

Recent changes to CTRP 20210726

This page provides an overview of the changes in CTRP. For any questions or issues regarding these feature enhancements, please contact the CTRO ([N CICTRO@mail.nih.gov](mailto:CICTRO@mail.nih.gov)).


July 2021

IRB fields are now exposed in the CTRP Registration application. IRB information can be added/modified when registering, updating/verifying and amending non-industrial trials. IRB fields are read-only when viewing trials on the Trial Details Page.

Registering, Amending or Updating/Verifying a non-industrial trial: IRB fields are modifiable

Institutional Review Board (IRB)

The information in this section is REQUIRED to enable "Upload from NCI CTRP" in [ClinicalTrials.gov](https://clinicaltrials.gov)

Board Affiliation:*	Case Western Reserve University		Look Up
Board Contact Mailing Address:*	2115 E Jefferson St		
Board Contact City:*	Rockville		
Board Contact State/Province:*	Maryland		
Board Contact Zip/Postal Code:*	20852		
Board Contact Country:*	United States		
Board Contact Phone:		Either a contact phone or an email address is required	
Board Contact Email Address:	foo@example.com		
Board Name:*			

✕ Clear IRB

Viewing a trial on the Trial Search page: IRB fields are read-only

Institutional Review Board (IRB)	
Board Affiliation	Vanderbilt University/Ingram Cancer Center
Board Contact Mailing Address	2200 Pierce Avenue
Board Contact City	Nashville
Board Contact State/Province	TN
Board Contact Zip/Postal Code	37232
Board Contact Country	United States
Board Contact Phone	877-936-8422
Board Contact Email Address	
Board Name	Test Board name - Updated

For additional information about the IRB fields in the CTRP Registration application, please visit these CTRP User Guide pages:

[Recording Institutional Review Board \(IRB\) Information](#)

[Updating Institutional Review Board \(IRB\) Information in Complete Trials](#)

June 2021


Transition to the NCIs multi-factor authentication system, Okta: **Your CTRP username is now your institutional email address.**

Migration of CTRP user accounts to Okta. Okta multi-factor authentication is used to provide additional security beyond just entering a username and password. Each Okta account requires the configuration of at least one of the following methods:

- Okta Verify: Use a 'Push Notification' sent to the Okta app on the users mobile device.
- SMS Authentication: Enter a single-use code sent to the users mobile device.
- Voice Call Authentication - Phone call authentication by following voice instructions.

New CTRP login page

Clinical Trials Reporting Program


NIH Login

OR

Username

Password

☐ Remember me

SIGN IN

Need help signing in?

Don't have an account? [Sign up](#)

For additional information about creating and setting up an Okta account, please visit these CTRP User Guide pages:

[Creating a CTRP Account](#)

[CTRP Okta Account Setup](#)

March 2021

Updates to the Data Table 4 (DT4) Anatomic Site values displayed on the CTRP-generated DT4 report:

Previous DT4 Anatomic Site Value	Updated DT4 Anatomic Site Value
Leukemia, not otherwise specified	Leukemia, other
Breast – Female	Breast
Breast – Male	Breast
Hodgkin's Lymphoma	Hodgkin Lymphoma
Non-Hodgkin's Lymphoma	Non-Hodgkin Lymphoma
Soft Tissue / Sarcoma	Soft Tissue

Note: For trials with numerous "Primary Sites" (DT4 Anatomic Sites), the value "Multiple" for the DT4 Anatomic Site Code will be used and displayed on the CTRP-generated DT4 report. *All existing trials in CTRP have been updated to reflect this change as well.*

For a complete list of DT4 anatomic site values displayed on the CTRP-generated DT4 report, please visit this CTRP User Guide page:

<https://wiki.nci.nih.gov/display/CTRPdoc/Data+Table+4+Anatomic+Site+Values>

Removal of the following fields from the Trial Summary Report (TSR):

- Keywords
- Program Code in the Data Table 4 Section
- Target Accrual in the Participating Sites Section
- Reporting Data Set Method

September 2020

CTRP Trial Record Verification: Improved the user experience for CTRP trial owners, trial submitters and site administrators with Verifying, Updating and/or Amending their trial records. Key highlights from this enhancement include:

1. New page highlighting all Trials Needing Verification

The Trials Needing Verification page displays a list of all trials either approaching their Record Verification Due Date or the Record Verification Due Date is in the past. The NCI requests that trial owners verify their trial records in CTRP at least every 6 months.

Select the NCI Trial Identifier to verify the trial record.

NCI Trial Identifier	Title	Record Verification Due Date	Lead Organization	Lead Org Trial Identifier	Available Actions	Current Trial Status
NCI-2017-00384	A Phase III Study Of Brentuximab Vedotin In Combination With Multi-Agent Chemotherapy	04/11/2017	Case Western Reserve University	UPCC 348-02	Select Action	In Review
NCI-2017-00389	A Phase III Study Of Brentuximab Vedotin In Combination With Multi-Agent Chemotherapy	04/11/2017	Case Western Reserve University	UPCC 34890534-4	Select Action	In Review
NCI-2017-00385	A Phase III Study Of Brentuximab Vedotin In Combination With Multi-Agent Chemotherapy II	04/11/2017	Case Western Reserve University	UPCC 348-02 II	Select Action	In Review
NCI-2017-00381	A Phase III Study Of Brentuximab Vedotin In Combination With Multi-Agent Chemotherapy	04/11/2017	Case Western Reserve University	UPCC 348-02h	Select Action	In Review
NCI-2017-02638	New Test Trial	06/28/2017	Case Comprehensive Cancer Center	UPCC 86422673 ss410	Select Action	In Review
NCI-2017-02636	test73834	06/28/2017	Case Comprehensive Cancer Center	test783484	Select Action	In Review

2. Ability to view all trial details on the Verify screen

Other Actions will allow users to Amend a trial when updating the Protocol Document or IRB Approval. This is also available on the Trials Needing Verification page and Trials Search page under Select Actions.

Amend
Change Status
View TSR
View XML
View Details

Update/Verify

3. Simplified workflow allowing users to Verify, Update or Amend trials within same form

4. New monthly email notification for alerting trial owners, trial submitters, and site administrators of **Trials Needing Verification**

Date: 07/31/2020

Dear first name lastname,

The following trial(s) are due for Data Verification in CTRP:

NCI ID	Lead Organization Trial ID	Verification Due Date
NCI-2017-02629	test7382	08/20/2020

The following trial(s) are past due for Data Verification in CTRP:

NCI ID	Lead Organization Trial ID	Verification Due Date
NCI-2017-02619	test945798	06/28/2018
NCI-2017-02623	test237823	06/28/2018
NCI-2017-02625	test648843	07/07/2018

NCI requests the verification of all trial data in CTRP at least every 6 months. The Data Verification due date is determined based on the following:

- Date the last data abstraction was verified (both new registration and amendment submissions) in CTRP
- Date the last Update was submitted in CTRP
- Date the last Data Verification was performed in CTRP

To perform the Data Verification, please follow these steps:

1. Log into the CTRP Registration Application via this direct link: <https://trials.nci.nih.gov/registry/protected/view/VerifyTrials.action>
2. Select the trial you wish to verify; review the TSR, if needed
3. If the data is accurate and up to date, click the Update/Verify button
4. If updates are needed, please address accordingly and then click the Update/Verify button

If you have questions on this process, please contact us at ncictro@mail.nih.gov

Thank you for your participation in the NCI Clinical Trials Reporting Program (CTRP).

Users will now receive monthly email notifications regarding trials due and past due for Data Verification. For example, trials due for Data Verification in May will start receiving the email notification in April. The notification will continue monthly until all trials due for Data Verification, both present and past, have been verified

For more information on the CTRP Trial Record Verification processes, please visit these CTRP User Guide pages:

<https://wiki.nci.nih.gov/display/CTRPdoc/Updating+Trial+Information>

<https://wiki.nci.nih.gov/display/CTRPdoc/How+to+Verify+Trial+Data>

<https://wiki.nci.nih.gov/display/CTRPdoc/How+to+Access+the+Trial+Data+Verification+Page>

<https://wiki.nci.nih.gov/display/CTRPdoc/Amending+Trials>

July 2020

Flexible Accrual: Enhanced the CTRP accrual reporting capabilities to include more "Flexible Accrual" reporting options. Centers can now request to update the default accrual reporting type on a study registered in CTRP. Changing the default accrual reporting type requires a ticket to be submitted to the CTRO (NCICTRO@mail.nih.gov) for review and approval, before any change is granted.

1. The current default accrual reporting types are as follows:

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

2. CTRP is also introducing a new accrual reporting type, "Partial Subject." Partial Subject accrual requires the reporting of Study Subject ID, Registration Date and Participating Site data only. The other accrual data fields are optional. The reporting of Partial Subject accrual also requires a ticket to be submitted to the CTRO (NCICTRO@mail.nih.gov) for review and approval, before any change is granted.

3. **Accrual Data Element changes:**

- a. **Study Subject Birth Date:** For any/all ways to report accrual, only the month and year (MM/YYYY) are required to be collected.
- b. **Study Subject Country:** Required for all methods of reporting accrual (was previously optional)
- c. **Disease:**
 - i. Study Subject: Required
 - ii. Partial Subject: Not required. However, for ICD-O-3 Disease Codes if Disease is reported, then Site must be reported.
- d. **Site:**
 - i. Study Subject: Required
 - ii. Partial Subject: Not required. However, for ICD-O-3 Disease Codes if Site is reported, then Disease must be reported.
- e. **Disease Codes:** CTRP uses a hybrid model with the codes from IACR and the codes in NCI SEER that are not available in IACR.

For more information on the CTRP Accrual process, including Flexible Accrual, Partial Subject accrual and other changes made within the Accrual application (e.g., ability to Delete All Trial Study Subjects,) please visit these CTRP User Guide pages:

<https://wiki.nci.nih.gov/display/CTRPdoc/About+Accrual>

<https://wiki.nci.nih.gov/display/CTRPdoc/Searching+for+Trials+in+Accrual>

If you would like to receive future CTRP announcements you may add yourself to the list here: <https://list.nih.gov/cgi-bin/wa.exe?SUBED1=ctrp-users-I&A=1>