


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 that are related to the disease being studied by the protocol.


 Note: This CRF is only for CTEP-sponsored studies.

- Details must be provided for the following on the appropriate Prior Therapy Case Report Form:
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



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 by CTMS.</p> <div> 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.</div> <div> Note: "Chemotherapy (NOS)" should be used only when it is not possible to determine whether the treatment was "single agent" or "multiple agent".</div>	Not applicable.
Any Therapy? ^(m)	Indicate whether or not the patient has received any prior treatment for the type of therapy listed. Y - Yes - then Date of Last Dose must be provided. N - No	Use pick list.

Number of Prior Chemotherapy Regimens ^{(u)(m)}	<p>Enter the number of prior regimes received for chemotherapies types of therapy. Do not use for other types of therapy.</p> <div>  Note: This field is only mandatory for studies that report data to CDS. </div>	2 digits
Date of Last Dose	<p>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 and "Ongoing" will be reported to CTMS or CDS.</p> <p>For combination therapies, record the date of the last dose of medication for the combination.</p>	DD-MMM-YYYY or MMM-YYYY



Legend: ^(d) derived field, ^(m) RDC mandatory, ^(c) for CTEP reporting only, ^(u) for CDS reporting only.

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