date_Of_Entry	Yes
Reg_Group_ID	No
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
Disease_Code_System	Yes
Resp_Eval_Status	No
Baseline_Abnormalities_Flag	No

COLLECTIONS TABLE

The Format for CTRP 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