Maintaining the Record

The study team must review the record and update the Record Verification Date every 12 months until all required registration and results information has been submitted, even if no other updates are required. The following fields must be updated within 30 days of a change, unless otherwise noted:

- Overall Recruitment Status
- Primary Completion Date
- Study Start Date
- Intervention names (must update to a non-proprietary name within 30 days after a non-proprietary name is established)
- Availability of Expanded Access (if Duke is the manufacturer and sponsor of the ACT)
- Expanded Access Status and Expanded Access Type
- Individual Site Status
- Human Subjects Protection Review Board Status
- Study Completion Date
- Responsible Party and RP Contact Information
- Changes in the protocol that are communicated to subjects
- Device Product Not Approved or Cleared by U.S. FDA (update within 15 days after change in approval or clearance status)

Errors in the Study Status section, like the ones below, are the most frequently seen comments on the ClinicalTrials.gov Problem Reports. Updating Completion date fields in a timely manner can prevent records from being flagged with errors.