

BTTC Follow up

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Purpose

The purpose of this Case Report Form (CRF) is to capture progression free survival post-treatment. Record each off treatment long-term follow-up contact made with patient per timeline identified in the protocol.

There is no need to complete this CRF if the patient died during the treatment portion of the study. Please ensure details of patient's death are entered on the Survival CRF.

Follow-up eCRF

[illegible]

Field Name	Description / Instructions	Format
Visit Date	The Visit Date is optional on this case report form. Hit the "Tab" key to leave it empty and move to the Date of Last Contact field.	DD- MMM- YYYY
Progression Date After Treatment	Enter the calendar date post-treatment of the return of a disease after a period of remission.	DD- MMM- YYYY
Basis of Diagnosis	Select the name of the technique or modality used to document the initial diagnosis of a patient: <ul style="list-style-type: none"> Clinical Histology Imaging 	Use pick list.
Date of Last Contact ^(m)	Enter the date the patient was last contacted. If the patient is being considered lost to follow-up (i.e.: unsuccessful contact with the patient / family / health care provider), please indicate the date that no further follow-up will be attempted.	DD- MMM- YYYY

Type of Contact ^(m)	Select how the information was obtained: 1. Telephone contact with patient 2. Telephone contact with patient's family 3. Telephone contact with patient's local physician 4. Social Security Death Index (SSDI) 5. Clinic Appointment 6. Mail contact with the patient 7. E-Mail contact with the patient 8. Other 9. Email from Family 10. Email From Doctor's Office 11. Mail Contact from Local MD(s) 12. Home Phone 13. Cell Phone 14. Office Visit	Use pick list.
Vital Status	Select one of the options below that indicates the patient's last known status. 1. Alive 2. Dead 3. Unknown 4. Unspecified	Use pick list.
A first relapse or PD not previously reported?	Select the text term to signify whether there was a first relapse or progression of disease. <ul style="list-style-type: none">• NO• YES• N/A• UNKNOWN	Use pick list.
New Anti-cancer Therapy?	Select the text term to signify whether a patient has started a new anticancer therapy that has not been reported. <ul style="list-style-type: none">• NO• YES• N/A• UNKNOWN	Use pick list.
Start Date of New Anti-cancer Therapy	Enter the calendar date on which new anticancer therapy is initiated.	DD- MMM- YYYY
Regimen Type	Term to describe the number of agents included in therapy regimen: <ul style="list-style-type: none">• MULTIPLE AGENTS• SINGLE AGENT• UNKNOWN	Use pick list.
Subsequent Therapy Type	Select the text classification of the type of treatment administered to an individual after going off the treatment portion of a clinical trial: <ul style="list-style-type: none">• BMT• CHEMOTHERAPY• HORMONAL THERAPY• IMMUNOTHERAPY• RADIATION THERAPY• SURGERY• SYSTEMIC THERAPY	Use pick list.
Received Treatment Since Last Contact? ^(m)	If the patient has received further treatment since the last contact, select Y - Yes N - No	Use pick list.



Legend: ^(d) derived field, ^(m) RDC mandatory.

Validations

Code	Description	Resolutions
FLW05	Date of Last Contact is in the future.	Enter a date earlier than, or equals to, the current date.

FLW06	Date of Last Contact is not within the Date Off Treatment and Date Off Study.	Date of Last Contact must fall between the Date Off Treatment and Date Off Study.
FLW07	Duplicate Date of Last Contact.	Date of Last Contact must be unique.
FLW08	Patient Status is "Unknown" and explanation is missing.	Patient Status "Unknown" requires an explanation.
FLW09	Explain "Unknown" Patient Status was provided, but Patient Status is not "Unknown".	Patient Status "Unknown" is required if an explanation for "Unknown" Patient Status is provided.

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