DF/HCC
DANA-FARBER / HARVARD CANCER CENTER

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

      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.

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7) Click on "Save" at bottom of page.

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

3. Beside "Next Step", Click "Approved"

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.**