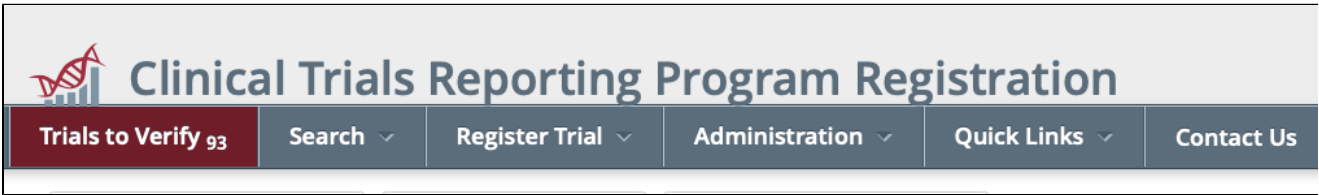


Amending Trials - Include v4.5

The **Amend Trial** page can be accessed by either of the following methods below:

- Using the **Trials to Verify** menu
- Using the **Search** menu



Using the **Trials to Verify** menu

1. Select the **Trials to Verify** menu from the main toolbar. The **Trials Needing Verification** page displays.

The image shows the 'Trials Needing Verification' page. At the top is the system logo and title. Below it is a secondary toolbar with 'Trials to Verify 93' (active), 'Search', 'Register Trial', 'Administration', 'Quick Links', 'Contact Us', and 'Help'. The main heading is 'Trials Needing Verification'. A text block explains that trials are listed here because they are approaching or past their record verification due date. Below this is a search bar and a 'Show' dropdown set to '10'. A table follows with columns: 'NCI Trial Identifier', 'Title', 'Record Verification Date', 'Lead Organization', and 'Lead Org Trial Identifier'. Two trials are listed: 'test Trial II without grants' and 'A Phase I/II Study Of Bximab Vedotin In Combination With Multi-Agent Chemotherapy'.

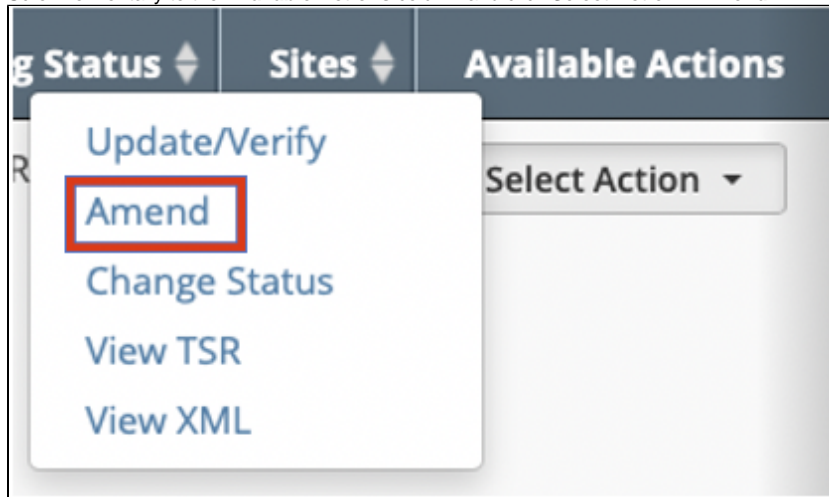
NCI Trial Identifier	Title	Record Verification Date	Lead Organization	Lead Org Trial Identifier
NCI-2017-00333	test Trial II without grants	03/30/2017	Case Western Reserve University	Ld 1234
NCI-2017-00331	A Phase I/II Study Of Bximab Vedotin In Combination With Multi-Agent Chemotherapy	03/30/2017	National Cancer Institute Division of	UPCC 34890534-434

2. Search for the trial in question by using the **Search:** box to perform a keyword search.
3. Once the trial has been identified, perform one of the following actions:
- a. Click on the Identifier in the **NCI Trial Identifier** column:

This is a close-up of the 'Trials Needing Verification' table. It shows the 'NCI Trial Identifier' column with the value 'NCI-2017-00333' and the 'Title' column with the value 'test Trial II without grants'. The identifier is underlined, indicating it is a clickable link.

NCI Trial Identifier	Title
NCI-2017-00333	test Trial II without grants

- b. Scroll horizontally to the **Available Actions** column and click **Select Action > Amend**.

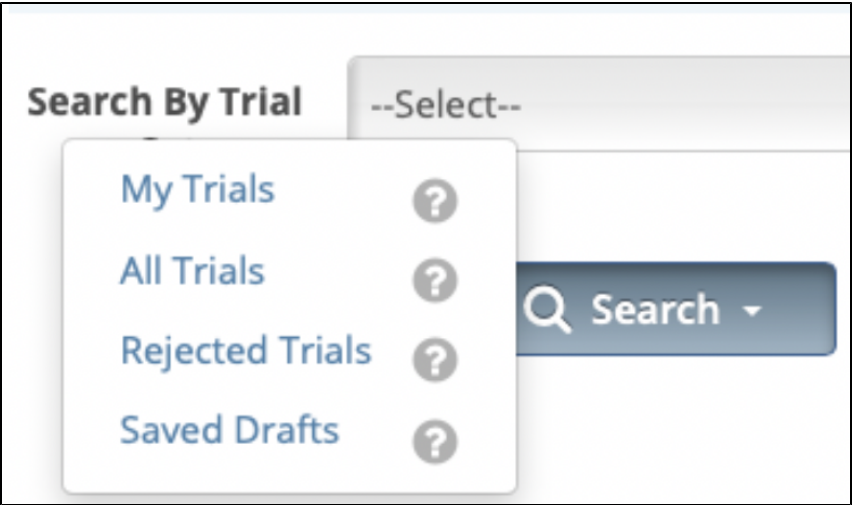


Using the **Search** menu

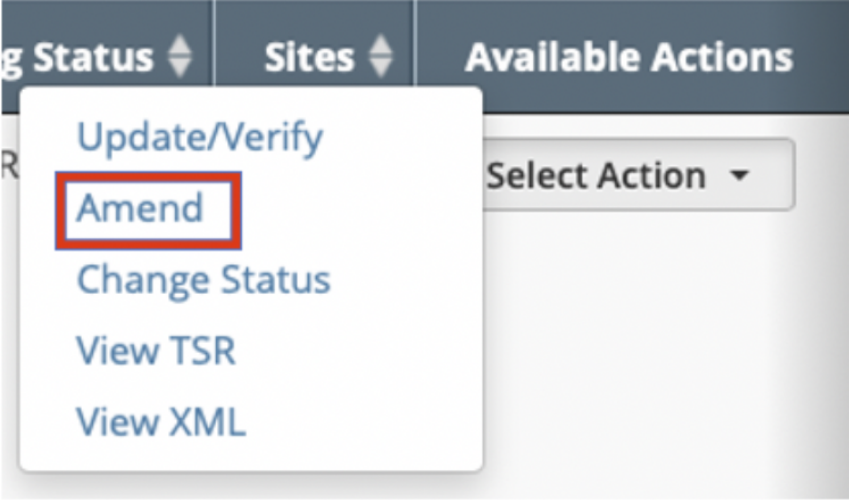
1. From the **Search** menu, select **Clinical Trials**. The **Search Clinical Trials** page displays.

A screenshot of the 'Clinical Trials Reporting Program Registration' web application. The page has a dark blue header with a logo on the left and navigation links: 'Trials to Verify 93', 'Search', 'Register Trial', 'Administration', 'Quick Links', 'Contact Us', and 'Help'. The 'Search' link is highlighted. Below the header, there are three tabs: 'Search Clinical Trials', 'Search Persons', and 'Search Organizations'. The 'Search Clinical Trials' tab is selected. The main content area contains a search form with the instruction 'Enter information for at least one of the criteria and then click Search.' The form includes several input fields and dropdown menus: 'Title' (text input), 'Phase' (dropdown), 'Purpose' (dropdown), 'Pilot Trial?' (dropdown), 'Identifier Type' (dropdown), 'Identifier' (text input with examples 'NCI-2008-00015; ECOG-1234'), 'Organization Type' (dropdown with a note 'Please select an organization type before selecting an organization'), 'Organization' (text input with a note 'Enter keyword and select an organization from'), 'Principal Investigator' (text input with a note 'Enter keyword and select a PI from the list'), and 'Search By Trial Category' (dropdown). At the bottom right of the form are two buttons: 'Search' and 'Reset'.

2. Search for the desired trial(s) by using any of the filter options available on the page, or select the **Search My Trials** option from the **Search** button.



3. On the Clinical Trials Search Results page, scroll horizontally to the **Available Actions** column and click **Select Action > Amend**.



4. The **Amend Trial** page displays the data currently registered with the CTRP.

Amend Trial

Trial Details

Amendment Date*

mm/dd/yyyy

Amendment #

Title*

test Trial II without grants

3972 characters left ?

Phase*

I

Is this a Pilot?

--Select--

Trial Type*

Interventional

Non-interventional

Primary Purpose*

Treatment

Secondary Purpose

--Select--

Trial Identifiers

NCI Trial Identifier

NCI-2017-00333

Lead Organization Trial Identifier*

Ld 1234

23 characters left ?

ClinicalTrials.gov Identifier

Other Identifiers

Other Trial Identifier

+ Add Other Identifier

5. Make changes to the fields as necessary. The system requires you to provide information for all fields marked with an asterisk (*). The instructions are the same for trial registration and trial amendment, with some exceptions:

- In the Amendment Details section, specify the appropriate information in the various fields. The following table describes the fields.

Field Label	Description/Instructions

Amendment Number	Enter an appropriate number.
Amendment Date*	Select or enter an appropriate date.

- You can select a different disease code only if accrual has not yet been reported to CTRP.
- A trial can capture program codes from different organization families. For example, a participating site might belong to a different organization family than the lead organization. When you amend a trial, the **Program Code** field displays all codes from the master list for the organization family of the lead organization.
- **Primary Completion Dates** are optional for non-interventional trials. The system excludes such trials when submitting XML documents to [ClinicalTrials.gov](https://clinicaltrials.gov). Otherwise, **Primary Completion Dates** are required.
- The system does not change the status of participating sites when you close a trial.
- For instructions on recording each field otherwise, refer to [Registering New Trials](#).

Submitting Amendments

1. Scroll to the bottom of the **Amend Trial** page, and click **Submit Amendment**.

The system checks for errors and missing information.

- a. If errors are found: An Error Message is displayed at the top of the **Amend Trial** page.

Amend Trial

Error Message: The form has errors and could not be submitted, please check the fields highlighted below

- i. Correct any errors if indicated, and re-submit the amendment as many times as necessary until the amendment is error-free.

- b. If no errors are found: The **Trial Details** page is loaded with a confirmation message at the top of the page:

Trial Details

The amendment to trial with the NCI Identifier NCI-2020-00057 was successfully submitted.

2. The system sends you an email notification — with the details of what has changed — whenever you amend trials.
3. Each time a trial is amended, the CTRP Registration application records the Date, Verification Method and Verified By in the **Trial Data Verifications** history after the Amendments has been abstracted by the CTRO. The **Trial Data Verifications** history can be found on the **Trial Details** and **Update/Verify Trial Data** pages.

Trial Data Verifications		
2 items found, displaying all items.1		
Date	Verification method	Verified By
2020-08-04 23:53:17.832	Manual Verification Entered	ctrpsubtractor CI
2017-06-28 12:41:40.055	Abstraction Verified Response	CTRO Staff