

Common Mistakes Found within ClinicalTrials.gov Records

Failing to Save or “Complete” Your Changes

- Any time you modify or update the information within your ClinicalTrials.gov record, you must save your changes by updating the **“Record Status”**. To save your updates/modifications, locate the **“Next Step”** field near the top of the ClinicalTrials.gov record. Click **“Entry Complete”** (*Note: following this process only indicates that your update is completed, NOT your trial*). The **Responsible Party** **MUST** then **“Approve”** and **“Released”** the ClinicalTrials.gov record in order 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.

- In order for any of 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 near the top of the ClinicalTrials.gov record. Click on **“Approve”** and then **“Release”**. 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 update ClinicalTrials.gov record has been posted or if there is an issue within ClinicalTrials.gov record.

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

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

What Is The Meaning Of Each Record Status?

- In Progress: User is creating or modifying the record
- 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 have occurred to the record, and update the **“Record Verification Date”** field. 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

- If at any time, the **“Completion Date”** of your clinical trial record changes, you must update the **“Primary Completion Date”** field in ClinicalTrials.gov. While the study is ongoing, the **“Primary Completion Date”** should be labeled as anticipated and updated whenever the date changes. Failing to properly update the **“Primary Completion Date”** (Anticipated) in ClinicalTrials.gov may require results to be posted before the study is actually completed. 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 Post Results in a Timely Manner

- The basic study results must be posted within 1 year of whichever date is earlier: the Primary Completion Date listed on ClinicalTrials.gov or actual completion date.
- FDAAA 801 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 your trial changes, you must submit an update 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.”** Also 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

- After changes to the record have been “**Entry Completed**” (or **Saved**) and “**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 with in ClinicalTrials.gov record. All ClinicalTrials.gov record issues must be addressed within 30 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.