TITLE: When and How to Update a ClinicalTrials.gov Record		
Maintained by: Office of Data Quality (ODQ)	**Page:** 1 of 5	**Effective Date:** 04/20/2023

1. **BACKGROUND:**
   - **a.** A ClinicalTrials.gov record is required to be updated at least every 6 months (regardless of changes) and within 30 days of a protocol change/recruitment status change. This document outlines the following topics regarding maintaining a ClinicalTrials.gov record.
     - **i. What Fields Need to be Updated/Reviewed Regardless of Changes.**
     - **ii. How to Login into ClinicalTrials.gov**
     - **iii. How to Update Fields in ClinicalTrials.gov**
     - **iv. How to Approve and Release a ClinicalTrials.gov Record for Review**
     - **v. The ClinicalTrials.gov QA Process**

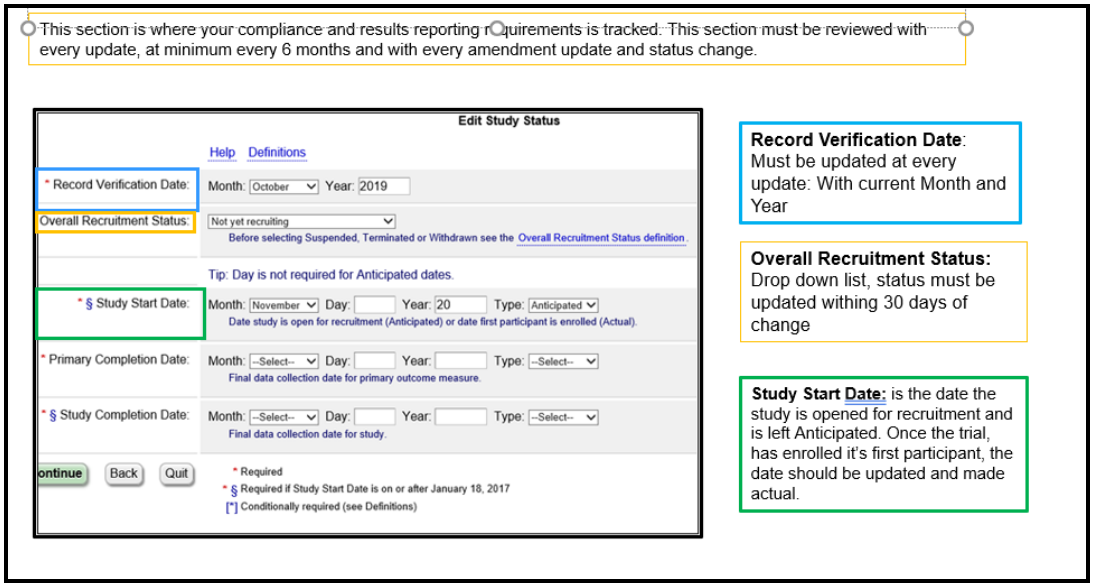
2. **ASSOCIATED DF/HCC POLICIES:**
   - **a.** REGIST-200

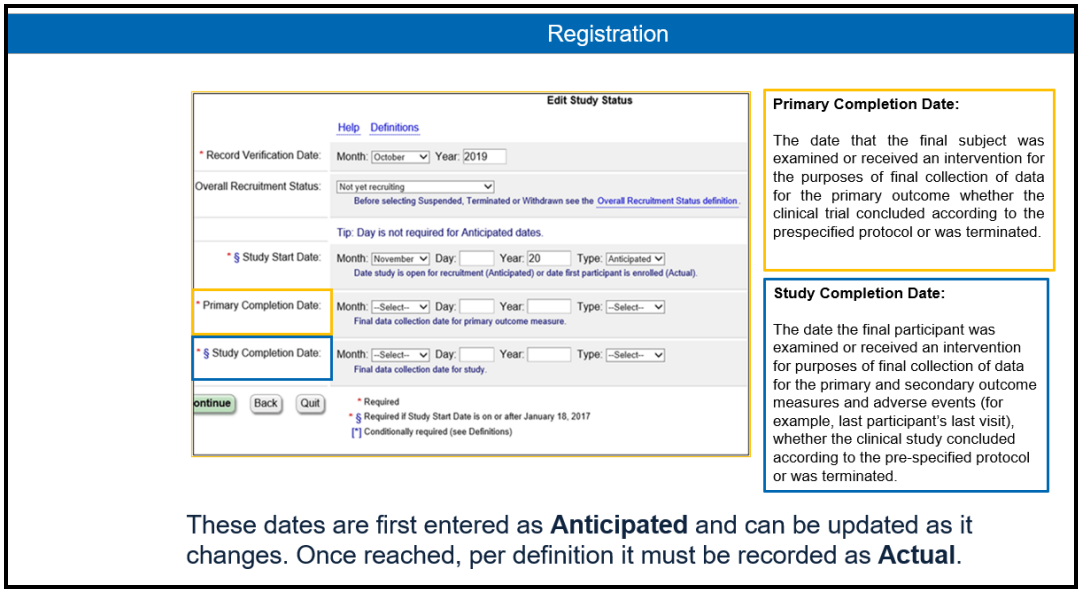
3. **PROCEDURE:**
   - **a. What Fields Need to be Updated/Reviewed.**
     - **i.** The following fields can be found in the "**Study Status**" section of the ClinicalTrials.gov record.
       1. "**Record Verification Date"** field – Must be **verified (with recorded timestamp) at least every 6 months**, even if there were no other changes made to the record.
       2. **"Recruitment Status" Or "Overall Status**" field – Require an update **within 30 days** of the change of recruitment status change.
       3. **Study Start Date**: The date the study is opened for recruitment and is left Anticipated. Once the trial, has enrolled the first participant, the date should be updated and made actual.
       4. **"Primary Completion Date"** field (Anticipated) – Must be verified and updated (if changed).
       5. "**Study Completion Date**" field (Anticipated) – Must be verified and updated (if changed).

a. "Please notify DFCIODQclinicaltrialsgov@partners.org of any changes made to the "**Primary or Study Completion Date.**"

ii. The Definitions of terms below https:// /ct2/about-studies/glossary

iii. ClinicalTrials.gov Record Status





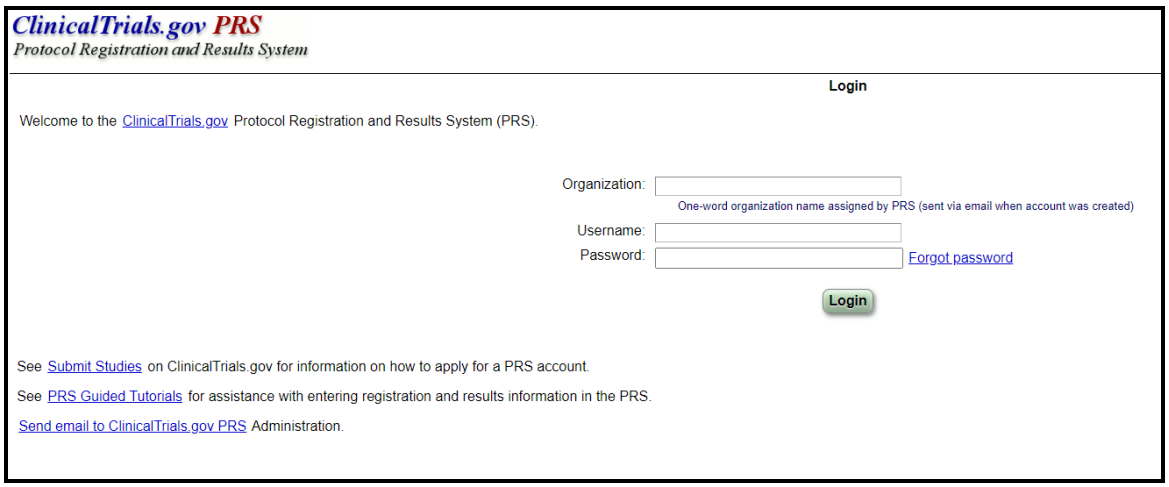
b. How to Login into ClinicalTrials.gov

i. Go to ClinicalTrials.gov https://register.clinicaltrials.gov/

ii. Enter Your Organization, User Name and Password :

1. DF/HCC institutions have established organizational Protocol Registration System (PRS) accounts to house their investigators' Clinicaltrials.gov records.
2. Please contact the Institution's contact for Clinicaltrials.gov account information.
   a. For **Dana Farber Cancer Institute**, please email DFCIODQClinicalTrialsGov@partners.org.
   b. For **Beth Israel Deaconess Medical Center**, please contact researchcompliance@bidmc.harvard.edu.
   c. **Massachusetts General Hospital** please email QIProgramCTgovTeam@partners.org
   d. **Brigham Women's Hospital** or any other **Mass General Brigham location**, please contact QIProgramCTgovTeam@partners.org

iii. Select login button at bottom of page 



c. How to Update a Field in ClinicalTrials.gov

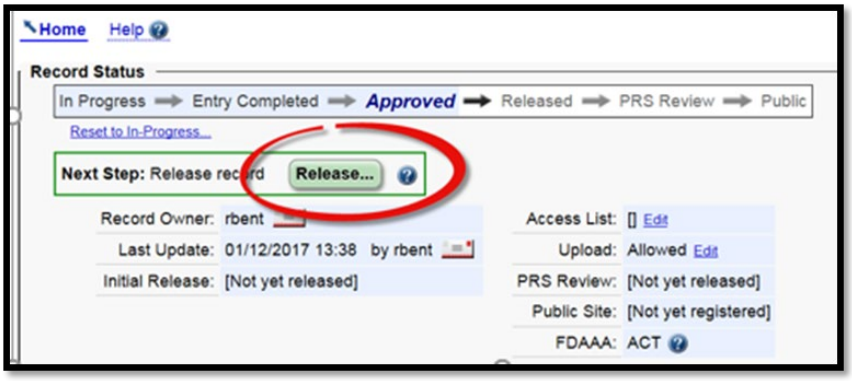
i. From the Main Record Page, locate the protocol of interest and Select [Open] (First Column).

ii. Review each of the sections of the ClinicalTrials.gov record and click [Edit] by the section that requires an update.

1. Once updates have been made Click on "Save" at bottom of page.

d. How to Approve and Release a ClinicalTrials.gov Record for Review

i. Beside the "**Next Step"** section: select **"Entry Complete,"** then select, **"Approve"** and then select **"Release**"(two step process).



ii. A release confirmation will appear after the record has been successfully released to ClinicalTrials.gov.

e. The ClinicalTrials.gov QA Process

i. After the ClinicalTrials.gov record is "Released," it is sent to ClinicalTrials.gov staff for internal quality assurance review (PRS Review).

ii. Review Process Timings

1. **Initial ClinicalTrials.gov review**, (ClinicalTrials.gov records without NCT numbers) take between 2-5 days.

2. **ClinicalTrials.gov record updated without results** associated with the record take between 2 to 5 business days.
3. **ClinicalTrials.gov records with results reported**, take 30 days once locked for review.

iii. Record Status

1. **Public:** A ClinicalTrials.gov record that is found "without issue" will be made public. The Responsible Party will be notified via email that the Clincialtrials.gov record has been made public. No action needed.
2. **In Progress:** If the ClinicalTrials.gov QA department determines that the information posted within the ClinicalTrials.gov record requires clarification, they will reset the record to "In progress" and an email notification will be sent to the Responsible Party.
   a. Corrections **MUST** be made to the ClinicalTrials.gov record or the Protocol Registration/Updates/Results Posting will not be successful.
      i. QA Reset Comments for Registrations and Updates, must be addressed within 15 days of reset date.
      ii. QA Reset Comments for Results Reporting, must be addressed within 30 days of reset date.
      iii. ClinicalTrials.gov QA findings can be found in the "QA Comments" section of the record. Once all comments have been addressed, the record needs to be "approved" and re-released by the Responsible Party to re-initiate ClinicalTrials.gov QA review.

f. References:

i. ClinicalTrials.gov Tutorials
https://prsinfo.ClinicalTrials.gov/tutorial/content/index.html#/