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NCI CTRP Accrual User Guide

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CTRP Resources

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- [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 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.

For instructions, refer to the following pages:

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 Birth Date (MM /YYYY)	Enter the subject's month and year of birth in the format MM/YYYY . Note: The subject's age reported in CTRP cannot be greater than 125 years.	R		Accrual application format: MM/YYYY REST Services format: YYYY-MM-DD Batch Upload format: YYYYMM
Study Subject Gender	Select the subject's biological sex. If biological sex information is not available, select Unknown .	R		Male Female Unspecified Undifferentiated Unknown
Study Subject Race	Select one or more values for race. To select multiple races, select one race, and then press and hold the CTRL /CMD key as you select the other(s).	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
Disease	Click Look Up , and follow the instructions in Selecting Diseases for Study Subject Records . Note: 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.	R		Partial Subject: Disease is <u>not required</u> . 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.
Site (for ICD-O-3 Disease Codes)	Click Look Up , and follow the instructions in Selecting Sites for Study Subject Records Using ICD-O-3 Codes . Site Code information is available at: http://www.iacr.com.fr/index.php?option=com_content&view=category&layout=blog&id=100&Itemid=577 Note: CTRP uses a hybrid model with the codes from IACR and the codes in NCI SEER that are not available in IACR.	C		Partial Subject: Site is <u>not required</u> . ICD-O-3: If Site is reported, Disease is also required. Study Subject: Site is required for all trial types. ICD-O-3: Site and Disease are required.


Participating Site	Select the appropriate site from the drop-down list.	R	R	
Study Subject method of payment	Select the appropriate payment method.			Private Insurance Medicare Medicare and Private Insurance Medicaid Medicaid and Medicare Military or Veterans Sponsored, NOS Military Sponsored (Including CHAMPUS & TRICARE) Veterans Sponsored Self-Pay (No Insurance) No Means of Payment (No Insurance) Managed Care State Supplemental Health Insurance Other Unknown

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

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

PATIENTS TABLE

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

COLLECTIONS TABLE

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

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 fully abstracted. 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's Guide.
2. New trial submissions are reviewed during the validation process. Protocol abstraction is performed by the CTRO after validation. The study must be fully abstracted, and that abstraction verified 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

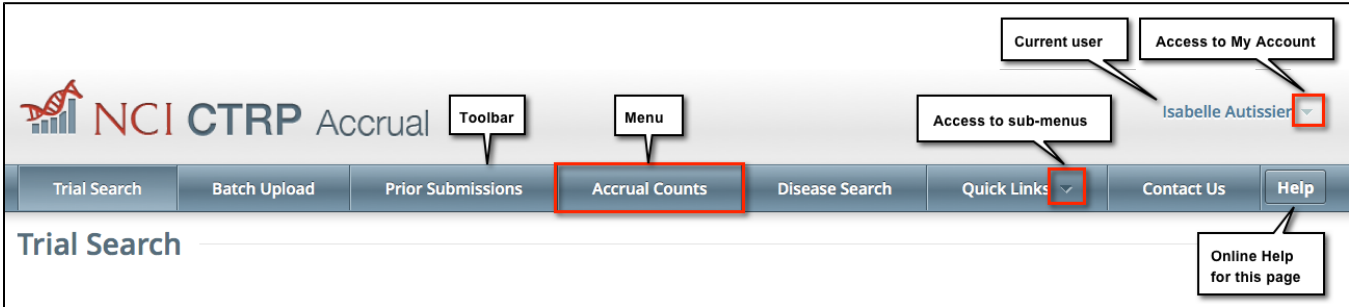


When reporting accrual via Batch Upload and REST Services, ensure the accrual reporting type is properly set on the study(ies) in the CTRP Accrual application. Accrual records reported with a different accrual reporting type than what is on the study record will be rejected. To update the accrual reporting 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 Toolbar in Accrual

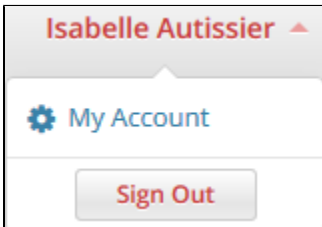
1. Visit the CTRP Accrual home page at <https://trials.nci.nih.gov>.
2. Log in using your CTRP account and navigate to the CTRP Accrual application.

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



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

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

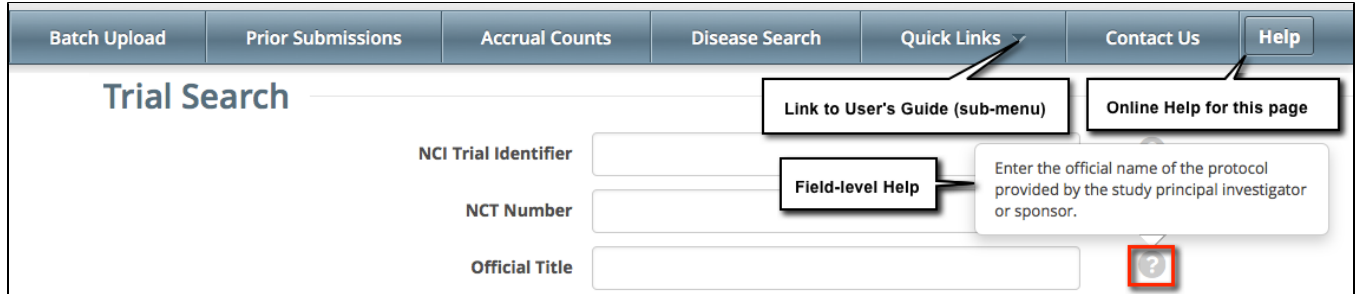


Getting Help in Accrual



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

Visit the CTRP Accrual home page at <https://trials.nci.nih.gov>.

Log in using your CTRP account and navigate to the CTRP Accrual application.

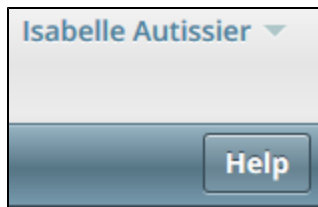


How to Display Instructions/Information for a Field

A Help icon  is available beside most fields in which you enter trial data. Hover your cursor over the Help icon  next to it.

How to Launch Online Help

Online Help provides instruction/information for the topic you are working on. On the right side of the toolbar, click **Help**.



How to Return to this User's Guide

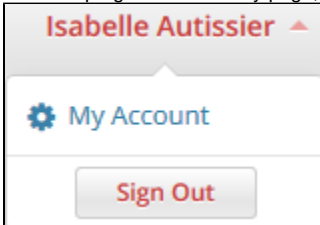
On the toolbar, click **Quick Links > Accrual User's Guide**.

Changing the Color Scheme in Accrual

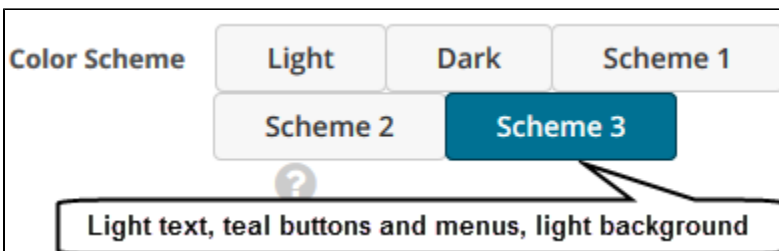
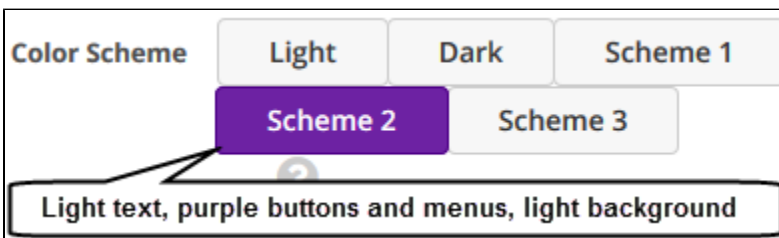
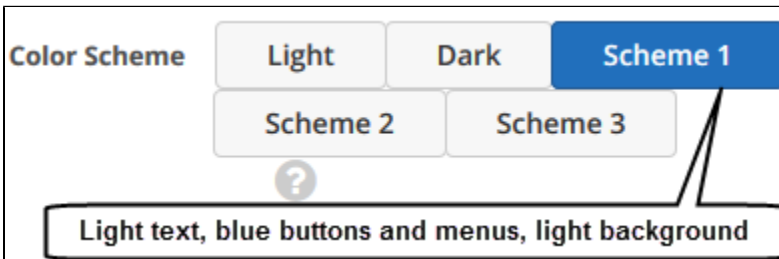
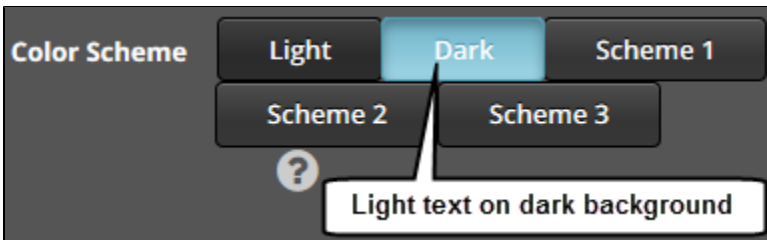
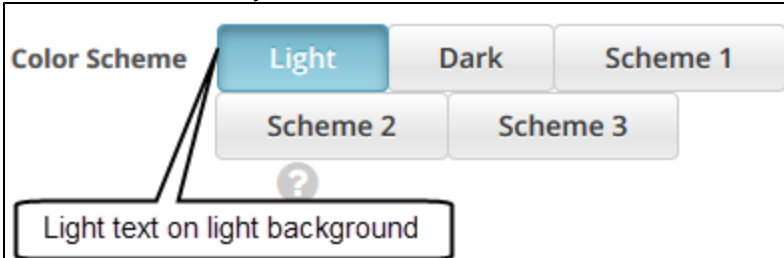
You can choose a site-wide color scheme to suit your preferences.

How to Change the Color Scheme

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



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



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

The screenshot shows the NCI CTRP Accrual Trial Search page. At the top, there is a navigation bar with tabs for Trial Search, Batch Upload, Prior Submissions, Accrual Counts, Disease Search, Quick Links, Contact Us, and Help. The main heading is "Trial Search".

Below the heading, there are three input fields: "NCI Trial Identifier", "ClinicalTrials.gov ID", and "Official Title". A "Search Trials" button and a "Reset" button are located below these fields. A callout box explains that users can filter the auto-populated List of Trials by entering criteria in these fields and executing the Search Trials button or by entering the criteria in the Search box and pressing enter.

The "List of Trials" section shows a table with columns: NCI Trial Identifier, Official Title, Current Trial Status, Trial Type, Trial Category, Accrual Type, and Accrual Disease Terminology. A "Search:" box and a "Choose columns" dropdown are located above the table. A callout box explains that "Choose columns" allows users to define data elements to display for their List of Trials.

The table contains the following data:

NCI Trial Identifier	Official Title	Current Trial Status	Trial Type	Trial Category	Accrual Type	Accrual Disease Terminology
NCI-2019-00038	ZcUNKCTdU79D5xmkuyE906 X3EUVC - 06/11/2019 14:00:41	Active	Interventional	Complete	Subject	
NCI-2019-00037	u mak3LwJbp3 6ZjSl Ob75Ht - 06/11/2019 14:00:39	Active	Interventional	Complete	Subject	
NCI-2018-03047	GLUT1: A Novel Tool Reflecting Proliferative Activity of Lung Neuroendocrine Tumors	Complete	Non-interventional	Abbreviated	Summary	
NCI-2018-03046	Pilot investigation of a Thoracolumbar Brace for Individuals With Parkinson's Disease	Complete	Interventional	Abbreviated	Summary	
NCI-2018-03045	accrual test 2 non-interventional	In Review	Non-interventional	Complete	Summary	
NCI-2018-03044	accrual test 1 interventional trial	In Review	Interventional	Complete	Subject	
NCI-2017-02835	A Phase I/II Study Of Brentuximab Vedotin In Combination With Multi-Agent Chemotherapy	In Review	Non-interventional	Complete	Subject	SDC
NCI-2017-02679	A Multi-center, Open-label, Exploratory Study of Bcr-Abl Kinetics in Adult Patients on Nilotinib With Philadelphia Chromosome Positive (Ph+) Chronic Myelogenous Leukemia in Chronic Phase (CML-CP) and a Suboptimal Molecular Response to Imatinib	Complete	Interventional	Abbreviated	Summary	



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 fully abstracted in CTRP.
- For Complete/Protocol studies:
 - The overall trial status history should include one of the open/recruiting statuses.
 - Studies with a status of In Review or Approved are not available in the accrual application. 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](#).

Note: 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.

List of Trials

Show 10 ▾

Select the **NCI Trial Identifier** to add or edit study subjects to the trial.

Accrual Disease Terminology can only be updated for trials without existing accrual records.

Search: Choose columns << 1 > >>

NCI Trial Identifier	Official Title	Current Trial Status	Trial Type	Trial Category	Accrual Type	Accrual Disease Terminology
NCI-2019-00038	ZcuNKCTdU79DSxnuukyE906 X3ELVC - 06/11/2019 14:00:41	Active	Interventional	Complete	Subject	ICD-O-3
NCI-2019-00037	u mak3Lwjbp3 oZjSl Ob75Ht - 06/11/2019 14:00:39	Active	Interventional	Complete	Subject	ICD-O-3
NCI-2018-03047	GLUT1: A Novel Tool Reflecting Proliferative Activity of Lung Neuroendocrine Tumors	Complete	Non-interventional	Abbreviated	Summary ▾	
NCI-2018-03046	Pilot Investigation of a Thoracolumbar Brace for Individuals With Parkinson's Disease	Complete	Interventional	Abbreviated	Summary ▾	
NCI-2018-03045	accrual test 2 non-interventional	In Review	Non-interventional	Complete	Summary	
NCI-2018-03044	accrual test 1 interventional trial	In Review	Interventional	Complete	Subject	SDC
NCI-2017-02835	A Phase I/II Study Of Brentuximab Vedotin In Combination With Multi-Agent Chemotherapy	In Review	Non-interventional	Complete	Subject ▾	SDC ▾
NCI-2017-02679	A Multi-center, Open-label, Exploratory Study of Bcr-Abl Kinetics in Adult Patients on Nilotinib With Philadelphia Chromosome Positive (Ph+) Chronic Myelogenous Leukemia in Chronic Phase (CML-CP) and a Suboptimal Molecular Response to Imatinib	Complete	Interventional	Abbreviated	Summary	

Accrual Type can be modified on Non-Interventional, Complete trials without existing accruals. For all other type of trials contact CTRO at NCICTRO@mail.nih.gov, to change the **Accrual Type**.

Showing 1 to 8 of 8

Export options: CSV | Excel

1 > >>

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.

List of Trials

Show Search: Choose columns << < 1 2 3 4 5 ... 101 > >>

NCI Trial Identifier	Official Title	Current Trial Status	Trial Type	Accrual Disease Terminology
NCI-2014-00508	Papillary Carcinoma Trial	Active	Interventional	<input type="button" value="ICD-O-3"/>
NCI-2014-00494	Phosphoproteomic Profiling of Normal B	Active	Non-interventional	<input type="button" value="ICD9"/>
NCI-2014-00281	Vaccination of Patients With Ovarian Cancer With Dendritic Cell/Tumor Fusions With GM-CSF and Imiquimod	Temporarily Closed to Accrual	Interventional	SDC
NCI-2014-00248	Global Proteomic and Phosphoproteomic Profiling of Normal B Cells Isolated From COG AAML1031 Study Patients in AML Remission	Complete	Non-interventional	<input type="button" value="SDC"/>

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

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.

¹ 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 New Study Subject**. The Add Study Subject page appears. (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.

		Required (R) /Conditional (C)	

Accrual Data Element	Definition	Subject	Partial Subject	Accepted Values
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 Birth Date (MM /YYYY)	Enter the subject's month and year of birth in the format MM/YYYY . Note: The subject's age reported in CTRP cannot be greater than 125 years.	R		Accrual application format: MM /YYYY REST Services format: YYYY-MM-DD Batch Upload format: YYYYMM
Study Subject Gender	Select the subject's biological sex. If biological sex information is not available, select Unknown .	R		Male Female Unspecified Undifferentiated Unknown
Study Subject Race	Select one or more values for race. To select multiple races, select one race, and then press and hold the CTRL/CMD key as you select the other(s).	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
Disease	Click Look Up , and follow the instructions in Selecting Diseases for Study Subject Records . Note: 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.	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.
Site (for ICD-O-3 Disease Codes)	Click Look Up , and follow the instructions in Selecting Sites for Study Subject Records Using ICD-O-3 Codes . Site Code information is available at: http://www.iacr.com.fr/index.php?option=com_content&view=category&layout=blog&id=100&Itemid=577 Note: CTRP uses a hybrid model with the codes from IACR and the codes in NCI SEER that are not available in IACR.	C		Partial Subject: Site is not required. ICD-O-3: If Site is reported, Disease is also required. Study Subject: Site is required for all trial types. ICD-O-3: Site and Disease are required.
Participating Site	Select the appropriate site from the drop-down list.	R	R	

Study Subject method of payment	Select the appropriate payment method.		Private Insurance Medicare Medicare and Private Insurance Medicaid Medicaid and Medicare Military or Veterans Sponsored, NOS Military Sponsored (Including CHAMPUS & TRICARE) Veterans Sponsored Self-Pay (No Insurance) No Means of Payment (No Insurance) Managed Care State Supplemental Health Insurance Other Unknown
--	--	--	---

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.

1. 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 Toolbar

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

How to Search for Diseases from the Toolbar

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

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

Search tips

Enter as many letters of the disease/condition name as possible to reduce the number of search results. The system adds wildcards on both sides of the search string (the series of letters you type) for you implicitly. You can type wildcard symbols (%) between characters of the string as necessary.

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

Category	ICD-10	SDC	ICD9	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

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.

Name	Code	System	Menu Display Name
Vascular myelopathies (336.1)	336.1	ICD9	Vascular myelopathies (336.1)
Vascular myelopathies	G95.1	ICD10	Vascular myelopathies
Unspecified osteomyelitis, site unspecified (730.20)	730.20	ICD9	Unspecified osteomyelitis, site unspecified (730.20)
Unspecified osteomyelitis involving upper arm (730.22)	730.22	ICD9	Unspecified osteomyelitis involving upper arm (730.22)

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

Add Study Subject

Study Subject ID: *

Study Subject Birth Date (MM/YYYY): * mm/yyyy

Study Subject Gender: * --Select--

Study Subject Race: *

- American Indian or Alaska Native
- Asian
- Black or African American
- Native Hawaiian or Other Pacific Isl
- Not Reported
- Unknown
- White

To select multiple races, select one race, and then press and hold the CTRL key as you select the other(s).

Study Subject Ethnicity: * --Select--

Study Subject Country: * United States

Study Subject Zip Code:

Registration Date: * mm/dd/yyyy

Study Subject method of payment: --Select--

Disease: * ?

Participating Site: * --Select--

3. To assign a disease to the study subject, next to the **Disease** field, click **Look Up**. The Search Diseases window appears.

Search Diseases

Disease Name: myel

Disease Code:

Disease Code System: SDC

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

Search tips

Type as many letters of the disease/condition or site name as possible to reduce the number of search results. The system adds wildcards on both sides of the search string (the series of letters you type) for you implicitly. You can type wildcard symbols (%) between characters of the string as necessary.

i 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

5. 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)

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

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

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

Search Diseases

Disease Name: Disease Code:

Disease Code System:

Show Search: << < 1 > >>

Name	Code	System	Menu Display Name	Select
Treatment related acute myeloid leukemia	10066353	SDC	Treatment related AML	<input type="button" value="Select"/>
Myeloma, NOS	10028566	SDC	Myeloma, NOS	<input type="button" value="Select"/>
Myelodysplastic syndrome, NOS	10028534	SDC	Myelodysplastic syndrome, NOS	<input type="button" value="Select"/>

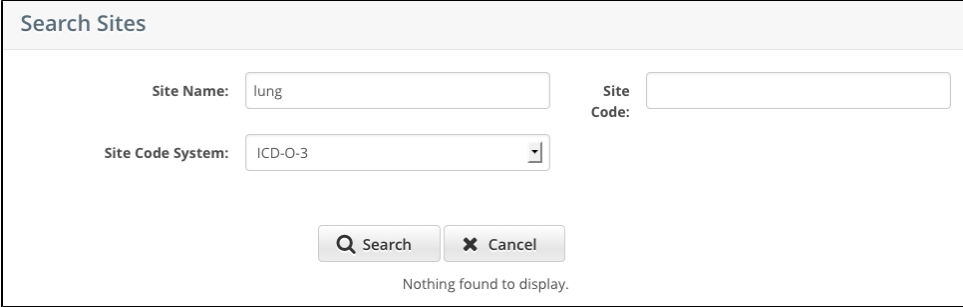
7. Navigate to the disease/condition being studied, and click **Select**. Refer to [Working with Accrual Tables and Search Results](#). The system populates the Disease field for you.

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. At the bottom of the **Search Study Subject** section, click **Add New Study Subject**. The Add Study Subject page appears.
3. To assign a site to the study subject, next to the **Site** field, click **Look Up**. The Search Sites window appears.




Search Sites

Site Name: Site Code:

Site Code System:

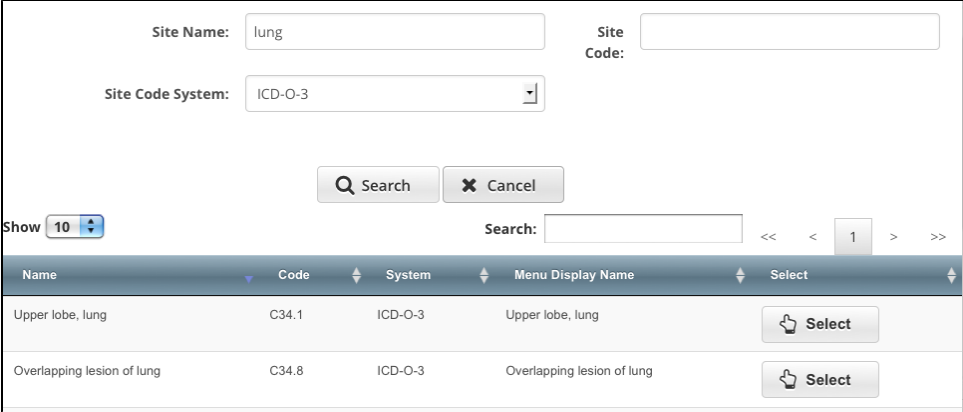
Nothing found to display.

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

 **Search tips**

Type as many letters of the site name as possible to reduce the number of search results. The system adds wildcards on both sides of the search string (the series of letters you type) for you implicitly. You can type wildcard symbols (%) between characters of the string as necessary.

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



Site Name: Site Code:

Site Code System:

Show

Search: << < 1 > >>

Name	Code	System	Menu Display Name	Select
Upper lobe, lung	C34.1	ICD-O-3	Upper lobe, lung	<input type="button" value="Select"/>
Overlapping lesion of lung	C34.8	ICD-O-3	Overlapping lesion of lung	<input type="button" value="Select"/>

6. 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.

Searching for Study Subjects

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

- Study Subject ID
- Participating Site
- Birth Date

You must select a trial before you can search for study subjects. For instructions, 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.

Search Study Subject

Study Subject ID

Participating Site

Study Subject Birth Date (MM/YYYY):

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

You can list all study subjects

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

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

List of Study Subjects

Show Search: << < 1 > >>

Study Subject ID	Registration Date	Participating Site	Last Update Date/Time	Actions
1	10/29/2013	Massachusetts General Hospital	02/07/2014 11:36	
2	10/29/2013	Massachusetts General Hospital	02/07/2014 11:36	
3	10/29/2013	Massachusetts General Hospital	02/07/2014 11:36	
4	01/03/2014	Massachusetts General Hospital	02/07/2014 11:36	
5	01/13/2014	Massachusetts General Hospital	02/07/2014 11:36	

Showing 1 to 5 of 5 << < 1 > >>

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.

Study Subject ID	Registration Date	Participating Site	Last Update Date/Time	Actions
1	10/29/2013	Massachusetts General Hospital	02/07/2014 11:36	
2	10/29/2013	Massachusetts General Hospital	02/07/2014 11:36	
3	10/29/2013	Massachusetts General Hospital	02/07/2014 11:36	
4	01/03/2014	Massachusetts General Hospital	02/07/2014 11:36	
5	01/13/2014	Massachusetts General Hospital	02/07/2014 11:36	

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

Study Subject ID: * 123456

Study Subject Birth Date (MM/YYYY): * 12/1991

Study Subject Gender: * Male

Study Subject Race: * Asian

Study Subject Ethnicity: * Hispanic or Latino

Study Subject Country: * United States

Study Subject Zip Code: 21452

Registration Date: * 07/10/2014

Study Subject method of payment: Private Insurance

Disease: * Treatment related acute myeloid leukemia

Participating Site: * Massachusetts General Hospital Cancer Center

User who created: Isabelle Autissier

Last Update Date/Time: 07/10/2014 15:42

[Back](#) [Edit](#)

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

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 trial.

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

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


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

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

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

For example,

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

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.

Deleting all Subjects from a Study

1. Click **Delete All Trial Study Subjects**
2. Select a value from the **Reason** listbox
3. Click **OK**

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

Search Study Subject

Study Subject ID

Participating Site

Study Subject Birth Date (MM/YYYY):

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 accrual count(s).
2. Click **OK**. The system deletes all of the accrual counts for the site(s) you selected.

List of Study Subjects

Show

Search:

Study Subject ID	Registration Date	Participating Site	Last Update Date/Time	Actions
Z-1011	09/16/2018	Novartis Pharmaceuticals	06/17/2019 14:30	
Z-1012	06/01/2019	Novartis Pharmaceuticals	06/17/2019 14:31	
Z-1013	06/01/2019	Novartis Pharmaceuticals	06/17/2019 14:33	
Z-1014	06/01/2019	Novartis Pharmaceuticals	06/17/2019 14:35	

Showing 1 to 4 of 4

Recording and Updating Participating Site Accrual Counts

How to Record and Update Site Subject Accrual Counts

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 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.
3. In the **# of Subjects Enrolled** field, enter the number of subjects currently enrolled in studies at your site.
4. (Optional) 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 considers the accrual submission date to be the cut-off date.
5. In the **Actions** column of the record you want to update, click **Save** (the floppy disk icon). A message at the top of the table indicates that the record has been updated successfully.
6. Designated Cancer Center users may view, add, edit or delete an entry. Clicking on an arrow 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.

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.

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. 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. 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.
3. In the **Actions** column of the site you want to add accrual information for, click the + symbol, this will open the **Add Accrual Count** dialog box.

Participating Site Subject Accrual Count

Show 10

Search:

PO ID	Site Name	# of Subjects Enrolled	Cut-Off Date	Date Last Updated	Actions
7434	Novartis Pharmaceuticals	3	10/23/2019	10/23/2019 16:02	+ [Print] [Delete]
2666	Case Comprehensive Cancer Center				+

Showing 1 to 2 of 2

4. In the **# of Subjects Enrolled** field(s), enter the **total cumulative** number of subjects currently enrolled in this study at your site.
5. 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 considers the accrual submission date to be the cut-off date.
6. In the **Actions** column of the record you want to update, click **Save** (the floppy disk icon). A message at the top of the table indicates that the record has been updated successfully. Because you reported accrual counts at the summary level, you must continue to report accruals at this level in the future.

Add Accrual Count
✕


PO ID	Site Name	# of Subjects Enrolled	Cut-Off Date	
7434	Novartis Pharmaceuticals	<input style="width: 100%;" type="text"/>	<input style="width: 100%;" type="text" value="mm/dd/yyyy"/>	<input type="button" value="Save"/>

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
<i>Access to accruals for your site or any organization affiliation member sites within CTRP</i>	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
<i>Access to accruals for your site or any organization affiliation member sites within CTRP</i>	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

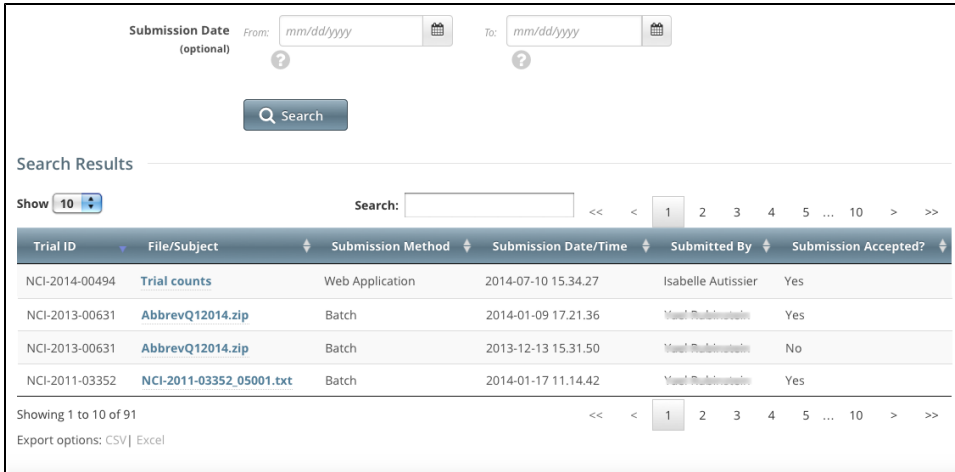
 Only the ZIP file submitter can download ZIP files from the Prior Submissions page.

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



Submission Date (optional) From: To:

Search Results

Show Search:

Trial ID	File/Subject	Submission Method	Submission Date/Time	Submitted By	Submission Accepted?
NCI-2014-00494	Trial counts	Web Application	2014-07-10 15.34.27	Isabelle Autissier	Yes
NCI-2013-00631	AbbrevQ12014.zip	Batch	2014-01-09 17.21.36	Yael Rubinstein	Yes
NCI-2013-00631	AbbrevQ12014.zip	Batch	2013-12-13 15.31.50	Yael Rubinstein	No
NCI-2011-03352	NCI-2011-03352_05001.txt	Batch	2014-01-17 11.14.42	Yael Rubinstein	Yes


Showing 1 to 10 of 91
Export options: CSV | Excel

2. To limit the list of submissions to a date, or range of dates, in the **From** field, select or enter the first date of the range or the exact date of the submission you are searching for. In the **To** field, enter the last date of the range. Then click **Search**.
3. In the **File/Subject** column for the non-industrial trial of interest, click the link to the file. Follow your browser/operating system instructions to view or save the document.

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 append data.
 - 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 Data 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, Private Insurance, 20060809, CALGB,
149280,,,,,,,,,238.7,,
PATIENTS, "NCI-2011-03861", 8732228, 84124, US, 196311, Male, Unknown, Private Insurance, 20060809, CALGB, 149280,,,,,,,,,
238.7,,
PATIENTS, "NCI-2011-03861", 1, 84124, US, 196311, Male, Unknown, Private Insurance, 20060809, CALGB, 149280,,,,,,,,,
185.0,,
"PATIENT_RACES", "NCI-2011-03861", 8732228, White
"PATIENT_RACES", "NCI-2011-03861", 873222899999999, Asian
"PATIENT_RACES", "NCI-2011-03861", 1, White
```

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 quarter, monthly accrual from study start date to present. Another option is to provide the Cut-Off Date in the batch load file. 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

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

For a list of all the CDUS fields for these tables, refer to [Comparison of CTRP and CDUS 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>,<Gender>,<Ethnicity>,<Payment_Method>,<Subject_Registration_Date>,<Registering_Group_Identifier>,<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",873222899999999,84124,US,196311,Male,Unknown,Private Insurance,20060809,CALGB,149280,,,,,238.7,,
PATIENTS,"NCI-2011-03861",8732228,84124,US,196311,Male,Unknown,Private Insurance,20060809,CALGB,149280,,,,,238.7,,
PATIENTS,"NCI-2011-03861",1,84124,US,196311,Male,Unknown,Private Insurance,20060809,CALGB,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",873222899999999,84124,US,196311,1,9,1,20060809,CALGB,149280,,,,,238.7,,
PATIENTS,"NCI-2011-03861",8732228,84124,US,196311,1,9,1,20060809,CALGB,149280,,,,,238.7,,
PATIENTS,"NCI-2011-03861",1,84124,US,196311,1,9,1,20060809,CALGB,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 tables in this section contain detailed information about each of the data elements included in the Batch Upload file. The CDUS Accepted Values are provided to show differences in case your system is already producing the CDUS file. In most cases, both CTRP and CDUS values are accepted.

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	Gender of a Person (7)	Text (10)
PATIENTS	Ethnicity (8)	Text (25)
PATIENTS	Payment Method (9)	Text (50)
PATIENTS	Subject Registration Date (10)	Date (YYYYMMDD)
PATIENTS	Registering Group Identifier (11)	Text (25)
PATIENTS	Study Site Identifier (12)	Text (25)
PATIENTS	Subject Disease Code (22) ¹	Number (10)
PATIENT_RACES	Study Identifier (2)	Text (35)
PATIENT_RACES	Study Subject Identifier (3)	Text (20)
PATIENT_RACES	Race (4)	Text (45)

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.

```

PATIENTS,NCI-2011-03861,8732228,84124,,196311,Male,Unknown,Private Insurance,20060809,CALGB,149280,,,,,,,,,238.7,,
{ 1 } { 2 } { 3 } { 4 } { 5 } { 6 }
TABLE
    
```

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.

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

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 CDUS Fields (Excluding the Table Name)	Number of Fields Used by CTRP (Excluding the Table Name)	Purpose
COLLECTIONS	10	1	Identifies the study for this data file
ACCRUAL_COUNT	(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 table contains detailed information about each of the data elements included in the Batch Upload file for Abbreviated Trials. The CDUS Accepted Values are provided to show differences in case your system is already producing the CDUS file.

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.

i 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 toolbar, click **Batch Upload**
The Batch Upload page appears.

Accrual Batch Upload

Click Browse and select the ZIP or TXT file that contains the accrual data. Then click Submit.

Batch File: No file selected.

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, gender, 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 re-submit.

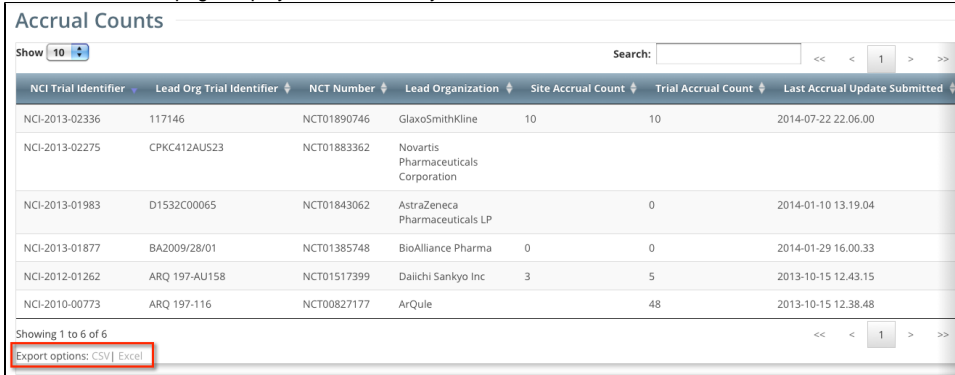
Downloading Accrual Count Reports

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

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

How to Download Accrual Account Reports

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



NCI Trial Identifier	Lead Org Trial Identifier	NCT Number	Lead Organization	Site Accrual Count	Trial Accrual Count	Last Accrual Update Submitted
NCI-2013-02336	117146	NCT01890746	GlaxoSmithKline	10	10	2014-07-22 22.06.00
NCI-2013-02275	CPKC412AU523	NCT01883362	Novartis Pharmaceuticals Corporation			
NCI-2013-01983	D1532C00065	NCT01843062	AstraZeneca Pharmaceuticals LP		0	2014-01-10 13.19.04
NCI-2013-01877	BA2009/28/01	NCT01385748	BioAlliance Pharma	0	0	2014-01-29 16.00.33
NCI-2012-01262	ARQ 197-AU158	NCT01517399	Daiichi Sankyo Inc	3	5	2013-10-15 12.43.15
NCI-2010-00773	ARQ 197-116	NCT00827177	ArQule		48	2013-10-15 12.38.48

Showing 1 to 6 of 6

Export options: [CSV](#) [Excel](#)

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

Managing Your CTRP Account

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 Choose columns . A list of available columns appears. Check or clear the boxes to indicate which columns you want to show or hide.
Search the list of results by keywords	In the Search field, type one or more characters contained in your keyword(s). The results are filtered as you type subsequent characters.
Export search results to a file	At the bottom of the page, click CSV to export the search results to a comma-separated file or Excel to export to a file in Microsoft Excel format.

The screenshot shows a search results page with several callouts pointing to specific UI elements:

- Select the number of records you want to display:** Points to the 'Show 10' dropdown menu.
- Filter the search results:** Points to the search input field containing 'place'.
- Select the columns you want to display:** Points to the 'Choose columns' button.
- Select the sort order:** Points to a dropdown arrow on the 'Accrual Disease' column header.
- Go to a specific page:** Points to the page number '3' in the pagination controls.
- Go to the next page:** Points to the right arrow '>' in the pagination controls.
- Go to the last page:** Points to the right double arrow '>>' in the pagination controls.
- Disease code change indicator:** Points to a dropdown menu showing 'ICD-O-3' and a message 'Value changed to ICD-O-3'.

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

Filtering Accrual Search Results

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

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

Search Diseases

Disease Name: Disease Code:

Disease Code System:

Show

Search: << < 1 > >>

Name	Code	System	Menu Display Name
Vasculitis limited to skin, unspecified	L95.9	ICD10	Vasculitis limited to skin, unspecified
Vasculitis limited to skin, not elsewhere classified	L95	ICD10	Vasculitis limited to skin, not elsewhere classified
Poikiloderma vasculare atrophicans	L94.5	ICD10	Poikiloderma vasculare atrophicans
Other vasculitis limited to skin	L95.8	ICD10	Other vasculitis limited to skin
Livedoid vasculitis	L95.0	ICD10	Livedoid vasculitis

Showing 1 to 5 of 5 (filtered from 322 total entries) << < 1 > >>

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

Search Diseases

Disease Name: Disease Code:

Disease Code System:

Show

Search: << < 1 > >>

Name	Code	System	Menu Display Name
Vasculitis limited to skin, unspecified	L95.9	ICD10	Vasculitis limited to skin, unspecified
Other vasculitis limited to skin	L95.8	ICD10	Other vasculitis limited to skin
Livedoid vasculitis	L95.0	ICD10	Livedoid vasculitis

Showing 1 to 3 of 3 (filtered from 322 total entries) << < 1 > >>