

Recent changes to CTRP V1

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).

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 screenshot shows the 'Trials Needing Verification' page. A callout box explains: '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'. Another callout points to the 'NCI Trial Identifier' column, stating: 'Select the NCI Trial Identifier to verify the trial record.' The table lists trials with columns for NCI Trial Identifier, Title, Verification Date, Lead Organization, Lead Org Trial Identifier, Available Actions, and Current Trial Status.

NCI Trial Identifier	Title	Verification 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 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

The screenshot shows the 'Update/Verify Trial Data' screen. A callout box explains: '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.' Another callout points to the 'Amend' button, stating: '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.' The form includes sections for Trial Details, Trial Identifiers, Lead Organization / Principal Investigator, and Regulatory Information.

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:**

- Study Subject Birth Date:** For any/all ways to report accrual, only the month and year (MM/YYYY) are required to be collected.
- Study Subject Country:** Required for all methods of reporting accrual (was previously optional)
- Disease:**
 - Study Subject: Required
 - Partial Subject: Not required. However, for ICD-O-3 Disease Codes if Disease is reported, then Site must be reported.
- Site:**
 - Study Subject: Required
 - Partial Subject: Not required. However, for ICD-O-3 Disease Codes if Site is reported, then Disease must be reported.
- 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>