

Guidance on Research Follow-Up

Defining a follow-up period is important to the research protocol (even if the follow-up period is “until progression” or “until death”).

Specify how subjects will be followed for assessment of treatment-related adverse events and therapeutic effect (even if the assessments are standard of care (SOC) – include them in your narrative) A table of follow-up parameters that incorporates the schedule is particularly useful.

Subject Status Definitions

Please consider the following definitions when referring to subject status.

- “On Study” – has signed consent and has been enrolled (assigned a subject identification number).
- “On Treatment” – subject is currently receiving protocol specific treatment.
- “Off Treatment” – end of study treatment for any reason (please note that off treatment date may not be the same date as last dose of treatment in some instances):
 - PI/treating physician determined that treatment is no longer appropriate,
 - Subject completed the treatment per protocol
 - Subject removed from treatment due to toxicities/side effects per PI/treating physician
 - Subject withdraws consent.
- “Follow-up” – all post-treatment visit data that is collected per protocol (including SOC assessments, if applicable).
- “Off Study” – subject has completed treatment and all follow up.

Follow-Up Time Periods

Example: If a study includes one cycle of therapy, and 3 follow up visits that are 3 months apart, after the subjects third follow-up visit at month 9, they will then be considered “off study”.

EXAMPLE: Subjects will be followed for toxicity for 30 days after treatment has been discontinued or until death, whichever occurs first.

The clinical course of each adverse event will be followed until resolution, stabilization, or until it has been determined that the study treatment or participation is not the cause.

Serious adverse events that are still ongoing at the end of the study period will necessitate follow-up to determine the final outcome. Any serious adverse event that occurs after the study period and is considered to be possibly related to the study treatment or study participation will be recorded and reported immediately.

Criteria for removal from study:

In the absence of treatment delays due to adverse events, treatment may continue for [# cycles] or until one of the following criteria applies:

- Disease progression
 - Intercurrent illness that prevents further administration of treatment
 - The investigator considers it, for safety reasons, to be in the best interest of the subject.
 - General or specific changes in the subject's condition render the subject unacceptable for further treatment in the judgment of the investigator,
 - Subject decision to withdraw from treatment (partial consent) or from the study (full consent),
 - Pregnancy during the course of the study for a child-bearing participant
 - Death, or
 - Sponsor reserves the right to temporarily suspend or prematurely discontinue this study.
- Unacceptable adverse event(s) [be specific]

Example: Unacceptable treatment related toxicity, NCI CTC AE version 4.0 Grade 3 or 4 that fails to recover to baseline or < Grade 3 in the absence of treatment within 4 weeks

Example: any toxicity or other issue that causes a delay of study drug administration by more than 4 weeks

The date and reason for discontinuation must be documented. Every effort should be made to complete the appropriate assessments.

Example: For indefinite follow up period:

Every 3 months for <2 years from study drug discontinuation

Every 6 months for 2-5 years from study drug discontinuation

Annually for 5+ years from study drug discontinuation