

Updating a ClinicalTrials.gov Record

Version 20221107

Steps to follow to update your study record

1. Open an Internet Browser (Internet Explorer, Google Chrome, etc.) and type <https://register.clinicaltrials.gov> into the address bar.
2. Click the “Open,” next to the study that needs to be updated.

ClinicalTrials.gov PRS
Protocol Registration and Results System

Quick Links
[New Record](#)
[Admin Quick Reference](#)
[Problem Resolution Guide](#)

Records Accounts Help

Record List
Group: [ALL] All Records (384) Problem Records (228) Custom Filter

Showing: 1-31 of 31 records (filtered from 384 records) All records per page

	Group	Protocol ID	Secondary IDs	ClinicalTrials.gov ID	Brief Title
Open	[None]	ABCDE-2345-003CS			The COLD SORE StudyCS
Open	[None]	ABCDE-2345_20170314	20170314 R01DA013131		The COLD SORE Study_20170314 (SHARE)
Open	[None]	ABCDE-2345-005-ICF	R01DA013131		The COLD SORE Study-ICF
Open	[None]	ABCDE-2345 YPD20170124			The COLD SORE Study ypd20170124

3. Click “Open,” next to the Protocol Section.

[Open](#) Protocol Section

Identifiers: [NCT ID not yet assigned] Unique Protocol ID: eProst ID

Brief Title: Testing PRS Updates

Module Status:

- Study Identification: 2 Notes
- Study Status:
- Sponsor/Collaborators:
- Oversight:
- Study Description: 1 Note
- Conditions:
- Study Design:
- Arms and Interventions:
- Outcome Measures:
- Eligibility:
- Contacts/Locations:
- References:

4. Click “Edit,” next to study status.

Record Summary | Preview | **Edit All** | Help | Definitions

Study Identification

Unique Protocol ID: eProst ID
 Brief Title: Testing PRS Updates
 NOTE: A title this short is probably not sufficiently descriptive.
 Official Title: Testing PRS Updates
 NOTE: A title this short is probably not sufficiently descriptive.
 Secondary IDs:

Study Status

Record Verification: May 2017
 Overall Status: Active, not recruiting
 Study Start: January 30, 2017 [Actual]
 Primary Completion: June 30, 2019 [Anticipated]
 Study Completion: June 30, 2020 [Anticipated]

5. Update and/or verify the relevant study status information.

Then click



Help | Definitions

* Record Verification Date: Month: May Year: 2017

* Overall Recruitment Status: Not yet recruiting

Tip: Day is not required for Anticipated dates.

* § Study Start Date: Month: August Day: 30 Year: 2017 Type: Anticipated

* Primary Completion Date: Month: October Day: 31 Year: 2021 Type: Anticipated

* § Study Completion Date: Month: August Day: 30 Year: 2023 Type: Anticipated

Save Cancel

* Required
 * § Required if Study Start Date is on or after January 18, 2017
 [*] Conditionally required (see Definitions)

Update the record by entering the **current** month and **current** year that you are editing the record.

Review and edit if the status recorded is no longer correct.

See Recruitment Status Flow Resource for guidance.

If these dates are in the past and the Type is indicated as anticipated, do one of the following:

- Update the date, or
- Change Type to “Actual”

6. After updating the record, click “Entry Complete.”



7. After completing record, the record will need to be ‘Approved’ by the Responsible Party.



8. After the record has been approved, the Responsible Party will need to “Release” the record.

Record Status

In Progress → Entry Completed → **Approved** → Released → PRS Review → Public

[Reset to In-Progress...](#)

Next Step: Release record **Release...** ⓘ

Record Owner:	h.osorio	Access List:	<input type="checkbox"/> Edit
Last Update:	05/31/2016 by h.osorio	Upload:	Allowed Edit
Initial Release:	[Not yet released]	PRS Review:	[Not yet released]
		Public Site:	[Not yet registered]
		FDAAA:	ACT ⓘ

9. The Record Protocol Record Verification is required by the Responsible Party.

- a. If the Verification Date (Step 5) was not previously updated, the Verification date and Responsible Party check boxes will appear.**

Release Protocol Record

Unique Protocol ID:	eProst ID
Brief Title:	Testing PRS Updates
Overall Status:	Active, not recruiting
Primary Completion Date:	June 30, 2019 [Anticipated]
Verification Date:	July 2016

This record is up-to-date and has been reviewed for accuracy and completeness. Verification date will be updated automatically.

I, Heather Osorio, Principal Investigator and Responsible Party for this trial.

Release (submit) Protocol Record to ClinicalTrials.gov PRS for review?

Release **Cancel**

b. If the Verification Date was previously updated, only the Responsible party check box will appear.

Release Protocol Record

Unique Protocol ID:	eProst ID
Brief Title:	Testing PRS Updates
Overall Status:	Active, not recruiting
Primary Completion Date:	June 30, 2019 [Anticipated]
Verification Date:	May 2017

I am Heather Osorio, Principal Investigator and Responsible Party for this trial.

Release (submit) Protocol Record to ClinicalTrials.gov PRS for review?

