

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 4	Effective Date: 08/08/2017

1. BACKGROUND:

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.

- What Fields Need to be Updated/Reviewed Regardless of Changes.
- How to Login into a Clinicaltrials.gov
- How to Update Fields in Clinicaltrials.gov
- How to Approve and Release a Clinicaltrials.gov Record for Review
- The Clinicaltrials.gov QA Process

2. ASSOCIATED DF/HCC POLICIES:

- REGIST-200

3. PROCEDURE:

3.1. What Fields Need to be Updated/Reviewed

The following fields can be found in the “**Study Status**“ section of the Clinicaltrials.gov record.

- “**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.
- “**Recruitment Status**” Or “**Overall Status**” field - Require an update **within 30 days** of the change of recruitment status change.
- “**Primary Completion Date**” field (Anticipated)- Must be verified and updated (if changed).
- “**Study Completion Date**” field (Anticipated)- Must be verified and updated (if changed).
 - “Please notify DFCIODQclinicaltrials.gov@partners.org of any changes made to the “**Primary or Study Completion Date**”.

3.2. How to Login into a Clinicaltrials.gov


- Go to ClinicalTrials.gov <https://register.clinicaltrials.gov/>

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- Enter Your Organization (Select DFCI for most DF/HCC protocols. MGH investigators should select MassGH.)

- Enter Username and Password. To request a password reset:
 - For DFCI, BIDMC or BWH, please email DFCIODQclinicaltrials.gov@partners.org
 - For MGH, please email irb@partners.org
- Select login button at bottom of page. 

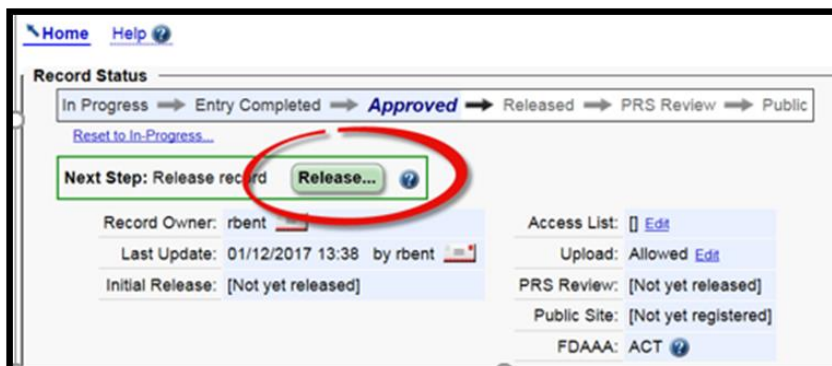
3.3. How to Update a Fields in Clinicaltrials.gov

- From the Main Record Page, locate the protocol of interest and Select [\[Open\]](#) (First Column).
- Review each of the sections of the Clinicaltrials.gov record and click [\[Edit\]](#) by the section that requires an update.
- Once updates have been made Click on “Save” at bottom of page.
- Beside the “Next Step” section: select “Entry Complete,” then select, “Approve” and then select “Release”.

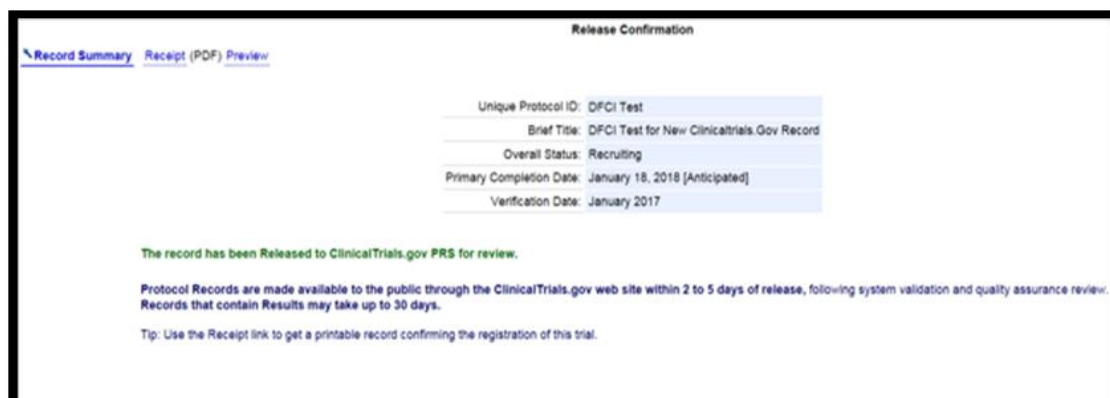
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- A release confirmation will appear after the record has been successfully released to Clinicaltrials.gov.



3.4. The Clinicaltrials.gov QA Process

- After the Clinicaltrials.gov record is “Released,” it is sent to Clinicaltrials.gov staff for internal quality assurance review (PRS Review). The Clinicaltrials.gov record review process can take between 2 to 5 business days.
 - **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

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action needed.

- **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.

Corrections **MUST** be made to the Clinicaltrials.gov record or the Protocol Registration/Updates/Results Posting will not be successful.

- QA Reset Comments for Registrations and Updates, must be addressed within 15 days of reset date.
 - QA Reset Comments for Results Reporting, must be addressed within 30 days of reset date.
- 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.

3.5. References

- **FDAAA-801 Requirements:** <https://clinicaltrials.gov/ct2/manage-recs/fdaaa>
- **ICMJE Clinicaltrials.gov Requirements:** <http://www.icmje.org/about-icmje/faqs/clinical-trials-registration/>
- **HHS and NIH Policy:** <https://www.nih.gov/news-events/summary-hhs-nih-initiatives-enhance-availability-clinical-trial-information>

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