



Monday Morning Practice Pearls #14

What is off-treatment versus off-study?

Off-Treatment

Off treatment is when no further treatment will be given. This includes any normal observation period associated with a cycle/course. The off treatment date is the date the patient is officially taken off-treatment with no further study-related treatment given. The off-treatment date generally, but not always, corresponds to a clinic visit that would have served as the pre-course visit had the patient continued on treatment.

Note: Off-treatment is *NOT* when you hold the intervention due to AEs as outlined in the protocol. The off-treatment date for an intervention that was held would be the date the MD Investigator determined that the patient would not be resuming the intervention.

<u>Off-treatment and the Protocol</u>	<u>Off-treatment and CRIS</u>
The protocol should state the off-treatment criteria. Section 3.9.1 in our protocol template is labeled “ <i>Criteria for removal from protocol therapy.</i> ” Study-specific follow-up procedures may still be needed and should be outlined in the protocol in the calendar of events or a narrative.	As a research nurse, you need to ensure that there is a note in CRIS documenting the date and reason the patient was taken off-treatment. Ideally this note really should be written by an MD, PA or NP. If you write this note, then you need to refer to the MD who made the decision to stop treatment.

Off-Study

Off-study is when all protocol-related procedures, activities, and follow-up have been completed. Once a patient is taken off study, no further data can be collected.

<u>Off-study and the Protocol</u>	<u>Off-study and CRIS</u>
The protocol should state the off-study criteria. This may include the completion of a 30-day follow-up period, participant requests to be withdrawn from the study, or death as a few examples.	As a research nurse, you need to ensure that there is a note in CRIS documenting the date and reason the patient was taken off-study. Ideally this note really should be written by an MD, PA or NP. If you write this note, then you need to refer to the MD who made the decision to take the patient off-study.

All participants who meet the off treatment and off study criteria must be taken off treatment and off study in [PRES](#).