

DANA-FARBER / HARVARD CANCER CENTER

Operations for Human Research

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).

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- a. “Please notify DFCIODQclinicaltrials.gov@partners.org of any changes made to the “**Primary or Study Completion Date.**”
- ii. **The Definitions** of terms below [https:// /ct2/about-studies/glossary](https://ct2/about-studies/glossary)
- iii. **ClinicalTrials.gov Record Status**

This section is where your compliance and results reporting requirements is tracked. This section must be reviewed with every update, at minimum every 6 months and with every amendment update and status change.

Record Verification Date:
Must be updated at every update: With current Month and Year

Overall Recruitment Status:
Drop down list, status must be updated withing 30 days of change

Study Start Date: is the date the study is opened for recruitment and is left Anticipated. Once the trial, has enrolled it's first participant, the date should be updated and made actual.

Registration

Primary Completion Date:
The date that the final subject was examined or received an intervention for the purposes of final collection of data for the primary outcome whether the clinical trial concluded according to the prespecified protocol or was terminated.

Study Completion Date:
The date the final participant was examined or received an intervention for purposes of final collection of data for the primary and secondary outcome measures and adverse events (for example, last participant's last visit), whether the clinical study concluded according to the pre-specified protocol or was terminated.

These dates are first entered as **Anticipated** and can be updated as it changes. Once reached, per definition it must be recorded as **Actual**.

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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

Login

ClinicalTrials.gov PRS
Protocol Registration and Results System

Login

Welcome to the [ClinicalTrials.gov](https://clinicaltrials.gov) Protocol Registration and Results System (PRS).

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

Username:

Password: [Forgot password](#)

See [Submit Studies](#) on ClinicalTrials.gov for information on how to apply for a PRS account.
See [PRS Guided Tutorials](#) for assistance with entering registration and results information in the PRS.
[Send email to ClinicalTrials.gov PRS Administration.](#)

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.

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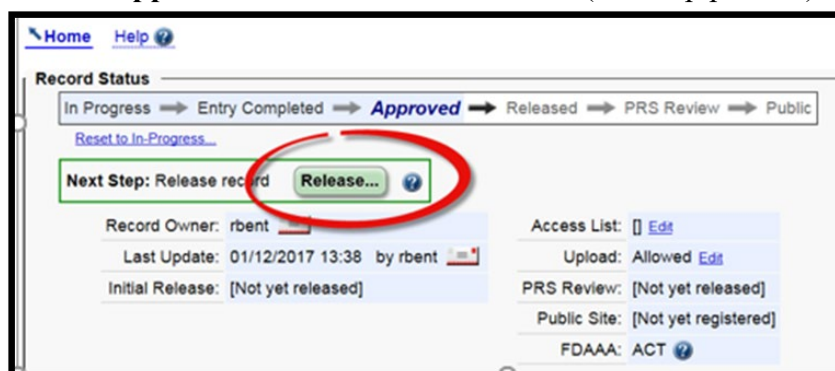
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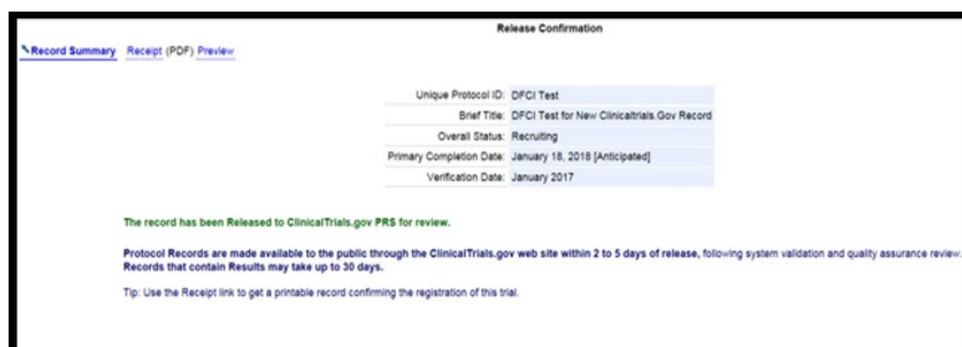
1. Once updates have been made Click on “Save” at bottom of page.

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.

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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 ClinicalTrials.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#/>