TITLE: How/When to Register a Protocol on ClinicalTrials.gov		
Maintained by: Office of Data Quality (ODQ)	**Page:** 1 of 4	**Effective Date:** 04/20/2023

1. BACKGROUND:

DF/HCC institutions have established organizational Protocol Registration System (PRS) accounts to house their investigators' Clinicaltrials.gov records.

As noted in DF/HCC policy REGIST-200: Registration on ClinicalTrials.gov, each institution may also have slightly different policies and procedures for Clinicaltrials.gov registration. The Office of Data Quality (ODQ), as well as each member institution, has appointed ClinicalTrials.gov administrators (see **DF/HCC Contacts for ClinicalTrials.gov Accounts and Initial Registration**) to assist investigators in establishing their personal Protocol Registration System (PRS) accounts for registration and management of protocols for which they are the designated "Responsible Party."

2. ASSOCIATED DF/HCC POLICIES:

2.1. REGIST-200

3. PROCEDURE:

3.1. Initial Registration

3.1.1. For DF/HCC-sponsored protocols, the Clinicaltrials.gov registration must be created in the institutional PRS account of the DF/HCC sponsor-investigator's home institution. Investigators must follow institutional policies and procedures regarding Clinicaltrials.gov registration

3.1.1.1. For sponsor-investigators with a primary appointment at Dana Farber Cancer Institute (DFCI), the DF/HCC Office of Data Quality (ODQ) will create the initial registration in the DFCI PRS account, and no records should be created in the DFCI PRS account without approval from ODQ.

3.1.1.2. The sponsor-investigator primary appointment at Boston Children's Hospital (CHB), Beth Israel Deaconess Medical Center (BIDMC), or Massachusetts General Brigham (MGB) should contact their institutional PRS Administrator to establish new accounts, gain access to the ClincalTrials.gov PRS site, or grant access to other members of the research team

3.2. For Sponsor-investigators with a primary appointment at Dana Farber Cancer Institute (DFCI), **ClinicalTrials.gov Initial Registration Transfer, Review Process, Approved and Released to ClinicalTrial.gov**

3.2.1. Once ODQ has finished the initial ClinicalTrials.gov registration, a transfer notification email will be sent to the "Responsible Party," to update, review, approve, and release the initial ClinicalTrials.gov registration for ClinicalTrial.gov QA review.

3.2.1.1. The transfer notification letter will outline the sections of the record that require review and possible update.

3.2.1.1.1.1. ClinicalTrials.gov Registration Review Criteria: https://prsinfo.ClinicalTrials.gov/ProtocolDetailedReviewItems.pdf

3.2.1.2. Once the Responsible Party has finished the review process, the ClinicalTrials.gov registration should be "**Approved**" and "**Released**" to ClinicalTrials.gov for internal quality assurance review (PRS Review).

3.3. **ClinicalTrials.gov PRS Review Process**

3.3.1. The ClinicalTrials.gov record review process can take between 2 to 5 business days and it will either be assigned a NCT number or will be reset without a NCT number.

3.3.2. **Records Assigned a NCT Number**

3.3.2.1. The ClinicalTrials.gov QA department will notify the Responsible Party of a successful ClinicalTrials.gov registration. This email notification will contain the NCT number for this ClinicalTrials.gov record. Please retain for future reference.

3.3.3. **Record Reset without a NCT Number**

3.3.3.1. A ClinicalTrials.gov record will be reset without the required NCT number if the ClinicalTrials.gov PRS team has determined the record does not meet their requirements. These ClinicalTrials.gov QA comments can be found in the "QA Comments" section of the record (see below).

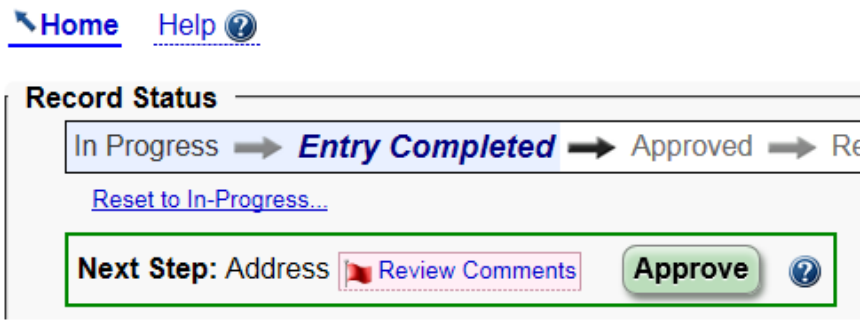
3.3.3.2. ClinicalTrials.gov records that have not been assigned NCT numbers are not considered successful registrations and the trials will not be able to activate for accrual.

3.3.3.2.1. All QA Reset Comments for Registrations and Updates must be addressed within 15 days of reset date.

3.3.3.3. Once all comments have been addressed, the record needs to be approved and re-released by the Responsible Party to ClinicalTrials.gov for QA review.

3.4. **How to resolve QA Comments**

3.4.1. Locate the "**Next Step: Address Review Comments"** field, found at the top of the ClinicalTrials.gov record.



3.4.2. Click on the "Review Comments," which will bring you to a "read-only" version of the ClinicalTrials.gov record. Scroll through the record to locate a "Comments" text box with a description of the "issue" found in the record.

3.4.3. To update the record, select [Edit] field by the protocol section that requires an update.

3.4.4. Update the section, per the guidelines specified by the ClinicalTrials.gov QA Comments.

3.4.5. Once the updates have been made Click on "Save" at the bottom of page. To release the updates the Responsible Party needs to "approve" and "release" the record for QA review.

1.1. References

- **FDAAA-801and Final Rule Requirements**: FDAAA 801 and the Final Rule - ClinicalTrials.gov
- **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