

Copy of Recent changes to CTRP <DT4PRAGRELEASE>

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)).

March 2023

Update to the CTRP-generated DT4 report display to include the pragmatic trial indicator. The field is labeled 'Prag' with values of 'Y' or 'N' and is abstracted by the CTRO. This value will be included in any format of the CTRP-generated DT4 report (e.g., pdf, csv). This update does not have any impact on CTRP REST Services or CTRP REST Service users.

CTRP Data Element	Description of CTRP Data Element	CCSG Column Name
Prag	An indication as to whether the trial is a pragmatic (prag) trial.	Prag

Prag values:

Y – Yes, this is a pragmatic trial

N – No, this is not a pragmatic trial

Also included in this release is the modification for the 'Pilot' field values to single characters on the CTRP-generated DT4 report:

Yes Y

No N

(Blank) N

For additional information about the pragmatic trial indicator on the CTRP-generated DT4 report, please visit the following CTRP User Guide page:

[Data Elements Included in the CTRP Data Table 4 Report](#)

August 2021

Update to the NIH Grant Information section in the CTRP Registration application. The field 'Is this trial funded by an NCI Grant?' with values of Yes/No has been updated to 'Is this trial NCI funded?' with values of Direct/Indirect/No. This field is available through the web application when registering and amending trials through the CTRP Registration user interface. This update does not have any impact on CTRP REST Services or CTRP REST Service users.

NIH Grant Information (for NIH funded Trials)

To record grant information, provide values for all fields, and then click the **Add Grant** button.

Is this trial NCI funded? * ☒ Direct ☐ Indirect ☐ No

Funding Mechanism ?	Institute Code ?	Serial Number ?	NCI Division/Program ?	
--Select-- v	--Select-- v		--Select-- v	+ Add Grant

Definitions:

Direct - Trials conducted under any type of contract, grant, or cooperative agreement supported by the NCI (e.g., R01, N01, SP0RE, P01, U01, U10) including all National trials (e.g., NCTN, ETCTN, NCORP) and all Intramural trials conducted by the NCI Center for Cancer Research (CCR).

Indirect - All trials conducted at an NCI-Designated Cancer Center (with P30 center core grant), including all industrial trials – without direct NCI funding.

No - NCI has not provided any Direct or Indirect funding for the trial.

For additional information about recording NIH Grant Information in the CTRP Registration application, please visit the following CTRP User Guide page:

[Recording NIH Grants](#)


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](#)

Board Affiliation:*	<input type="text" value="Case Western Reserve University"/>		<input type="button" value="Look Up"/>
Board Contact Mailing Address:*	<input type="text" value="2115 E Jefferson St"/>		
Board Contact City:*	<input type="text" value="Rockville"/>		
Board Contact State/Province:*	<input type="text" value="Maryland"/>		
Board Contact Zip/Postal Code:*	<input type="text" value="20852"/>		
Board Contact Country:*	<input type="text" value="United States"/>		
Board Contact Phone:	<input type="text" value=""/>		
Board Contact Email Address:	<input type="text" value="foo@example.com"/>		
Board Name:*	<input type="text" value=""/>		
<input type="button" value="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](#)

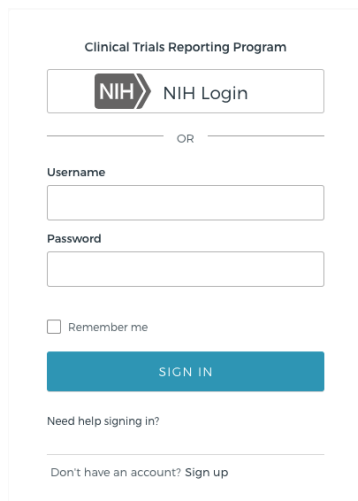
June 2021

Transition to the NCI's 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



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:

[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 to ensure that the trial information is accurate and up to date.

Select the **NCI Trial Identifier** to verify the trial record.

NCI Trial Identifier	Title	Registration Date	Lead Organization	Lead Org Trial Identifier	Available Actions	Current Trial Status
NCI-2017-00384	A Phase I/II 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 I/II Study Of Brentuximab Vedotin In Combination With Multi-Agent Chemotherapy	04/11/2017	Case Western Reserve University	UPCC 348-02 II	Select Action	In Review
NCI-2017-00385	A Phase I/II Study Of Brentuximab Vedotin In Combination With Multi-Agent Chemotherapy II	04/11/2017	Case Western Reserve University	UPCC 348-02h	Select Action	In Review
NCI-2017-00381	A Phase I/II Study Of Brentuximab Vedotin In Combination With Multi-Agent Chemotherapy	06/28/2017	Case Comprehensive Cancer Center	UPCC 86422673 ss410	Select Action	In Review
NCI-2017-02638	test73834	06/28/2017	Case Comprehensive Cancer Center	test7383484	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**.

Trials owners, trial submitters, and site administrators can review and edit trial data prior to selecting the **Update/Verify** button. Once selected, the **Date**, **Verification Method**, and **Verified By** is recorded within the **Trial Data Verification** section on the **Update/Verify Trial Data** page. The page reloads to the **Trials Needing Verification** page.

Please verify ALL the trial information you provided on this screen before clicking "Update/Verify". Even if no data was changed, a Data Verification record will be saved with today's date.

Update/Verify

Cancel

Other Actions

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/viewVerifyTrials.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 ncictr@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 additional 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 additional 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>