

DANA-FARBER / HARVARD CANCER CENTER
Operations for Human Research

TITLE: When and How to Submit Results to Clinicaltrials.gov		
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1. BACKGROUND:

- 1.1. The DF/HCC responsible party for investigator-sponsored trials must submit aggregate results and summary adverse event information in ClinicalTrials.gov for protocols as required by either the [Food and Drug Administration \(FDA\) Amendments Act of 2007](#) (FDAAA-801), the [Health and Human Services \(HHS\) Final Rule, or NIH policy](#) (2017).

2. ASSOCIATED DF/HCC POLICIES:

- 2.1. REGIST-200

3. PROCEDURE

- 3.1. The Responsible Party must report results and adverse events in Clinicaltrials.gov **within 12 months** of either the estimated **Primary Outcome Completion Date** (as per ClinicalTrials.gov registration) or the actual date of **Primary Outcome Completion** endpoint.

3.1.1. **Primary Completion Date:** The date that the final participant was examined or received an intervention for the purposes of final collection of data for the primary outcome, whether the clinical study concluded according to the pre-specified protocol or was terminated.

3.1.2. In the case of clinical studies with more than one primary outcome measure with different completion dates, this term refers to the date on which data collection is completed for all primary outcomes.

3.1.3. Results submission needs to involve a person who knows the details of the study design and analysis, such as an investigator or statistician. ODQ strongly recommends that you contact your study's biostatistician for assistance with results reporting.

3.2. Preparing the Clinicaltrials.gov Record for Results

- 3.2.1. The Clinicaltrials.gov record needs to be reviewed and updated prior to results being entered. The following Clinicaltrials.gov record fields **must be updated before** beginning results:

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- **Overall Study Status** must be consistent with Study Start and Study Completion Dates and cannot have a status of “Recruiting” or “Not Yet Recruiting”.
- **Primary Completion Date** must be “Actual” and dated in the past.
- **Enrollment** must be “Actual” and will need to be the same as the Number “Started” in Participant Flow.
- **Intervention** names need to be consistent with information to be entered in the Results Section
- **Arms/Groups** in Protocol Section need to be consistent with Arms/Groups to be entered in the Results Section.
- **Site Recruitment Status** in Location Section are consistent with **Overall Study Status**

3.2.2. Once the Clinicaltrials.gov record has been updated, the Responsible Party needs to “Approve” and “Release” the record for Clinicaltrials.gov QA approval. The Clinicaltrials.gov QA review can take from 2-5 days.

3.2.3. Results can be entered once Clinicaltrials.gov record has been made “public” by the Clinicaltrials.gov QA department.

3.3. Required Data Elements and Formatting

3.3.1. Please use the references below to assist with results reporting.

- **Results Data Elements Definitions:** details on the results data items (required and optional) that are entered via the PRS https://prstest.nlm.nih.gov/prs/html/results_definitions.html
- **Results Review Criteria:** describes review criteria for submitted study records. <https://prsinfo.clinicaltrials.gov/ResultsDetailedReviewItems.pdf>

3.3.2. The study results must be summarized in a tabular format, per Arm/Group, in four (4) scientific modules: **Participant Flow**, **Baseline Characteristics**, **Outcome Measures and Statistical Analyses**, and **Adverse Events**. The modules allow for the entry and display of information in a series of data tables with supporting notes but without narrative conclusions about the results. Summary results information may be submitted once data are available for one or more primary outcome measures and for each arm of the study.

3.3.3. Each Results module help page describes the module's purpose, uses

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examples to illustrate the module's basic table structure and fields, and shows examples of results entry for various study designs. Example results entries for common study designs (PDF): [Parallel](#); [Cross-Over](#); [Factorial](#); [Dose Escalation](#); [Multiple Period](#)

3.4. How to Post Results in Clinicaltrials.Gov

3.4.1. Please follow instructions available at <https://clinicaltrials.gov/ct2/manage-recs/how-report> A brief step-by-step is included below.

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

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

ClinicalTrials.gov PRS
Protocol Registration and Results System

Login

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

For lost or forgotten passwords, please email:
DFCI Clinicaltrials.gov Accounts: DFCIODQclinicaltrials.gov@partners.org
MassGH Clinicaltrials.gov Accounts: irb@partners.org

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

Username:

Password: [Forgot password](#)

Login

See [Submit Studies](#) on ClinicalTrials.gov for information on how to apply for an account, how to register your study, and how to submit results.
[Send email to ClinicalTrials.gov PRS Administration](#)

3.4.4. 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

3.4.5. Select login button at bottom of page.



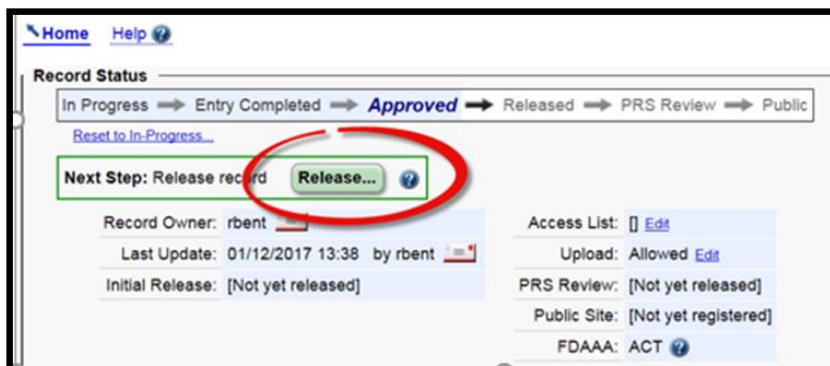
3.4.6. Once updates have been made Click on “Save” at bottom of page.

3.4.7. Beside the “Next Step” section: select “Entry Complete,” then select, “Approve” and then select “Release”.

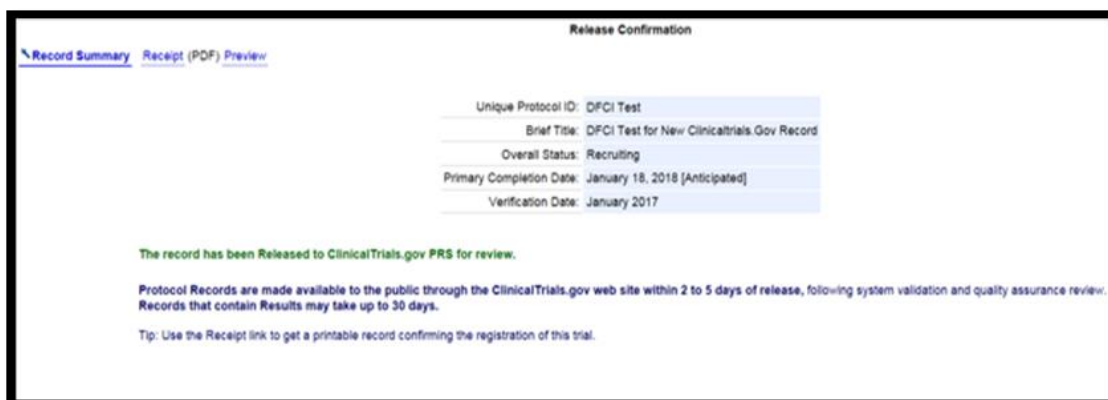
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3.4.8. A Release Confirmation will appear after the record has been successfully released to Clinicaltrials.gov.



3.5. The Clinicaltrials.gov QA Process

3.5.1. After the Clinicaltrials.gov record is “Released,” it is sent to Clinicaltrials.gov staff for internal quality assurance review (PRS Review). The Clinicaltrials.gov results review process can take a minimum of 30 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 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.

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- Corrections **MUST** be made to the Clinicaltrials.gov record or the Results Posting will not be successful. QA Reset Comments for Results Reporting, must be addressed within 30 days of reset date.

3.5.2. 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.

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