How to Determine Primary Completion & Study Completion Dates

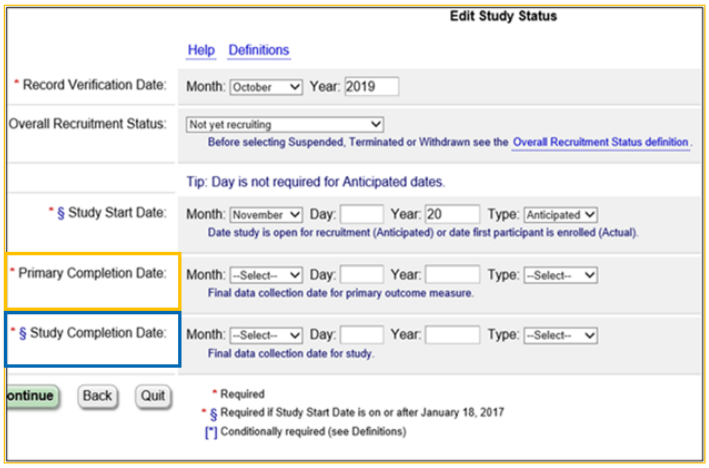
What is the Primary and Study Completion Date?

- **The Primary Completion Date?**
    - Definition: *This 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 whether the clinical trial concluded according to the prespecified protocol or was terminated."*
        - This date (whether *Type* is "actual" or "anticipated") will be used by ClinicalTrials.gov to determine when results reporting for "Applicable Clinical Trials" are due for the primary endpoint(s).
            - Results are due for the primary endpoint(s) within 12 months of reaching the Primary Completion Date.
            - Result reporting for secondary endpoints can be reported staggered if not reached by the Primary Completion Date, but should be posted within a year of reaching the Study Completion Date.
        - The *Type* should remain "anticipated" until the Primary Completion Date has been reached at which point the "responsible party" should update this to "actual" and complete the results reporting.

- **The Study Completion Date?**
    - *Definition: This is the final date on which data was (or is expected to be) collected*
        - Results reporting for the secondary endpoints must be reported within a year of reaching the Study Completion Date.

Updating the Primary Completion Date and Study Completion Date in the Clinicaltrials.gov Record

- **At Initial Clinicaltrials.gov Registration (ODQ)**
    - The Office of Data Quality (ODQ) will enter the Primary Completion Date and Study Completion as provided in the New Protocol Application.
- **Investigator Responsibility**
    - The Primary Completion Date and Study Completion Date should be reviewed/updated as needed per definition throughout the course of the trial by the Responsible Party.
    - If the Primary Completion Date and Study Completion Date is edited, please notify ODQ via email to DFCIQACTClinicalTrialsGov@partners.org, so these dates can be updated in the Oncore database.



Primary Completion Date:

The date that the final subject was examined or received an intervention for the purposes of final collection of data for the primary outcome whether the clinical trial concluded according to the prespecified protocol or was terminated.

Study Completion Date:

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.

Calculating the Primary Completion Date and Study Completion Date

- **To calculate the Primary Completion Date**
  - *IRB Approval Date + Expected Duration of Trial + 120 days*
    - Expected Duration of the Trial is determined from the statistical section of the protocol.
      - When this information is not provided in the protocol the following estimates are used:

Phase of Trial	Expected Duration
Pilot/Feasibility	36 months
Phase I	36 months
Phase I-II	36 months
Phase II	42 months
Phase II-III	48 months
Phase III	48 months
Phase IV	48 months

  - **Tips Regarding Defining the Primary Completion Date***
    - If the primary endpoint is response and no other important endpoint requires substantial follow-up, the completion date is the date of data extraction for the clinical study report or the last treatment date, whichever comes first.
    - If the primary endpoint is a time-to-event endpoint, then the date of data extraction listed in the Clinical Study Report is usually considered to be the primary completion date.
    - If another endpoint applies, the primary completion date should be determined by a reasonable evaluation of the protocol statistical sections and may require review by the statistician. Examples might include 4-month response rate or 6-month progression-free rates.

- If a study closes early due to slow accrual and a full clinical study report is not necessary, the primary completion date will be considered the last date of treatment. The status of the study in clinicaltrials.gov would be "Terminated." Results reporting is still required.
- If patients are still on treatment, give an anticipated (not actual) study completion date.

*Adapted from ECOG's notes on primary completion date

- **To Calculate the Study Completion Date**
  - *IRB Approval Date + Expected Duration of Trial + <see chart>*
    - Expected Duration of the Trial is determined from the statistical section of the protocol.

Pilot/Feasibility	Add 2 years
Phase I	Add 3 years
Phase I-II	Add 4 years
Phase II	Add 4 years
Phase II-III	Add 5 years
Phase III	Add 5 years
Phase IV	Add 6 years