

BTTC Prior Treatment Summary

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
Purpose

Record whether or not the patient has received any treatments for each of the prior therapy types listed. These treatments are specifically related to the disease being studied by the BTTC protocol (e.g. glioblastoma, ependymoma).

Details recorded here must also be provided on the Prior Therapy CRF. These include:

1. The last treatment prior to enrollment.
2. Any prior stem cell toxic therapy (e.g. mitomycin C) or cardiotoxic therapy (e.g. doxorubicin or other anthracycline) if relevant to the study agent.
3. Any therapies used to determine "extensive prior therapy" if specified in protocol.
4. Any therapies restricted by the protocol eligibility criteria, either specific drugs or number of prior therapies (e.g. no more than two prior chemotherapy regimens for metastatic disease).
5. Any therapies that are clinically significant for evaluation of the current study.
6. Additionally as required specifically by the protocol.

Prior Treatment Summary eCRF


**CENTER FOR
CRIMINAL
RESEARCH**

Date: 07/27/04 File: 00000000 Patient: 01



Visit Date: Admin CRP Date: Comment:

(Enter text)

PRIOR TREATMENT SUMMARY

Treatment Type	Wp Therapy	Wp Therapy	Wp Therapy	Date of Last Eval
PSYCHOSOCIAL/PSYCHIATRIC THERAPY				
OUTPATIENT THERAPY				
COMMUNITY SERVICE AGENT MEET				
COMMUNITY SERVICE AGENT 2				
COMMUNITY MEET				
GENERAL THERAPY				
REENTRY				
WFO MEET/ WFO COMMUNITY				
DEFENSIVE THERAPY				
LIMITED OBSERVATION				
VACCINATION (G)				
WFO THERAPY THERAPY				
WFO THERAPY				
PSYCH THERAPY (G)				
COMMUNITY NON-STRUCTURED				
WFO-STRUCTURED THERAPY				
WFO MEET				
STRUCTURED THERAPY				
REENTRY				

Number of the Current Release:

Field Name	Description / Instructions	Format
Visit Date ^(m)	Enter the date the form was completed (i.e. the date information was gathered).	DD-MMM-YYYY
Therapy Type	<p>Name of the type of therapy. The appropriate list of therapy types is provided.</p> <div>  <p>Note: "Limited Radiation" is therapy using ionizing radiation to a limited (<50%) portion of the body, while "Extensive Radiation" exposes a significant portion of the body (>50%), e.g. cardiospinal, pelvic, or total-body.</p> </div> <div>  <p>Note: "Chemotherapy (NOS)" should be used only when it is not possible to determine whether the treatment was "single agent" or "multiple agent".</p> </div>	Not applicable.
Any Therapy? ^(m)	<p>Indicate whether or not the patient has received any prior treatment for the type of therapy listed.</p> <p>Y - Yes - then Date of Last Dose must be provided.</p> <p>N - No</p>	Use pick list.
Number of Prior Systemic Regimens ^(m)	Enter the number counting the total systemic regimens of therapy the patient received prior to enrolling the current protocol, where multiple drugs or a staged therapy count as a single regimen. Do not use for other types of therapy	2 digits

Date of Last Dose	Enter the date of the last dose of the most recent prior treatment regimen for each therapy type. Partial dates are acceptable when the day is not known. Leave it blank if the treatment is currently being received. For combination therapies, record the date of the last dose of medication for the combination.	DD-MMM-YYYY or MMM-YYYY
Number of the Current Relapse	Enter the numeric value sequentially counting the return of cancer symptoms in a patient who received treatment and had a limited period of successful response.	2 digits



Legend: ^(m) RDC mandatory

Validations

Code	Description	Resolutions
PTX02	Date of Last Dose is specified for a therapy type but the respective "Any Therapy?" is not checked 'Yes'.	Verify Date of Last Dose and/or "Any Therapy?".
PTX03	Date of Last Dose, which could be partial, is in the future.	Enter a Date of Last Dose that is equal to or earlier than the current date.
PTX04	Number of Prior Regimens is negative or not a number. (Note: only for studies reporting data to CDS)	Enter a number between 0 and 99 when applicable.
PTX05	Some of the 'Any Therapy?' answers were not provided.	Answer 'Y' or 'N' for all the 'Any Therapy?' questions.

Derivations

Code	Field Name	Description
PTX1001	Therapy Type	Drive Therapy Type Code based on matching Therapy Type