ClinicalTrials.gov FAQs

Which studies need to be registered?

Studies need to be registered for the following reasons:

1. **Required by Law** (Registration and results)
   - **Applicable Clinical Trials**: Interventional trials with drugs, biologics, or devices with US FDA jurisdiction (e.g. IND/IDE, US site, manufactured in the US)
     - Phase 2 – 4 drug trials; or
     - Device trials, with the exception of small feasibility studies or those that test a prototype device where the primary outcome relates to feasibility and not to health outcomes
   - Phase 1 drug trials conducted under an IND with an efficacy outcome (Registration only)

2. **NIH-Funded Clinical Trial** (Registration and results)
   - NIH requires registration and results reporting for all prospective, interventional trials that are funded in whole or part by the NIH

3. **Billing Insurance** (Registration)
   - CMS qualifying trials that are billing insurance. The National Clinical Trial (NCT) Number that is assigned by ClinicalTrials.gov has to be included on claims to bill Medicare

4. **Required for publication per ICMJE guidelines** (Registration)
   - Prospective, interventional clinical trials with a health outcome
     - Interventions include procedures, behavioral treatments, dietary interventions and process-of-care changes
     - Health outcomes include any biomedical or health-related measure obtained in participants, including pharmacokinetic measures and adverse events

Do results need to be entered for all studies?

No, only Applicable Clinical Trials and NIH-funded clinical trials need results entered within 12 months of the Primary Completion Date. However, investigators are encouraged to enter results for all trials.

Is the Primary Completion Date the same as the Study Completion Date?

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 What are Completion Dates job aid on the DOCR web page, Reporting and Publishing the Outcome section. https://medschool.duke.edu/research/clinical-and-translational-research/duke-office-clinical-research.

How often do I need to update my registration?

- Certain data elements need to be updated within 30 days of a change (e.g. Overall Study Status, Completion Dates, Study Start Date, individual site status. Please see visit the DOCR website for a more comprehensive list of applicable data elements.)
- Review and update your record at least annually until all required registration and results information has been submitted. Compliance is tracked by ClinicalTrials.gov using the Record Verification Date field in the Study Status section. Change this date each time you update your record.