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 (NCICTRO@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	
Type	Interventional
Primary Purpose	Treatment
Pragmatic Trial	Yes

"Pragmatic Trial" values on the TSR:

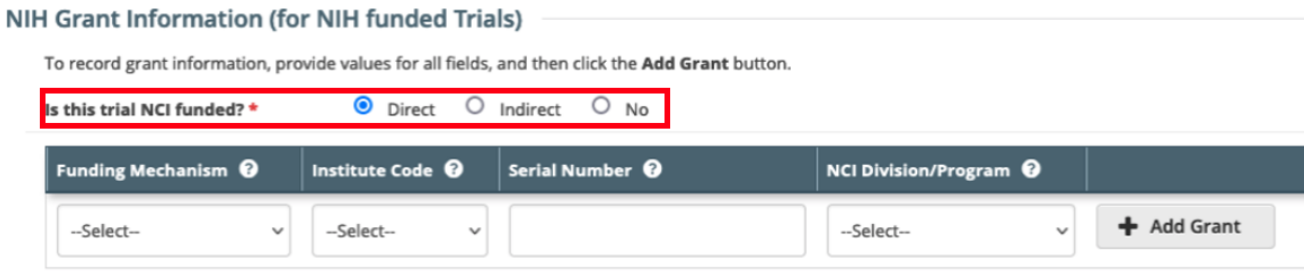
Yes – This is a pragmatic trial
No – This is not a pragmatic trial
No Data Available – CTRP currently does not have information as to whether or not this is a pragmatic trial

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

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.



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.

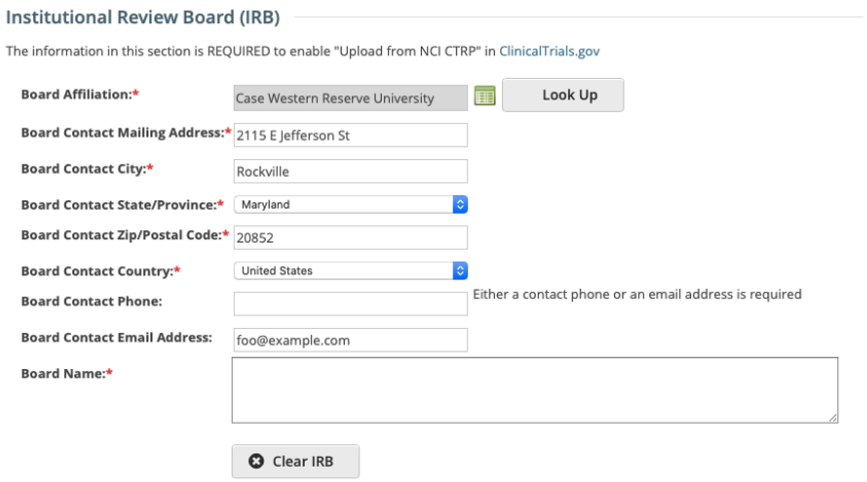
For additional information about recording NIH Grant Information in the CTRP Registration application, please visit the following CTRP User Guide page:

Recording NIH Grants

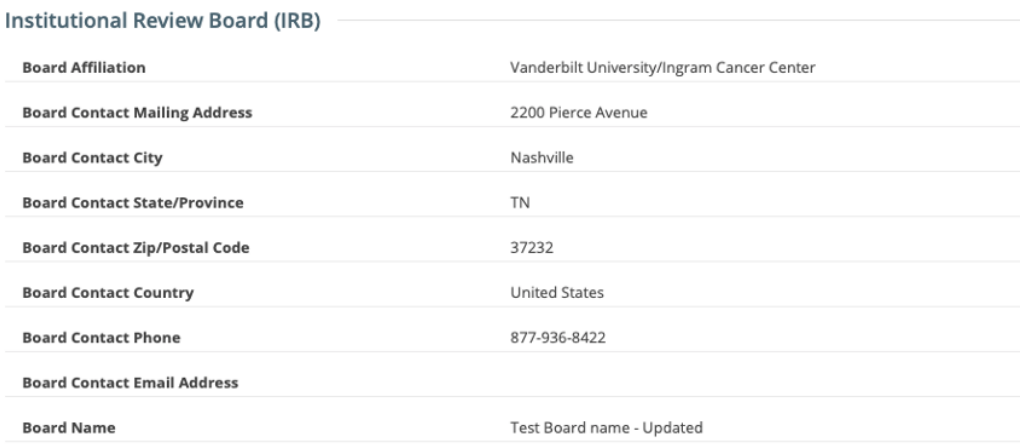
July 2021

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



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

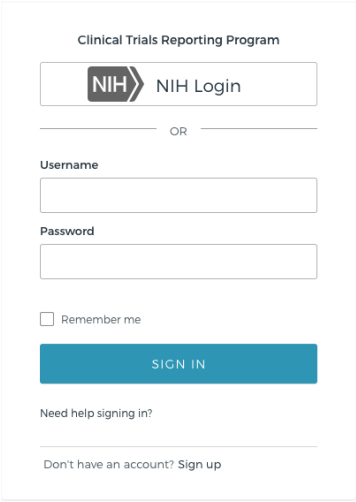
June 2021

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



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

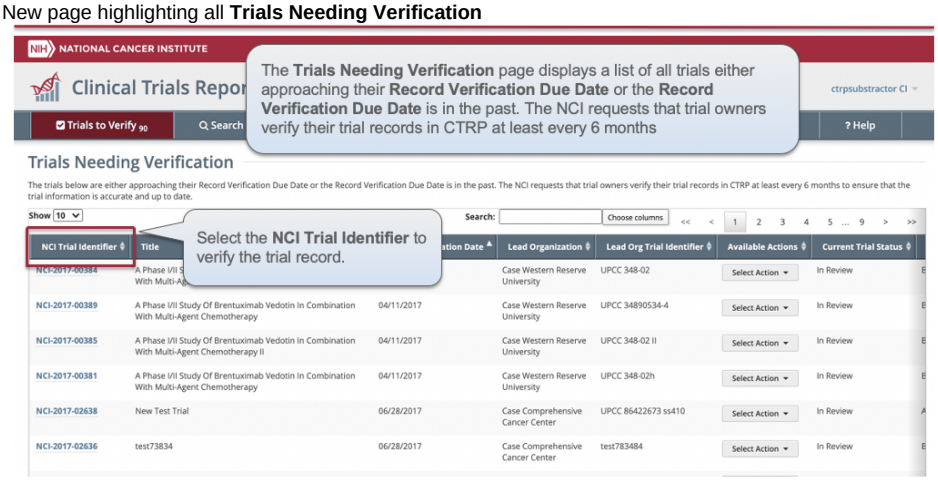
Removal of the following fields from the Trial Summary Report (TSR):

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

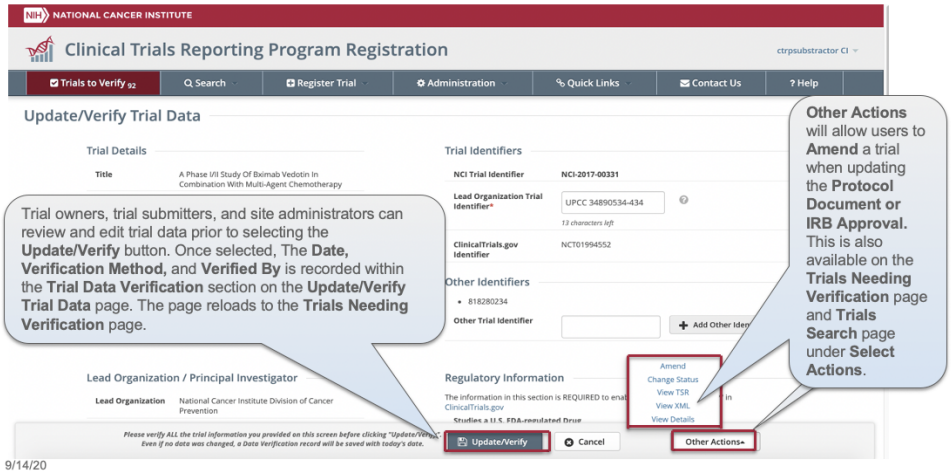
September 2020

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**

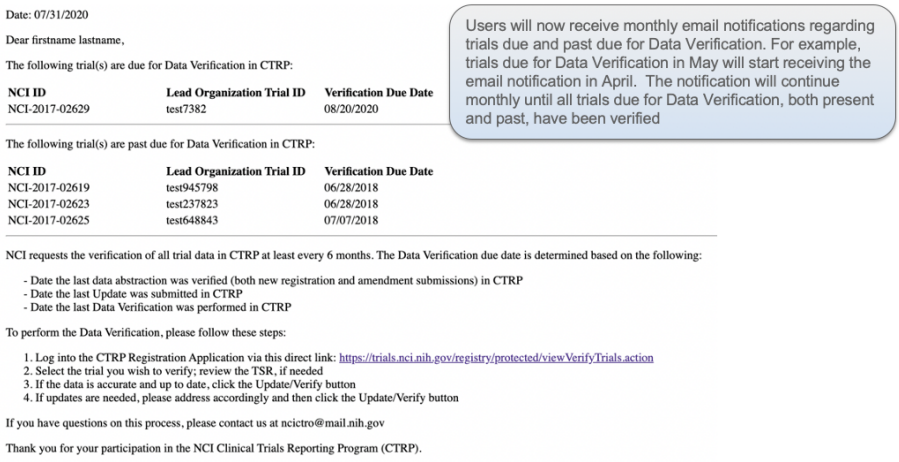


2. Ability to view all trial details on the **Verify** screen



9/14/20

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 firstname 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 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 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-l&A=1