

# Prior Therapy Supplement

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## Purpose

Record details of prior therapies related to the disease being studied by the protocol or when the details would be clinically significant for the evaluation of this study as indicated on the Prior Treatment Summary case report form.

## Prior Therapy Supplement 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
Date of First Dose^(m)^	Enter the date of the first dose of the prior therapy. Partial dates are acceptable when the day is not known.	DD-MMM-YYYY or MMM-YYYY
Date of Last Dose	Enter the date of the last dose of the prior therapy. Partial dates are acceptable when the day is not known. Leave it blank if the treatment is currently being received. "Ongoing" will be reported to CTMS or CDS.	DD-MMM-YYYY, MMM-YYYY
Agent Name	Select the generic name of the agent that was used.  <div> <i>Note:</i> For standard regimen (multiple agents given as one regimen), enter one record for each agent. </div>	Use pick list.
Schedule	Select the schedule on which the agent (or combination) was given.	24 characters
Total Dose	Enter the total dose of the agent.	8 characters
Total Dose UOM	Enter the total dose units of measurement.	12 digits
Total No. of Courses Administered	Enter the total number of cycles or courses of the specified drug or therapy agent administered to the patient as of the reported period	3 digits
Best Response	Select the best response encountered: CR - Complete Response MR - Minimal/Marginal Response NA - Not Assessed NE - Not Evaluable PD - Progressive Disease PR - Partial Response SD - Stable Disease UK - Unknown <b>Leave this field blank if the treatment is ongoing.</b>	Use pick list.

NonResponse Therapy Type	Select the therapy type for which the conventional response calls are not appropriate. AJ - Adjuvant Therapy PA - Palliative Therapy NJ - Neoadjuvant Therapy	Use pick list.
Therapy Type <sup>(m)</sup> <sup>(d)</sup>	<p>Select the appropriate type of prior therapy:</p> <ul style="list-style-type: none"> <li>• Anti-Retroviral Therapy</li> <li>• Antisense</li> <li>• Bone Marrow Transplant</li> <li>• Chemotherapy (NOS)</li> <li>• Chemotherapy multiple agents systemic</li> <li>• Chemotherapy non-cytotoxic</li> <li>• Chemotherapy single agent systemic</li> <li>• Gene Transfer</li> <li>• Hormonal Therapy</li> <li>• Drug and/or Immunotherapy</li> <li>• Immunotherapy</li> </ul> <div>  Note: Do not use <b>Immunotherapy</b> for CTEP sponsored studies (CTMS and CDUS reporting). </div> <ul style="list-style-type: none"> <li>• Oncolytic Virotherapy</li> <li>• Vaccine</li> <li>• Prior Therapy (NOS)</li> <li>• Hematopoietic Stem Cell Transplantation</li> <li>• Image Directed Local Therapy</li> <li>• No prior Therapy</li> </ul>	Use pick list.

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

## Validations

Code	Description	Resolutions
PTS01	Date of First Dose is greater than Date of Last Dose.	Enter a Date of First Dose that is equal to or earlier than the Date of Last Dose.
PTS02, PTS03	Date of First Dose and Date of Last Dose are in the future.	Enter a date that is equal to or earlier than the current date.
PTS04	Both Best Response and Nonresponse Therapy Type are present /absent.	One and only one fields should be entered.

## Derivations

Code	Field Name	Description
PTS1001	Therapy Type	Derive Therapy Type Code based on matching Therapy Type