We're building a better ClinicalTrials.gov. Check it out and tell us what you think!

U.S. National Library of Medicine

Clinical Trials.gov

Find Studies ▼ About Studies ▼ Submit Studies ▼ Resources ▼ About Site ▼ <u>PRS Login</u>

Do you or someone you know want to participate in a clinical study? See information for patients and families.

# How to Edit Your Study Record

## Contents

- Editing and Updating a Record
- View Earlier Versions of Your Study Record

### Editing and Updating a Record

This page describes the overall process of editing a study record. If you would like step-by-step instructions for entering registration or results information into the PRS, see the <u>PRS Guided Tutorials</u>. The tutorials include a quick overview guide called <u>Updating a Study Record</u> that briefly summarizes how to use the tutorials to support editing a study record. [Requires a browser that supports HTML5.]

At any time, you can make updates and edits to a record published on ClinicalTrials.gov by logging into the <u>Login to ClinicalTrials.gov PRS</u> and clicking on **Edit Record** under the Protocol Records heading on the PRS main menu. After you finish making changes, you will need to release (submit) the record to ClinicalTrials.gov for review and processing. See the <u>ClinicalTrials.gov Protocol Review Criteria</u> (PDF) for a description of items that should be addressed before releasing the record to ClinicalTrials.gov. See the <u>ClinicalTrials.gov Protocol Information Review Process</u> for more information.

#### **Required Registration Updates**

Responsible Parties should update their records within 30 days of a change to any of the following:

- <u>Recruitment Status</u> and <u>Overall Recruitment Status</u> data elements on ClinicalTrials.gov
- Completion Date (See <u>Primary Completion Date data element</u> on ClinicalTrials.gov)

Other changes or updates to the record, such as protocol amendments, must be made at least every 12 months. It is recommended that the Record Verification Date be updated at least every 6 months for studies that are not yet completed, even if there were no changes to the record.

## Submitting Results

For certain clinical trials subject to Section 801 of the Food and Drug Administration Amendments Act (FDAAA 801), the Responsible Party must submit summary results no later than 12 months after the date of final data collection for the prespecified primary outcome measure (see <u>Primary Completion Date data element</u> on ClinicalTrials.gov). See <u>How to Submit Your Results</u> and <u>FDAAA 801 and the Final Rule</u> for more information.

#### View Earlier Versions of Your Study Record

The most recent version of a study record is displayed on ClinicalTrials.gov. A history of changes made to a study record is available on the ClinicalTrials.gov archive site. You will need to click on the **History of Changes** link near the bottom of the full text view to see the archived versions.

This page last reviewed in May 2021

TO TOP