NIH NATIONAL CANCER INSTITUTE

ClinicalTrials.gov Registration and Results Reporting for CTEP-Supported Trials

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ClinicalTrials.gov registration and results reporting is required by law and NIH policy for CTEP-supported clinical trials.

Statutory requirements: Section 801 of the Food and Drug Administration Amendments Act, commonly called FDAAA, has required registration and results reporting at ClinicalTrials.gov for most clinical trials since 2007. The Final Rule (42 CFR Part 11) clarified and expanded the regulatory requirements and procedures for submitting registration and results information for certain trials to ClinicalTrials.gov as of January 2017.

NIH Policy requirements: The NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information, effective January 2017, requires clinical trials registration and results reporting in ClinicalTrials.gov for all NIH-funded trials.

The Lead Protocol Organization (LPO) is responsible for ensuring the trials they lead are in compliance with FDAAA 801, the Final Rule, and the NIH policy requirements for clinical trials registration and results reporting. This includes trials under CTEP IND.

ClinicalTrials.gov Initial Registration

CTEP IND Studies

- For trials under NCI CTEP IND, the NCI's Clinical Trial Reporting Office (CTRO) registers the trial on ClinicalTrials.gov from the NCI's ClinicalTrials.gov account.
- The CTRO abstraction source for the ClinicalTrials.gov registration information is the approved protocol document. CTRO cannot make changes to the trial record that differ from the approved protocol document. However, if you have any feedback about how the trial has been abstracted – particularly about the outcome measures and timeframes – contact the CTRO as soon as possible with your feedback on the abstraction.
- Re-review the trial record on ClinicalTrials.gov after any amendments that change the study design to ensure you understand how the trial has been abstracted and what results reporting will be required.

Non-CTEP IND and IND Exempt Studies

- The LPO is responsible for registering the trial in ClinicalTrials.gov.
- The registration information must match the approved protocol.

All Trials

- CTEP will not issue final approval for trial activation until this registration is complete.
- The LPO will be responsible for the results reporting for all primary and secondary outcome measures in the protocol.

ClinicalTrials.gov Updates

The ClinicalTrials.gov trial registration information must be updated regularly in accordance with the FDAAA requirements. Many data elements in the ClinicalTrials.gov study record must be updated within 30 calendar days of any changes (https://clinicaltrials.gov/policy/faq#updatesToCT). The LPO is responsible for monitoring these dates and status changes.

The LPO must make any updates in the CTEP systems (for instance, by updating the study status and anticipated/actual primary completion dates in RSS) in a timely manner.

- For CTEP IND trials, this will allow CTRO to make the required updates in the ClinicalTrials.gov record.
- For Non-CTEP IND and IND Exempt trials, this will ensure the information in the CTEP systems matches the LPO's updates in ClinicalTrials.gov. The LPO is responsible for updating the information in ClinicalTrials.gov.

Make sure all status and completion date changes are in alignment with the ClinicalTrials.gov official definitions (https://clinicaltrials.gov/policy/protocol-definitions#study-status).

ClinicalTrials.gov Results Reporting Scope and Key Definitions

Scope: Results must be reported for all trials subject to FDAAA or NIH Policy that have enrolled one or more patients. Even if a trial is terminated early, if one or more patients have been enrolled, some level of results reporting by the deadline is required to be in compliance with the requirements.

Timelines:

- Results reporting in ClinicalTrials.gov for the Primary Outcome is required within 12 months of the Primary Completion Date for the trial.
    - The Actual Primary Completion Date is generally the last date that a participant was examined to collect data for the primary outcome (see official definition at https://clinicaltrials.gov/policy/protocol-definitions#study-status).
    - Sometimes the Actual Primary Completion Date is identified after the fact, especially if, for instance, a study is closed at an interim analysis or an early dose level.
- Results reporting for any Secondary Outcome Measures and additional Adverse Events not collected by the primary completion date is required within 12 months of final data collection and no later than a year after the Study Completion Date.

ClinicalTrials.gov Results Reporting Process

CTEP IND Studies

NCI CTRO *facilitates* the results reporting process for trials under NCI CTEP IND. The LPO is responsible for ensuring compliance with all ClinicalTrials.gov results reporting requirements by ensuring the trial anticipated and actual primary completion dates (as defined by FDAAA) are updated within 30 days of any changes in RSS and preparing the trial data for submission well in advance of the results reporting deadlines.

- When the actual Primary Completion Date (as updated by the LPO in RSS) is reached, the CTRO will reach out to the results reporting designee(s)/PI to confirm the date and the Trial Summary Report (TSR) that includes the outcomes current registered in ClinicalTrials.gov.
- Once the Completion dates(s) and TSR have been confirmed, the CTRO provides access to the study record in the NCI's ClinicalTrials.gov account for results data entry. A separate Clinicaltrials.gov account for each authorized user is required and is created by the CTRO.
- Once the results are entered and ready to be released, the LPO should contact the CTRO to notify them the results are ready for review.
- Results for studies under CTEP IND must be submitted 3-4 weeks before the results reporting deadline so that CTEP and any company partners can review them prior to final submission. Errors in the submitted results may require additional time for revision and re-submission.
- Once CTEP has approved the results submission, the Clinicaltrials.gov record will be released to the National Library of Medicine (NLM), which oversees ClinicalTrials.gov, for a separate review process. The results are considered "submitted" for the purposes of meeting the deadline at the time they are released to NLM. NLM may require additional revisions, which will be processed and reviewed following the above steps.

Non-CTEP IND and IND Exempt Studies

The LPO is responsible for all aspects of results reporting, including tracking and updating the anticipated and actual Primary Completion Dates in RSS and in the ClinicalTrials.gov record within 30 days of any changes, coordinating access to the ClinicalTrials.gov account, reviewing the results submission, releasing the results to NLM by the results reporting deadline, and making any required revisions.