How to Determine Primary Completion & Study Completion Date

What is the Primary Completion Date?

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 are delinquent (12 months beyond this date). Therefore, it is very important that this date be reviewed and appropriately updated by the "responsible party." We recommend review of this date every 6 months (the required record update interval).

The *Type* should remain "anticipated" until the primary completion has been reached at which point the "responsible party" should update this to "actual" and complete the results reporting.

At Initial Registration

To facilitate the initial registration, the the Office of Data Quality (ODQ) will assign the anticipated primary completion date as follows:

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

Investigator Responsibility

Confirm the Primary Completion Date OR Edit the Primary Completion Date

- If the Primary Completion Date is edited, please notify (ODQ) via email to DFCIQACTClinicalTrialsGov@partners.org, so that we can update the DF/HCC protocol database

Tips Regarding 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 to be 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 anticipated (not actual) study completion date.

*Adapted from ECOG's notes on primary completion date

What is the Study Completion Date?

This is the final date on which data was (or is expected to be) collected.

At Initial Registration

To facilitate the initial registration, the Office of Data Quality (ODQ) will assign the anticipated study completion date as follows:

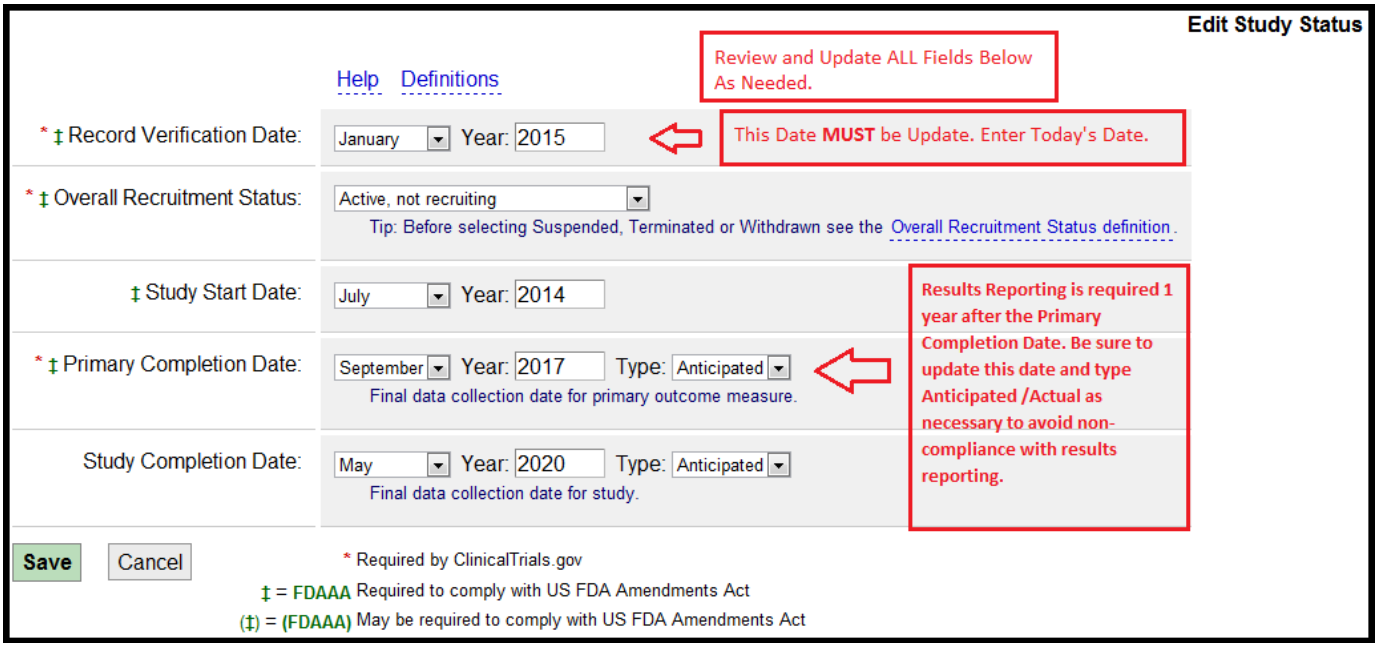
IRB Approval Date + Expected Duration of Trial + <see chart>

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

Investigator Responsibility

Confirm the Study Completion Date OR Edit the Study Completion Date

- If the Study Completion Date is edited, please notify ODQ via email to DFCIQACTClinicalTrialsGov@partners.org, so that we can update the DF/HCC protocol database


Edit Study Status
Help
Definitions
Review and Update ALL Fields Below As Needed.
* ‡ Record Verification Date:
January
Year: 2015
This Date MUST be Update. Enter Today's Date.
* ‡ Overall Recruitment Status:
Active, not recruiting
Tip: Before selecting Suspended, Terminated or Withdrawn see the Overall Recruitment Status definition.
‡ Study Start Date:
July
Year: 2014
* ‡ Primary Completion Date:
September
Year: 2017
Type: Anticipated
Final data collection date for primary outcome measure.
Study Completion Date:
May
Year: 2020
Type: Anticipated
Final data collection date for study.
Results Reporting is required 1 year after the Primary Completion Date. Be sure to update this date and type Anticipated /Actual as necessary to avoid non-compliance with results reporting.
Save
Cancel
* Required by ClinicalTrials.gov
‡ = FDAAA Required to comply with US FDA Amendments Act
(‡) = (FDAAA) May be required to comply with US FDA Amendments Act