ClinicalTrials.gov:
What are Completion Dates?

The Primary and Study Completion Dates may be the same date, but they have different definitions. The Primary Completion Date is based on the data collection for the Primary Outcome Measure. The Study Completion Date is based on the last data collection point for the last patient.

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, whether the clinical trial concluded according to the pre-specified protocol or was terminated.”

The **Study Completion Date** is defined as “the date the final subject was examined or received an intervention for purposes of final collection of data for the primary and secondary outcome measures and adverse events (e.g., last subject’s last visit), whether the clinical trial concluded according to the pre-specified protocol or was terminated.”

- Both dates are determined by when data were collected, not the date data were analyzed, the date the study was published or the date the study closed with the IRB.

- For **Applicable Clinical Trials** and NIH-funded clinical trials, results must be entered one year after the **Primary Completion Date**. If there are 2 or more Primary Outcome Measures, results are due one year from the latest Primary Completion date.

- Required data includes results for the Primary Outcome Measure, participant flow (the number of participants who started, completed, and dropped out of each period of the study), baseline demographics and adverse event/serious adverse event data.

- Results for Secondary Outcome Measures must be entered one year after the Completion Date for the specific Secondary Outcome Measure.

- It is possible that data for the Primary Outcome Measure has to be entered before data collection for a Secondary Outcome Measure is complete (see example).

- The study does not need to be closed in the IRB to be complete in ClinicalTrials.gov. However, if the IRB is closed, the ClinicalTrials.gov record should be finished also. You may need to reopen a study in order to review PHI for results entry.

Need help? Please contact us: DOCR-CTGov@dm.duke.edu

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Example

Primary Outcome Measure (POM)

**Title**: Change in Anxiety  
**Time Frame**: baseline and month 6  
**Description**: Anxiety will be measured using the Zung Self-Rating Anxiety Scale. The scale is self-administered, with each response using a 4-point scale from ‘none of the time” to “most of the time.” Higher scores indicate more anxiety.

**Study Completion**: The study will end after the 2 year follow-up for survival

Secondary Outcome Measure (SOM)

**Title**: Overall Survival  
**Time Frame**: 2 years  
**Description**: Overall survival will be reported as the number of patients living 2 years after the start of study drug.

In this example, results for the Primary and Secondary Outcome Measures will need to be entered at different times. The **Primary Completion Date** is the date the last subject completes the month 6 anxiety assessment. The **Study Completion Date** is the same as the completion date for the secondary outcome measure: the date of the 2 year survival assessment for the last subject. Results entry for the Primary Outcome Measure, participant flow, baseline demographics and AE/SAE data would be required before the data was collected for the secondary outcome measure.

**Study Timeline**

- Dec 1, 2014: Enrollment ends
- Jun 1, 2015: The last subject completes the 6 month anxiety assessment (the Primary Outcome Measure)
- Jun 1, 2016: Results are due for the Primary Outcome Measure. Results should include participant flow, baseline demographics and AE/SAE data.
- Dec 1, 2016: The last subject was assessed for the 2 year survival (Secondary Outcome Measure)
- Dec 1, 2017: Results are due for the Secondary Outcome Measure.