

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).

Surgery 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 and CDASHIG v2.1 metadata tables:

- FA – Findings About (v2.0)
- PR – Procedures (v2.0)
- TR – Tumor/Lesion Results (v2.1)

Mapping to the SDTM:

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

- FA – Findings About (v3.3)
- PR – Procedures (v3.3)
- TR – Tumor/Lesion Results (v3.3)

Surgery 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
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
Surgical Procedure Name (o) 7063813 PRSRGTY	The name of surgical procedure. CDASH: PRTRT (6411539); SDTM: PRTRT (No CDE)	CHARACTER. Use choice list.
Surgical Procedure Text (o) 7063816 PRSRGTYX	The name of surgical procedure not previously listed. CDASH: PRTRT (6411539); SDTM: PRTRT (No CDE)	CHARACTER

Field Name (Partition Status) CDE ID # Short Name	Definition CDISC Mapping and Instruction	Format
Surgical Procedure Technique Type (o) 7063818 PRSGTYP	The surgical approach or technique used in executing the surgical procedure. CDASH: No CDE; SDTM: If PRSGTYP (No CDE) = "Procedure not performed", PRPRES (No CDE) = "Y" and PROCCUR (No CDE) = "N"; All other situations, No CDE; Can be a supplemental qualifier in SDTM	CHARACTER. Use choice list.
Surgical Procedure Technique Text (o) 7063820 PRSGTYPX	The surgical approach or technique used in executing the surgical procedure not previously listed. CDASH: No CDE; SDTM: No CDE; Can be a supplemental qualifier in SDTM	CHARACTER
Surgical Procedure Technique Reason Text (o) 7063821 PRSGTYRN	The explanation of the reason for the surgical approach or technique. CDASH: No CDE; SDTM: No CDE; Can be a supplemental qualifier in SDTM	CHARACTER
Surgical Procedure Resection Type (o) 7063822 PRRSCTY	The name of the surgical resection procedure. CDASH: PRTRT (6411539) where PRSCAT (6413048) = "Surgical Resection"; SDTM: PRTRT (No CDE) where PRSCAT = "Surgical Resection"	CHARACTER. Use choice list.
Surgical Procedure Resection Text (o) 7063823 PRRSCTYX	The name of the surgical resection procedure not previously listed. CDASH: PRTRT (6411539) where PRSCAT (6413048) = "Surgical Resection"; SDTM: PRTRT (No CDE) where PRSCAT = "Surgical Resection"	CHARACTER

Field Name (Partition Status) CDE ID # Short Name	Definition CDISC Mapping and Instruction	Format
Surgeon Name (o) 64344 SURGEON_NAME	the free text field for the name of operating surgeon. Not for FDA submission	CHARACTER
First Postoperative Bowel Movement Date (o) 3122716 FIRST_PO_BM_DT	The date of the first postoperative bowel movement. Not for FDA submission	DATE
First Postoperative Flatus Date (o) 3123041 FIRST_PO_FLATUS_DT	he date of first postoperative gas or air in the gastrointestinal tract. Not for FDA submission	DATE
Surgical Procedure Estimate Total Blood Loss Value (o) 7063827 FAESBLDL	The estimated blood loss during the surgical procedure represented as a numeric value. CDASH: FAORRES (6421467) where FAOBJ (6421465) = "Blood Loss", FATEST (6423016) = "Estimate Volume", FACAT (6413046) = "SURGERY"; SDTM: FAORRES (No CDE) where FAOBJ (No CDE) = "Blood Loss", FATEST (No CDE) = "Estimate Volume", FATESTCD (6651723) = "VOLUME_E", FACAT (No CDE) = "SURGERY"	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) = "Blood Loss", FATEST (6423016) = "Estimate Volume", FACAT (6413046) = "SURGERY"; SDTM: FAORRESU (No CDE) where FAOBJ (No CDE) = "Blood Loss", FATEST (No CDE) = "Estimate Volume", FATESTCD (6651723) = "VOLUME_E", FACAT (No CDE) = "SURGERY"	CHARACTER. Use choice list.
Surgical Procedure Surgical Finding (o) 7063828 FAOPRFND	The description of findings discovered during the surgical procedure. CDASH: FAORRES (6421467) where FAOBJ (6421465) = "Surgical Procedure", FATEST (6423016) = "Operative Findings", FACAT (6413046) = "SURGERY"; SDTM: FAORRES (No CDE) where FAOBJ (No CDE) = Surgical Procedure", FATEST (No CDE) = "Operative Findings", FATESTCD (6651723) = "OPRTFND", FACAT (No CDE) = "Surgery"	CHARACTER
Surgical Incision Final Length Value (o) 7063829 FASURLNG	The final length of the surgical incision represented as a numeric value. CDASH: FAORRES (6421467) where FAOBJ (6421465) = "Surgical Incision", FATEST (6423016) = "Length", FACAT (6413046) = "SURGERY"; SDTM: FAORRES (No CDE) where FAOBJ (No CDE) = "Surgical Incision", FATEST (No CDE) = "Length", FATESTCD (6651723) = "LENGTH", FACAT (No CDE) = "SURGERY"	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) = "Blood Loss", FATEST (6423016) = "Estimate Volume", FACAT (6413046) = "SURGERY"; SDTM: FAORRESU (No CDE) where FAOBJ (No CDE) = "Blood Loss", FATEST (No CDE) = "Estimate Volume", FATESTCD (6651723) = "VOLUME_E", FACAT (No CDE) = "SURGERY"	CHARACTER. Use choice list.
Tumor Long Axis Size Result (o) 6922528 LDIAM	Result of the measurement of the tumor long axis dimension. CDASH: TRORES (No CDE) where TRTEST (No CDE) = "Longest Diameter"; SDTM: TRORES (6642371) where TRTESTCD (6659342) = "LDIAM", TRTEST (6659339) = "Longest Diameter"	CHARACTER
Original Units (o) 6619597 TRORESU	The unit of measure for the result of the tumor results assessment as originally received or collected. CDASH: TRORESU (No CDE) where TRTEST (No CDE) = "Longest Diameter"; SDTM: TRORESU (6619597)	CHARACTER. Use choice list.

Field Name (Partition Status) CDE ID # Short Name	Definition CDISC Mapping and Instruction	Format
Surgical Margin Distance Surgeon Measured (o) 7063831 FASURMRG	The distance from the closest point of the lesion to the closest point of the surgical margin determined by the surgeon represented as a numeric value. CDASH: FAORRES (6421467) where FAOBJ (6421465) = "Surgical Margin", FATEST (6423016) = "Distance", FACAT (6413046) = "SURGERY"; SDTM: FAORRES (No CDE) where FAOBJ (No CDE) = "Surgical Margin", FATEST (No CDE) = "Distance", FATESTCD (6651723) = "DISTANCE", FACAT (No CDE) = "SURGERY"	NUMBER
Findings About Result Unit (o) 6409841 FAORRESU	The unit of the result as originally received or collected. CDASH: FAORRESU (6409841) where FAOBJ (6421465) = "Blood Loss", FATEST (6423016) = "Estimate Volume", FACAT (6413046) = "SURGERY"; SDTM: FAORRESU (No CDE) where FAOBJ (No CDE) = "Blood Loss", FATEST (No CDE) = "Estimate Volume", FATESTCD (6651723) = "VOLUME_E", FACAT (No CDE) = "SURGERY"	CHARACTER. Use choice list.
Surgical Margin Resection Status (o) 7063832 PRSRMGST	The description of the state of the tissue margin following surgical resection. 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
Gross Disease or Disorder Focus Status (o) 7063833 PRGDESST	The status of the gross disease foci. CDASH: No Match; SDTM: No Match; Can be a supplemental qualifier in SDTM	CHARACTER. Use choice list.
Surgical Site Surgical Procedure Condition Type (o) 7063834 PRSRGCND	The name of the procedure or condition occurring during or immediately after the surgical procedure. CDASH: No Match; SDTM: No Match, Can be a supplemental qualifier in SDTM	CHARACTER. Use choice list.
Blood Transfusion Type (o) 7063835 PRTRNFTY	The type of infusion of blood or blood components. CDASH: PRSCAT (6413048); SDTM: PRSCAT (No CDE)	CHARACTER. Use choice list.
Blood Transfusion Blood Product Name (o) 7063836 PRTRNFCP	The type of blood or blood components used in the infusion. CDASH: PRTRT (6411539); SDTM: PRTRT (No CDE)	CHARACTER. Use choice list.
Blood Transfusion Timepoint Administered Type (o) 7063837 PRTRNFTP	The protocol timepoint when blood or blood components were transfused. CDASH: No Match; SDTM: PRTPT (6640412) where PRTRT (No CDE) = "Blood transfusion"	CHARACTER. Use choice list.
Procedure Dose Description (o) 6421531 PRDSTXT	The dose/amount administered during the procedure. CDASH: PRSDTXT (6421531); SDTM: PRDOSE (6659626) where PRTRT (No CDE) = "Blood transfusion"	CHARACTER

Field Name (Partition Status) CDE ID # Short Name	Definition CDISC Mapping and Instruction	Format
Surgical Procedure Document Method Type (o) 7063839 SRGDCMTH	The method used to document surgical procedure details. CDASH: No Match; SDTM: No Match	CHARACTER. Use choice list.
Surgical Procedure Required Total Number (o) 3123223 SURG_PRO_REQ_TTL_NUM	Total number of surgeries needed for a given intervention. Not for FDA submission	NUMBER
Procedure Start Date (o) 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 (o) 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
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
Neoplasm Gross Evidence Indicator (o) 7063841 FAGSEVTU	The indication of whether or not there was gross evidence of a tumor. CDASH: FAORRES (6421467) where FAOBJ (6421465) = "Gross Tumor", FATEST (6423016) = "Occurrence Indicator", FACAT (6413046) = "SURGERY"; SDTM: FAORRES (No CDE) where FAOBJ (No CDE) = "Gross Tumor" FATEST (No CDE) = "Occurrence Indicator", FATESTCD (6651723) = "OCCUR", FACAT (No CDE) = "SURGERY"	CHARACTER. Use choice list.
Surgical Procedure Resection Date (o) 7063842 PRRSCDAT	The date of surgical resection, represented in an unambiguous date format (e.g., DD-MON-YYYY). CDASH: PRSTDAT (6409578) where PRSCAT (6413048) = "Surgical Resection"; SDTM: PRSTDTC (No CDE) where PRSCAT (No CDE) = "Surgical Resection"	DATE

Annotated CRF: Surgery 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: Surgery CDISC Aligned NCI Standard Template

Mandatory Questions

CRF Question	Value Domain
<p>Surgery Date (6409578) CDE Short Name: PRSTDAT</p> <p>CDASH: PRSTDAT (6409578)</p> <p>SDTM: PRSTDTC (No CDE)</p>	<p>DATE – Maximum Length = 11</p>

Optional Questions

CRF Question	Value Domain
<p>Surgical procedure type (7063813) CDE Short Name: PRSRGTY</p> <p>CDASH: PRTRT (6411539)</p> <p>SDTM: PRTRT (No CDE)</p>	<p>CHARACTER – Maximum Length = 100</p> <p>List of 113 PVs</p>
<p>Surgical procedure type, Other specify (7063816) CDE Short Name: PRSRGTYX</p> <p>CDASH: PRTRT (6411539)</p> <p>SDTM: PRTRT (No CDE)</p>	<p>CHARACTER – Maximum Length = 200</p>

Surgical approach (7063818)

CDE Short Name: PRSGTYP

CDASH: No CDE

SDTM: If PRSGTYP (No CDE) = "Procedure not performed", PRPRES (No CDE) = "Y" and PROCCUR (No CDE) = "N"; All other situations, No CDE; Can be a supplemental qualifier in SDTM

CHARACTER – Maximum Length = 100

- Endoscopic ultrasound-guided fine-needle aspiration (EUS-FNA) – Endoscopic Ultrasound-Guided Fine-Needle Aspiration
- Hand-assisted – Hand assisted laparoscopic
- Laparoscopic – Laparoscopic Surgery
- Laparoscopic converted to open – Laparoscopic converted to open.
- Laparoscopic hand-assisted – Laparoscopic hand-assisted
- Laparoscopic-assisted – Laparoscopic assisted dissection
- Minimally Invasive – Minimum Invasive
- open – open
- Open Operation/Resection/Biopsy – Open Operation/Resection/Biopsy
- Other – Other
- Primary – Primary
- Procedure not performed – Surgical Procedure Not performed
- Robot assisted laparoscopic (da Vinci) – Robot Assistance Laparoscopy
- Robotic – Robot
- Robotic converted to open – Robotic Converted to Open
- Robotic-assisted – Robotic-assisted
- Salvage – Salvage
- Stereotactic needle biopsy – Stereotactic Needle Biopsy
- Thoracoscopy/Video-assisted (VATS) – Video-assisted Thoracic Surgery
- Thoracoscopy/Video-assisted (VATS), with conversion to thoracotomy – Thoracotomy Video-assisted Thoracic Surgery
- Transnasal Endoscopic Biopsy/Resection – Transnasal Endoscopic Biopsy/Resection
- Transoral Laser Surgery – Transoral Laser Surgery
- Transoral Robotic Surgery – Transoral Robotic Surgery
- Transventricular Endoscopic Biopsy/Resection – Transventricular Endoscopic Biopsy/Resection

CRF Question	Value Domain
	<input type="checkbox"/> Ultrasound-Guided Transbronchial Needle Aspiration (EBUS-TBNA) – Ultrasound-Guided Transbronchial Needle Aspiration
<p>Surgical approach other specify (7063820) CDE Short Name: PRSGTYPX</p> <div style="border: 1px solid blue; padding: 2px; margin: 5px 0;">CDASH: No CDE</div> <div style="border: 1px solid red; padding: 2px; margin: 5px 0;">SDTM: No CDE; Can be a supplemental qualifier in SDTM</div>	CHARACTER – Maximum Length = 200
<p>Reason for surgical approach (7063821) CDE Short Name: PRSGTYRN</p> <div style="border: 1px solid blue; padding: 2px; margin: 5px 0;">CDASH: No CDE</div> <div style="border: 1px solid red; padding: 2px; margin: 5px 0;">SDTM: No CDE; Can be a supplemental qualifier in SDTM</div>	CHARACTER – Maximum Length = 200
<p>Resection type (7063822) CDE Short Name: PRRSCTY</p> <div style="border: 1px solid blue; padding: 2px; margin: 5px 0;">CDASH: PRTRT (6411539) where PRSCAT (6413048) = "Surgical Resection"</div> <div style="border: 1px solid red; padding: 2px; margin: 5px 0;">SDTM: PRTRT (No CDE) where PRSCAT = "Surgical Resection"</div>	CHARACTER – Maximum Length = 50 <ul style="list-style-type: none"> <input type="checkbox"/> Extensive Subtotal – Extensive Subtotal <input type="checkbox"/> Gross total – Gross Total <input type="checkbox"/> Minor – Minor <input type="checkbox"/> Optimal debulking – Optimum Debulking <input type="checkbox"/> Other – Other <input type="checkbox"/> Partial debulking – Partial debulking <input type="checkbox"/> Segmental – Segmental <input type="checkbox"/> SMV/PV patch – Superior Mesenteric Vein Portal Vein Patch <input type="checkbox"/> Suboptimal – Suboptimal <input type="checkbox"/> Suboptimal debulking – Suboptimal Debulking <input type="checkbox"/> Subtotal – subtotal

CRF Question	Value Domain
<p>Resection type other specify (7063823) CDE Short Name: PRRSCTYX</p> <div data-bbox="282 321 769 436" style="border: 1px solid blue; padding: 5px; margin-bottom: 10px;"> <p>CDASH: PRTRT (6411539) where PRSCAT (6413048) = "Surgical Resection"</p> </div> <div data-bbox="282 468 769 583" style="border: 1px solid red; padding: 5px;"> <p>SDTM: (mapping instruction) PRTRT (No CDE) where PRSCAT = "Surgical Resection"</p> </div>	<p>CHARACTER – Maximum Length = 200</p>
<p>Surgeon Name (64344) CDE Short Name: SURGEON_NAME</p> <div data-bbox="282 711 769 764" style="border: 1px solid blue; padding: 5px; margin-bottom: 10px;"> <p>CDASH: Not for FDA submission</p> </div> <div data-bbox="282 795 769 848" style="border: 1px solid red; padding: 5px;"> <p>SDTM: Not for FDA submission</p> </div>	<p>CHARACTER – Maximum Length = 100</p>
<p>Date of first postop bowel movement (3122716) CDE Short Name: FIRST_PO_BM_DT</p> <div data-bbox="282 1016 769 1068" style="border: 1px solid blue; padding: 5px; margin-bottom: 10px;"> <p>CDASH: Not for FDA submission</p> </div> <div data-bbox="282 1100 769 1152" style="border: 1px solid red; padding: 5px;"> <p>SDTM: Not for FDA submission</p> </div>	<p>DATE – Maximum Length = 8</p>
<p>Date of first postop flatus (3123041) CDE Short Name: FIRST_PO_FLATUS_DT</p> <div data-bbox="282 1283 769 1335" style="border: 1px solid blue; padding: 5px; margin-bottom: 10px;"> <p>CDASH: Not for FDA submission</p> </div> <div data-bbox="282 1367 769 1419" style="border: 1px solid red; padding: 5px;"> <p>SDTM: Not for FDA submission</p> </div>	<p>DATE – Maximum Length = 8</p>

CRF Question	Value Domain
<p>Estimated Blood Loss (cc) (7063827) CDE Short Name: FAESBLDL</p> <div style="border: 1px solid blue; padding: 5px; margin: 10px 0;"> <p>CDASH: FAORRES (6421467) where FAOBJ (6421465) = "Blood Loss", FATEST (6423016) = "Estimate Volume", FACAT (6413046) = "SURGERY"</p> </div> <div style="border: 1px solid red; padding: 5px; margin: 10px 0;"> <p>SDTM: FAORRES (No CDE) where FAOBJ (No CDE) = "Blood Loss", FATEST (No CDE) = "Estimate Volume", FATESTCD (6651723) = "VOLUME_E", FACAT (No CDE) = "SURGERY"</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) = "Blood Loss", FATEST (6423016) = "Estimate Volume", FACAT (6413046) = "SURGERY"</p> </div> <div style="border: 1px solid red; padding: 5px; margin: 10px 0;"> <p>SDTM: FAORRESU (No CDE) where FAOBJ (No CDE) = "Blood Loss", FATEST (No CDE) = "Estimate Volume", FATESTCD (6651723) = "VOLUME_E", FACAT (No CDE) = "SURGERY"</p> </div>	<p>CHARACTER – Maximum Length = 100</p> <p><input type="checkbox"/> mL– Milliliter</p>
<p>Operative Findings (7063828) CDE Short Name: FAOPRFND</p> <div style="border: 1px solid blue; padding: 5px; margin: 10px 0;"> <p>CDASH: FAORRES (6421467) where FAOBJ (6421465) = "Surgical Procedure", FATEST (6423016) = "Operative Findings", FACAT (6413046) = "SURGERY"</p> </div> <div style="border: 1px solid red; padding: 5px; margin: 10px 0;"> <p>SDTM: FAORRES (No CDE) where FAOBJ (No CDE) = Surgical Procedure", FATEST (No CDE) = "Operative Findings", FATESTCD (6651723) = "OPRTFND", FACAT (No CDE) = "Surgery"</p> </div>	<p>CHARACTER – Maximum Length = 200</p>

CRF Question	Value Domain
<p>Final incision length (including if laparoscopy was converted to open) (7063829) CDE Short Name: FASURLNG</p> <div data-bbox="284 384 769 556" style="border: 1px solid blue; padding: 5px; margin-bottom: 10px;"> <p>CDASH: FAORRES (6421467) where FAOBJ (6421465) = "Surgical Incision", FATEST (6423016) = "Length", FACAT (6413046) = "SURGERY"</p> </div> <div data-bbox="284 590 769 762" style="border: 1px solid red; padding: 5px;"> <p>SDTM: FAORRES (No CDE) where FAOBJ (No CDE) = "Surgical Incision", FATEST (No CDE) = "Length", FATESTCD (6651723) = "LENGTH", FACAT (No CDE) = "SURGERY"</p> </div>	<p>NUMBER – Maximum Length = 5</p>
<p>Unit (6409841) CDE Short Name: FAORRESU</p> <div data-bbox="284 894 769 1066" style="border: 1px solid blue; padding: 5px; margin-bottom: 10px;"> <p>CDASH: FAORRESU (6409841) where FAOBJ (6421465) = "Blood Loss", FATEST (6423016) = "Estimate Volume", FACAT (6413046) = "SURGERY"</p> </div> <div data-bbox="284 1100 769 1293" style="border: 1px solid red; padding: 5px;"> <p>SDTM: FAORRESU (No CDE) where FAOBJ (No CDE) = "Blood Loss", FATEST (No CDE) = "Estimate Volume", FATESTCD (6651723) = "VOLUME_E", FACAT (No CDE) = "SURGERY"</p> </div>	<p>CHARACTER – Maximum Length = 100</p> <p><input type="checkbox"/> cm – Centimeter</p>
<p>Tumor size longest diameter (as determined by surgeon) (6922528) CDE Short Name: LDIAM</p> <div data-bbox="284 1476 769 1587" style="border: 1px solid blue; padding: 5px; margin-bottom: 10px;"> <p>CDASH: TRORRES (No CDE) where TRTEST (No CDE) = "Longest Diameter"</p> </div> <div data-bbox="284 1621 769 1761" style="border: 1px solid red; padding: 5px;"> <p>SDTM: TRORRES (6642371) where TRTESTCD (6659342) = "LDIAM", TRTEST (6659339) = "Longest Diameter"</p> </div>	<p>CHARACTER – Maximum Length = 100</p>

CRF Question	Value Domain
<p>Original Units (6619597) CDE Short Name: TRORRESU</p> <div data-bbox="282 321 769 436" style="border: 1px solid blue; padding: 5px; margin: 10px 0;"> <p>CDASH: TRORRESU (No CDE) where TRTEST (No CDE) = "Longest Diameter"</p> </div> <div data-bbox="282 468 769 520" style="border: 1px solid red; padding: 5px; margin: 10px 0;"> <p>SDTM: TRORRESU (6619597)</p> </div>	<p>CHARACTER – Maximum Length = 100</p> <p><input type="checkbox"/> cm – Centimeter</p>
<p>Surgical margin distance (as determined by surgeon) (7063831) CDE Short Name: FASURMRG</p> <div data-bbox="282 680 769 825" style="border: 1px solid blue; padding: 5px; margin: 10px 0;"> <p>CDASH: FAORRES (6421467) where FAOBJ (6421465) = "Surgical Margin", FATEST (6423016) = "Distance", FACAT (6413046) = "SURGERY"</p> </div> <div data-bbox="282 856 769 1060" style="border: 1px solid red; padding: 5px; margin: 10px 0;"> <p>SDTM: (FAORRES (No CDE) where FAOBJ (No CDE) = "Surgical Margin", FATEST (No CDE) = "Distance", FATESTCD (6651723) = "DISTANCE", FACAT (No CDE) = "SURGERY"</p> </div>	<p>NUMBER – Maximum Length = 5</p>
<p>Unit (6409841) CDE Short Name: FAORRESU</p> <div data-bbox="282 1190 769 1365" style="border: 1px solid blue; padding: 5px; margin: 10px 0;"> <p>CDASH: FAORRESU (6409841) where FAOBJ (6421465) = "Blood Loss", FATEST (6423016) = "Estimate Volume", FACAT (6413046) = "SURGERY"</p> </div> <div data-bbox="282 1396 769 1600" style="border: 1px solid red; padding: 5px; margin: 10px 0;"> <p>SDTM: FAORRESU (No CDE) where FAOBJ (No CDE) = "Blood Loss", FATEST (No CDE) = "Estimate Volume", FATESTCD (6651723) = "VOLUME_E", FACAT (No CDE) = "SURGERY"</p> </div>	<p>CHARACTER – Maximum Length = 100</p> <p><input type="checkbox"/> cm – Centimeter</p>
<p>Residual Disease after Surgery (7063832) CDE Short Name: PRSRMGST</p> <div data-bbox="282 1734 769 1787" style="border: 1px solid blue; padding: 5px; margin: 10px 0;"> <p>CDASH: No Match</p> </div> <div data-bbox="282 1818 769 1900" style="border: 1px solid red; padding: 5px; margin: 10px 0;"> <p>SDTM: No Match, Can be a supplemental qualifier in SDTM</p> </div>	<p>CHARACTER – Maximum Length = 20</p> <p><input type="checkbox"/> Gross Residual – Gross Residual</p> <p><input type="checkbox"/> Micro residual – Micro Residual</p> <p><input type="checkbox"/> No residual – No Residual</p> <p><input type="checkbox"/> Not applicable – Not Applicable</p>

CRF Question	Value Domain
<p>Is gross disease unifocal or multifocal? (7063833) CDE Short Name: PRGDESST</p> <p>CDASH: No Match</p> <p>SDTM: No Match; Can be a supplemental qualifier in SDTM</p>	<p>CHARACTER – Maximum Length = 35</p> <p><input type="checkbox"/> Multifocal – Multifocal</p> <p><input type="checkbox"/> Unifocal – Unifocal</p> <p><input type="checkbox"/> Unknown – Unknown</p>
<p>Operative conditions/procedures (7063834) CDE Short Name: PRSRGCND</p> <p>CDASH: No Match</p> <p>SDTM: No Match, Can be a supplemental qualifier in SDTM</p>	<p>CHARACTER – Maximum Length = 20</p> <p><input type="checkbox"/> Drain placed – Drainage Place</p> <p><input type="checkbox"/> Drain removed – Drainage Removed</p> <p><input type="checkbox"/> Ostomy placed – Ostomy Place</p> <p><input type="checkbox"/> Rectum intact – Rectum Intact</p> <p><input type="checkbox"/> Sphincter preserved – Sphincter Preservation</p>
<p>Transfusion Type (7063835) CDE Short Name: PRTRNFTY</p> <p>CDASH: PRSCAT (6413048)</p> <p>SDTM: PRSCAT (No CDE)</p>	<p>CHARACTER – Maximum Length = 50</p> <p><input type="checkbox"/> Allogeneic – Allogenic</p> <p><input type="checkbox"/> Autologous – Autologous</p> <p><input type="checkbox"/> Donor Directed – Donor Directed</p> <p><input type="checkbox"/> Donor Leukocyte Infusion – Donor Leukocyte Infusion</p> <p><input type="checkbox"/> Homologous – Homologous Recombination</p> <p><input type="checkbox"/> Other – Other</p> <p><input type="checkbox"/> Total – Total</p>

CRF Question	Value Domain
<p data-bbox="245 212 683 239">Transfusion Component (7063836)</p> <p data-bbox="245 247 618 275">CDE Short Name: PRTRNFCP</p> <div data-bbox="282 323 769 373" style="border: 1px solid blue; padding: 2px; margin: 10px 0;"> <p data-bbox="297 338 630 365">CDASH: PRTRT (6411539)</p> </div> <div data-bbox="282 407 769 457" style="border: 1px solid red; padding: 2px; margin: 10px 0;"> <p data-bbox="297 422 599 449">SDTM: PRTRT (No CDE)</p> </div>	<p data-bbox="824 212 1284 239">CHARACTER – Maximum Length = 45</p> <ul style="list-style-type: none"> <li data-bbox="824 289 1094 317"><input type="checkbox"/> Albumin – Albumin <li data-bbox="824 331 1260 359"><input type="checkbox"/> Cryoprecipitate – Cryoprecipitate <li data-bbox="824 373 1206 401"><input type="checkbox"/> FFP – Fresh Frozen Plasma <li data-bbox="824 415 1304 478"><input type="checkbox"/> Manipulated Lymphocytes – Treated (Primed) Lymphocytes <li data-bbox="824 493 1330 520"><input type="checkbox"/> No Blood Products – No Blood product <li data-bbox="824 535 1341 598"><input type="checkbox"/> Packed RBC – Packed Red Blood Cells Transfusion <li data-bbox="824 613 1349 676"><input type="checkbox"/> Packed RBC, Autologous – Packed Autologous Red Blood Cells Transfusion <li data-bbox="824 690 1354 774"><input type="checkbox"/> Packed RBC, Autologous, Irradiated – Packed Autologous Irradiated Red Blood Cells Transfusion <li data-bbox="824 789 1373 873"><input type="checkbox"/> Packed RBC, Autologous, Leukoreduced – Packed Autologous Leukoreduced Red Blood Cells Transfusion <li data-bbox="824 888 1330 951"><input type="checkbox"/> Packed RBC, Irradiated – Packed Irradiated Red Blood Cells Transfusion <li data-bbox="824 966 1321 1083"><input type="checkbox"/> Packed RBC, Irradiated and Leukoreduced – Irradiated Leukocyte-reduced Packed Red Blood Cell Transfusion <li data-bbox="824 1098 1341 1161"><input type="checkbox"/> Packed RBC, Leukopoor – Packed Leukopoor Red Blood Cells Transfusion <li data-bbox="824 1176 1325 1260"><input type="checkbox"/> Packed RBC, Leukoreduced – Packed Leukoreduced Red Blood Cells Transfusion <li data-bbox="824 1274 1081 1302"><input type="checkbox"/> Platelet – Platelet <li data-bbox="824 1316 1325 1379"><input type="checkbox"/> Platelets, HLA Match – Platelets, HLA-Matched <li data-bbox="824 1394 1360 1421"><input type="checkbox"/> Platelets, Irradiated – Platelets, Irradiated <li data-bbox="824 1436 1349 1520"><input type="checkbox"/> Platelets, Irradiated and Leukoreduced – Irradiated Leukocyte-reduced Platelet Transfusion <li data-bbox="824 1535 1295 1598"><input type="checkbox"/> Platelets, Leukoreduced – Platelets, Leukoreduced <li data-bbox="824 1612 1174 1640"><input type="checkbox"/> WBC – White Blood Cells <li data-bbox="824 1654 1308 1717"><input type="checkbox"/> WBC, Irradiated – White Blood Cells, Irradiated <li data-bbox="824 1732 1200 1759"><input type="checkbox"/> Whole Blood – Whole blood

CRF Question	Value Domain
<p>Blood transfusion (7063837) CDE Short Name: PRTRNFTP</p> <p>CDASH: No Match</p> <p>SDTM: PRTPT (6640412) where PRTRT (No CDE) = "Blood transfusion"</p>	<p>CHARACTER – Maximum Length = 35</p> <ul style="list-style-type: none"> <input type="checkbox"/> During or after evaluation – During or after evaluation <input type="checkbox"/> Intraoperative – Intraoperative <input type="checkbox"/> Post cell therapy – Post Cellular Therapy <input type="checkbox"/> Preoperative – Preoperative <input type="checkbox"/> Simultaneous – Concurrent <input type="checkbox"/> Since exposure but prior to evaluation – Since exposure but prior to evaluation <input type="checkbox"/> Unknown – Unknown <input type="checkbox"/> Within 30 days post-operative – Within 30 days post-operative
<p>Units (6421531) CDE Short Name: PRDSTXT</p> <p>CDASH: PRSDTXT (6421531)</p> <p>SDTM: PRDOSE (6659626) where PRTRT (No CDE) = "Blood transfusion"</p>	<p>CHARACTER – Maximum Length = 200</p>
<p>Surgical documentation method(s) (7063839) CDE Short Name: SRGDCMTH</p> <p>CDASH: No Match</p> <p>SDTM: No Match</p>	<p>CHARACTER – Maximum Length = 50</p> <ul style="list-style-type: none"> <input type="checkbox"/> Medical record – Medical Record <input type="checkbox"/> Video – Video Recording
<p>Number of surgeries (3123223) CDE Short Name: SURG_PRO_REQ_TTL_NUM</p> <p>CDASH: Not for FDA submission</p> <p>SDTM: Not for FDA submission</p>	<p>NUMBER – Maximum Length = 2</p>
<p>Start Date (6409578) CDE Short Name: PRSTDAT</p> <p>CDASH: PRSTDAT (6409578)</p> <p>SDTM: PRSTDTC (No CDE)</p>	<p>DATE – Maximum Length = 11</p>

CRF Question	Value Domain
<p>Stop Date (6409579) CDE Short Name: PRENDAT</p> <div data-bbox="282 321 769 373" style="border: 1px solid blue; padding: 2px;">CDASH: PRENDAT (6409579)</div> <div data-bbox="282 407 769 459" style="border: 1px solid red; padding: 2px;">SDTM: PRENDTC (No CDE)</div>	<p>DATE – Maximum Length = 11</p>
<p>Start Time (6790405) CDE Short Name: PRSTTIM</p> <div data-bbox="282 594 769 646" style="border: 1px solid blue; padding: 2px;">CDASH: PRSTTIM (6790405)</div> <div data-bbox="282 680 769 732" style="border: 1px solid red; padding: 2px;">SDTM: PRSTDTC (No CDE)</div>	<p>CHARACTER – Maximum Length = 8</p>
<p>Stop Time (6790406) CDE Short Name: PRENTIM</p> <div data-bbox="282 867 769 919" style="border: 1px solid blue; padding: 2px;">CDASH: PRENTIM (6790406)</div> <div data-bbox="282 953 769 1005" style="border: 1px solid red; padding: 2px;">SDTM: PRENDTC (No CDE)</div>	<p>CHARACTER – Maximum Length = 8</p>
<p>Was there gross evidence of tumor? (7063841) CDE Short Name: FAGSEVTU</p> <div data-bbox="282 1178 769 1350" style="border: 1px solid blue; padding: 2px;"> <p>CDASH: FAORRES (6421467) where FAOBJ (6421465) = "Gross Tumor", FATEST (6423016) = "Occurrence Indicator", FACAT (6413046) = "SURGERY"</p> </div> <div data-bbox="282 1383 769 1587" style="border: 1px solid red; padding: 2px;"> <p>SDTM: FAORRES (No CDE) where FAOBJ (No CDE) = "Gross Tumor" FATEST (No CDE) = "Occurrence Indicator", FATESTCD (6651723) = "OCCUR", FACAT (No CDE) = "SURGERY"</p> </div>	<p>CHARACTER – Maximum Length = 2</p> <ul style="list-style-type: none"> <input type="checkbox"/> N – No <input type="checkbox"/> NA – Not Applicable <input type="checkbox"/> U – Unknown <input type="checkbox"/> Y – Yes

CRF Question	Value Domain
<p data-bbox="240 205 600 237">Date of Resection (7063842)</p> <p data-bbox="240 243 620 275">CDE Short Name: PRRSCDAT</p> <div data-bbox="282 321 769 436" style="border: 1px solid blue; padding: 5px;"><p data-bbox="293 333 748 424">CDASH: PRSTDAT (6409578) where PRSCAT (6413048) = "Surgical Resection"</p></div> <div data-bbox="282 468 769 583" style="border: 1px solid red; padding: 5px;"><p data-bbox="293 480 716 571">SDTM: PRSTDTC (No CDE) where PRSCAT (No CDE) = "Surgical Resection"</p></div>	<p data-bbox="821 205 1187 237">DATE – Maximum Length = 11</p>