

Step-by-Step Guidance for Registering a Protocol on ClinicalTrials.gov

1) To Get a NEW ClinicalTrials.gov Password

- a. Send an email message to the DFCI QACT ClinicalTrials.gov Administrator at: DFCIQACTClinicalTrialsGov@partners.org

**Include your name, phone #, and email address*

2) Login to ClinicalTrials.gov

- a. When you have a username and password:
 - i. Go to ClinicalTrials.gov registration website: <https://register.clinicaltrials.gov/>
 - ii. Enter Your Organization (DFCI, MassGH)
 - iii. Enter Username and Password

ClinicalTrials.gov PRS
Protocol Registration and Results System

Welcome to the [ClinicalTrials.gov](#) Protocol Registration and Results System (PRS).

Login

Organization: DFCI MassGH
One-word organization name assigned by PRS (sent via email when account was created)

Username:

Password: [Forgot password](#)

[Lost/Forgot Password?](#)
Email: DFCIQACTClinicalTrials.gov@partners.org

See [Submit Studies](#) on ClinicalTrials.gov for information on how to apply for an account, how to register your study, and how to submit results.
[Send email to ClinicalTrials.gov PRS Administration](#)

- iv. If this is your first time and/or you are using a temporary password, please change your password immediately. To do this:
 1. On the Main Menu page, under "Account> Change Password," follow the instructions to change your password

3) From the Main Record Page.

4) Locate the protocol of interest and Select [[Open](#)] (First Column).

5) Review each of the section of the Clinicaltrials.gov record and make any necessary changes/updates.

6) To update the record, select [[Edit](#)] by the section that requires an update. Once updates have been made.

7) Click on “Save” at bottom of page.

The screenshot shows the 'Record Status' section of a web application. At the top, a progress bar indicates the status: **In Progress** → Entry Completed → **Approved** → Released → PRS Review → Public. Below this, the 'Next Step' is 'Confirm data entry complete', and a button labeled 'Entry Complete' is highlighted with a red circle. The page also displays metadata for the record, including the owner, last updated date (04/08/2014 08:10), initial release date (03/14/2014), last release date (04/08/2014), and a link to a receipt PDF. On the right side, there are links for 'Access List', 'Upload', 'PRS Review', and 'Public Site'.

1. Click on “Record Summary” (top of page)
2. Beside “Next Step”, Click [“Entry Complete”]

The screenshot shows the 'Record Status' section of a web application. The progress bar now shows: In Progress → Entry Completed → **Approved** → Released → PRS Review → Public. The 'Next Step' is 'needs to Release record', and the 'Approved' button in the progress bar is highlighted with a red circle. The page also displays updated metadata, including the last updated date (01/23/2015 12:27), initial release date (05/10/2012), last release date (03/17/2014), and results expected (March 2017). On the right side, there are links for 'Access List', 'Upload', 'PRS Review', and 'Public Site'.

3. Beside “Next Step”, Click “Approved”

Record Status	
In Progress → Entry Completed → Approved → Released → PRS Review → Public	
Reset to In-Progress...	
Record Owner: <input type="text"/>	Access List: <input type="checkbox"/> Edit
Last Updated: 02/05/2015 11:58 by <input type="text"/>	Upload: Allowed Edit
Initial Release: 03/09/2009	PRS Review: Review History
Initial Results Release: 02/14/2014	Public Site: Last public update: 02/23/2015 View on ClinicalTrials.gov
Last Release: 02/05/2015 Receipt (PDF)	

4. Beside “Next Step”, Click “Released”
5. Confirm that the “Record Status” is “Released”]

NOTE: The Record Status must say “Released” for any changes to be posted on clinicaltrials.gov.

Final Step: ClinicalTrials.Gov Quality Assurance Process:

- 1) When the Protocol Record is “Released” by the “Responsible Party”, the record is sent to Clinicaltrials.gov staff for internal quality assurance review (PRS Review).
 - i. If the record has no problems, then an email notification will be sent to the “Responsible Party” and confirming that the record has been made “Public” to the Clinicaltrials.gov website. This review process can take between 2 to 5 days.
 - ii. If there are problems during the review process (such as missing information), ClinicalTrials.gov will send email notification to the “Responsible Party” and change the record status to “ In Progress”.
 - iii. If a record is “In Progress”, corrections **MUST** to be made to the record or the Protocol Registration will not be successful. To do this, please review the “Review Comments” Section located at the top of the record. This section will outline the problems within the record. Please update the record according to the ”Comments” Section and then repeat all steps in this document from # 2 on. When the trial has been “Released” again, the trial will be reviewed by ClinicalTrials.gov again. The process will repeat until all problems are resolved.

Note: The “Responsible Party” is obligated to maintain and update the ClinicalTrials.gov record according to the FDAA required timelines, a minimum of every 6 months.

For more information see the DF/HCC guidance on **When/How to Update a ClinicalTrials.gov Record.**