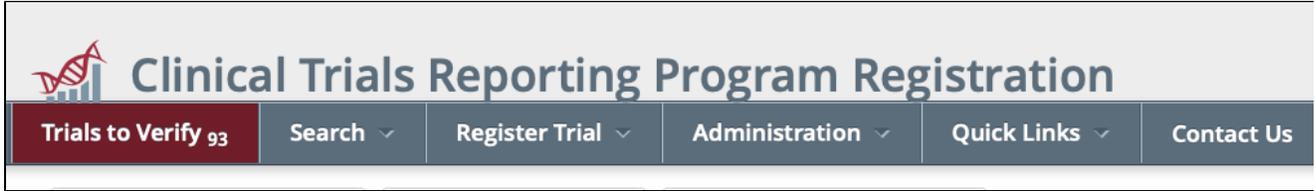


Amending Trials - Include v4.5

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

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

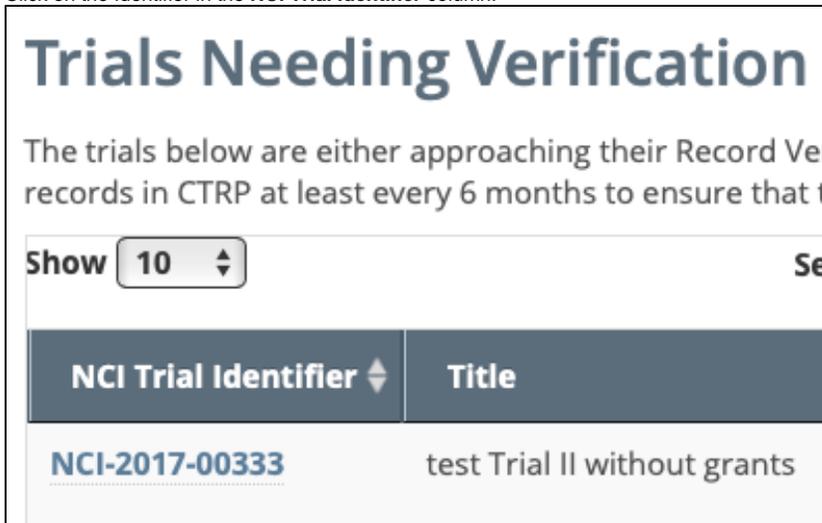


Using the **Trials to Verify** menu

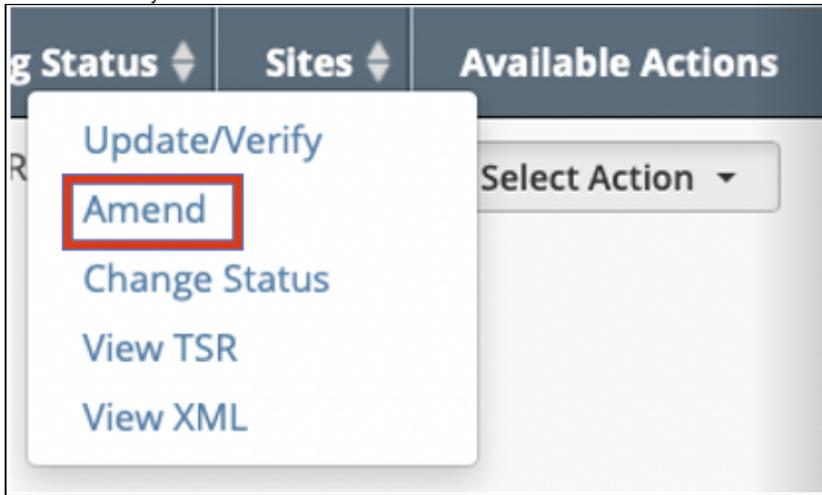
1. Select the **Trials to Verify** menu from the main toolbar. The **Trials Needing Verification** page displays.



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:



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

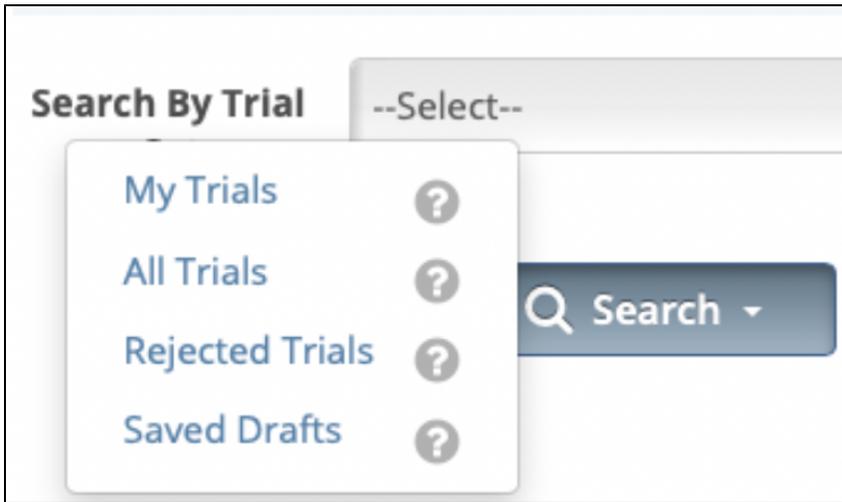


Using the **Search** menu

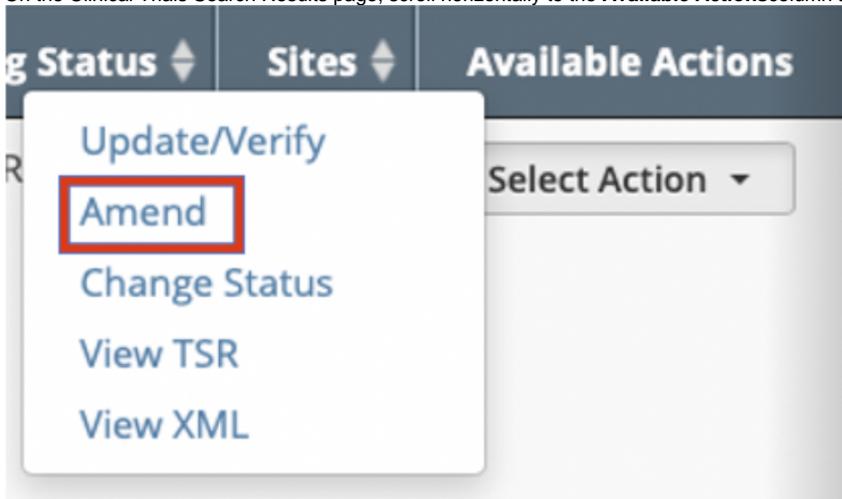
1. From the **Search** menu, select **Clinical Trials**. The **Search Clinical Trials** page displays.

A screenshot of the 'Clinical Trials Reporting Program Registration' search page. The page has a dark blue header with the title and a user profile 'ctrpsubtractor CI'. Below the header is a navigation bar with 'Trials to Verify 93', 'Search', 'Register Trial', 'Administration', 'Quick Links', 'Contact Us', and 'Help'. The main content area has three tabs: 'Search Clinical Trials' (selected), 'Search Persons', and 'Search Organizations'. Below the tabs, there is 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), '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 'Search' and 'Reset' buttons.

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*

Amendment #

Title*

Phase*

Is this a Pilot?

Trial Type* Interventional Non-interventional

Primary Purpose*

Secondary Purpose

Trial Identifiers

NCI Trial Identifier

Lead Organization Trial Identifier*

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	ctrpsubstructor CI
2017-06-28 12:41:40.055	Abstraction Verified Response	CTRO Staff