Validating Trial Status - Include 20170822

ⓘ **Validate the trial status for Complete trials only.**

Trial Status validation does not pertain to *Abbreviated* trials.

For information on trial statuses, refer to Trial Status Values in the CTRP and ClinicalTrials.gov. Ensure that the relationships between statuses and dates follow the rules provided in Status Transition Rules and the following table:

If you transition from this status...	To this status...	The system creates this status
In Review	Active, or Enrolling by Invitation	Approved
Active, or Enrolling by Invitation	Closed to Accrual and Intervention	Closed to Accrual
Active, or Enrolling by Invitation	Completed	- Closed to Accrual - Closed to Accrual and Intervention
Temporarily Closed to Accrual	Administratively Completed	Temporarily Closed to Accrual and Intervention
Temporarily Closed to Accrual	Closed to Accrual	None
Temporarily Closed to Accrual	Closed to Accrual and Intervention	None
Temporarily Closed to Accrual and Intervention	Closed to Accrual	None
Temporarily Closed to Accrual and Intervention	Closed to Accrual and Intervention	None

How to Review Trial Status Details

1. Select a trial to validate by following the instructions in Selecting Trials that Require Validation. The Trial Identification page displays the trial details.
2. On the **Trial Identification** page, check out the trial. For instructions, refer to Checking In and Checking Out Trials. (This checkout step is optional for Super Abstractors.)
3. On the **Validation** menu, click **Trial Status**. The Trial Status page appears.
4. To view trial status information previously recorded, in the upper right corner of the **Trial Status** section, click **History.**
5. In the various status fields, specify the appropriate information. The following table describes the fields. An asterisk (*) indicates a required field.

Field Label	Description/Instructions
Current Trial Status*	Select the trial's accrual status from the drop-down list. For valid ClinicalTrials.gov recruitment values, refer to Trial Status Values in the CTRP and ClinicalTrials.gov and Expanded Access Statuses.
Current Trial Status Date*	Enter the date on which the current trial status became effective.
Why Study Stopped	If you selected the **Administratively Complete**, **Withdrawn**, or **Temporarily Closed to Accrual** status, type the reason why the study has ended or is not currently accruing.

6. In the various date fields, specify dates as they occur according to the rules specified in CTRP System Rules for Study Status and Dates. The following table describes the fields. In this table, an asterisk (*) indicates a required field and an asterisk within square brackets ([*]) indicates a conditionally required field.

Field Label	Description/Instructions
Trial Start Date*	Enter the date on which the trial started, or is expected to start.
Primary Completion Date [*]	Enter the date on which the final subject was examined or received an intervention, or the date on which that is expected to happen. Primary Completion Dates are optional in the following cases: - For non-interventional trials. - For DCP trials, if you select **N/A** as the type. In both cases, the system excludes such trials when submitting XML documents to ClinicalTrials.gov. Otherwise, Primary Completion Dates are required.
Completion Date	Enter the final date on which data was (or is expected to be) collected for the trial.

7. Indicate whether each date you entered is **Actual** or **Anticipated**, according to the rules specified in Status Rules for Trial Dates.
8. If you made any changes, click **Save**.

9. If the system displays errors and/or warnings, correct them according to the instructions in Abstracting Trial Status Histories.