# **Recent Changes to CTRP**

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).

## 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

Update to the CTRP Trial Summary Report (TSR) to include the pragmatic trial indicator. The field is labeled "Pragmatic Trial" and is in the 'Trial Design' table.

Trial Design		
Туре	Interventional	
Primary Purpose	Treatment	
Pragmatic Trial	Yes	

"Pragmatic Trial" values on the TSR:

Yes - This is a pragmatic trial

No - This is not a pragmatic trial

No Data Available - CTRP currently does not have information as to whether or not this is a pragmatic trial

For additional information about the pragmatic trial indicator on the TSR, please visit the following CTRP User Guide page:

Trial Design

Pragmatic Trials Definition and Characteristics

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.



#### **Definitions:**

**Direct** - Trials conducted under any type of contract, grant, or cooperative agreement supported by the NCI (e.g., R01, N01, SPORE, 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.

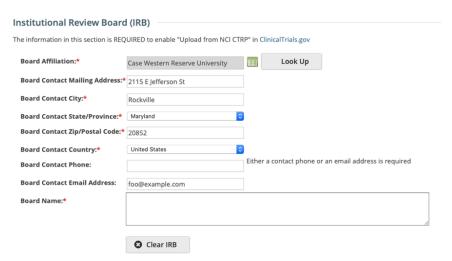
For additional information about recording NIH Grant Information in the CTRP Registration application, please visit the following CTRP User Guide page:

**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



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

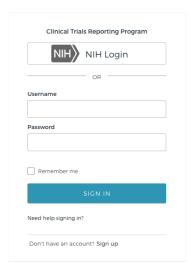
## June 2021

<u>Transition to the NCIs multi-factor authentication system, Okta:</u> 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

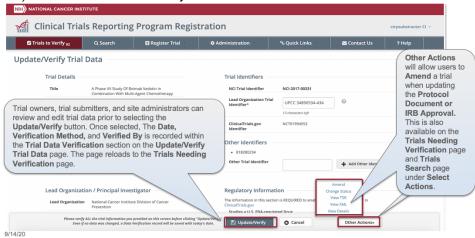
# September 2020

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:

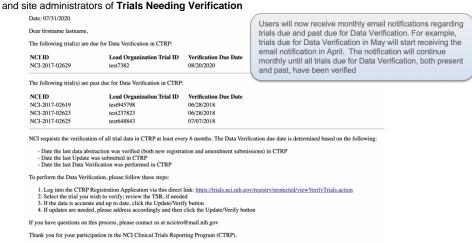
1. New page highlighting all Trials Needing Verification



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



- 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



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**

<u>Flexible Accrual</u>: 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 <u>requires a ticket to be submitted to the CTRO (NCICTRO@mail.nih.gov)</u> 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 require s 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. <u>Disease</u>:
    - 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-l&A=1