Amending Trials - Include 20170807

How to Amend Trials

- 1. On the toolbar, click Search > Clinical Trials. The Search Trials page appears.
- 2. Click Search > My Trials. The Search Results page displays the results of your search and actions available (if any) for each record.

Accepted Select Action ▼ Abstractio Response Amend Change Status View TSR View XML Verify Data	Current Processing Status 🔷		Available Actions	¢
Abstractio Response Amend Change Status View TSR View XML	Accepted		Select Action 🔻	
		Amend Change Status View TSR View XML	Select Action 🔻	

- In the Available Actions column, click Select Action > Amend. The Amendment Trial page displays the data currently registered with the CTRP.
 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 the trial has not accrued any subjects to date.
- A trial can accumulate 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 and for DCP trials. In both cases, the system excludes such trials when submitting XML documents to 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.
- 5. Review the amendment. Refer to Reviewing and Submitting Trial Amendments.
- 6. Submit the amended trial to the CTRP. The system sends you an email notification with the details of what has changed whenever you amend accepted trials.