

Manual for the Completion of CDISC Aligned NCI Standard Case Report Form (CRF) Modules

Introduction

In 2006, members of the National Cancer Institute's Center for Biomedical Informatics and Information Technology (NCI CBIIT) in conjunction with the cancer Data Standards Registry and Repository (caDSR) user community initiated a Case Report Form (CRF) harmonization activity. CRFs submitted from the community were reviewed and inventoried. The Harmonization group then reviewed all questions on the CRF and partitioned them into four categories:

- **Mandatory** – A data collection variable that must be on the CRF (e.g., a regulatory requirement (if applicable)).
- **Conditional** – A data collection variable that must be collected on the CRF for specific cases that may be dictated by local or sponsor defined business rules.
- **Optional** – A data collection variable that is available for use if needed. There is no regulatory or business requirement for inclusion of this element on the CRF; if the design and scientific questions posed in the study dictate the need to collect this type of data; this is the element to include on the CRF.
- **Non-harmonized** – A data collection variable that is, by consensus, to primarily belong to a different CRF module or is not belonging to any defined module.

A template form with modules that contain questions or variables representing data to be collected and a companion electronic CRF instruction manual was developed. These CRF modules were vetted and adopted by the caDSR stakeholder community as metadata standards.

Since the original CRFs and manuals were adopted, the Food & Drug Administration (FDA) published guidelines for submission of clinical trial study data using the Clinical Data Interchange Standards Consortium (CDISC) Study Data Tabulation Model (SDTM) for Investigational New Drug (IND) trials starting after December 2017. In response, NCI CBIIT has aligned the NCI Standard CRF modules with the CDISC data collection standard, Clinical Data Acquisition Standards Harmonization (CDASH) where data is expected to be submitted to FDA in SDTM format.

The instruction manual is a set of directions to guide data collection in each module template. Specific implementation instructions are not present; various groups may wish to implement the contents of a module in a variety of software applications.

The instructions include the field name, description or definition of each field, and any special formatting notes that apply to entries – such as the inclusion of full dates, use of values from a choice list only, etc. Finally, each question (or data item) is noted as Mandatory (m), Conditional (c), or Optional (o).

Radiation Therapy CDISC Aligned NCI Standard Template Module Definitions

Mapping to the CDASH:

This NCI Standard Template Form maps to the following domains in the CDASHIG v2.0 metadata table:

- FA – Findings About (v2.0)
- PR – Procedures (v2.0)

Mapping to the SDTM:

This NCI Standard Template Form maps to the following domains in the SDTMIG v3.3 metadata table:

- AG – Procedure Agents (v3.3)
- FA – Findings About (v3.3)
- PR – Procedures (v3.3)
- DU – Device In-Use (SDTMIG for Medical Devices v1.1)

Radiation Therapy CDISC Aligned NCI Standard Template Module Template Instructions

Field Descriptions and Instructions

Field Name (Partition Status) CDE ID # Short Name	Definition CDISC Mapping and Instruction	Format
Radiation Therapy Administered Type (m) 7063715 PRRTTY	The type of radiation therapy administered. CDASH: PRDECOD (6421526); SDTM: PRTRT (No CDE)	CHARACTER. Use choice list.
Radiation Therapy Administered Text (m) 7063722 PRRTTYX	The type of radiation therapy administered not previously listed. CDASH: PRTRT (6411539); SDTM: PRTRT (No CDE)	CHARACTER
Radiation Therapy Modality Administered Type (m) 7063723 PRRTMODL	The modality of radiation therapy administered. CDASH: No Match; SDTM: No Match, Can be a supplemental qualifier in SDTM	CHARACTER. Use choice list.

Field Name (Partition Status) CDE ID # Short Name	Definition CDISC Mapping and Instruction	Format
Procedure Start Date (m) 6409578 PRSTDAT	The date or start date of when the procedure started or was performed represented in an unambiguous date format (e.g., DD-MON-YYYY). CDASH: PRSTDAT (6409578); SDTM: PRSTDTC (No CDE)	DATE
Procedure End Date (m) 6409579 PRENDAT	The end date of the procedure represented in an unambiguous date format (e.g., DD-MON-YYYY). CDASH: PRENDAT (6409579); SDTM: PRENDTC (No CDE)	DATE
Internal Radiation Therapy Administration Method Type (c) 7063724 PRBRTTY	The brachytherapy radiation delivery method. CDASH: No Match; SDTM: No Match, Can be a supplemental qualifier in SDTM; Conditionality Rule: For inclusion if Brachytherapy is in use.	CHARACTER. Use choice list.
Internal Radiation Therapy Administration Method Text (c) 7063725 PRBRTTYX	The brachytherapy radiation delivery method not previously listed. CDASH: No Match; SDTM: No Match, Can be a supplemental qualifier in SDTM; Conditionality Rule: For inclusion if Brachytherapy is in use.	CHARACTER
Internal Radiation Therapy Radioactive Seed Implant Dosing Unit Identifier (c) 7063726 PRBIMPX	A unique identifier for the brachytherapy seed implant. CDASH: No Match; SDTM: No Match; Conditionality Rule: For inclusion if Brachytherapy is in use.	CHARACTER.
Internal Radiation Therapy Stranded Seed Implant Sequence Number (c) 7063727 PRBSTRN	The number representing the order of implantation of the brachytherapy seed implant. CDASH: No Match; SDTM: No Match; Conditionality Rule: For inclusion if Brachytherapy is in use.	NUMBER

Field Name (Partition Status) CDE ID # Short Name	Definition CDISC Mapping and Instruction	Format
Internal Radiation Therapy Stranded Seed Implant Total Administration Dose (c) 7063728 FABSITDS	The total dose of radiation administered as a brachytherapy seed implant represented as a numeric value. CDASH: FAORRES (6421467) where FAOBJ (6421465) = "Brachytherapy Seed Implantation Suture Material", FATEST (6423016) = "Total Dose", FACAT (6413046) = "RADIATION THERAPY"; SDTM: FAORRES (No CDE) where FAOBJ (No CDE) = "Brachytherapy Seed Implantation Suture Material", FATEST (No CDE) = "Total Dose", FATESTCD (6651723) = "TOTDOSE", FACAT (No CDE) = "RADIATION THERAPY"; Conditionality Rule: For inclusion if Brachytherapy is in use.	NUMBER
Findings About Result Unit (c) 6409841 FAORRESU	The unit of the result as originally received or collected. CDASH: FAORRESU (6409841) where FAOBJ (6421465) = "Brachytherapy Seed Implantation Suture Material", FATEST (6423016) = "Total Dose", FACAT (6413046) = "RADIATION THERAPY"; SDTM: FAORRESU (No CDE) where FAOBJ (No CDE)= "Brachytherapy Seed Implantation Suture Material", FATEST (No CDE) = "Total Dose", FATESTCD (6651723) = "TOTDOSE", FACAT (No CDE) = "RADIATION THERAPY"; Conditionality Rule: For inclusion if Brachytherapy is in use.	CHARACTER. Use choice list.

Field Name (Partition Status) CDE ID # Short Name	Definition CDISC Mapping and Instruction	Format
Internal Radiation Therapy Radioactive Seed Implant Dosing Unit Length Value (c) 7063729 FABILNGT	The measurement of the length of the brachytherapy seed implant represented as a numeric value. CDASH: FAORRES (6421467) where FAOBJ (6421465) = "Brachytherapy Implant", FATEST (6423016) = "Length", FACAT (6413046) = "RADIATION THERAPY"; SDTM: FAORRES (No CDE) where FAOBJ (No CDE) = "Brachytherapy Implant", FATEST (No CDE) = "Length", FATESTCD (6651723) = "LENGTH", FACAT (No CDE) = "RADIATION THERAPY"; Conditionality Rule: For inclusion if Brachytherapy is in use.	NUMBER
Findings About Result Unit (c) 6409841 FAORRESU	The unit of the result as originally received or collected. CDASH: FAORRESU (6409841) where FAOBJ (6421465) = "Brachytherapy Seed Implantation Suture Material", FATEST (6423016) = "Total Dose", FACAT (6413046) = "RADIATION THERAPY"; SDTM: FAORRESU (No CDE) where FAOBJ (No CDE) = "Brachytherapy Seed Implantation Suture Material", FATEST (No CDE) = "Total Dose", FATESTCD (6651723) = "TOTDOSE", FACAT (No CDE) = "RADIATION THERAPY"; Conditionality Rule: For inclusion if Brachytherapy is in use.	CHARACTER. Use choice list.

Field Name (Partition Status) CDE ID # Short Name	Definition CDISC Mapping and Instruction	Format
Internal Radiation Therapy Radioactive Seed Implant Dosing Unit Width Value (c) 7063730 FABIWDTH	The measurement of the width of the brachytherapy seed implant represented as a numeric value. CDASH: FAORRES (6421467) where FAOBJ (6421465) = "Brachytherapy Implant", FATEST (6423016) = "Width", FACAT (6413046) = "RADIATION THERAPY"; SDTM: FAORRES (No CDE) where FOABJ (No CDE) = "Brachytherapy Implant", FATEST (No CDE) = "Width", FATESTCD (6651723) = "WIDTH", FACAT (No CDE) = "RADIATION THERAPY"; Conditionality Rule: For inclusion if Brachytherapy is in use.	NUMBER
Findings About Result Unit (c) 6409841 FAORRESU	The unit of the result as originally received or collected. CDASH: FAORRESU (6409841) where FAOBJ (6421465) = "Brachytherapy Seed Implantation Suture Material", FATEST (6423016) = "Total Dose", FACAT (6413046) = "RADIATION THERAPY"; SDTM: FAORRESU (No CDE) where FAOBJ (No CDE)= "Brachytherapy Seed Implantation Suture Material", FATEST (No CDE) = "Total Dose", FATESTCD (6651723) = "TOTDOSE", FACAT (No CDE) = "RADIATION THERAPY"; Conditionality Rule: For inclusion if Brachytherapy is in use.	CHARACTER. Use choice list.

Field Name (Partition Status) CDE ID # Short Name	Definition CDISC Mapping and Instruction	Format
Internal Radiation Therapy Stranded Seed Implant Total Administration Number (c) 7063731 PRBITNUM	The total number of brachytherapy seed implants. CDASH: No Match; SDTM: No Match, Can be a supplemental qualifier in SDTM; Conditionality Rule: For inclusion if Brachytherapy is in use.	NUMBER
Fractionated Stereotactic Radiation Therapy Total Fraction Number (c) 7063732 PRBITFRC	The number of fractions of stereotactic radiation administered. CDASH: No Match; SDTM: No Match, Can be a supplemental qualifier in SDTM; Conditionality Rule: For inclusion if Brachytherapy is in use.	NUMBER
Internal Radiation Therapy Radioactive Seed Implant Dosing Unit Lost Indicator (c) 7063733 PRBLOSS	The indication of whether or not the brachytherapy seed implant was lost or expelled. CDASH: No Match; SDTM: No Match, Can be a supplemental qualifier in SDTM; Conditionality Rule: Use when RT is delivered in the form of seeds.	CHARACTER. Use choice list.
Reported Agent Name (o) 6790641 AGTRT	The name of an agent used as part of a procedure reported in a clinical trial. CDASH: No Match; SDTM: AGTRT (6790641)	CHARACTER
Radiosurgery Medical Device Type (o) 7063743 TRTUNIT	The device/treatment unit used to administer radiation therapy that can be focused on tumors or lesions while reducing radiation received to surrounding tissue. CDASH: No Match; SDTM: DUORRES (NO CDE) where DUTESTCD (NO CDE) = "TRTUNIT", DUTEST (No CDE) = "Treatment Unit"	CHARACTER. Use choice list.

Field Name (Partition Status) CDE ID # Short Name	Definition CDISC Mapping and Instruction	Format
Internal Radiation Therapy Radioactive Seed Implant Dosing Unit Lost Text (o) 7063753 PRBRSDLS	The description of how radioactive seeds have been lost or expelled. CDASH: No Match; SDTM: No Match, Can be a supplemental qualifier in SDTM	CHARACTER
Radiation Therapy Body Position Type (o) 7063754 PRPOS	The position of the patient during radiation therapy. CDASH: No Match; SDTM: No Match; Can be a supplemental qualifier in SDTM	CHARACTER. Use choice list.
Radiation Therapy Administration Extent Type (o) 7063755 PRRTTYP	The extent of radiation exposure administered to the patient's body during radiation therapy. CDASH: PRSCAT (6413048); SDTM: PRSCAT (No CDE)	CHARACTER. Use choice list.
Dose per Administration (o) 6790646 AGDOSE	The dose of study procedure agent taken per administration. CDASH: No Match; SDTM: AGDOSE (6790646)	NUMBER
Dose Units (o) 6824805 AGDOSU	The unit of measure for the dosage form related to agents used as part of a procedure. CDASH: No Match; SDTM: AGDOSU (6824805)	CHARACTER. Use choice list.
Start Time of Procedure (o) 6790405 PRSTTIM	The time at which a procedure is to start or did start. CDASH: PRSTTIM (6790405); SDTM: PRSTDTC (No CDE)	CHARACTER
End Time of Procedure (o) 6790406 PRENTIM	The time when a procedure has ceased. CDASH: PRENTIM (6790406); SDTM: PRENDTC (No CDE)	CHARACTER

Field Name (Partition Status) CDE ID # Short Name	Definition CDISC Mapping and Instruction	Format
Radiation Therapy Interruption Indicator (o) 7063756 PRRTINT	The indication of whether or not radiation therapy was interrupted. CDASH: No Match; SDTM: No Match, Can be a supplemental qualifier in SDTM	CHARACTER. Use choice list.
Radiation Therapy Interruption Text (o) 7063757 PRRTINTX	The explanation for interruptions in the radiation therapy treatment schedule. CDASH: No Match; SDTM: No Match, Can be a supplemental qualifier in SDTM	CHARACTER
Radiation Therapy Planning Target Volume Value (o) 7063758 FAPTV	The planned volume of tissue irradiated that ensures the prescribed radiation dose is absorbed in the clinical target volume represented as a numeric value. CDASH: FAORRES (6421467) where FAOBJ (6421465) = "PRTRT", FATEST (6423016) = "Planned Targeted Volume", FACAT (6413046) = "RADIATION THERAPY"; SDTM: FAORRES (No CDE) where FAOBJ (No CDE) = "PRTRT", FATEST (No CDE) = "Planned Targeted Volume", FATESTCD (6651723) = PTV", FACAT (No CDE) = "RADIATION THERAPY"	NUMBER

Field Name (Partition Status) CDE ID # Short Name	Definition CDISC Mapping and Instruction	Format
Findings About Result Unit (o) 6409841 FAORRESU	The unit of the result as originally received or collected. CDASH: FAORRESU (6409841) where FAOBJ (6421465) = "Brachytherapy Seed Implantation Suture Material", FATEST (6423016) = "Total Dose", FACAT (6413046) = "RADIATION THERAPY"; SDTM: FAORRESU (No CDE) where FAOBJ (No CDE)= "Brachytherapy Seed Implantation Suture Material", FATEST (No CDE) = "Total Dose", FATESTCD (6651723) = "TOTDOSE", FACAT (No CDE) = "RADIATION THERAPY"; Conditionality Rule: For inclusion if Brachytherapy is in use.	CHARACTER. Use choice list.
Radiation Therapy Clinical Target Volume Value (o) 7063759 FACTV	The gross target volume of tissue plus additional sub-clinical microscopic disease represented as a numeric value. CDASH: FAORRES (6421467) where FAOBJ (6421465) = "PRTRT", FATEST (6423016) = "Clinical Targeted Volume", FACAT (6413046) = "RADIATION THERAPY"; SDTM: FAORRES (No CDE) where FAOBJ (No CDE) = "PRTRT", FATEST (No CDE) = "Clinical Targeted Volume", FATESTCD (6651723) = "CTV", FACAT (No CDE) = "RADIATION THERAPY"	NUMBER

Field Name (Partition Status) CDE ID # Short Name	Definition CDISC Mapping and Instruction	Format
Findings About Result Unit (o) 6409841 FAORRESU	The unit of the result as originally received or collected. CDASH: FAORRESU (6409841) where FAOBJ (6421465) = "Brachytherapy Seed Implantation Suture Material", FATEST (6423016) = "Total Dose", FACAT (6413046) = "RADIATION THERAPY"; SDTM: FAORRESU (No CDE) where FAOBJ (No CDE)= "Brachytherapy Seed Implantation Suture Material", FATEST (No CDE) = "Total Dose", FATESTCD (6651723) = "TOTDOSE", FACAT (No CDE) = "RADIATION THERAPY"; Conditionality Rule: For inclusion if Brachytherapy is in use.	CHARACTER. Use choice list.
Radiation Therapy Planning Target Volume Greater Than 95 Percent Unit Exposure Dose Value (o) 7063760 FAPTV95	The percentage of planning target volume tissue that was exposed to more than 95% of the radiation dose. CDASH: FAORRES (6421467) where FAOBJ (6421465) = "PRTRT", FATEST (6423016) = "Percent of PTV receiving > 95% of dose", FACAT (6413046) = "RADIATION THERAPY"; SDTM: FAORRES (No CDE) where FAOBJ (No CDE) = "PRTRT", FATEST (No CDE) = "Percent of PTV receiving > 95% of dose", FATESTCD (6651723) = "PTVGT95", FACAT (No CDE) = "RADIATION THERAPY"	NUMBER

Field Name (Partition Status) CDE ID # Short Name	Definition CDISC Mapping and Instruction	Format
Findings About Result Unit (o) 6409841 FAORRESU	The unit of the result as originally received or collected. CDASH: FAORRESU (6409841) where FAOBJ (6421465) = "Brachytherapy Seed Implantation Suture Material", FATEST (6423016) = "Total Dose", FACAT (6413046) = "RADIATION THERAPY"; SDTM: FAORRESU (No CDE) where FAOBJ (No CDE)= "Brachytherapy Seed Implantation Suture Material", FATEST (No CDE) = "Total Dose", FATESTCD (6651723) = "TOTDOSE", FACAT (No CDE) = "RADIATION THERAPY"; Conditionality Rule: For inclusion if Brachytherapy is in use.	CHARACTER. Use choice list.
Radiation Therapy Planning Target Volume Greater Than 107 Percent Unit Exposure Dose Value (o) 7063761 FAPTV107	The percentage of planning target volume tissue that was exposed to more than 107% of the radiation dose. CDASH: FAORRES (6421467) where FAOBJ (6421465) = "PRTRT", FATEST (6423016) = "Percent of PTV receiving > 107% of dose", FACAT (6413046) = "RADIATION THERAPY"; SDTM: FAORRES (No CDE) where FAOBJ (No CDE) = "PRTRT", FATEST (No CDE) = "Percent of PTV receiving > 107% of dose", FATESTCD (6651723) = "PTVGT107", FACAT (No CDE) = "RADIATION THERAPY"	NUMBER

Field Name (Partition Status) CDE ID # Short Name	Definition CDISC Mapping and Instruction	Format
Findings About Result Unit (o) 6409841 FAORRESU	The unit of the result as originally received or collected. CDASH: FAORRESU (6409841) where FAOBJ (6421465) = "Brachytherapy Seed Implantation Suture Material", FATEST (6423016) = "Total Dose", FACAT (6413046) = "RADIATION THERAPY"; SDTM: FAORRESU (No CDE) where FAOBJ (No CDE)= "Brachytherapy Seed Implantation Suture Material", FATEST (No CDE) = "Total Dose", FATESTCD (6651723) = "TOTDOSE", FACAT (No CDE) = "RADIATION THERAPY"; Conditionality Rule: For inclusion if Brachytherapy is in use.	CHARACTER. Use choice list.

Annotated CRF: Radiation Therapy CDISC Aligned NCI Standard Template

This annotated CRF is ONLY used to show CDISC mapping without consideration of the CRF layout. CDASH mapping is in **Blue**, and SDTM mapping is in **Red**.

Form Name: Radiation Therapy CDISC Aligned NCI Standard Template

Mandatory Questions

CRF Question	Value Domain
<p>Radiation Therapy Type (7063715) CDE Short Name: PRRTTY</p> <div style="border: 1px solid blue; padding: 2px; margin: 5px 0;">CDASH: PRDECOD (6421526)</div> <div style="border: 1px solid red; padding: 2px; margin: 5px 0;">SDTM: PRTRT (No CDE)</div>	<p>CHARACTER – Maximum Length = 25</p> <ul style="list-style-type: none"> <input type="checkbox"/> 2D Conventional – 2-Dimensional Conventional Radiation Therapy <input type="checkbox"/> 3D Conformal – 3D Conformal <input type="checkbox"/> Brachytherapy HDR – High-Dose Rate Brachytherapy <input type="checkbox"/> Brachytherapy LDR – Low-Dose Rate Brachytherapy <input type="checkbox"/> IMRT – Intensity-Modulated Radiation Therapy <input type="checkbox"/> Other specify – Other Specify <input type="checkbox"/> Proton Beam – Proton Beam Radiation Therapy <input type="checkbox"/> Stereotactic Body RT – Stereotactic Body Radiation Therapy <input type="checkbox"/> Stereotactic Radiosurgery – Stereotactic Radiosurgery <input type="checkbox"/> Unspecified – Unspecified <input type="checkbox"/> WBRT – Whole Brain Radiation Therapy
<p>Radiation Therapy Type Other Specify (7063722) CDE Short Name: PRRTTYX</p> <div style="border: 1px solid blue; padding: 2px; margin: 5px 0;">CDASH: PRTRT (6411539)</div> <div style="border: 1px solid red; padding: 2px; margin: 5px 0;">SDTM: PRTRT (No CDE)</div>	<p>CHARACTER – Maximum Length = 200</p>

CRF Question	Value Domain
<p>Radiation Therapy Modality (7063723) CDE Short Name: PRRTMODL</p> <p>CDASH: No Match</p> <p>SDTM: No Match, Can be a supplemental qualifier in SDTM</p>	<p>CHARACTER – Maximum Length = 30</p> <ul style="list-style-type: none"> <input type="checkbox"/> Alpha – Alpha <input type="checkbox"/> Carbon – Carbon <input type="checkbox"/> Electron – Electron <input type="checkbox"/> Mixed – Mixed <input type="checkbox"/> Neutron – Neutron <input type="checkbox"/> Photon – Photon <input type="checkbox"/> Proton – Proton
<p>RT Begin Date (6409578) CDE Short Name: PRSTDAT</p> <p>CDASH: PRSTDAT (6409578)</p> <p>SDTM: PRSTDTC (No CDE)</p>	<p>DATE – Maximum Length = 11</p>
<p>RT End Date (6338240) CDE Short Name: PRENDAT</p> <p>CDASH: PRENDAT (6409579)</p> <p>SDTM: PRENDTC (No CDE)</p>	<p>DATE – Maximum Length = 11</p>

Conditional Questions

CRF Question	Value Domain
<p>Brachytherapy Delivery Technique Type (7063724) CDE Short Name: PRBRTTY</p> <div data-bbox="289 411 769 464" style="border: 1px solid blue; padding: 2px; margin-bottom: 10px;">CDASH: No Match</div> <div data-bbox="289 495 769 575" style="border: 1px solid red; padding: 2px; margin-bottom: 10px;">SDTM: No Match, Can be a supplemental qualifier in SDTM</div>	<p>CHARACTER – Maximum Length = 25</p> <ul style="list-style-type: none"> <input type="checkbox"/> Double strand – Double strand <input type="checkbox"/> Fletcher-suit – Fletcher-suit <input type="checkbox"/> Individual Seeds – Individual Seeds <input type="checkbox"/> Manchester ovoid – Manchester ovoid <input type="checkbox"/> Mesh – Mesh <input type="checkbox"/> Mesh seeds – Mesh Radioactive Seed Implant Dosing Unit <input type="checkbox"/> Mini ovoids – Mini ovoids <input type="checkbox"/> Needle(s) – Brachytherapy Needle <input type="checkbox"/> Other – Other <input type="checkbox"/> Standard (point-directed) – Standard (point-directed) <input type="checkbox"/> Tandems – Tandems <input type="checkbox"/> Vaginal cylinder – Vaginal cylinder <input type="checkbox"/> Volume-directed – Volume-directed
<p>Brachytherapy modality other, specify (7063725) CDE Short Name: PRBRTTYX</p> <div data-bbox="289 1125 769 1178" style="border: 1px solid blue; padding: 2px; margin-bottom: 10px;">CDASH: No Match</div> <div data-bbox="289 1209 769 1289" style="border: 1px solid red; padding: 2px; margin-bottom: 10px;">SDTM: No Match, Can be a supplemental qualifier in SDTM</div>	<p>CHARACTER – Maximum Length = 200</p>
<p>Implant Number (7063726) CDE Short Name: PRBIMPX</p> <div data-bbox="289 1419 769 1472" style="border: 1px solid blue; padding: 2px; margin-bottom: 10px;">CDASH: No Match</div> <div data-bbox="289 1503 769 1583" style="border: 1px solid red; padding: 2px; margin-bottom: 10px;">SDTM: No Match, Can be a supplemental qualifier in SDTM</div>	<p>CHARACTER – Maximum Length = 40</p>
<p>Strand (7063726) CDE Short Name: PRBSTRN</p> <div data-bbox="289 1713 769 1766" style="border: 1px solid blue; padding: 2px; margin-bottom: 10px;">CDASH: No Match</div> <div data-bbox="289 1797 769 1856" style="border: 1px solid red; padding: 2px; margin-bottom: 10px;">SDTM: No Match</div>	<p>NUMBER – Maximum Length = 10</p>

CRF Question	Value Domain
<p>Total Activity (7063728) CDE Short Name: FABSITDS</p> <div style="border: 1px solid blue; padding: 5px; margin: 10px 0;"> <p>CDASH: FAORRES (6421467) where FAOBJ (6421465) = "Brachytherapy Seed Implantation Suture Material", FATEST (6423016) = "Total Dose", FACAT (6413046) = "RADIATION THERAPY"</p> </div> <div style="border: 1px solid red; padding: 5px; margin: 10px 0;"> <p>SDTM: FAORRES (No CDE) where FAOBJ (No CDE) = "Brachytherapy Seed Implantation Suture Material", FATEST (No CDE) = "Total Dose", FATESTCD (6651723) = "TOTDOSE", FACAT (No CDE) = "RADIATION THERAPY"</p> </div>	<p>NUMBER – Maximum Length = 10</p>
<p>Unit (6409841) CDE Short Name: FAORRESU</p> <div style="border: 1px solid blue; padding: 5px; margin: 10px 0;"> <p>CDASH: FAORRESU (6409841) where FAOBJ (6421465) = "Brachytherapy Seed Implantation Suture Material", FATEST (6423016) = "Total Dose", FACAT (6413046) = "RADIATION THERAPY"</p> </div> <div style="border: 1px solid red; padding: 5px; margin: 10px 0;"> <p>SDTM: FAORRESU (No CDE) where FAOBJ (No CDE) = "Brachytherapy Seed Implantation Suture Material", FATEST (No CDE) = "Total Dose", FATESTCD (6651723) = "TOTDOSE", FACAT (No CDE) = "RADIATION THERAPY"</p> </div>	<p>CHARACTER – Maximum Length = 100</p> <ul style="list-style-type: none"> <input type="checkbox"/> cGy – Centigray <input type="checkbox"/> mCi – Millicurie <input type="checkbox"/> mCi/kg – Millicurie per Kilogram <input type="checkbox"/> mCi/L – Millicurie per Liter

CRF Question	Value Domain
<p>Length (7063729) CDE Short Name: FABLNGT</p> <div style="border: 1px solid blue; padding: 5px; margin: 10px 0;"> <p>CDASH: FAORRES (6421467) where FAOBJ (6421465) = "Brachytherapy Implant", FATEST (6423016) = "Length", FACAT (6413046) = "RADIATION THERAPY"</p> </div> <div style="border: 1px solid red; padding: 5px; margin: 10px 0;"> <p>SDTM: FAORRES (No CDE) where FAOBJ (No CDE) = "Brachytherapy Implant", FATEST (No CDE) = "Length", FATESTCD (6651723) = "LENGTH", FACAT (No CDE) = "RADIATION THERAPY"</p> </div>	<p>NUMBER – Maximum Length = 5</p>
<p>Unit (6409841) CDE Short Name: FAORRESU</p> <div style="border: 1px solid blue; padding: 5px; margin: 10px 0;"> <p>CDASH: FAORRESU (6409841) where FAOBJ (6421465) = "Brachytherapy Seed Implantation Suture Material", FATEST (6423016) = "Total Dose", FACAT (6413046) = "RADIATION THERAPY"</p> </div> <div style="border: 1px solid red; padding: 5px; margin: 10px 0;"> <p>SDTM: FAORRESU (No CDE) where FAOBJ (No CDE) = "Brachytherapy Seed Implantation Suture Material", FATEST (No CDE) = "Total Dose", FATESTCD (6651723) = "TOTDOSE", FACAT (No CDE) = "RADIATION THERAPY"</p> </div>	<p>CHARACTER – Maximum Length = 100</p> <p><input type="checkbox"/> cm – Centimeter</p> <p><input type="checkbox"/> mm – Millimeter</p>
<p>Mesh Width (7063730) CDE Short Name: FABIWDTH</p> <div style="border: 1px solid blue; padding: 5px; margin: 10px 0;"> <p>CDASH: FAORRES (6421467) where FAOBJ (6421465) = "Brachytherapy Implant", FATEST (6423016) = "Width", FACAT (6413046) = "RADIATION THERAPY"</p> </div> <div style="border: 1px solid red; padding: 5px; margin: 10px 0;"> <p>SDTM: FAORRES (No CDE) where FOABJ (No CDE) = "Brachytherapy Implant", FATEST (No CDE) = "Width", FATESTCD (6651723) = "WIDTH", FACAT (No CDE) = "RADIATION THERAPY"</p> </div>	<p>NUMBER – Maximum Length = 5</p>

CRF Question	Value Domain
<p>Unit (6409841) CDE Short Name: FAORRESU</p> <div style="border: 1px solid blue; padding: 5px; margin-bottom: 10px;"> <p>CDASH: FAORRESU (6409841) where FAOBJ (6421465) = "Brachytherapy Seed Implantation Suture Material", FATEST (6423016) = "Total Dose", FACAT (6413046) = "RADIATION THERAPY"</p> </div> <div style="border: 1px solid red; padding: 5px;"> <p>SDTM: FAORRESU (No CDE) where FAOBJ (No CDE)= "Brachytherapy Seed Implantation Suture Material", FATEST (No CDE) = "Total Dose", FATESTCD (6651723) = "TOTDOSE", FACAT (No CDE) = "RADIATION THERAPY"</p> </div>	<p>CHARACTER – Maximum Length = 100</p> <p><input type="checkbox"/> cm – Centimeter <input type="checkbox"/> mm – Millimeter</p>
<p>Total # Seeds (7063731) CDE Short Name: PRBITNUM</p> <div style="border: 1px solid blue; padding: 5px; margin-bottom: 10px;"> <p>CDASH: No Match</p> </div> <div style="border: 1px solid red; padding: 5px;"> <p>SDTM: No Match, Can be a supplemental qualifier in SDTM;</p> </div>	<p>NUMBER – Maximum Length = 10</p>
<p>Total Number of Fractions (7063732) CDE Short Name: PRBITFRC</p> <div style="border: 1px solid blue; padding: 5px; margin-bottom: 10px;"> <p>CDASH: No Match</p> </div> <div style="border: 1px solid red; padding: 5px;"> <p>SDTM: No Match, Can be a supplemental qualifier in SDTM</p> </div>	<p>NUMBER – Maximum Length = 10</p>
<p>Seed loss (7063733) CDE Short Name: PRBLOSS</p> <div style="border: 1px solid blue; padding: 5px; margin-bottom: 10px;"> <p>CDASH: No Match</p> </div> <div style="border: 1px solid red; padding: 5px;"> <p>SDTM: No Match, Can be a supplemental qualifier in SDTM;</p> </div>	<p>CHARACTER – Maximum Length = 2</p> <p><input type="checkbox"/> N – No <input type="checkbox"/> NA – Not Applicable <input type="checkbox"/> U – Unknown <input type="checkbox"/> Y – Yes</p>

Optional Questions

CRF Question	Value Domain
<p>Agent Name (6790641) CDE Short Name: AGTRT</p> <p>CDASH: No Match</p> <p>SDTM: AGTRT (6790641)</p>	<p>CHARACTER – Maximum Length = 200</p>
<p>Treatment Unit (7063743) CDE Short Name: TRTUNIT</p> <p>CDASH: No Match</p> <p>SDTM: DUORRES (NO CDE) where DUTESTCD (NO CDE) = "TRTUNIT", DUTEST (No CDE) = "Treatment Unit"</p>	<p>CHARACTER – Maximum Length = 25</p> <ul style="list-style-type: none"> <input type="checkbox"/> Cyberknife – Robot Stereotactic Radiosurgery <input type="checkbox"/> Gamma Knife – Gamma Knife <input type="checkbox"/> Linear Accelerator – Linear Accelerator <input type="checkbox"/> Other (specify) – Other (specify) <input type="checkbox"/> Other stereotactic – Other Stereotactic
<p>Seed Loss Details (7063753) CDE Short Name: PRBRSDLS</p> <p>CDASH: No Match</p> <p>SDTM: No Match, Can be a supplemental qualifier in SDTM</p>	<p>CHARACTER – Maximum Length = 200</p>
<p>Participant Position (7063754) CDE Short Name: PRPOS</p> <p>CDASH: No Match</p> <p>SDTM: No Match; Can be a supplemental qualifier in SDTM</p>	<p>CHARACTER – Maximum Length = 15</p> <ul style="list-style-type: none"> <input type="checkbox"/> Prone – Prone Position <input type="checkbox"/> Semiprone – Semiprone <input type="checkbox"/> Sitting – Sitting <input type="checkbox"/> Standing – Standing <input type="checkbox"/> Supine – Supine Position <input type="checkbox"/> Unknown – Unknown <input type="checkbox"/> Upright – Upright
<p>Radiation Type (7063755) CDE Short Name: PRRTTYP</p> <p>CDASH: PRSCAT (6413048)</p> <p>SDTM: PRSCAT (No CDE)</p>	<p>CHARACTER – Maximum Length = 24</p> <ul style="list-style-type: none"> <input type="checkbox"/> Extensive Radiation – Extensive Radiation <input type="checkbox"/> Limited Radiation – Limited Radiation Therapy <input type="checkbox"/> Radiation, NOS – Radiation Therapy

CRF Question	Value Domain
<p>Dose (6790646) CDE Short Name: AGDOSE</p> <p>CDASH: No Match</p> <p>SDTM: AGDOSE (6790646)</p>	<p>NUMBER – Maximum Length = 15</p>
<p>Units of Measure (6824805) CDE Short Name: AGDOSU</p> <p>CDASH: No Match</p> <p>SDTM: AGDOSU (6824805)</p>	<p>CHARACTER – Maximum Length = 100</p> <p>List of 750 PVs</p>
<p>Start Time (6790405) CDE Short Name: PRSTTIM</p> <p>CDASH: PRSTTIM (6790405)</p> <p>SDTM: PRSTDTC (No CDE)</p>	<p>CHARACTER – Maximum Length = 8</p>
<p>Stop Time (6790406) CDE Short Name: PRENTIM</p> <p>CDASH: PRENTIM (6790406)</p> <p>SDTM: PRENDTC (No CDE)</p>	<p>CHARACTER – Maximum Length = 8</p>
<p>Radiation Therapy Temporary Interruption (7063756) CDE Short Name: PRRTINT</p> <p>CDASH: No Match</p> <p>SDTM: No Match, Can be a supplemental qualifier in SDTM</p>	<p>CHARACTER – Maximum Length = 2</p> <p><input type="checkbox"/> N – No</p> <p><input type="checkbox"/> NA – Not Applicable</p> <p><input type="checkbox"/> U – Unknown</p> <p><input type="checkbox"/> Y – Yes</p>
<p>RT Interruptions Reason (7063757) CDE Short Name: PRRTINTX</p> <p>CDASH: No Match</p> <p>SDTM: No Match, Can be a supplemental qualifier in SDTM</p>	<p>CHARACTER – Maximum Length = 200</p>

CRF Question	Value Domain
<p>PTV (7063758) CDE Short Name: FAPTV</p> <div style="border: 1px solid blue; padding: 5px; margin: 10px 0;"> <p>CDASH: FAORRES (6421467) where FAOBJ (6421465) = "PRTRT", FATEST (6423016) = "Planned Targeted Volume", FACAT (6413046) = "RADIATION THERAPY"</p> </div> <div style="border: 1px solid red; padding: 5px; margin: 10px 0;"> <p>SDTM: FAORRES (No CDE) where FAOBJ (No CDE) = "PRTRT", FATEST (No CDE) = "Planned Targeted Volume", FATESTCD (6651723) = PTV, FACAT (No CDE) = "RADIATION THERAPY"</p> </div>	<p>NUMBER – Maximum Length = 5</p>
<p>Unit (6409841) CDE Short Name: FAORRESU</p> <div style="border: 1px solid blue; padding: 5px; margin: 10px 0;"> <p>CDASH: FAORRESU (6409841) where FAOBJ (6421465) = "Brachytherapy Seed Implantation Suture Material", FATEST (6423016) = "Total Dose", FACAT (6413046) = "RADIATION THERAPY"</p> </div> <div style="border: 1px solid red; padding: 5px; margin: 10px 0;"> <p>SDTM: FAORRESU (No CDE) where FAOBJ (No CDE) = "Brachytherapy Seed Implantation Suture Material", FATEST (No CDE) = "Total Dose", FATESTCD (6651723) = "TOTDOSE", FACAT (No CDE) = "RADIATION THERAPY"</p> </div>	<p>CHARACTER – Maximum Length = 100</p> <p><input type="checkbox"/> % – Percentage</p>
<p>CTV (7063759) CDE Short Name: FACTV</p> <div style="border: 1px solid blue; padding: 5px; margin: 10px 0;"> <p>CDASH: FAORRES (6421467) where FAOBJ (6421465) = "PRTRT", FATEST (6423016) = "Clinical Targeted Volume", FACAT (6413046) = "RADIATION THERAPY"</p> </div> <div style="border: 1px solid red; padding: 5px; margin: 10px 0;"> <p>SDTM: FAORRES (No CDE) where FAOBJ (No CDE) = "PRTRT", FATEST (No CDE) = "Clinical Targeted Volume", FATESTCD (6651723) = "CTV", FACAT (No CDE) = "RADIATION THERAPY"</p> </div>	<p>NUMBER – Maximum Length = 5</p>

CRF Question	Value Domain
<p>Unit (6409841) CDE Short Name: FAORRESU</p> <div style="border: 1px solid blue; padding: 5px; margin-bottom: 10px;"> <p>CDASH: FAORRESU (6409841) where FAOBJ (6421465) = "Brachytherapy Seed Implantation Suture Material", FATEST (6423016) = "Total Dose", FACAT (6413046) = "RADIATION THERAPY"</p> </div> <div style="border: 1px solid red; padding: 5px;"> <p>SDTM: FAORRESU (No CDE) where FAOBJ (No CDE) = "Brachytherapy Seed Implantation Suture Material", FATEST (No CDE) = "Total Dose", FATESTCD (6651723) = "TOTDOSE", FACAT (No CDE) = "RADIATION THERAPY"</p> </div>	<p>CHARACTER – Maximum Length = 100</p> <p><input type="checkbox"/> % – Percentage</p>
<p>Percent of PTV receiving > 95% of dose (7063760) CDE Short Name: FAPTV95</p> <div style="border: 1px solid blue; padding: 5px; margin-bottom: 10px;"> <p>CDASH: FAORRES (6421467) where FAOBJ (6421465) = "PRTRT", FATEST (6423016) = "Percent of PTV receiving > 95% of dose", FACAT (6413046) = "RADIATION THERAPY"</p> </div> <div style="border: 1px solid red; padding: 5px;"> <p>SDTM: FAORRES (No CDE) where FAOBJ (No CDE) = "PRTRT", FATEST (No CDE) = "Percent of PTV receiving > 95% of dose", FATESTCD (6651723) = "PTVGT95", FACAT (No CDE) = "RADIATION THERAPY"</p> </div>	<p>NUMBER – Maximum Length = 5</p>

CRF Question	Value Domain
<p>Unit (6409841) CDE Short Name: FAORRESU</p> <div style="border: 1px solid blue; padding: 5px; margin: 10px 0;"> <p>CDASH: FAORRESU (6409841) where FAOBJ (6421465) = "Brachytherapy Seed Implantation Suture Material", FATEST (6423016) = "Total Dose", FACAT (6413046) = "RADIATION THERAPY"</p> </div> <div style="border: 1px solid red; padding: 5px; margin: 10px 0;"> <p>SDTM: FAORRESU (No CDE) where FAOBJ (No CDE) = "Brachytherapy Seed Implantation Suture Material", FATEST (No CDE) = "Total Dose", FATESTCD (6651723) = "TOTDOSE", FACAT (No CDE) = "RADIATION THERAPY"</p> </div>	<p>CHARACTER – Maximum Length = 100</p> <p><input type="checkbox"/> % – Percentage</p>
<p>Percent of PTV receiving > 107% of dose (7063761) CDE Short Name: FAPTV107</p> <div style="border: 1px solid blue; padding: 5px; margin: 10px 0;"> <p>CDASH: FAORRES (6421467) where FAOBJ (6421465) = "PRTRT", FATEST (6423016) = "Percent of PTV receiving > 107% of dose", FACAT (6413046) = "RADIATION THERAPY"</p> </div> <div style="border: 1px solid red; padding: 5px; margin: 10px 0;"> <p>SDTM: FAORRES (No CDE) where FAOBJ (No CDE) = "PRTRT", FATEST (No CDE) = "Percent of PTV receiving > 107% of dose", FATESTCD (6651723) = "PTVGT107", FACAT (No CDE) = "RADIATION THERAPY"</p> </div>	<p>NUMBER – Maximum Length = 5</p>

CRF Question	Value Domain
<p>Unit (6409841) CDE Short Name: FAORRESU</p> <div data-bbox="289 321 769 527" style="border: 1px solid blue; padding: 5px; margin: 10px 0;"> <p>CDASH: FAORRESU (6409841) where FAOBJ (6421465) = "Brachytherapy Seed Implantation Suture Material", FATEST (6423016) = "Total Dose", FACAT (6413046) = "RADIATION THERAPY"</p> </div> <div data-bbox="289 558 769 793" style="border: 1px solid red; padding: 5px; margin: 10px 0;"> <p>SDTM: FAORRESU (No CDE) where FAOBJ (No CDE)= "Brachytheray Seed Implantation Suture Material", FATEST (No CDE) = "Total Dose", FATESTCD (6651723) = "TOTDOSE", FACAT (No CDE) = "RADIATION THERAPY"</p> </div>	<p>CHARACTER – Maximum Length = 100</p> <p><input type="checkbox"/> % – Percentage</p>