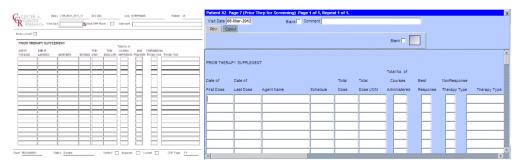
Prior Therapy Supplement

Purpose Prior Therapy Supplement eCRF Validations Derivations

Purpose

Record details of prior therapies related to the disease being studies 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	ield Name Description / Instructions		
Visit Date^(m)^	Enter the date the form was completed (i.e. the date information was gathered).		
Date of First Dose^(m)^			
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. Y		
Agent Name	Select the generic name of the agent that was used.		
	Note: For standard regimen (multiple agents given as one regimen), enter one record for each agent.		
Schedule	Select the schedule on which the agent (or combination) was given. Enter the total dose of the agent.		
Total Dose			
Total Dose UOM	Enter the total dose units of measurement.	12 digits	
Total No.of Courses Administered	ourses of the reported period		
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 Leave this field blank if the treatment is ongoing.	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^ (m)^	Select the appropriate type of prior therapy: Anti-Retroviral Therapy Antisense Bone Marrow Transplant Chemotherapy (NOS) Chemotherapy multiple agents systemic Chemotherapy non-cytotoxic Chemotherapy single agent systemic Gene Transfer Hormonal Therapy Drug and/or Immunotherapy Immunotherapy	Use pick list.
	Note: Do not use Immunotherapy for CTEP sponsored studies (CTMS and CDUS reporting). Oncolytic Virotherapy Vaccine Prior Therapy (NOS) Hematopoietic Stem Cell Transplantation Image Directed Local Therapy No prior Therapy	



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