



ClinicalTrials.gov

How Are the Primary Completion Date and the Study Completion Date Different?

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 defined as the *“final date on which data was collected.”*

- The **Primary Completion Date** is based on the data collection for the **Primary Outcome Measure**.
- 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.
- The **Primary Completion Date** may or may not be the same as the **Study Completion Date**.
- For [Applicable Clinical Trials](#), results must be entered 1 year after the **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.
- It is possible that data for the **Primary Outcome Measure** is required to be entered before data collection for a **Secondary Outcome Measure** is complete (see example below).
- 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.

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.

Secondary Outcome Measure (SOM)

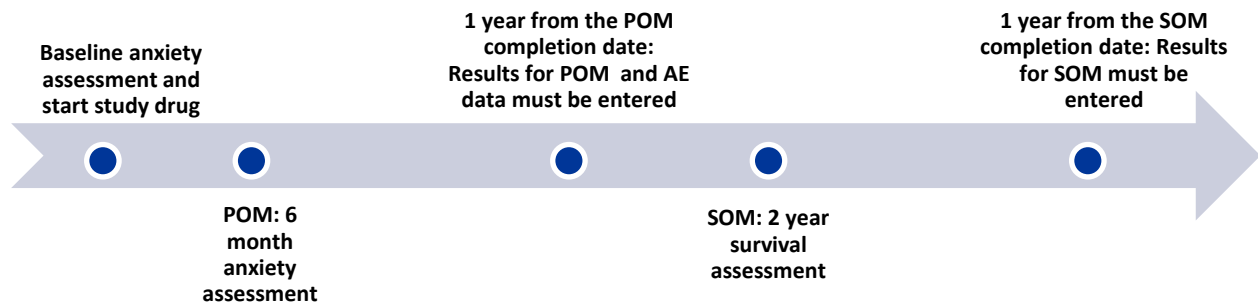
Title: Overall Survival

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. If this was an Applicable Clinical Trial, 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 Time Line



Dec 1, 2014: Enrollment ends

Jun 1, 2015: The last subject completes the 6 month anxiety assessment (the Primary Outcome Measure)

Jun 1, 2016: Deadline for the entry of the results 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: Deadline for the entry of the results for the Secondary Outcome Measure.

