Off Treatment

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Purpose

Record information concerning the patient's off treatment date, reason and best response to treatment.

For studies without a protocol specified follow-up period, also complete the Off Study case report form entering the same Date, Reason and, if applicable, the Reason Explanation and Date of Disease Progression. Also complete the Off Study form with the same information when the Reason Off Treatment prevents the follow-up period from occurring.

Off Treatment eCRF

Field Name	Description / Instructions	Format
Visit Date^(m)^	Enter the date the form is being completed.	DD-MMM-YYYY
Date Off Treatment^(m)^	Enter the date when all courses have been completed (including the normal observation period) or discontinued and no further treatment courses are planned. This date will correspond to the clinic visit that would have served as the pre-course visit had the patient continued on therapy. This is the date the patient has been officially taken off treatment.	DD-MMM-YYYY

Reason Off Treatment^(m)^	Select an off treatment reason from one of the following reason groups: 1) If the patient's participation has been completed as per protocol, and the protocol does not specify a follow-up observation period, select: **C - Study Completed** ⓘ Note: Option 'C' is only available for studies without a follow-up period. 2) For patients who were evaluated for entry to the protocol and signed an informed consent form, but were not treated (never received any drugs or therapies per the protocol), select one of the following: **X - Patient Declined to Participate** (before treatment started.) **B - Disease Progression before Treatment.** **Z - No Treatment, per protocol.** **U - Not Treated - Other Reasons, explain** - Enter an explanation in the Reason Other field 3) When the patient's participation terminated during treatment period, select one of the following: **P - Disease Progression On Study:** The patient was taken off treatment for disease progression. This must be reflected by an increase in the non-measurable or measurable disease state. (See Course Assessment and Extent of Disease Forms). This can be manifested as clinical deterioration. **A Date of Progression must be entered.** **D - Death During Treatment:** The patient has died during the treatment phase. The cause of death should be listed on the Survival case report form and, if applicable, on the Adverse Events case report form as well. **T - Adverse Events / Side Effects:** The patient experienced any toxicity that was considered related to the study medication, which prohibited further protocol treatment. Patients discontinued due to toxicity are evaluable provided the observation period has been completed per protocol. The toxicity must be listed on the Adverse Events form. **S - Complicating Disease / Intercurrent Illness:** Patient was taken off treatment due to complicating disease not related to malignancy. This should be included in the Adverse Event form by an event not considered to be related to therapy. **G - Cytogenetic Resistance.** **A - Switched to Alternative Treatment:** The patient was taken off treatment due to a decision to pursue alternative therapy (such as palliative radiation). **R - Refused Further Treatment:** If at any time the patient refused further treatment. **I - Late Determination of Ineligibility:** Patient was taken off treatment following treatment because follow-up tests indicate that patient was not eligible for the study. **V - Protocol Violation:** If a major protocol violation has occurred, the reason must be stated in the Comments part of this case report form. **2 - Patient Noncompliance:** If the patient did not comply with the study plan. ⓘ Note: For CTMS protocols, the actual Reason sent is 'O' and the explanation text is - 'Patient Noncompliance'. **N - PI Discretion:** If PI made the decision. For CTMS protocols, the actual Reason sent is 'O' and the explanation text is - PI Discretion'. **O - Other:** Other reasons may be given for taking the patient off treatment, although they may not be included in the protocol stipulated rules. The patient's evaluability will subsequently be determined. Enter an explanation in the Reason 'Other' field. 4) When the patient completes protocol-specified treatment period, select the following: **Q - Treatment Period Completed** ⓘ Note: Option 'Q' is only available for studies with a follow-up period.	Use pick list.
Explain 'Other' Reason Off Treatment	Enter an explanation for selecting "Other" for a Reason Off Treatment.	50 characters
Patient Began Protocol Specified Follow-up^(m)^	Indicate whether or not the patient began the protocol-specified follow-up period. Y - Yes N - No ⓘ Note: This field is only available for protocols with a specified follow-up period.	Use pick list.
Date of Last Medication Administration (d)	Indicates date the last medication was administered.	DD-MMM-YYYY

Best Response to Treatment^ (m)^	Select the best overall response to treatment while on protocol. **CR** - Complete response **MR** - Less than partial response **NA** - Not assessed **NE** - Not evaluable **NP** - Not applicable per protocol **PD** - Progressive disease **PR** - Partial response **SD** - Stable disease **TE** - Too early to access, per protocol **CRU** - Complete Response Unconfirmed **NON-CR/NON-PD** - Non Complete Response and Non Progressive Disease **DU** - Disease Unchanged For protocols not using RECIST criteria in assessing response, the following might be applicable to use. Consult/follow protocol for definition and usage criteria. **MX** - Mixed Response **RP** - Response **NR** - No Response According to RECIST and WHO guidelines this would be the best response assessed from the start of treatment until disease progression. Ordinarily this would be the best of the responses reported on the course assessment CRFs. For example, do not enter "SD" if the patient was assessed only with progressive disease. **Please be sure to enter the best response, not necessarily the response on the last course.** For example, if the patient was assessed with a PR followed by a PD, enter the "PR". If response was not assessed at all during the protocol treatment, enter the best response as NA; similarly for NE and NP. RECIST: Unless the protocol includes specific response evaluation criteria, the following RECIST and WHO guidelines should be observed: Responses of PR and MR are assessed relative to the baseline at start of treatment, not to previous courses. They must be confirmed by repeat assessments. Subsequent evaluations at which tumor sizes are substantially unchanged should be assessed again as the same PR/MR. A response of PD is relative to the best disease status (smallest tumor measurement) since treatment began. Thus a tumor re-growth after a PR would be assessed as PD not an MR. A PR or MR cannot follow a CR.	Use pick list.
Date of Best Response	Enter the date that a Best Response of Treatment response of CR, PR, or MR was first observed, or that an SD response began. This date must be consistent with the date entered on the Course Assessment case report form(s) and with evaluations on the Extent of Disease Form.	DD-MMM-YYYY
Date of Disease Progression	Enter the date that progression (or relapse) was first observed (i.e.: date of scan). **This date is required if the Reason for Off Treatment is for Disease Progression.** This date must be consistent with the date of progression entered on the Course Assessment form(s) and with evaluations on the Extent of Disease Form. Progression is the worsening of disease following a period of stable disease or a response. Relapse is the reoccurrence of disease in a patient with no evaluable disease at enrollment (e.g. on an adjuvant treatment study).	DD-MMM-YYYY

> ✓ Legend: (d) derived field, (m) RDC mandatory, (c) for CTEP reporting only.

Validations

Code	Description	Resolutions
OTS05	Best Response to Treatment is not 'PD/NA/NE/NP/TE' and Date of Best Response is missing.	If anything other than 'PD/NA/NE/NP/TE' is checked for Best Response to Treatment, then Date of Best Response must be entered.
OTS07	Best Response to Treatment is 'Disease Progression' and Date of Progression is missing.	If 'Disease Progression' is checked for Best Response to Treatment, then Date of Progression must be entered.
OTS08	Date of Progression is not equal to the earliest Date of Progression reported on the Course Assessment forms.	Date of Progression must be consistent with Date of Progression on Course Assessment form(s).
OTS09	Best Response to Treatment is not the same as the best response reported on Course Assessment forms.	Best response should be validated against responses on Course Assessment form(s).
OTS10 OTS11 OTS12	Date Off Treatment, Date of Best Response and/or Date of Progression cannot be a date in the future.	Enter a date earlier than, or equals to, the current date.
OTS16	Reason Off Treatment is 'Death' and Date Off Treatment is not equal to Date of Death on Survival form.	If patient died during treatment, Date Off Treatment must the same as the Date of Death on the Survival form.

OTS17	Reason Off Treatment is 'Death' and Date Off Treatment is not equal to Date of Study on Off Study form.	If patient died during treatment, Date Off Treatment must the same as the Date Off Study on the Off Study form.
OTS18	Best Response date to Treatment is not same as the Best Response reported on Course Assessment forms	Best response date should be validated against response date on Course Assessment form.
OTS19	Reason Off Treatment is Protocol Violation and a comment with the date the patient ended treatment does not exist.	If patient discontinued due to Protocol Violation, then reason must be stated in the Comments tab of this form.
OTS20	Explain 'Other' Reason provided, but Reason Off Study is not 'U', 'O' or 'K'.	Only 'Other' reasons can have an explanation.
OTS21	Reason Off Study is 'U', 'O' or 'K' and Explain 'Other' Reason not provided.	'Other' reasons must have an explanation in the Explain 'Other' Reason field.
OTS26	For studies with protocol-specified follow-up period only: Answer to 'Patient Began Protocol-Specified Follow-up Period' is 'N - No' and there is no Off Study case report form or Off Study Reason is missing.	Please review the answer to 'Patient Began Protocol-Specified Follow-up Period' or enter an Off Study Reason.
OTS27	Other Reason in Off Treatment has more than 24 characters	Make Explanation for 'Other Reason' is less than 24 characters.
OTS28	Date of Disease Progression on Off Treatment is provided but there is no Date of Progression reported on the Course Assessment forms.	Make data consistent.

Derivations

Code	Field Name	Description
OTS1002	Date of Last Medication Administration	Indicates date the last medication was administered.