Copy of Recent changes to CTRP <TSR RELEASE> - ALT 2 /13/2024 v2.0

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 2024

New CTRP trials.nci.nih.gov login page and new Accrual application are now live.

New Login page with accompanying landing page allows users to select and launch the new Accrual, Registration, Protocol Abstraction, or Person /Organization CTRP applications.

CTRP has developed a new Accrual Reporting application available via trials.nci.nih.gov. The new version maintains most of the previous Accrual *(e.g., now referred to as Classic Accrual)'s* functionality; however, the user interface is updated, and user experience is enhanced. These enhancements include:

- Trial Search
    - The Accrual Counts and Trial Search page in classic Accrual have been combined. Please note the Accrual Counts page is decommissioned.
    - The ability to show/hide columns is expanded to the newly added fields absorbed from the Accrual Counts page.
    - Search and filter capabilities have been expanded beyond NCI Trial Identifier, ClinicalTrials.gov Identifier, and Official Title fields.
    - The ability to filter prior submissions by the NCI Trial Identifier is available under the "Actions" column.
- Study Subject
    - Study subject records still inherit the trial record's selected accrual disease terminology; however, study subject records are now allowed to not match the accrual disease terminology selected at trial-level.
    - The field "Study Subject Gender" is relabeled to display "Study Subject Sex" throughout the application.
    - The "Method of Payment" and "Registering Group Identifier" fields have been decommissioned throughout the new Accrual application.
    - Study Subject ZIP Code will allow users to enter 9 digits for US-based subjects; however, new Accrual will only save the first 5 digits.
- Prior Submissions
    - The "Rejection Reason" column has been added to the page and is included in file export *up* to a 1,000 characters.

> ✅ **Please Note**
>
> The generated email notification for accrual submission is still providing the most comprehensive information, especially for large batch submissions. The list displayed in the new Accrual application can provide initial, aggregated information to users.
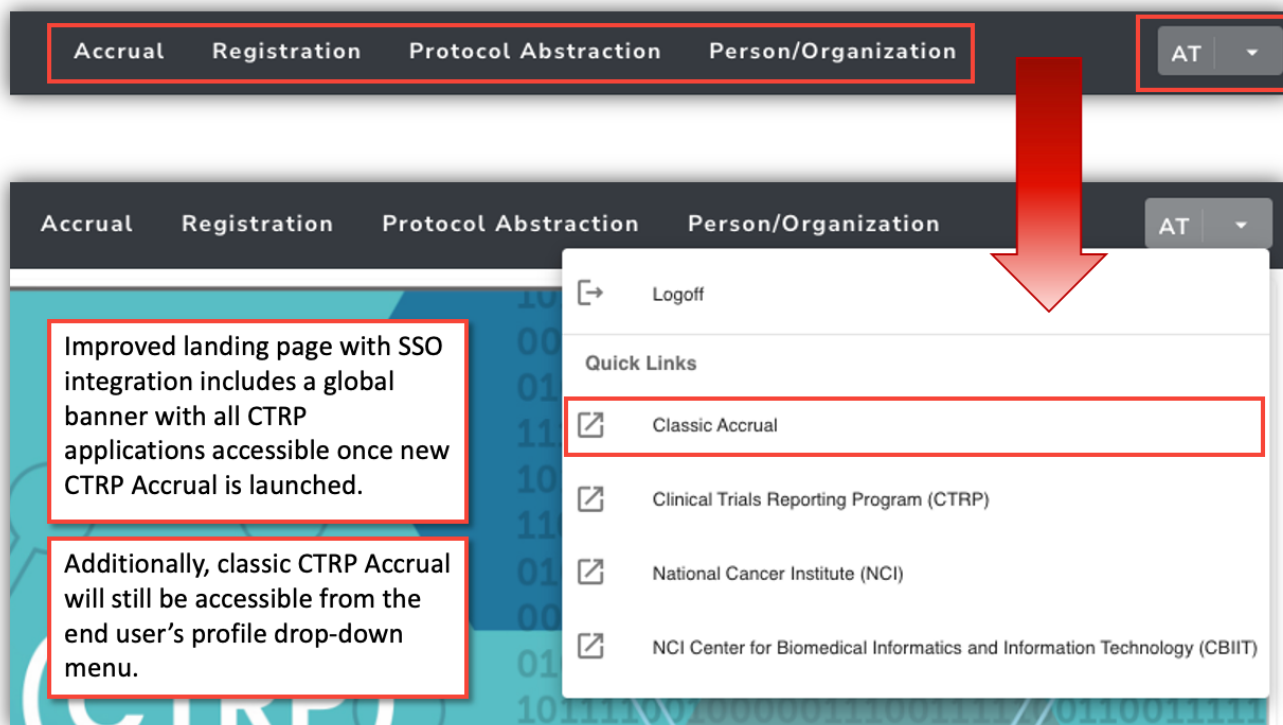
- Session Time-out Changes
    - The new application no longer has an automatic log-out after sixty-minutes.

Learn how to use the new Accrual via updated CTRP Accrual User Guide

- Logging in to CTRP page
- Accrual User Guide (updated with new Accrual information)

Please note: The new Accrual application will be released in parallel with the current Classic Accrual application. Users will have the option to utilize either application for a brief period, until the Classic Accrual application is deprecated and no longer available. The use of the new Accrual application is highly encouraged.

To access Classic Accrual: On main landing page, within the top right-hand menu, a user can click the Profile down button, and the Classic Accrual application is listed within the Quick Links menu.

Improved landing page with SSO integration includes a global banner with all CTRP applications accessible once new CTRP Accrual is launched.

Additionally, classic CTRP Accrual will still be accessible from the end user's profile drop-down menu.

Please report any technical questions about CTRP applications using ctrp_support@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

Institutional Review Board (IRB)

The information in this section is REQUIRED to enable "Upload from NCI CTRP" in 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

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

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

Trials Needing Verification

The trials below are 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.

NCI Trial Identifier	Title	...tion Date	Lead Organization	Lead Org Trial Identifier	Available Actions	Current Trial Status
NCI-2017-00384	A Phase I/II S... With Multi-A...		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 34890534-4	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 348-02 II	Select Action ▾	In Review
NCI-2017-00381	A Phase I/II 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**.

Trial 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.

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**

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