

Common Mistakes Found within ClinicalTrials.gov Records

Failing to Save or “Complete” Your Changes

- Any time a ClinicalTrials.gov record is modified or updated, the “updated” section must be saved, by selecting the save button at the bottom of the section
- To save **all the updates/modifications** made to the ClinicalTrials.gov record, Click “**Entry Complete** locate the “**Next Step**” field near the top of the ClinicalTrials.gov record.” (*Note: following this process only indicates that your update is completed, NOT your trial*). The **Responsible Party** **MUST** then “**Approve**” and “**Release**” the ClinicalTrials.gov record for the updates to be posted on ClinicalTrials.gov.

Failing to “Approve” and “Release” Your Protocol Record Status after Updates and Modifications Have Been Made To The ClinicalTrials.gov Record

- For the updates and modifications to be posted on ClinicalTrials.gov, the **Responsible Party** must “**Approve**” and “**Release**” the ClinicalTrials.gov record status.
- To do this, locate the “**Next Step**” field in the Record Status Section near the top of the ClinicalTrials.gov record. Click on “**Approve**” and then “**Release**” (**two step process**). The record will then be sent to ClinicalTrials.gov for the ClinicalTrials.gov Quality Assurance review to confirm that the record meets basic standards. An email notification from ClinicalTrials.gov will be sent to the “**Responsible Party**” if the updated ClinicalTrials.gov record has been posted or if there is an issue within the ClinicalTrials.gov record.

What Does The ClinicalTrials.gov “Record Status” Mean?

- The current “**Record Status**” which indicates the current ClinicalTrials.gov record status, is located under the “**Next Step**” field and will be outlined in a text box. The “**Record Status**” should not be confused with the “**Overall Status**” which is the actual status of the protocol.

- **What Is The Meaning Of Each Record Status?**
 - **In Progress:** User is creating or modifying the record or the Clinicaltrials.gov record has been reset
 - **Entry Completed:** User has finished updating the record and is ready for review
 - **Approved:** Responsible Party has reviewed record and made necessary changes
 - **Released:** Responsible Party has submitted the record to Clinicaltrials.gov
 - **PRS Review:** The record is currently under review by the Clinicaltrials.gov PRS Team
 - **Public:** The record passed PRS Review and is, or soon will be, posted (or updated) on the Clinicaltrials.gov website

Failing To Update Your ClinicalTrials.gov Record

- **The Responsible Party** must go into the ClinicalTrials.gov record a minimum of every **6 months**, even if no changes (i.e. amendment changes/status changes) have occurred and update the “**Record Verification Date**” field located in the **Study Status Section**, with the current month and year the record is being updated.
- **The Responsible Party** must always “**Approve**” and “**Release**” the ClinicalTrials.gov record status in order for any of the changes to be posted. *The “**Record Verification Date**” field should also be updated any time changes are made to your record.*

Failing To Update the Responsible Party or Other Study Personnel Listed in ClinicalTrials.gov

- If at any time the **Responsible Party** or other personnel (or their contact information) listed in ClinicalTrials.gov record changes, the record needs to be updated within 30 days. Failing to promptly update this information means that you will not receive email communications from ClinicalTrials.gov and may not receive notifications of other needed updates.

Failing To Update the Primary Completion Date

- **The Primary Completion Date:**
 - Definition: *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.*
- 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 of the primary outcomes.
- While the study is ongoing, the “**Primary Completion Date**” should be labeled as anticipated and reviewed/updated per definition. Failing to properly update the “**Primary Completion Date**” (Anticipated) in ClinicalTrials.gov may result in the ClinicalTrials.gov record appearing to require results reporting before the trial is officially required.
 - Please Note: Once the date of the last subject’s last treatment or examination becomes known the “**Primary Completion Date**” should be labeled as actual and the date updated if needed.

Failing to Update the Study Completion Date

- **The Study Completion Date:**
 - Definition: *The date the final participant was examined or received an intervention for purposes of final collection of data for the primary and secondary outcome measures and adverse events (for example, last participant’s last visit), whether the clinical study concluded according to the pre-specified protocol or was terminated.*
- While the study is ongoing, the “**Study Completion Date**” should be labeled as anticipated and reviewed/updated per definition. Failing to properly update the “**Study Completion Date**” (Anticipated) in ClinicalTrials.gov may result in the ClinicalTrials.gov record appearing to require results reporting before the trial is officially required.

- Please Note: Once the date of the last subject's *final participant was examined or received an intervention for purposes of final collection of data for the primary and secondary outcome measures and adverse events* becomes known the “**Study Completion Date**” should be labeled as actual.

Failing To Post Results in a Timely Manner

- Results reporting for the Primary Endpoint must be reported within 12 months of the posted Primary Completion Date (actual). Results reporting for the secondary outcome can be reported staggered if not reached by the Primary Completion Date. All the Secondary Outcomes must be posted within a year of the posted actual Study Completion Date.
- [FDAAA 801/Final Rule/NIH Policy](#) establishes penalties for Responsible Parties who fail to comply with registration or results submission requirements. Penalties include civil monetary penalties and, for federally funded studies, the withholding of grant funds.

Failing To Change ClinicalTrials.gov Record Recruitment Status

- *If the recruitment status of the trial changes, an update must be made to the ClinicalTrials.gov record within 30 days of the change in recruitment status.*
 - For instance, if enrollment has been completed, but subjects are still being treated or examined, the status should be updated to “**Active, not recruiting**”. The status of your study within ClinicalTrials.gov should be changed to “**Completed**” within 30 days of the last subject’s last research procedure.

Failing To Address ClinicalTrials.gov Quality Assurance Comments or Red Flags Within The Record

- Once a ClinicalTrials.gov Record has been “**Approved**” and “**Released**” by the “**Responsible Party**,” ClinicalTrials.gov will complete a Quality Assurance review to confirm that the record meets basic standards.

- An email notification from ClinicalTrials.gov will be sent to the “**Responsible Party**” if the record has been posted or if there is an issue within the ClinicalTrials.gov record.
- All ClinicalTrials.gov record issues must be addressed within the following time period:
 - 15 days for Registration Updates
 - 25 days for Results Reporting days.
- The ClinicalTrials.gov office will change the “record status” to “**In Progress.**” All record updates will not be posted until all comments/red flags have been addressed.