



Proposal Submission

Award and Account Establishment

After Research Commences

Closeout

How do I update my Clinical Trials Record?

The Record List on the home page lists all your records along with status information for each record. Open the record that you wish to update and use the edit link(s) on the left to modify the desired section of the record. Data is saved as each page is filled in, so that you can "Quit" at any time, saving the record for later completion.

How often do I need to update my Clinical Trials Record?

Study records for active studies must be reviewed and modified, as needed, at least once every 12 months. [Some data elements](#) must be updated sooner (e.g., within 30 days of a change) based on the requirements in Section 801 of FDAAA and 42 CFR 11.64. Pay special attention to recruitment statuses, location, and contact information, as the accuracy and timeliness of this information is extremely important to patients and health care professionals. Update the Record's Verification Date (in the Protocol section, Study Status module) to confirm that the record has been reviewed.

What if I need to modify my Clinical Trials Record?

Your record can be modified at any point if it's not locked by Protocol Registration and Results System (PRS) for review and comments. If a record's status is Entry Completed, Approved, Released or Public, and the record is modified, the record status is automatically reset to In Progress. Remember to mark the record as Entry Completed when finished editing.

My Clinical Trials Record has problems, how do I address them?

The Record List on the Home page includes a Problems column listing issues for each record. To address problems, open the record and make the necessary changes, following the instructions in the Next Step box near the top of the Record Summary page.

PROBLEM	ACTION
Entry Not Completed	Log in, update record, and mark entry as complete.
Pending PRS Comments	Log in, review comments, update record as needed, mark entry as complete.
Not Recently Updated	Log in, review the record, modify as necessary, update the verification date, mark entry as complete.
Record Has Errors	Log in, find and correct errors, mark entry as complete.
Missing FDAAA Information	Log in, review and modify the record until all WARNING messages have been resolved, mark entry as complete.
Late Results – Per FDAAA	Log in, determine whether results are required, or if a certification or extension request to delay results is appropriate.
Incomplete Results – Per FDAAA	Enter additional results in record summary. Mark entry as complete once data is entered.
Ready for Review and Approval	Responsible Party should mark record as Approve and Release for PRS to review.
Never Released	Determine if study should be posted on Clinical Trials, change owner if needed, update as necessary, mark entry as complete.
Update Not Released	Determine who should finish updating record, change ownership if necessary, review and update the record, mark entry as complete.

Responsible Party should approve and release records upon entry completion for PRS review.

<https://prsinfo.clinicaltrials.gov/prs-users-guide.html#section8>