

Prior Radiation Supplement

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Purpose

Record details of prior radiation therapy related to the disease being studied by the protocol or when the details would be clinically significant for the evaluation of this study.

Prior Radiation Supplement eCRF

Field Name	Description / Instructions	Format
Visit Date^(m) ^	Enter the date the form was completed. <div> <i>i</i> Note: If the information was obtained at multiple visits, please enter the date the form was completed. </div>	DD-MMM-YYYY
Date of First Dose^(m) ^	Enter the date of the first dose of the radiation 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 radiation therapy. Partial dates are acceptable when the day is not known. Leave it blank if the therapy is currently being received. "Ongoing" will be reported to CTMS or CDS.	DD-MMM-YYYY, MMM-YYYY
Radiation Type^(m) ^	Select the type of radiation therapy, e.g.: "proton beam", "external beam" or "implant".	Use pick list.
Other, Specify	Enter an explanation when 'Other, Specify' is selected as a 'Radiation Type'	100 Characters
Radiation Extent^(m) ^	Select the extent of the radiation therapy as follows: Limited Radiation: therapy using ionizing radiation to a limited (<50%) portion of the body. Extensive Radiation: therapy using ionizing radiation to a significant portion of the body (>50%), e.g. cardiopinal, pelvic, or total-body. Radiation (NOS): Extent is not known.	Use pick list.
Site^(m) ^	Select the site of the radiation therapy.	Use pick list.
Schedule	Select the radiation therapy schedule on which it was given.	24 characters
Total Dose	State the total radiation dose the patient received during the treatment period. Leave this field as well as the Total Dose UOM blank if the radiation therapy is ongoing.	8 characters
Total Dose UOM	Select the radiation dose units of measurement (e.g. cGy or rad, or cSv or rem).	Use pick list.

Best Response	Select the best response for the irradiated lesion. It applies to the type of therapy/intervention for which conventional response calls are appropriate. Leave this field blank if the radiation therapy is ongoing. CR - Complete Response PR - Partial Response MR - Minimal/Marginal Response SD - Stable Disease PD - Progressive Disease NE - Not Evaluable NA - Not Assessed UK - Unknown NR - No Response	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 PR - Prophylaxis	Use pick list.

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

Validations

Code	Description	Resolutions
PRD01	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.
PRD02 , PRD03	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.
PRD04	Both Best Response and Nonresponse Therapy Type are present /absent.	One and only one fields should be entered.
PRD05	Prior Radiation Type 'Other Specify' and 'Other, Specify' field are not present together.	Enter 'Other Specify' if 'Other Specify' is selected as Prior Radiation Type.

Derivations

Code	Field Name	Description
PRD1001	Therapy Type	Derive Therapy Type Code based on matching Therapy Type