1. PURPOSE

1.1. The purpose of this procedure is to describe when results reporting is required for clincialtrials.gov, and when it must be completed.
1.2. This procedure begins when a study reaches its Primary and .Study Completion Dates or one year after the study terminates if the study is not completed.
1.3. This procedure ends when all results have been entered and publicly posted on clinicaltrials.gov.

2. POLICY

2.1. The Principal Investigator as Responsible Party[1] must ensure the timely, accurate and complete entry of all outcome results and adverse event information. Results entry is encouraged for all studies, and is required for the following categories of studies:

2.1.1. Applicable Clinical Trials as defined by FDAAA 801
2.1.2. Clinical Trials subject to NIH registration policy
2.1.3. If required by sponsor or other authority.

3. RESPONSIBILITY

3.1. The Responsible Party must ensure the timely, accurate and complete entry of all outcome results and adverse event information.

4. PROCEDURE

4.1. Result Reporting

4.1.1. Primary Outcomes

4.1.1.1. Results for the Primary Outcome(s) are due, and must be entered and submitted for posting, 12 months after the study's Primary Completion Date, or 12 months after the study termination if not completed.

4.1.1.2. In addition to results entry, the final study protocol and Statistical Analysis Plan (if not already included in the study protocol) must be uploaded into the record under the Document Section

4.1.1.2.1. Allowable protocol redactions: names, addresses or any other personally identifiable information, trade secret and/or confidential commercial information as defined by Federal Freedom of Information Act or Trade Secrets Act unless otherwise required to be submitted.

4.1.2. Secondary outcomes and Adverse Events

4.1.2.1. Reporting on remaining outcomes (secondary outcomes) and all adverse events are due, and must be entered and submitted for posting, 12 months after the Study Completion date or 12 months after the study termination if not completed.

4.1.3. Unfinished studies, abandoned outcomes

4.1.3.1. Reporting of result data is required even if the study is abandoned and not completed.

[1] See CTGov-002 for designation of Responsible Party

4.1.3.2. Reporting of result data is required even if an outcome is abandoned if any intervention is performed and/or data is collected for the purposes of the outcome.

4.1.3.3. Explanation regarding the irregularity of data is addressed via notation in the record.

4.1.4. Completion of results reporting

4.1.4.1. Results reporting is not complete until all Major Issues identified by PRS Administrators are resolved and the results have been posted (or accepted for posting with delay) on clinicaltrials.gov.

4.2. Request for Delay

4.2.1. The Responsible Party may request delay in

4.2.1.1.1. results reporting for “good cause” upon application to, and approval by, the central PRS Administrators. Pending publication or workload are not considered to constitute “good cause”

4.2.1.1.2. public posting of results for a period of 2 years upon application to, and approval by, the central PRS Administrators if there is a pending NDA or marketing application or pending approval for a new use or indication.

5. REFERENCES

5.1. https://clinicaltrials.gov/ct2/manage-recs/how-register
5.2. https://www.federalregister.gov/documents/2016/09/21/2016-22129/clinical-trials-registration-and-results-information-submission
5.3. https://clinicaltrials.gov/ct2/manage-recs/how-report
5.4. FDA

5.4.1. 42 USC 282
5.4.2. 42 CFR Part 11

5.5. NIH

5.5.1. https://grants.nih.gov/policy/clinical-trials/reporting/index.htm