**Frequently Asked Questions**

**Question:** Who can enter the registration information into ClinicalTrials.gov?

**Answer:** Anyone listed on study key personnel may enter the registration information into ClinicalTrials.gov. You must have a ClinicalTrials.gov account to register a study. The person who creates the registration is designated as the Record Owner, or the main contact for the record. To change the Record Owner, contact the DOCR ClinicalTrials.gov team. The Record Owner can give edit rights to additional study personnel by adding them to the access list on the Record Summary page.

**Question:** Who is the Responsible Party?

**Answer:** The Responsible Party (RP) is responsible for registering the trial on ClinicalTrials.gov, ensuring accuracy, and making sure the content is up-to-date. For trials run under an IND or IDE, the IND/IDE holder is the Responsible Party and will be required to approve and release the record to ClinicalTrials.gov. For studies without an IND or IDE, Duke is the Responsible Party and DOCR will release the record to ClinicalTrials.gov. The PI is ultimately responsible for the accuracy of the data that is entered in ClinicalTrials.gov.

**Question:** How can I check the status of my study in ClinicalTrials.gov?

**Answer:** Check the Record Summary page which contains an overview of a trial's current status, actions required for finishing the registration or results submission, and a summary of the status of each module within the sections.

**Question:** How do I get access to a study in ClinicalTrials.gov?

**Answer:** The person listed as the “Record Owner” can add you from the access list on the Record Summary Page if you have an account. If you don’t have an account or the Record Owner is no longer at Duke, contact the DOCR ClinicalTrials.gov team.

**Question:** Is the Primary Completion Date the same as the Study Completion Date?

**Answer:** Not necessarily. The Primary Completion Date is defined as “the date that the final subject was examined or received an intervention for the purposes of final collection of data for the primary outcome [measure], whether the clinical trial concluded according to the pre-specified protocol or was terminated.” The Study Completion Date is the “final date on which data was collected.” Refer to the [How Are the Primary Completion Date and the Study Completion Date Different? Tip Sheet](https://www.clinicaltrials.gov) for more information.
Question: Do results need to be entered for all studies?

Answer: No, only those studies that are Applicable Clinical Trials and NIH-funded clinical trials need to have results entered. Results must be entered within 12 months of the Primary Completion Date. For more information on results entry, visit the Reporting and Publishing the Outcome section of this website.